Human Research Protection Program (HRPP) Standard Operation Procedures (SOP)

Contents

These Standard Operating Procedures (SOPs) are the University of Colorado Colorado Springs (UCCS) processes that guide the implementation of the Human Research Protection Program (HRPP) and the Institutional Review Board (IRB).

The University of Colorado Colorado Springs (UCCS) supports the IRB and an HRPP to assure that the rights and welfare of human subjects are adequately protected in research. All activities involving 'research' and 'human subjects' conducted by UCCS faculty, staff, or students, are subject to the UCCS IRB/HRPP. All individuals contributing to 'research' involving 'human subjects' are expected to adhere to the Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research (hereafter referred to as the *Belmont Report*). Additionally, UCCS is committed to ensuring that all human subjects research, regardless of funding source, follows the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (except that reporting requirements for non-DHHS projects shall be waived). Thus, campus policies and guidelines conform to federal regulations. The UCCS IRB for human research participants is registered with the federal government (IRB #00000973; FWA #00002481).

Participation of humans in research projects may raise fundamental ethical and civil rights questions. All such research carried out by UCCS students, faculty, or other University employees as part of their University roles and responsibilities, whether on or off campus, sponsored or not sponsored, shall be covered by the UCCS Institutional Review Board for the Protection of Human Research Participants, hereinafter referred to as the IRB.

A. Regulatory Compliance:

UCCS abides by the following regulatory authorities, carried out by the UCCS IRB and the HRPP:

1. U.S. Department of Health and Human Services Title 45, Part 46, Subparts A, B, C, and D.

B. Principles of Ethical Research:

The UCCS IRB adheres to the basic ethical principles from the *Belmont Report* in the review of all research activities, including informed consent, risk/benefit analysis, and the selection of subjects for research.

1. ***Respect for Persons:*** The principle of respect for persons means respecting an individual's autonomy (someone's right to make decisions for them self). This means that individuals should participate in research voluntarily and be given enough information to make an informed decision about whether or not to participate. The *Belmont Report* further specifies that persons with diminished autonomy (e.g., children, cognitively impaired persons) are entitled to protection. This principle is upheld through the informed consent process by ensuring that consent be provided in a manner that is understandable, that subjects have adequate opportunity to consider participation, and that the decision is made free from coercion.

2. ***Beneficence:*** The principle of beneficence requires that the investigator not only protect individuals from harm, but also make efforts to secure their well-being. When the investigator and the IRB perform a systematic risk/benefit assessment, they are applying the principle of beneficence. Risk is evaluated by considering both the chance or probability of harm and the severity or magnitude of the possible harm. Risk may include consideration of psychological, physical, legal, social, and economic harm. Benefit, on the other hand, is the anticipated positive value of the research to either the subject directly or to society in terms of knowledge to be gained.

3. ***Justice:*** The principle of justice means that the benefits and burdens of the research are fairly distributed. The principle of justice requires that there be fair procedures and outcomes in the selection of research subjects. It is a violation of the principle of justice to select a class of subjects (e.g., welfare patients, an ethnic minority, institutionalized persons) simply because of easy availability rather than for reasons directly related to the problem being studied.

II. Applicability of these Standard Operating Procedures (SOPs)		
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The IRB Standard Operating Procedures apply to all activities that involve human subjects research, regardless of sponsorship, in which the university is considered to be engaged. UCCS is engaged in research when the project qualifies as human subjects research, and the following applies:

- The research is conducted by members of the university faculty, staff, or students acting in their university capacity, regardless of the location of the research.

The following definitions are used to provide guidance when conducting research.

A. Definitions:

1. ***Research:*** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the development of generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration, quality improvement activities, and service programs may include research activities and require IRB review. The following activities are deemed ***not*** to be research:

    a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

    b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

    c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

    d. Authorized, operation activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

    (adapted from 45 CFR 46.102).

    Note- If your scholarly or journalistic activity fits solidly within #1 above you do not need IRB approval/review. If you have any doubts or questions, please contact the irb@uccs.edu. Number 2 through 4 apply only to activity performed by or on behalf of an authorized (Federal, State or local) government authority, and so are unlikely to apply to activity at UCCS.

2. ***Human research participant:*** A living individual from whom an investigator (whether professional or student) conducting research obtains data through the following methods:

a. An intervention, interacting with the individual and using, studying, or analyzing the information or biospecimens, or
b. Obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens (adapted from 45 CFR 46.102).

Supporting Definitions:

a. ***Systematic investigation*** involves a predetermined system, method or plan for studying a topic, answering a question, testing a hypothesis, or developing a theory.
b. ***Generalizable knowledge*** is information that is collected or gathered to draw general conclusions, inform policy, inform professional knowledge in a discipline, or generalize outcomes beyond a specific group, entity, or institution being studied.
   Examples of activities that typically are not generalizable include:
   - biographies
   - service or course evaluations, unless they can be generalized to other individuals
   - services, or concepts where it is not the intention to share the results beyond UCCS or any agency supporting the research
   - quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the UCCS community
c. ***Intervention*** includes both physical procedures by which information or biospecimens are gathered (e.g., education program, drug treatment, venipuncture) and manipulations of the human research participant (i.e., exercise program, diet therapy) or the human research participant's environment (i.e., music, room light) that are performed for research purposes (adapted from 45 CFR 46.102).
d. ***Interaction*** includes communication or interpersonal contact between investigator and the human research participant.
e. ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical record or student record information) that may identify the individual (adapted from 45 CFR 46.102).
f. ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information (adapted from 45 CFR 46.102).
g. ***Identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen (adapted from 45 CFR 46.102).
h. ***Legally authorized representative*** means an individual, or judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research (adapted from 45 CFR 46.102).
i. ***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily

life or during the performance of routine physical or psychological examinations or tests (adapted from 45 CFR 46.102).

j. ***Written***, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

3. ***Clinical Trial:*** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes (adapted from 45 CFR 46.102).

4. ***Protected Health Information (PHI):*** Individually identifiable health information, including demographic information collected from an individual that is either created or received by a healthcare provider, public health authority, life insurer, health plan, employer, school or university, or health care clearinghouse. It is provided for specific purposes by an individual with the expectation that the information (i.e., a medical record or student records) will not be made public. Private information must be individually identifiable (i.e., the identity of the research participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants. PHI means the identity of the participant is or may readily be ascertained by the investigator or associated with the information. This includes information about the past, present, or future physical or mental health of an individual, the provision of health care to an individual, payment for care, and genetic information. PHI includes written, electronic, or oral information (adapted from HIPAA Privacy Rule).

5. ***Health Insurance Portability and Accountability Act (HIPAA):*** The 1996 Act that regulates the transfer and collection of Protected Health Information (PHI) between and within covered entities defined as (a) health care plans, (b) health care clearinghouse, and (c) health care providers who electronically transmit any health information (adapted from HIPAA Privacy Rule).

III. Human Research Protection Program Quality Assurance/Improvement Elements		
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UCCS supports a quality assurance/quality improvement program in its operation of the IRB/HRPP.

A. Training:

UCCS provides the following training and education to the institution to improve awareness about human subjects research protections:

1) UCCS fulfills the federal mandate to ensure all researchers involved in human subjects research are trained by requiring initial and continuing education through the Collaborative IRB Training Initiative (CITI).

   a) Initial training: complete the CITI Basic Human Subjects Protection online training in either:
      i. Social and Behavioral Research
      ii. Vulnerable Population Research
   b) Continuing education requirement:
      Every 3 years, individuals who have completed a CITI Basic Human Subjects course must complete a CITI Refresher Human Subjects Protection course.

   *In some cases, other human subjects training may be substituted (i.e., NIH training) for the CITI training. The substitution is evaluated on a case-by-case basis.

2) IRB members are required to complete CITI training for IRB Members.

3) Training is provided at the department or classroom level as requested.

4) IRB/HRPP reference material is available through OSPRI for the campus community to obtain additional information regarding the history and conduct of research activities.

B. Post-Approval Monitoring:

UCCS supports the following efforts to evaluate the conduct of ongoing research:

1. Encouraging questions, concerns, and self-reporting by participants, investigators, and research staff as an avenue to evaluate knowledge and implementation of ethical and compliant research.
2. Continuing review by the IRB and required reporting.
3. Performing for-cause post approval monitoring of UCCS study sites and/or protocols.
   a. For-cause post approval monitoring may be initiated by a complaint from the sponsor, the Institutional Official (IO), HRPP staff, or a finding of research non-compliance.
   b. For-cause post approval monitoring may include requests for study documents such as consent forms, data, or other relevant information.
   c. If a PI does not comply with post-approval monitoring requests, the process outlined in SOP section Special Topics: XII will be applied.

D. Assessment of the UCCS IRB/HRPP:

The function and performance of the UCCS IRB/HRPP is continually monitored and evaluated by OSPRI staff and the IRB Chair(s). OSPRI staff monitors the conduct of IRB meetings as well as provides resources and guidance for Full Board, Expedited, Exempt reviews, and determinations of non-human subject research. The IRB provides opportunities for feedback and input for quality assessment and improvement from PIs and research personnel through optional end of process survey and email communication.

E. Reporting of the UCCS IRB/HRPP:

The Research Compliance Program Director (RCPD) is responsible for tracking the metrics below to monitor major elements of quality control and quality improvement which fall to the institution to monitor and measure:

1. Number of business days from submission to review for Full, Expedited and Exempt research;
2. Number of protocols reviewed by fiscal year;
3. Level of reviews by category (Full, Expedited, Exempt);
4. Number of applications by college by fiscal year;
5. Number of Unanticipated Events/Protocol Deviations and instances of non-compliance.

IV. IRB Membership		
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A. General Principles of Membership

The IRB shall have ***at least seven members (Common Rule only requires 5)*** with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The IRB shall be sufficiently qualified through the experience and expertise of its members, their diversity, including consideration of ethnicity, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research participants. In addition to possessing the necessary professional competence to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB will have at least one member who is not affiliated with UCCS except for IRB membership (adapted from 45 CFR 46.107).

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

B. Selection of Members and Chair

The Research Integrity Officer (RIO) at UCCS is the responsible official for appointing members to the IRB. The RIO:

1. May seek nominations for IRB membership and IRB Chair position(s) from the current IRB, Deans, Directors, the Faculty Assembly Chair, or others as appropriate.
    a. Appointments are for a one-year term with an automatic annual renewal. Ending of a term should be accompanied by written notice. Justification is not required for notice of a member's or chair's term end (by either party).
2. Appoints the IRB Chair(s), general members, and alternate members. Appoints at least one individual from each group listed below to be IRB members:
    a. College of Education
    b. College of Public Service
    c. Helen and Arthur E. Johnson Beth-El College of Nursing and Health Sciences
    d. College of Letters, Arts, and Sciences
    e. Member-at-large (may be from any other college, school, or campus unit)
    f. One person from the community (i.e., not an employee of the university)
    g. One nonscientific member

*Individuals may fill multiple roles (i.e., the chair can represent the college, the non-scientific member can also be the community member, etc.).

3. Alternate Members:
    a. Alternates, if appointed, are designated for specified member(s) by the HRPP staff, in consultation with the IRB Chair(s). If both the alternate and the member attend a meeting, only one of these two may vote. In these cases, the minutes reflect who is in attendance as a voting member.
4. Maintains a list of IRB members including name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations, and employment or other relationship between each member and the institution.

C. IRB Member Responsibilities

Members have the following general responsibilities while serving an IRB appointment:

a. Complete all required UCCS human subject protections training and seek additional training where necessary to maintain an effective understanding of human subject protection regulations.
b. Complete assigned reviews in a timely fashion as assigned by the Chair and HRPP staff.
c. Review panel meeting agenda prior to the convened meeting, ensuring that all materials are reviewed for familiarity of protocol and be prepared to participate and contribute to discussion.
d. Speak freely to discuss their point of view and listen respectfully regarding studies under review.
e. Participate openly in appropriate discussions, and motioning and/or voting to approve, disapprove, require modifications, or table each submission during the IRB meetings.
f. Maintain confidentiality of protocols, decisions, and discussions both inside and outside of Panel meetings.
g. Work collegially with investigators and other IRB members to facilitate human subjects' protections.
h. If IRB member is also a research investigator, research conducted must be ethical and must maintain IRB studies in good standing.
i. Announce conflicts of interest with research under review and recuse themselves from the review of studies where conflicts of interest exist or may appear to exist.
j. Attend IRB meetings.
k. Provide prior notice of intention to resign from the IRB Chair(s) and the HRPP staff.

V. Use of Consultants for IRB Review		
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A. Informal Consultation:

IRB members are encouraged to seek informal consultation as a normal part of their review process. Informal consultations may occur with other IRB members as well as other members of the university community providing that the individual has the appropriate expertise. If the consultation is done as an informal discussion, the formal steps (below) do not apply. However, care should be taken regarding confidentiality and conflict of interest issues.

B. Formal Consultation:

At its discretion, an IRB panel may invite scientists or non-scientists from within or outside the university who have special expertise to function as consultants and ad hoc reviewers of a research protocol application. These individuals are considered guests to the IRB meeting and have access to all documents submitted to the IRB relevant to the specific project under review, may participate in the deliberations and make recommendations on the project, but may not vote.

A consultant may not participate in the IRB's review of any project in which the consultant has a conflicting interest, except to provide information requested by the IRB. A consultant is considered to have a conflicting interest when the consultant, the consultant's spouse or partner, or any of the consultant's dependent children have a non-financial interest in the design, conduct, or reporting of the research, or have any financial interest in the research.

Consultants having a conflict of interest shall:

- Announce the conflict and disqualify themselves from participation before review of that research project except to provide information on request, and
- Leave the meeting during the discussion and the vote on any motion to approve, require changes, or disapprove the research in question.

Offices of Sponsored Programs and Research Integrity (OSPRI) staff, IRB Chair, or primary/secondary reviewer may evaluate a protocol and make their own determination that additional expertise is needed. If this decision is made by any one of these individuals, a consultant will be provided.

VI. Changes to Policies and Procedures		
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A. Compliance to Applicable Regulations

The IRB Standard Operating Procedures (SOPs) shall not be in conflict with 45 CFR Part 46, or other applicable Federal, State, local law or regulations, or university policy and shall be changed as may be necessary to eliminate any conflict.

B. Review of IRB Standard Operating Procedures

Students, staff, faculty, or administration may propose changes to any section of the SOPs at any time. Such requests must be made in writing and may be considered at the subsequently convened IRB meeting, provided the change was requested at least ***ten business days*** prior to the meeting.

Any person (investigator, staff, research subject, etc.) may contact the Offices of Sponsored Programs and Research Integrity to make comments and/or recommend changes to the procedures followed by the UCCS IRB/HRPP. It is helpful to get feedback about the usefulness of these SOPs, the websites, and other procedures. Specific suggestions for improvement are always welcome and often result in constructive additions/changes.

Question or suggestions may be directed to:

Offices of Sponsored Programs and Research Integrity
719-255-3044 or composp@uccs.edu

A. Meeting Processes, Records, and Communication

1. Meeting Dates and Times

   IRB meetings are generally held the last Tuesday of each month during the academic year, and as needed, during the summer months. Meeting dates are posted on the IRB website. The IRB Chair(s) may cancel meetings or convene additional meetings as necessary. Members must be notified at least 72 hours in advance of any such additional meetings. Meetings may be cancelled when there are no proposals to be reviewed or a quorum cannot be reached. PIs will be notified at least 5 business days before the meeting date if their protocol is to be reviewed at a Full Board meeting.

B. The Meeting

1. ***Quorum***: A majority of IRB members must be present to conduct business. The IRB cannot act on a proposal unless at least one member whose primary concerns are in a non-scientific area is present. Members present may, by simple majority vote, or defer agenda items if they believe requisite members of the IRB are not present.

2. ***Order of Business***: The agenda for IRB meetings shall be:
   a. Review of, and action on, minutes of previous meetings.
   b. Old and New Business related to IRB functions.
   c. Review, discussion of, and action on new full review proposals.
   d. Review and discussion of, and action (if needed) on new expedited proposals.
   e. Review, discussion of, and action on continuing review proposals.
   f. Review, discussion of, and action on substantive changes to previously approved proposals.
   g. Other business as identified by any member of the IRB.

3. ***Actions***: The meeting shall be conducted in accordance with the most recent edition of Robert's Rules of Order. Proposals shall be approved, approved with revisions, disapproved, or tabled until a specified future date by majority vote of those members present.

4. ***Attendance by non-IRB members***: IRB meetings are generally open to all members of the university community and the community-at-large. The IRB members may, on majority vote, close meetings for compelling reasons, as long as such closure does not conflict with 45 CFR Part 46, or other applicable Federal, State, or local law or regulations. Anyone may speak for or against a proposal, but remarks must be based only on the *Criteria for Approval*. The Chair(s) may limit the duration of comments or the number of speakers for and against a proposal to serve the best interest of committee functioning. Written comments received by the Chair(s) prior to the meeting will be distributed and appended to the minutes, insofar as they address the *Criteria for Approval*.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available to the IRB.

The IRB may, at its discretion, request attendees to sign agreements to not release any information from the meeting which may violate the PIs ownership of intellectual property or confidentiality.

5. ***Only IRB members may vote*** (adapted from 45 CFR 46.107(e)).

6. ***Conflict of Interest***: IRB members and anyone speaking or submitting written comments must declare any potential conflict of interest in advance.
   a. Members may speak for, but may not vote on their own proposals, proposals of students they are sponsoring, or any proposal in which an IRB member is or is likely to be a participant.
   b. Written comments shall explicitly address any conflict of interest or its absence.
   c. Any individual who declares a conflict of interest must be recorded by name in the meeting minutes.

7. ***Minutes***: The IRB will keep minutes of the proceedings. The minutes document:
   a. Attendance;
   b. A summary of the discussion taking place during each review, including concerns;
   c. The basis for requiring changes in or disapproving research;
   d. A written summary of the discussion of controverted issues and their resolution;
   e. Actions taken by IRB;
      The vote on these actions including the number of members voting for, against, and abstaining;
   f. Criteria for initial and continuing review, the approval period; and
   g. Any conflict of interest declared (adapted from 45 CFR 46.115).

C. IRB Records

Office of Sponsored Programs and Research Integrity (OSPRI) is the repository for all IRB records. OSPRI shall keep the following documentation of IRB activities on file for at least three years after completion or closure of the research:

1. Required documents for each protocol:
   a. Copies of all proposals received;
   b. Any scientific evaluations (if any) that accompany the proposals;
   c. All internal and external correspondence related to each proposal;
   d. Letters of access (if needed);
   e. Approved consent document(s);
   f. Any instruments to be used in the research;
   g. Any advertisements recruiting human research participants;
   h. Any significant new research findings that changed the study outcome;
   i. All progress reports and reports of change (if any) submitted by the investigator
   j. The rationale for conducting continuing review of research that otherwise would not require continuing review (as described);

k. The rationale for a determination that research appearing on the expedited review list published in the Federal Register (list is not currently published and may be updated) is more than minimal risk;
l. Adverse event reports (if any); **and**
m. Any other document(s) deemed relevant by the IRB.

D. IRB Decisions

The IRB will notify investigators and the institution of its decision to approve or disapprove the proposed research activity or of requests for modifications to secure IRB review of the research activity. The IRB relies upon the following general methods of communication:

1. ***Letters of Review***
   The IRB shall inform principal investigators in writing of the decision of the UCCS IRB for any human subjects research application that is reviewed completely.

2. ***Requests for Revisions/Modifications (in order to complete the IRB review)***
   The IRB primary reviewer will itemize any requested changes that must be made to the research as a condition of IRB review of the proposed research. PIs will be notified via email and complete revisions in the electronic application.

3. ***Letters of Disapproval***
   Letters of Disapproval are only sent after the protocol has been reviewed at an IRB meeting. The IRB shall inform the principal investigator in writing via email of any disapproval.

4. ***Reporting to the Institution***
   The IRB shall provide the Signatory Official for the institution's Federalwide Assurance (FWA) with reports of the activity of the IRB at the end of every fiscal year.

VIII. Required Reporting of Unanticipated Events and Deviations		
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Consistent with federal regulations, UCCS requires reporting to the IRB of unanticipated problems posing risks to participants or others. This policy applies to both behavioral research and biomedical research and includes (but is not limited to) the reporting of **adverse events, protocol deviations/violations, and confidentiality breaches.**

Principal Investigators (PI) are required to submit the "Unanticipated Event Form" for each incident of an unanticipated event and/or deviation from an approved protocol **within 5 days** of the PI becoming aware of the occurrence.

A. Examples of Reportable Events (including, but not limited to):

1. An unplanned protocol deviation that harmed participants or others; that indicates participants or others may be at increased risk of harm; that could adversely affect the safety or welfare of subjects; or that compromises the integrity of the research data. (Note: A planned protocol deviation requires IRB approval of a request for change prior to implementation.)
2. Any change made to the research without prior IRB approval in order to eliminate apparent immediate harm.
3. Any unforeseen harmful or unfavorable occurrence to participants or others that is related or possibly related to the research protocol (such as injuries, psychological events, or drug errors).
4. Any unforeseen development related or possibly related to the research, that potentially increases the likelihood of harm to participants or others in the future.
5. Adverse events which, in the opinion of the PI, are both unexpected and related or possibly related to the subject's participation in the research.
6. Information that indicates a change to the risks or potential benefits of the research.
7. Breach of privacy or confidentiality.
8. Incarceration of a participant in a protocol not approved to enroll prisoners.
9. Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
10. Sponsor-imposed suspension for risk.
11. Allegation of non-compliance with protocol requirements or IRB policies.
12. Any safety reporting requirements specified by the IRB as a condition of approval.
13. Any other problem or event that the investigator considers to be unanticipated and indicates that subjects or others are at increased risk of harm.

B. Definitions:

1. ***Unanticipated Event:*** Any incident, experience, or outcome that meets **all** the following criteria:
   a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

b. Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized (http://www.hhs.gov/ohrp/policy/advevntguid.html)

2. ***Deviations:*** Variances from the IRB approved protocol and protocol related materials that have **not** been pre-approved.

All proposals to conduct research involving human research participants must be submitted to the UCCS IRB (https://uccs.my.irbmanager.com/Login.aspx).All members of the research team must complete CITI training and/or other training required by the UCCS IRB. No protocol will be reviewed if the investigator and the entire research team have not successfully completed initial or refresher training ***within three years.***

Additionally:

- No protocol will be accepted without being submitted electronically.
- The faculty advisor must review and electronically sign the student's IRB protocol; otherwise, it will not be accepted.
- If any of the investigators or members of the research team have a conflict of interest (COI), it must be declared and explained on the IRB protocol. In some cases, a signed COI management plan will also be requested.
- If the research qualifies as an NIH clinical trial, Good Clinical Practice training must be completed prior to submission (see OSPRI website).
- Letters of access or verification of specific site permission may be required for certain types of off campus locations. **Please acquire these permissions before completing your application.** If you have questions about what is considered acceptable verification or if your site needs such verification, please contact HRPP staff.
- **Important Note: the UCCS IRB currently cannot review FDA regulated research. Our current policy is to defer to the most appropriate outside IRB. If you have sponsored research or are proposing research, please account for this cost in your budget. UCCS will do everything we can to work with our partners so there is not a fee for FDA review, but we cannot guarantee this. If you believe your project is regulated under FDA regulations, please contact IRB staff before starting an application.**

A. HRPP Review:

Human Research Protection Program (HRPP) staff will perform the following tasks before assigning a submitted IRB application to a primary IRB reviewer:

1. Confirm that the application is submitted; verify that graduate and undergraduate applications are signed by a faculty advisor. (If not, it is to be returned without action);
2. CITI Training (or other training) is complete and on record for each investigator listed on the application. (If not, it is to be returned without action);
3. Confirm any applicable addendums have been attached if the research includes children; prisoners; pregnant women, human fetuses, and/or neonates; or international research;
4. Confirm any applicable additional permissions are submitted with the application (i.e., Registrar or IBC permissions); **and**
5. Use the New IRB Application Processing Checklist.

The designated IRB reviewer will review the IRB application in relation to the review categories found in 45 CFR 46 (described in SOP numbers 10, 11, and 12) and will perform the following steps:

1. Review every document submitted and contact the principal investigator if there is any protocol-related information requiring clarification (via email);
2. Contact HRPP staff when needed; **and**
3. Submit the Reviewer Checklist notifying when the protocol approval is ready to be sent out.

HRPP staff may review QA/QI applications and amendments/requests for change involving only personnel updates.

Upon notification of the reviewer decision, HRPP staff will review all final study documents and send out the approval to the principal investigator. This review will include ensuring all documents are present, accurate, and a quality check that review level was appropriate.

X. Review Category: Exempt		
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Before any research takes place with human subjects, the investigator ***must*** obtain IRB review and approval. Investigators may request that research be reviewed using one of three processes: Exempt, Expedited, or Full. The IRB Chair or any member of the IRB has the prerogative to elevate the review if there are any concerns about risk or to the population of study.

Resources:

1. IRB Resources - Exempt Initial Review Checklist

A. Initial Review for Exempt

The UCCS IRB makes ALL determinations of exemptions.

All proposed projects that involve human subjects and that satisfy the definition of research must be reviewed prior to the activity beginning. The types of initial review are Exempt, Expedited, and Full. Exempt initial review is described below.

Exempt research is "exempted" from federal regulations outlined in 45 CFR 46; which means that the research is not subject to a formal informed consent process or to continuing review by the IRB, unless the category is subject to a limited IRB review.

When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Reviewer and the campus Privacy Officer and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications (to secure approval), or disapprove all research activities. (Adapted from 45 CFR 46.109(a))

Exempt research involves risks or stressors that are ***not greater*** than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

1. Qualifications for Exempt Initial Review:

   Research approved under an exemption: ***(1) must not be more than minimal risk, (2) must fit into one or more of the following categories, and (3) must comply with any additional conditions outlined within this policy.***

   The **general definition of minimal risk** defined in 45 CFR 46.102(j): "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

2. Standards for Approval of Exempt Research:

The following standards must be met in order to approve research as exempt:

a. The research involves no more than minimal risk to subjects.
b. In accordance with Exempt categories of review.
c. There are adequate provisions to maintain the privacy interests of subjects.
d. If the research involves interaction or intervention with research subjects who can consent, there is an appropriate consent process that includes:

    1. Providing sufficient opportunity for research subjects to consider whether to participate
    2. Disclosing funding (if applicable)
    3. Minimizing the possibility of coercion or undue influence
    4. Not including exculpatory language
    5. Disclosing sufficient information to make a decision in understandable language, such as:
        a) The study is research
        b) The expected durations of the research subject's participation
        c) The procedures that will be followed
        d) The extent, if any, to which confidentiality will be maintained
        e) That participation is voluntary, and participants may withdraw at anytime
        f) Whom to contact for questions about the research
        g) Whom to contact for concerns about the research

(Researchers are encouraged to use the IRB Informed Consent Template available on the OSPRI website)

3. Categories of Exemption:

In accordance with the federal regulations, the following categories of research may be exempt per 45 CFR 46.104(d):

a. ***Category 1:*** Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Special note for research in schools: In order for a project involving educational research (research conducted in classrooms) to be reviewed under the Exempt, the investigator may be asked to supply a letter from the appropriate school district official that certifies that the project meets the following conditions. The research activities will:

1) not differ in any significant ways from the normal range of activities of the classroom, school, or district;
2) involve only customary and non-controversial instructional goals;
3) not deny any students educational benefits they would otherwise receive;
4) promise direct benefits (at least in the form of evaluative information) to the classroom, school, or district;
5) incorporate adequate safeguards to protect the privacy (i.e., anonymity or confidentiality) of all individuals who might be human research participants.

b. ***Category 2:*** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
   1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

c. ***Category 3:*** Research involving benign interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

   For the purposes of this provision, benign behavioral interventions are brief in duration (less than or approximately two hours, depending on surrounding circumstances), harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. Additional information can be found on the Secretary's Advisory Committee on Human Research Protection (SACHRP) website.

   If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

d. ***Category 4:*** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
   a) The identifiable private information or identifiable biospecimens are publicly available;
   b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
   d) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

e. ***Category 5:*** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs including alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Set site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

   Note:* **This category may not be used without OHRP prior approval.

f. ***Category 6:*** Research that involves taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or if a food is consumed that contains an ingredient at or below the level and for a use found to be

safe, by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture (45 CFR 46.104). (Identifiers may be retained only under the conditions outlined in Conditions for Use of Exemption section below.)

g. ***Category 7:*** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

h. ***Category 8:*** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
   2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;
   3) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
   4) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

NOTE Currently UCCS is not approving studies under category 7 or 8, as UCCS does not have the required structure to record and track broad consent. If this changes in the future, use of category 7 & 8 will be revisited.

B. Conditions for Use of Exemption:

1. The following conditions are in conjunction with the 6 exemption categories above:

   a. The exemptions at 45 CFR 46.104(d), as listed above:
      - **May** apply to pregnant women.
      - **May NOT** apply to research involving prisoners as the primary population (adopted from 45 CFR 46.104(b)(2)
      - **May** apply to **children (See bullet b below**)

   b. Exemption 2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does **NOT** apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption 2(iii), where identifiable information is obtained, and the IRB conducts a limited IRB review, is **NOT** applicable to research in children. Exemption 3 does **NOT** apply to research involving children. 45 CFR 46.104(b)(3)

c. ***For Category 2***, two conditions must apply in order to allow for the collection of identifiable data:
    1) The investigator must provide reasonable assurance of data protection/confidentiality.
    AND,
    2) The sensitivity of the data collected must not increase the overall risk to the research participants.

    If the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, a limited IRB review must be conducted as required by 46 CFR 46.111(a)(7).

d. ***For Category 3***, two conditions must apply in order to allow for the collection of identifiable data:
    1) The investigator must provide reasonable assurance of data protection/confidentiality.
    AND,
    2) The sensitivity of the data collected must not increase the overall risk to the research participants.

    If the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, a limited IRB review must be conducted as required by 45 CFR 46.111(a)(7).

e. ***For Category 4, 'existing data'*** means data that exists at the time of IRB submission. Exempt category 4 does not allow for protocols designed to collect data that does not yet exist or has not yet been collected at the time the protocol is submitted to the IRB.

f. ***For Category 5***, the following additional criteria apply:
    1) OHRP (or the applicable federal agency) has authorized or concurred with this exemption determination
    2) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
    3) The research or demonstration project must be conducted pursuant to specific federal statutory authority.
    4) There must be no statutory requirement that an IRB review the project.
    5) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

g. ***For Category 6***, Other than exempt category 6, the exempt categories do not apply to research that is also FDA-regulated.

h. ***For Category 7,*** Exempt category 7 always requires limited IRB review and is only available when broad consent will be (or has been) obtained. Currently UCCS does not have the required structure to record and track broad consent. If this changes future use of category 7 will be revisited.

i. ***For Category 8***, Exempt category 8 always requires limited IRB review and is only available when broad consent will be (or has been) obtained. Currently UCCS does not have the required structure to record and track broad consent. If this changes future use of category 8 will be revisited.

Resources:

1. IRB Resources - Expedited Initial Review Checklist

A. Initial Review for Expedited

The UCCS IRB makes all determinations of expedited reviews. All proposed projects that involve human subjects and that satisfy the definition of research must be reviewed prior to the activity beginning. The types of initial review are Exempt, Expedited and Full. Expedited initial review is described below.

The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures. 45 CFR 46.110(a)

1. Qualifications for Expedited Initial Review:

   Expedited research poses **no more than minimal risk** to human research participants. If the research purpose focuses on sensitive or personal aspects of the human research participant's behavior or certain vulnerable populations, it **may not qualify for Expedited review**. The designated reviewer makes the final decision as to whether or not the protocol meets the applicability to be reviewed as expedited.

   If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB.

   The **general definition of minimal risk** defined in 45 CFR 46.102(j): "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

2. Minimal Risk Determination:

   The expedited initial review applies to research projects that:
   a. pose no more than minimal risk, **AND**
   b. meets the conditions for one or more of the 9 expedited research categories listed below.

3. Standards for Approval of Expedited Research:

   The following standards should be met in order to approve research as expedited:
   a. The research involves **no more than minimal risk** to subjects, and risks to human research subjects are reasonable in relation to the anticipated benefits.
   b. Selection of human research participants is equitable, meaning that risk/reward are not unfairly distributed among participants (see Belmont Report, B (3)).
   c. Eligible for review under an Expedited Research Category(s).

d. Review funding (if applicable).
e. There are adequate provisions in place to maintain the privacy interests of subjects.
f. If the research involves interaction or intervention with research subjects who can consent there is an informed consent document (See the Section on Informed Consent).
g. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of human research participants.
h. When some or all of the human research participants are likely, to be vulnerable to coercion or undue influence, (e.g., children, prisoners, pregnant women, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of these human research participants (adapted from 45 CFR 46.111, 116, 117).
i. Determine the research meets the requirements for subparts B, C and D, when applicable by using the correct special population SOP.
j. Review any recruitment procedures involving advertisements.
k. The limited IRB review that is required for certain exempt research (See Section 3) may be conducted using expedited review procedures. 45 CFR.110(b)(1)(iii)
l. Determine the requirement for continuing review and any other additional requirements (see Section XVII. Continuing Review and Lapses in Review). Continuing review of research is not required for research that qualifies for expedited review unless the IRB determines that it is required and documents the rationale within the IRB record.

4. Expedited Review Categories:

The conditions listed below identify typical types of research that are considered Expedited (if carried out through standard methods) (45 CFR 46.110). Types of research reviewed may include:

1. ***Category 1:*** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. ***Category 2:*** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
    b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. ***Category 3:*** Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) decannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. ***Category 4:*** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. ***Category 5:*** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.)

6. ***Category 6:*** Collection of data from voice, video, digital, or image recordings made for research purposes.

7. ***Category 7:*** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (**NOTE**: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104(d)(1) and (d)(2). This listing refers only to research that is not exempt.)

8. ***Category 8:*** Continuing review of research previously approved by the convened IRB as follows:
    a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b) where no subjects have been enrolled and no additional risks have been identified; or
    c) where the remaining research activities are limited to data analysis.

9. ***Category 9:*** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

XII. Review Category: Full Board		
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A. Initial Review for Full Board

All proposed projects that involve human subjects and that satisfy the definition of research must be reviewed prior to the activity beginning. The types of initial review are Exempt, Expedited, and Full. Full Board review is required when the research may not be reviewed in the Exempt or Expedited review categories. The UCCS IRB makes all determinations of Full reviews. Full Board initial review is described below.

Full review is generally for research involving **more than minimal risk** to participants, or research using vulnerable human subjects which does not specifically fit an exempt or expedited review category. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests, or have special protections defined under 45 CFR 46 Subparts B,C, and D. Vulnerable human research participants include children less than 18 years, prisoners, pregnant women, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, persons who are not proficient in the language of the research study, and any human research participants likely to be vulnerable to coercion or undue influence (adapted from 45 CFR 46.111).

Examples of research that may involve more than minimal risk (mental or physical) and need full board review include:

- Surveys, questionnaires, or interviews that solicit information regarding personal or sensitive aspects of the human research participants' behavior, including sexual practices, instances of child or sexual abuse suffered by the human research participant, criminal activities, drug and alcohol use, or studies of eating disorders.
- Stress testing, , and/or studies where human research participants are asked to do more than moderate physical exercise that could result in injury to the human research participant.
- Studies with certain health exclusion criteria or which utilize FDA regulated devices or substances.
- Cannabis, drug, and alcohol use by human research participants for research purposes.Research with children that involves greater than minimal risk (45 CFR 46.405, 45 CFR 46.406).

- Studies which involve major deception of participants.

When a protocol is determined to need full board review, members and the PI will be notified as soon as possible. The PI is encouraged, but not required to attend the meeting. Protocol materials and the primary review are distributed to members in sufficient time prior to the meeting to allow for adequate review. This includes, but is not limited to, the full protocol, consent document, recruitment materials and supporting documents. Each protocol will be assigned to a primary reviewer, typically the chair, who will be responsible for a full review of all materials. The primary reviewer will write a summary of major issues they feel the board needs to address,

which will be distributed to members and the PI prior to the meeting. Where necessary, a consultant review or vulnerable population review will also be provided to the board members.

If there is any protocol-related information requiring clarification, the primary and/or secondary reviewers may contact the Principal Investigator (or appropriate designee) directly prior to the meeting.

B. Full Board Meeting Process:

a. The primary reviewer will lead the discussion of the protocol, the complete grant application (as applicable) and the risk/benefit ratio.
b. Members will review funding for restrictions and additional guidelines (if applicable).
c. Reviewer comments are presented by the primary and secondary reviewers (e.g., vulnerable population representative).
d. If present the PI may present relative information or be asked questions by the board at large.
e. Meeting minutes are kept by IRB staff during the entirety of the meeting.
f. During the meeting the board must show and document the following as appropriate:
    1. Confirmation that the research meets the criteria for review found at 45 CFR 46.111;
    2. Confirmation that the research meets the requirements found in Subparts B, C and D, when applicable, and the precise information justifying each of the determinations;
    3. Confirmation that the research meets the requirements for informed consent, including consent alterations or waivers, and the precise information justifying each of the determinations;
    4. Confirmation that the research meets the requirements for assent, including whether the permission of one or both parents is required, if applicable;
    5. Review of any recruitment procedures, including advertisements;
    6. Approval period dates (if less than annual continuing review is recommended) or detailed limitations to approval periods (such as limitations to enrollment numbers prior to reporting back for continuing review).
g. PIs and guests are dismissed and a full and complete discussion regarding ethical concerns and issues impacting research subjects takes place. Any controverted issues must be documented and resolved during this discussion.
h. A motion to approve or deny the protocol application must be made by a member, followed by a secondmotion, then a final vote.
i. The actions of the panel are recorded by the HRPP staff and communicated in writing to the Principal Investigator by the primary reviewer.

The IRB views informed consent as a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. It is both an initial and ongoing process, not just a form or document, which enables prospective and current research participants to voluntarily decide whether or not to continue to participate as a research subject.

The IRB has developed two written Informed Consent Templates which provide investigators with guidance in developing an informed consent document. There is one template designed for paper informed consent documents and one for electronic informed consent documents. The templates, format, and language have been approved by the UCCS IRB and are available on the OSPRI website. This template is drafted to include all 8 required elements of informed consent that are provided in both DHHS and FDA regulations as well as the additional elements. Certain elements may not apply to the research (particularly in low-risk studies).

It should be noted that the intentional exclusion, omission, or alteration of some or all elements of the informed consent process requires justification. This justification process supports a "waiver of some or all elements of informed consent" when only certain elements are waived, they are considered individually. When all elements of informed consent are waived, they are considered both individually and collectively.

Additionally, the informed consent requirements stated are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

Resources:
1. IRB Informed Consent Templates
2. IRB Consent Checklist
3. IRB Waiver or Alteration of Consent Checklist

A. Informed Consent Process:

The procedures used in obtaining informed consent should be designed to educate the subject population in terms they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language" (i.e., understandable to the people being asked to participate).

General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in sections B and C. Broad consent may be obtained in lieu of informed consent obtained in accordance with section B of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of

state or local officials is described in section D, along with general waiver or alteration of informed consent.

Adequacy of consent is of great importance. The following points are detailed within the regulations:

a. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
b. An investigator shall seek such consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
c. The information that is given to the subject or the legally authorized representative (see definition in SOP II) shall be in language understandable to the subject or the legally authorized representative.
d. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and have an opportunity to discuss that information.
e. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
f. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might now want to participate.
g. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The UCCS IRB has the authority to observe or have a third party observe the consent process and the research.

B. Elements of Consent:

The BASIC and ADDITIONAL requirements for informed consent (as dictated by federal regulations) are quoted below. The UCCS IRB requires that the basic elements, required by regulation, be provided to human participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects. These elements must appear within the consent form for both expedited and full board. See exempt review section above for details regarding consent for research that meets exempt category. Note that element #6 below applies only to research that is greater than minimal risk and is therefore not applicable to inclusion in a consent form for expedited review research.

BASIC ELEMENTS 45 CFR 46.116(b):

Except as provided in paragraph (c), (d), or (e) of this section, in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    A. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    B. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be distributed for future research studies.

ADDITIONAL ELEMENTS 45 CFR 46.116(c):

In addition to the above basic elements of informed consent, for each of the following, the UCCS IRB requires additional elements in the informed consent disclosure:

a. ***If the risk profile of any research-related interventions is not well known:*** Then a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable must be provided.
b. ***If the research includes women of childbearing potential or pregnant women, and the risk profile of any research interventions or interactions on embryos and fetuses is not well known:*** Then a statement that the particular treatment or procedures may involve risks to the embryo or fetus, if the participant is or may become pregnant, which is currently unforeseeable must be disclosed.

c. ***If there are anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent:*** Then anticipated circumstances under which the participant may be terminated by the investigator without the participants' consent must be provided.
d. ***If there are costs to the participant that may result from participation in the research:*** Then additional costs associated with study participation must be disclosed.
e. ***If there are adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research:*** Then consequences of a participant's decision to withdraw from the research must be disclosed.
f. ***If there are adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research:*** Then procedures for an orderly termination of participation must be provided.
g. ***Unless significant new findings during the course of the research which may relate to the participant's willingness to continue participation are unlikely:*** A statement that new findings developed during the course of the research that may relate to the participant's willingness to continue in the research study should be provided to the participant.
h. ***Unless the approximate number of participants involved in the study is not important to a decision to take part in the research:*** Then the approximate number of participants involved in the study should be disclosed.
i. ***If the subject's biospecimens are involved:*** Then a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit, and whether the subject will or will not share in this commercial profit should be provided.
j. ***If clinically relevant research results are expected***: Then a statement should be included regarding whether clinically relevant research results, including the individual research results, will be disclosed to subjects, and if so, under what conditions.
k. ***If the research involves biospecimens:*** Then a statement whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) must be included.

C. Elements of Broad Consent for the Storage, Maintenance, and Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens

CURRENTLY UCCS DOES NOT HAVE THE REQUIRED STRUCTURE TO RECORD AND TRACK BROAD CONSENT. IF THIS CHANGES, FUTURE USE WILL BE REVISITED.

Per, 45 CFR 46.116(d), broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs (a) and (b) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

1. A description of any reasonably foreseeable risks or discomforts to the subject;
2. A description of any benefits to the subject or to others which may reasonably be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
5. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
6. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the type of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
7. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposed (with period of time could be indefinite);
8. ***Unless the subject or legally authorized representative will be provided details about specific research studies***, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subjects identifiable private information or identifiable biospecimens, including the purpose of the research, and that they might have chosen not to consent to some of those specific research studies;
9. ***Unless it is known clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances***, a statement that such results may not be disclosed to the subject.
10. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.
11. ***If the subject's biospecimens are involved:*** A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
12. ***If the research involves biospecimens:*** A statement whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

D. Waiver of Some or All Elements of Informed Consent:

The IRB may approve a consent procedure, which does not include, or which alters some or all of the elements of informed consent in accordance with the following two regulatory citations from 45 CFR 46:

45 CFR 46.116(e) – Regarding research involving public benefit and service programs conducted by or subject to the approval of state or local officials.

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit, or alter one or more basic or additional elements of consent (an "Alteration"), under this provision the UCCS IRB must determine and document that the below criteria are satisfied.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    a) Public benefit or service programs;
    b) Procedures for obtaining benefits or services under those programs;
    c) Possible changes in or alternatives to those programs or procedures; or
    d) Possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

Restrictions:

1. Waivers
    a. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in Section B and Elements of Broad Consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. Alterations –
    a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in Section B or Elements of Broad Consent.
    b. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Elements of Broad Consent.

45 CFR 46.116(f) – General waiver or alteration of consent

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the UCCS IRB must determine and document that the below criteria are satisfied.

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representative will be provided with additional pertinent information after participation.

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Restrictions:

1. Waivers –
    a. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in Section B and Elements of Broad Consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. Alterations –
    a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in Section B
    b. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 8.3

*Note: In general, UCCS does not encourage or approve passive or opt out consent processes. However, in some cases such a process may be necessary for the research to be practicable. In those cases, researchers would request an alteration of consent under the guidelines laid out above. An opt out process for minors cannot be approved in the following cases. 20 U.S.C. § 1232h requires prior consent of minor students and their parent/guardian for surveys, analyses, or evaluations that reveal information concerning:

(1) political affiliations or beliefs of the student or the student's parent;
(2) mental or psychological problems of the student or the student's family;
(3) sex behavior or attitudes;
(4) illegal, anti-social, self-incriminating, or demeaning behavior;
(5) critical appraisals of other individuals with whom respondents have close family relationships;
(6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
(7) religious practices, affiliations, or beliefs of the student or student's parent; or
(8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

E. Modification of the Informed Consent Document:

In some cases, a modified consent document may be approved by the IRB. For Exempt studies, a shortened consent form is available on the IRB website.

Additionally, modifications to the consent document may be required when deficiencies are noted or when additional information will improve the consent process (this helps ensure ongoing informed consent). If revisions are significant, the PI and/or the IRB may require that currently enrolled subjects sign the new informed consent.

In some cases, especially in work with minors, researchers may be mandatory reporters. Language reflecting this may be required to be added to the consent documents. Examples are available on the IRB website. While the CU system also has a mandatory reporting requirement under Title IX for some employees and circumstances (CU APS 504), it does not require researchers to report if specifically investigating sexual misconduct among adults. If you have questions about this requirement or exception, please contact the Office of Institutional Equity.

F. Screening, Recruiting, or Determining Eligibility

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, as long as one of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective or legally authorized representative, or

2. The investigator will obtain identifiable information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Note – This is not a waiver of consent, but rather an exception to the requirement. Please note that if the information obtained is more than minimal risk, the informed consent will be required prior to screening. Possible inquiries eligible for screening include, but are not limited to, asking if the subject is married, asking if they are within a certain age range, or requesting a standard blood draw.

Also, HIPAA requirements will still apply, if applicable. Those working with the Lane Center should contact the Privacy Officer before accessing any medical records to ensure compliance.

G. Posting of Clinical Trial Consent Form

For each clinical trial conducted or supported by a federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the federal department or agency component conducting the trial on a publicly available federal web site that will be established as a repository for such informed consents.

If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal web site (e.g., confidential commercial information), such federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on a federal web site after the clinical trial is closed for recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol (adapted from 45 CFR 46.116).

NIH funded studies have guidelines and timelines that vary from OHRP guidelines regarding registering trials, posting consent forms and results. Guidelines should be provided at funding, please contact HRPP staff if you have questions about these deadlines.

Clinicaltrials.gov is a common site on which to post to satisfy this requirement. The UCCS PRS administrator will provide PIs guidance documents and assistance with this process upon request. Contact HRPP staff if you have questions.

XIV. Scientific Merit Review		
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A key component of an Institutional Review Board (IRB) review is considering scientific merit as a function of protecting the rights and welfare of human subjects. Excerpts of Federal regulations 45 CFR 46.111 and 21 CFR 56.111 are quoted below to support review of the scientific basis for the proposed research when evaluating the risks and benefits associated with the proposal. Research that is not scientifically sound and cannot achieve its stated objectives may not be considered ethical research. The IRB evaluates whether the design of the research protocol is sound and minimizes risks to participants.

> "(1) Risks to participants are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
>
> (2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result."

Note – research protocols that qualify for exemption from federal regulations per 45 CFR 46.104(d) do not require scientific review.

A. Review of Scientific Merit

There are several options researchers and the IRB may use to ensure the scientific merit of research submitted to the IRB for review:

1. **For research previously subjected to full peer review (e.g., reviewed by a study section, grant committee or grant agency):** No additional internal scientific review is required. This assumes that the actual research study submitted to the IRB was peer reviewed in its current form. Note the IRB may request a copy of the proposal as part of the review processes.
2. **For social, behavioral and educational research (all levels of review) that is "no greater than minimal risk":** Scientific review is the responsibility of the college, school, department, or faculty advisor.
3. **If research is determined to be "greater than minimal risk"* the UCCS IRB reserves the right to request information about the scientific review process, or to require a scientific review on a study-by-study basis:** These reviews are not designed or intended to serve as a peer review to maximize scientific quality, but designed to meet regulatory criteria outlined above with regard to human subjects protection. The review may be performed by members of the IRB reviewing the study, and is based on 45 CFR 46.111.

If the IRB does not believe it has the appropriate expertise to review a particular study, then it will call upon the help of an outside consultant with the appropriate expertise.

*Less than 1% of studies reviewed by the IRB in a given year are determined to be "greater than minimal risk".

XV. Review Expectations		
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Researchers are typically contacted within ***five to ten business days*** after receipt of an IRB application by the IRB office. The IRB makes every effort to provide timely responses, but some reviews may take longer. Additionally, timely reviews may be dependent upon IRB members and staff workload.

Protocols that qualify for exempt review usually are approved as quickly as possible. Exemption is determined by the IRB. Expedited reviews may take up to ***20 business days*** after receipt in the IRB office to review.

Full reviews may require up to ***50 business days*** to review. The protocol must be submitted to the IRB Office ***ten business days prior*** to the scheduled IRB meeting to be reviewed at that meeting. The IRB will make every effort to review the protocol at the next monthly scheduled IRB meeting (see IRB website for the monthly meeting dates). If the protocol requires revisions, it may not be reviewed at the scheduled meeting. Please note in some cases meetings may be canceled or dates may change depending on the ability of a quorum.

Office of Sponsored Programs and Research Integrity staff, IRB Chair, or any IRB Member may request that research be reviewed at a higher level of review.

IRB approval is contingent upon a timely response from the principal investigator. Any PI who does not respond or make required changes to the IRB protocol under view within ***20 business days after*** a communication from the IRB will nullify the IRB application. The PI will be required to submit a new IRB protocol application.

NOTE THAT SUBMISSION OF THE APPLICATION TO THE IRB DOES NOT CONSITUTUTE IRB APPROVAL AND RESEARCH (INCLUDING INITIATION OF RECRUITMENT AND OBTAINING CONSENT OF PARTICIPANTS) CANNOT BEGIN UNTIL RECEIPT OF AN APPROVAL LETTER FROM THE IRB.

XVI. Actions by the IRB and Institution		
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A. Suspensions and Terminations of Previously Approved Research:

The IRB Chair shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to human research participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB action and shall be reported promptly to the PI, college department and dean, Research Integrity Officer (RIO), the Provost and Executive Vice Chancellor for Academic Affairs, as determined by the RIO. The IRB committee shall be informed of any suspension or termination of IRB approval at the next scheduled IRB meeting.

Any individual who does not stay within the parameters of his/her approved IRB protocols will be referred to the Research Integrity Officer (RIO) and the Provost and Executive Vice Chancellor for Academic Affairs, as determined by the RIO. If the research protocol infraction falls within the definition of scientific misconduct, the RIO in consultation with the IRB Chair will convene the UCCS Committee on Misconduct in Research, Scholarship and Creative Activities. If the infraction does not fit the definition of research misconduct, the IRB Chair or delegate will follow the Special Topic SOP for the Handling of Allegations of Non-Compliance with Human Subject Protection Regulations.

1. Disapproval of Research:

   No research proposal will be disapproved until it has been reviewed in accordance with the Full review procedures set forth in this document. If the IRB disapproves of a research proposal, a written statement of the reasons for its decision will be given to the principal investigator. The investigator will have an opportunity to respond in person or in writing to the IRB (adapted from 45 CFR 46.109).

B. Actions by the Institution

Research that is approved by the IRB may be subject to further review by the Institution. However, the Institution may not approve research that has not been approved by the IRB (adapted from 45 CFR 46.112).

A. Continuing Review:

The revised Common Rule modifies when continuing review is required. Unless the UCCS IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:

1. Research eligible for expedited review in accordance with 45 CFR 46.110;
2. Research reviewed by the IRB in accordance with limited IRB review as described in Section 3;
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, **or**
    b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

The UCCS IRB may determine that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine that continuing review is required when:

1. Required by other applicable regulations (e.g., FDA);
2. The research involves topics, procedures, or data that may be considered sensitive or controversial;
3. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
4. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
5. An investigator has a history of noncompliance

When the UCCS IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

If an investigator fails to provide continuing review information to the IRB, or the IRB has not reviewed and approved a research study by the continuing review expiration date specified by the IRB approval/review, the research may be suspended until continuing review is completed. Enrollment of new human research participants cannot occur after the expiration of IRB approval or during suspension of a study. Any data collected during the expiration or suspension periods cannot be included in the study.

All ongoing protocols of more than minimal risk that do not meet the criteria for continuing review must receive continuing review by a convened IRB committee at an interval appropriate to the level of risk, but not less than once per year.

It is ultimately the **investigator's responsibility to initiate a Continuing Review submission**, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. Retrospective approval for work done after the expiration date cannot be granted.

While continuing review may not be a requirement, annual status updates will be completed for all Expedited reviews via email. Status updates will include, but may not be limited to, listing current personnel to confirm training requirements, conflict of interest update, status of protocol, and reporting of unanticipated events/deviations.

B. Request for Changes (ROC) to Approved Research

Changes to an Approved IRB Protocol **must be approved** by the IRB through the submission of a "Request for Change" form. Changes that increase the level of risk or are more than minor protocol changes may need a higher level of review (i.e. full review). The researcher should not implement any changes to the originally approved protocol without IRB approval. In addition, the IRB must be notified of any changes in principal investigator(s), faculty sponsorship, or additional personnel. Investigators must submit changes via the Request for Change form to the IRB at irb@uccs.edu (adapted from 45 CFR 46.103).

Principal Investigators must report planned modifications in the research protocol and receive IRB approval **prior** to implementing the proposed change. Principal Investigators are informed of the need to submit changes to the IRB for review in the IRB approval letter.

To ease administrative burden on researchers and HRPP staff, student personnel can be added to faculty protocols without a ROC application, as long as those students have completed the CITI training. Please contact the IRB in these cases to update your personnel.

C. Lapse in IRB Approval

The regulations (45 CFR 46) make no provision for any grace period extending the conduct of research beyond the expiration date of the IRB approval. Therefore, Continuing Review or re-approval of research must occur by the last date of the approval period ("expiration date").

The continuation of research after a lapse of the IRB approval is a violation of the regulations. If IRB approval has lapsed (i.e., the study is "expired"), research activities must stop, including recruitment (media advertisements must be pulled), enrollment, consent, interventions, interactions, and data collection, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

A lapse in approval may occur even if the investigator has submitted the continuing review submission on the last date of the approval period. The investigators must allow ***10 business***

days for IRB review and approval before the end of the approval period. Failure to submit Continuing Review information within ten business days of the expiration may result in non-compliance and will be handled by the IRB Chair or delegate.

If the investigator with an expired protocol is actively pursuing Continuing Review, and the IRB believes that an over-riding safety or ethical concern to the participants is involved with stopping the

protocol, a request to continue current research subjects can be made. Even if such a request is approved, enrollment of new subjects is not permitted.

If the study has lapsed for 20 business days (i.e., no Continuing Review is filed), and the researcher wants to continue the research, the IRB may request a new IRB application be submitted.

XVIII. External Relationships (non-UCCS): Outside Researchers and Other IRBs		
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A. External IRBs (Institutional Authorization Agreements):

The Institutional Official (or delegate) may defer the responsibilities of the UCCS IRB to another IRB with a current Federalwide Assurance (FWA) (to act as the IRB of record for studies to be conducted by, or with the assistance of UCCS personnel) in some cases. To request that UCCS defer to an outside IRB for an already approved protocol at another institution, please complete the online form in IRBManager. These requests are reviewed by HRPP personnel and the IO, review may take up to 10 business days to complete. PI's may be asked to provide additional information for review. The status of deferred studies should be updated yearly with the IRB via the online "Check-in" form. PI's will be sent a yearly reminder for these check-ins.

Currently the UCCS IRB will serve as the IRB of record for another institution on a case-by-case bases. Determinations are made by the IO and HRPP staff. PIs may request that UCCS serve as the IRB of record for an outside site at the time of initial IRB application submission. If you are working on a funding proposal and wish for UCCS to serve as the IRB of record, please reach out to OSPRI staff to ensure this is possible **BEFORE** any contracts are signed. For studies already in progress, please complete a Request for Changes application.

Most arrangements will require a fully executed IRB Institutional Authorization Agreement under the Federalwide Assurance (FWA) Process. Such authorization agreements should outline the basic responsibilities of each institution engaging in the reliance. UCCS is not currently a member of SMART IRB. UCCS will generally consider agreements to serve as the IRB of record for multiple sites for Exempt and Expedited studies only. Full board protocols will not be considered at this time.

B. NIH Single IRB Requirement (UCCS Strategy)

Effective January 20, 2020 NIH implemented the single IRB requirement (§46.114) for approved research. Currently, the default position for UCCS regarding the NIH Single IRB requirement is to cede oversight to an external IRB. This external IRB could be either a commercial IRB or another academic partner. Please note that the fees for an external IRB, if utilized, must be included in the proposal budget. UCCS will however, upon request on a case-by-case basis serve as the IRB of record for NIH funded studies where UCCS is the prime awardee. In those instances, a fully executed reliance agreement signed by the appropriate IO/institutional delegate of each institution will be put in place before the protocol commences. These agreements will be kept on file in the electronic protocol.

NIH only allows exceptions to this policy if the study is NOT also subject to the revised Common Rule sIRB provision. Exception requests to the NIH Single IRB policy must provide sufficient information to demonstrate a compelling justification for an exception to the NIH Single IRB Policy. Note that NIH does not consider the cost associated with a single IRB as a compelling justification. (The COVID public health exception expired May 11, 2003.)

The NIH sIRB policy does not apply to a) career development, research training, or fellowship awards, b) studies conducted at foreign sites, c) studies where a single IRB would be prohibited by federal, state, or tribal law, regulation or policy.

Please use the guidance above to determine the appropriate course of action for your study. Contact HRPP staff if you have questions.

C. External Researchers (Individual Investigator Agreements):

The Institutional Official (or delegate) may extend the UCCS Federalwide Assurance (FWA) to non-UCCS researchers who are not working at an institution with a current FWA. On a case-by-case basis, the UCCS FWA may be extended to researchers working at another FWA-holding institution as long as the research being conducted is outside their duties at the other institution.

Generally, UCCS does not extend IRB oversight to research by outside investigators engaged in human subjects research. However, consideration will be given on a case-by-case basis when the following conditions are met:

1. A UCCS employee or student is the Principal Investigator (PI) who is primarily responsible for the design and oversight of the research protocol;
2. The outside investigator is assisting the PI;
3. The outside investigator is not employed by, or a student of, an institution regularly engaged in human subjects research or has their own FWA; and
4. The outside investigator does not supervise or direct UCCS employees or students.

If it is determined that an outside investigator (non-UCCS personnel) may be named in the IRB application, then a fully executed Individual Investigator Agreement (IIA) needs to be on record. The IIA is signed by the outside investigator and the Institutional Official or their delegate. Contact the HRPP staff with questions.

XIX. IRB Policy for HIPAA Compliance		
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The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was written to allow for insurance portability but also as a Privacy Rule to protect the privacy and security of a person's identifiable health information. The purpose of this policy is to provide researchers with the information they need to comply with the Privacy Rule associated with HIPAA.

In the research context, HIPAA establishes the conditions under which protected health information (PHI) may be created, obtained, used or disclosed by covered entities for research purposes. As defined by HIPAA, the term "covered entity" includes, health care providers who engage in certain financial or administrative transactions electronically. Because the University's activities include both HIPAA covered and non-covered functions, the University has a status as a "hybrid" HIPAA entity.

A. HIPAA Covered Research at UCCS:

The majority of colleges, schools, centers, and departments within the University of Colorado Colorado Springs **do not** function as covered medical entities under HIPAA. University of Colorado is a covered entity that has chosen hybrid status. Therefore, certain areas of the University have to comply directly with HIPAA. The UCCS HealthCircle Clinics are considered to be covered parts or covered healthcare components of the UCCS covered entity.

PHI may be involved if any of the following are involved:

- Accessing or collecting information from a medical record
- Adding information to the hospital or clinical record
- Creating or collecting information as part of health care
- Using information collected from the study to make health care decisions

Please note that if your research involves PHI and is subject to HIPAA, a Privacy Board review is required prior to obtaining IRB approval, and in some cases may be required without IRB review. If you have questions about how HIPAA may impact human subjects research, contact Privacy Board at Comply@uccs.edu.

B. HIPAA Covered Research Outside UCCS:

If you conduct research at a covered entity outside UCCS, please contact those covered entities directly and provide the UCCS IRB with copies of HIPAA Authorization and/or HIPAA Waivers approved by their Privacy Boards.

PHI may be involved if any of the following are involved:

- Accessing or collecting information from a medical record
- Adding information to the hospital or clinical record
- Creating or collecting information as part of health care
- Using information collected from the study to make health care decisions

If you have questions if HIPAA may impact your research or if you have questions about how to secure HIPAA data provided to you by an outside covered entity, contact Privacy Board at Comply@uccs.edu.

XX. Required Training		
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Training in human research participant protection is required for IRB members, Principal and Co-Principal Investigators, faculty advisors, students, and staff who participate in research reviewed by the IRB.

A. Researchers and Faculty Advisors:

All researchers, including additional personnel and Faculty Advisors, involved in human subjects research are required to complete the Collaborative IRB Training Initiative (CITI) training referenced below before a protocol will be reviewed by the IRB.

1. Initially complete the CITI Basic Human Subjects Protection* online training in either:
   - Social and Behavioral Research
   - Vulnerable Population Research
2. Continuing Education Requirement
   - Every 3 years, individuals who have completed a CITI Basic Human Subjects Protection course must complete a CITI Refresher Human Subjects Protection course.

* In some cases, other human subjects training may be substituted (i.e., NIH training) for the CITI training. The substitution is evaluated on a case by case nature by the IRB.

B. IRB Members and HRPP Staff:

All IRB members and HRPP Staff are required to complete CITI training referenced below.

1. Initially complete the CITI IRB Members Only Training. (This training also meets the training requirements described in the section above.)
2. Continuing Education Requirement
   - Every 3 years, individuals who have completed the, CITI IRB Members Only Training, must complete a CITI Refresher Human Subjects Protection course.

C. Research involving Clinical Trials:

UCCS fulfills the NIH requirement to ensure that all personnel on NIH funded clinical trial research that is classified as a clinical trial are required to complete Good Clinical Practice (GCP) training. UCCS makes this training available through the Collaborative IRB Training Initiative (CITI) training referenced below, which must be completed before a protocol will be reviewed by the IRB. For most studies at UCCS, research personnel should be able to take the GCP – Social and Behavioral Research Practices for Clinical Research. If you are unsure of the course to take, please contact IRB@uccs.edu.

UCCS expectation for fulfilling NIH GCP requirements:

- All study team members involved in the design, conduct, recording, or reporting of an active NIH-funded clinical trial must be GCP through a qualifying training provider (e.g., CITI);
- Administrative Staff on an NIH-funded clinical trial are not required to complete GCP, unless directed to do so by the principal investigator on a project or per unit-specific (e.g., clinical trial support unit) business process;
- The study team member is responsible for obtaining a GCP training displaying the course completion date, and providing that certificate upon request of the research sponsor or the institutional review board (IRB);
- GCP training must be renewed every three (3) years upon initial certification expiration, as long as the study team member is involved on an active clinical trial. Most studies at UCCS should be able to take the GCP- Social and Behavioral Research Practices for Clinical Research. See the training documents below to learn how to sign up.

NOTE - In order to qualify as a clinical trial, all of the following must be true:

- The study involves human participants.
- The participants are prospectively assigned to an intervention.
- The study is designed to evaluate the effect of the intervention on the participants.
- The study effect is evaluating a health-related biomedical or behavioral outcome.

XXI. Responsibilities of the Principal Investigator		
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After IRB approval is obtained, it is the Principal Investigator's responsibility to:

1. Provide the IRB with all protocol and consent revisions or amendments
2. Submit Continuing Review forms ***10 business days*** before the expiration date for all applicable protocols indicated in the Approval letter from the IRB.
3. Respond to any status updates (requested on an annual basis).
4. Report any unanticipated and unintentional adverse events to human research participants to the IRB Chair or designee within ***5 business days*** of the event (http://www.uccs.edu/osp/).
5. Report any changes to the approved protocol. Changes must be approved by IRB prior to implementing the changes (http://www.uccs.edu/osp/).
6. Notify the IRB when the research is complete.
7. Report any Conflict of Interest or Perceived Conflict of Interest (COI) to the IRB when the protocol is submitted, or if there is a newly identified COI.
8. Conduct research in an ethical and appropriate manner, refraining from research misconduct activities, which include, but are not limited to, plagiarism, falsification, fabrication, and failure to protect the confidentiality of human research participants.
9. Report any or suspected research misconduct to the Research Integrity Officer.
10. Register the protocol with ClinicalTrials.gov, if required. Additional information is available in SOP Special Topics XXXII: IRB Policy for NIH Funded Clinical Trial Compliance.
11. Post an informed consent where required by the Common Rule. Additional information is available in XIII. Informed Consent Process, Section G.
12. Follow any data security requirements required by your sponsor or related to the nature of the data being worked with i.e., HIPAA.
13. Adhere to all policies and procedures set forth by the University and by the IRB, as well as all applicable local, state, and federal regulations.

Failure to comply with these responsibilities may result in suspension or termination of the IRB Approved Protocol, and possible disciplinary action. (See Special Topics SOP Special Topics: XXI. Non-Compliance).

Special Topics: XXII. Non-Compliance		
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A. Introduction:

This document describes the process that the University of Colorado Colorado Springs (UCCS) Institutional Review Board (IRB) follows for allegations and findings of non-compliance with policies and regulations governing research involving human subjects.

The UCCS IRB is responsible for review and approval of all investigations involving human subjects in accordance with 45 CFR 46 and 21 CFR 50 and 56. The primary concern of the IRB is the protection of the rights, welfare, and safety of human subjects and is responsible for review and approval of all investigations involving human subjects in accordance with 45 CFR

46 and 21 CFR 50 and 56.

All members of the research community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional policies and procedures governing the conduct of research involving human subjects.

The IRB encourages those who are aware of, or concerned about the potential of non-compliance by researchers, to report their concerns to the IRB.

B. Applicability:

This SOP applies to all faculty, staff, and students conducting human subject research as defined by the UCCS IRB Standard Operating Procedures.

C. Definitions:

Complainant: The Complainant is the individual who presents an allegation of non-compliance with Human Subject Protection Regulations. The University requires any person who makes an allegation of non-compliance to proceed in good faith and with a reasonable basis for believing that non-compliance occurred.

***Executive Committee*:** The Executive Committee is comprised of the following members: the UCCS Research Integrity Officer (RIO), the IRB Chair, and an IRB member appointed by the RIO. Additional members may be appointed by the RIO if specialized knowledge is required to resolve an allegation of non-compliance. The Research Compliance Coordinator and Legal Counsel shall serve in an advisory capacity. The RIO will serve as chair of the Executive Committee.

Respondent: The Respondent is the person against whom an allegation of non-compliance with Human Subject Protection Regulations has been made.

Allegation of non-compliance: An unconfirmed report of non-compliance.

Finding of non-compliance: A determination of non-compliance (by the Executive Committee) that is determined by using the "Process for Evaluating Allegations of Non-compliance" found below.

***Non-compliance*:** Non-compliance is the failure (intentional or unintentional) to comply with relevant federal, state, or local laws or regulations, IRB SOPs, or following procedures in an approved IRB protocol.

Non-compliance may be minor or serious, sporadic or continuing. The degree of non-compliance is evaluated on a case-by-case basis and will take into account considerations such as, to what degree the subjects were harmed or placed at an increased risk and the willfulness of the non-compliance.

Examples of non-compliance include, but are not limited to the following:

- Conducting human subjects research without a proper exemption or approval.
- Failing to cooperate with the IRB in fulfilling application and reporting requirements.
- Failing to respond to requests for information and documentation.
- Enrolling research subjects who fail to meet inclusion or exclusion criteria of a protocol.
- Enrolling research subjects after study approval has lapsed.
- Substantially modifying an IRB-approved protocol without approval from the IRB and the deviation increases the risk to the subject.
- Willfully or negligently placing human subjects in a situation that could very likely lead to serious harm.
- Applying coercion or undue influence to recruit or keep human subjects in a study against their will.
- Breaching subject confidentiality.
- Failing to report an adverse event(s) or unanticipated problems within five business days of discovery of non-compliance.

Serious Non-compliance: Non-compliance that has the potential to increase the risks to participants or adversely affect research participants' rights or wellbeing. Some examples of serious non-compliance include but are not limited to the following: conducting human subjects research without IRB approval, failing to provide accurate reports on adverse events or unanticipated problems in a timely manner, and breaching subject confidentiality. If the IRB finds that the investigator intentionally misled subjects, other investigators, study sponsors, or any others, then the non-compliance is considered serious. Serious non-compliance may be reported to the Office of Human Research Protection (OHRP). Only the IRB/Executive Committee can make the determination of serious non-compliance.

Continuing Non-compliance: Non-compliance that has been previously reported, or a pattern of non-compliance that suggests a lack of understanding of human subjects protection requirements that continues after attempts to educate the Principal Investigator (PI). Some examples of continuing non-compliance include but are not limited to the following: repeated failures to renew IRB application ten working days before the protocol expires resulting in lapses of IRB review, inadequate oversight of ongoing research, or failure to respond to a request to resolve an episode of non-compliance within ten business days. Continuing non-compliance may be reported to OHRP.

D. Reporting Allegations of Non-compliance:

Allegations of non-compliance may be discovered in several ways, including but not limited to:

- Reported by the Office of Human Subjects Research Protection (OHRP);
- New applications or continuing reviews submitted to the IRB;
- Post-approval monitoring;
- Reports from collaborators, study personnel, employees, research participants and/or their family members, community members; or
- Complaints from anonymous sources.

The following are the preferred methods to report allegations of non-compliance:

- Send an email to composp@uccs.edu.
- Report via the CU Ethics line (must be used if you wish to remain anonymous) - https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=14973.

Allegations should include as much information as possible, such as:

- A detailed description of the allegation or indication of non-compliance***;**
- Name of the investigator;
- The name(s) of personnel alleged to have committed/be committing non-compliance; and
- The title and number of the protocol.

*****Required when reporting an allegation of non-compliance.

It is a violation for any individual to engage in retaliatory acts against any individual who reports an incident of non-compliance, or assists, or participates in a proceeding or investigation relating to allegations of non-compliance.

E. Process for Evaluating Allegations of Non-compliance:

1. Upon receiving an allegation of non-compliance, the RIO and IRB Chair will consult to determine if there is a need for the Executive Committee to be established, with the RIO making the final determination. If there is no need for the Executive Committee, the RIO will determine any next steps, including documentation. If an Executive Committee is formed, it will review all material provided by the complainant to determine whether an investigation is warranted. This may include interviewing the complainant, if known, and reviewing any other documents the Executive Committee deems appropriate. The Executive Committee shall make reasonable efforts to avoid real or apparent conflicts of interest on the part of those involved in the inquiry phase.

2. If the Executive Committee determines that there is not sufficient information to determine whether non-compliance has occurred and/or has no basis in fact, no further investigation will be required. The Executive Committee shall notify the complainant, if known, of the reasons for the decision.

3. If the Executive Committee determines the allegation constitutes possible research misconduct, the allegation shall be referred to the Research Misconduct Committee. No further investigation will be required of the Executive Committee.

4. If the Executive Committee determines an investigation is warranted for matters other than research misconduct, the Executive Committee shall notify the respondent in writing, stating:
    a. The specific nature of the allegation;
    b. An investigation will be conducted; **and**
    c. The respondent will have an opportunity to respond to the allegations as part of the investigation.

5. At any time during the investigation process, the Executive Committee may convene the IRB to determine whether research procedures should be modified or whether the research or study enrollment should be suspended while investigating the allegation.

6. The Executive Committee shall conduct a thorough investigation to determine whether the allegation is serious and/or continuing non-compliance. The investigation may include, but is not limited to:
    a. Requesting a written response from the respondent regarding the allegations;
    b. Interviewing members of the research team, the respondent, the complainant, and/or subjects;
    c. Conducting an unannounced laboratory visit; **and**
    d. Reviewing research records.
7. Upon conclusion of the investigation, the Executive Committee shall prepare a written report detailing the investigation process that includes summaries of all interviews conducted, and the evidence reviewed. The report will also document the conclusions of the Executive Committee, including whether there was non-compliance and, if so, whether the non-compliance is serious and/or continuing as determined by a majority vote.

If the Executive Committee determines a finding of non-compliance, the type of non-compliance will be identified and the procedures in either section F or G will be followed, according to which is appropriate for the type of non-compliance identified.

F. Non-Compliance Determined not to be Serious or Continuing Non-Compliance Procedure:

1. If the non-compliance is determined to be neither serious nor continuing, the Executive Committee may decide what actions to take and report the outcome to the full IRB at the next convened meeting.

2. The actions may include, but are not limited to:
    a. Sending a letter of reprimand to the PI (copy to the department chair, dean, institute and/or center director, faculty advisor (student research) and research compliance coordinator);
    b. Educating the PI, department, institute, center, or staff; and/or
    c. Requiring that the PI create a plan of action to remedy the non-compliance.

G. Non-compliance Determined to be Serious or Continuing Non-compliance Procedure:

1. If the non-compliance is determined to be serious or continuing, the finding is brought to the full IRB at a convened meeting for consideration of actions to be taken.

2. The following information is distributed to the IRB:
    a. A copy of the approved IRB protocol;
    b. Minutes from the relevant IRB meeting, if the protocol warranted a full review;

c. The title and abstract of the research project and/or grant proposal in which the non-compliance occurred;
d. The number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
e. A copy of the original submitted non-compliance allegation (if available);
f. A detailed description of the research/investigation performed by the Executive Committee; **and**
g. Any other relevant materials that were reviewed by the Executive Committee during their investigation.

3. The IRB shall determine what actions to take to protect the rights and welfare of the human subjects. These actions may include, but are not limited to:
   a. Obtaining more information pending a final decision;
   b. Requesting a corrective action plan;
   c. Educating the investigator and/or all research staff;
   d. Suspending or terminating the research;
   e. Suspending all protocols of the investigator (temporarily or permanently);
   f. Conducting random audits of the investigator and/or all research staff;
   g. Modifying the research protocol;
   h. Confiscating all data collected during the period of non-compliance;
   i. Notifying current participants (required when such information may relate to participants' willingness to continue to take part in the research);
   j. Requiring current participants to re-consent to participate;
   k. Modifying the continuing review schedule;
   l. Suspending or revoking the privilege to conduct human research as a PI or Co-PI or serve as a faculty advisor of student research at UCCS; **and**
   m. Submitting the allegation to the Research Misconduct Committee.

4. The Executive Committee shall report serious or continuing non-compliance with regulations and the action(s) taken, or in progress, to regulatory and supporting agencies, as required, the IRB, the department chair, dean, institute and/or center director, faculty advisor (student research), research compliance coordinator, and other institutional officials as appropriate.

5. The IRB must report to OHRP, under 45 CFR 46.103(a) and 46.108(a) or FDA, under 21 CFR 56.113. See the following for what must be reported:
   a. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to
      i. Subjects or others - http://www.hhs.gov/ohrp/policy/advevntguid.html;
   b. Any serious non-compliance;
   c. Continuing non-compliance with IRB requirements; or
   d. Any suspension or termination of IRB approval -
      i. http://www.hhs.gov/ohrp/compliance/reports/index.html.

Applicable Regulations/Guidance:
21 CFR 50.25(b)(5), 21 CFR 56.108(b)(2), 21 CFR 56.112, 21 CFR 56.113, 21 CFR 56.115(b), 45 CFR 46.108(a)(3)(i), 45 CFR 46.111(b)(5), 45 CFR 46.112, 45 CFR 46.113, 45 CFR 46.115(b), "Guidance on Reporting Incidents to OHRP" (06/20/11)

Special Topics: XXIII. Research with Children		
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University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of human subjects research projects, including research with children. With this in mind, the Institutional Review Board (IRB) at UCCS requires that ***ALL research targeting*** children as the population of interest be reviewed according to Subpart D of 45 CFR 46.401-409. Research involving children may be reviewed by a designated IRB reviewer as permitted by the regulations or at a convened IRB meeting. This type of research may be reviewed as Exempt, Expedited, or Full as determined by the IRB reviewer.

OHRP Guidance for Research Involving Children:

1. Children: Information on Special Protections for Children as Research Subjects
2. Children Involved as subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process (2005) PDF http://www.hhs.gov/ohrp/policy/populations/guidance_407process.html

Resources:

1. IRB Resources - Children Checklist

A. Applicability:

There are special federal regulations which govern research involving children enrolled as study subjects. Subpart D of 45 CFR 46 applies whenever any human subject is a child. A child is defined as a person or persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted (see 45 CFR 46.402(a)). When the IRB reviews study protocols that will involve the use of children as participants, a children's representative may be asked to participate in several types of these reviews:

a. Initial;
b. Continuing review (renewal);
c. Requests for changes; **or**
d. Adverse events, etc.

In order for the IRB to approve a study, the research must fit into one of four categories (described below). A check list may be used to help facilitate this process.

B. Definitions:

The following key definitions are provided at §46.402 and are in addition to the definitions provided at §46.102:

1. ***Children:*** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (Note: When research is conducted in Colorado all individuals under the age of 18 years are children. For research outside of Colorado, a determination of who is a child is to be made.)
2. ***Assent:*** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

3. ***Permission:*** The agreement of parent(s) or guardian to the participation of their child or ward in research.
4. ***Parent:*** A child's biological or adoptive parent.
5. ***Guardian (Legally Authorized Representative):*** An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. If there is no applicable law addressing the issue, the institutional policy regarding the guardian should be utilized.

C. Review of by the IRB:

The IRB at UCCS will make the determination that research involving children fits into one of the categories found in 45 CFR 46 subpart D for research (see below) and will document (may use the children checklist) the required findings for the category used for approval. Protocols involving children as human subjects may be reviewed by a designated IRB reviewer or they may be reviewed at a convened IRB meeting in which a designated children representative is present.
Criteria to determine level of review:

1. No Greater than Minimal Risk - §46.404 (Section E) may be reviewed as Expedited
2. Greater than Minimal Risk (with a Prospect of Direct Benefit) - §46.405 (Section F)
3. Greater than Minimal Risk (with No Prospect of Direct Benefit) - §46.406 (Section F)
4. Not Otherwise Approvable (Consult with the IRB) - §46.407 (Section F)

When completing the IRB New Submission application, the addendum for research involving children must also be completed and submitted to be taken into consideration during the IRB review.

D. Exempt Review:

Two of the eight exemptions of research involving human subjects is narrowed (45 CFR 46.104(d)(2) and 46.104(d)(3)) in scope by Subpart D's additional protections for research involving children.

The other six exemptions apply to research involving children as human subjects in the same way that they apply to research involving adults.

The narrowed exemptions are the exemptions at 45 CFR 46.104(d)(2) and 46.104(d)(3), which generally applies to research involving educational tests, interviews or survey procedures or observation of public behavior, if the data are recorded without individual identifiers, or if disclosure of the recorded responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Where children will be involved as research subjects, however, the use of survey or interview procedures is eliminated from this exemption, and so is research involving the observation of public behavior if the investigators participate in the activity being observed.

In other words, Exempt Category 2(i) and (ii), for research involving survey or interview procedures or observations of public behavior, does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exempt Category 2(iii), where identifiable information is obtained, and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exempt Category 3 does NOT apply to research involving children. 45 CFR 46.104(b)(3)

To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the

subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Otherwise, all the requirements of the human subjects regulations apply.

E. Expedited Review:

1. §46.404 Research not involving greater than minimal risk to the children

   The UCCS IRB must determine and document using the checklist that **all** of the following 3 conditions have been met:
   1. The research presents no greater than minimal risk to the children;
   2. Adequate provisions are made for soliciting the assent of the children are in place; and,
   3. Adequate provisions for permission of their parents or guardians are in place per 45 CFR 46.408.

F. Must be reviewed as Full:

1. §46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.

   The UCCS IRB must determine and document that **all** of the following 4 conditions have been met:
   1. Research involves **greater than minimal risk**;
   2. The risk is justified by the anticipated benefits to the subjects;
   3. The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and,
   4. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians are in place per 45 CFR 46.408.

2. §46.406 Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition

   The UCCS IRB must determine and document that **all** of the following 5 conditions have been met:
   1. The risk of the research represents a minor increase over minimal risk;
   2. The intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
   3. The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition;
   4. Adequate provisions are made for soliciting the assent of the children are in place; and,
   5. Adequate provisions for permission of their parents or guardians, per 45 CFR 46.408.

   A fourth category of research *requires a special level of HHS review* beyond that provided by the IRB.

3. §45 CFR 46.407- Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the

understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

a. The IRB finds that the research does not meet the requirements of 45 CFR 46.404, 46.405, or 46.406;
b. The IRB finds that the research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children; and
c. The HHS Secretary (after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment) has determined either:
    i. that the research, in fact, is found to satisfy the conditions of 45 CFR 46.404, 46.405, or 46.406, as applicable, or
    ii. the following:
        1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
        2) The research will be conducted in accordance with sound ethical principles;
        3) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 46.408.

In the case of the above category's required reporting to DHHS, such reporting is initiated by correspondence to DHHS, from the UCCS IRB chairperson or designee, who will report directly to the Office for Human Research Protections (OHRP) on this matter. The OHRP Guidance Document: "Special Protections for Children as Research Subjects" (45 CFR 46.407 Process) will be followed by the UCCS IRB. Not until the appropriate official has issued determinations in writing back to the IRB (as documented in the official record) will the IRB be able to fully review the research and consider its approval status.

G. Additional Items of Concern 45 CFR 46.408 and 46.409:

§46.408 Assent and Documentation of Assent

The UCCS IRB must determine and document the following 3 criteria have been met:

1. Language: The process of assent of children shall include an explanation of the research in language suitable to the age and competence of the children. The explanation will describe the purpose of the research and a simple explanation of risks and benefits associated with the child's participation in the research. (The reviewer may use the Flesch-Kincaid readability test found in Microsoft Word to review the readability of a document.)

2. Assent Process: The assent procedure can include variations presented by the investigator, such as:
    a. An oral and/or written explanation of the research presented to the child. Unlike the consent or parental permission process, federal regulations do not specify the elements of assent. The content of the assent process should be developmentally appropriate as to length and content.
    b. How, and whether, assent is applicable to all, some, or no children. If assent is only applicable to some children, indicate which children are asked to provide their assent to participate.
    c. The child is asked to assent orally and may be asked to sign the assent or parental permission form, indicating willingness to participate in the proposed research study.
    d. Although written documentation of the child's assent is not required, the investigator and the IRB will consider providing an assent signature line for children to sign, as appropriate.

e. Written assent using the UCCS IRB assent template.

3. Conditions for Waiver of Assent: Assent may be waived in accordance with waiver of consent regulations at 45 CFR 46.116 (Subpart A), for research not regulated by the FDA, or at 21 CFR 50.55(d) for research regulated by the FDA.
   Unless age-specific waiver of assent is requested and approved, children of age 6 to 18 are expected to be part of the discussion about the research. An IRB approved waiver of assent for children below age 6 is not required. To request a waiver of assent for some or all participants, due to age or anticipated condition, the PI must provide a sufficient justification. Child participants not meeting the age or condition specified (in the waiver) must give assent in order to participate in the research. The justification for waiver of assent may include (but is not limited to) the following examples:
   1. The PI has determined that some or all of the subjects over age 6 will not be capable of providing assent based on their developmental status or impact of illness (Note: The PI will need to support this determination, but the UCCS IRB relies upon the professional opinion of the investigator for determining an individual's capacity for assent;
   2. The research offers a prospect of direct benefit not available outside of the research; and/or,
   3. The same conditions under which parental permission can be waived apply [45 CFR 46.116(c-d)].

§46.408 Parental/Guardian Permissions

All of the requirements of 45 CFR 46.116 concerning informed consent apply to parental permission, including the general and required elements. Additionally, there will be an appropriate mechanism for protecting the children who will be participants in the research.

1. *Parental/Guardian Signatures:* As per 45 CFR 46.408(b), consent forms should be drafted to allow for BOTH parents to provide permission for a child to participate in research. The inclusion of two consent signature lines will help to ensure that both parents are encouraged to provide and document their permission in all cases, however:
   a. For research involving categories 404 and 405, the permission of one parent or guardian may be allowed by the IRB (if the IRB deems this to be appropriate and the solicitation of only one signature is clearly requested by the PI in the application).
   b. For research involving §46.406 or §46.407, the permission of BOTH parents is required (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child).

   Only for categories §46.404 and/or §46.405, may the IRB decide that the permission of one parent or guardian is sufficient.
2. Waiver of Parental Permission: Parental/guardian permission may be waived only if the IRB determines that a research protocol is designed in such a way that parental/guardian permission is not a reasonable requirement in order to ensure the protection of the research participants (for example, neglected or abused children).
3. Guardian Permission: Note that any persons acting in place of or instead of a child's parent or parents must be a legally authorized guardian for the child.
4. Children who are in court-appointed or state custody

§46.409 Wards

The content below is directly from 45 CFR 46.

- Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:
    a. Related to their status as wards; or
    b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Special Topics: XXIV. Research with Pregnant Women, Human Fetuses, and Neonates		
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University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of human subjects research projects; with this in mind, the IRB at UCCS requires that ***ALL research targeting pregnant women, human fetuses, and/or neonates*** is reviewed according to Subpart B of 45 CFR 46.201-207. Research-involving pregnant women, human fetuses, and/or neonates may be reviewed by a designated IRB reviewer as permitted by the regulations or at a convened IRB meeting. This type of research may be reviewed as Exempt, Expedited, or Full Board.

Resources:

1. IRB Resources - Checklist for Research involving Pregnant Women, Human Fetuses and Neonates Involved in Research.

The UCCS IRB requires the principal investigator to document (within the IRB submission and Sponsor's Protocol [if applicable]) the inclusion of pregnant women, fetuses, and neonates as defined under Subpart B of 45 CFR 46. Further, principal investigators must provide detailed information in accordance with the required findings below.

When the IRB reviews study protocols that will target pregnant women, human fetuses, and/or neonate's a secondary reviewer familiar with the target population may be asked to participate in several types of these reviews:

1. Initial;
2. Continuing review (renewal);
3. Requests for changes; **or**
4. Adverse events, etc.

In order for the IRB to approve a study, the research must meet the requirements described below. A check list may be used to help facilitate this process.

A. Applicability:

1. "Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research" (Subpart B) applies to research that allows for the inclusion of data on pregnant women, human fetuses, and or neonates.
2. Subpart B is not required to be applied to research that has been determined to qualify for Exemption [45 CFR 46.104(d)(1) through (8)], unless the UCCS IRB determines that the applicability of the Subpart will provide additional protections.
3. 45 CFR 46.110 are applicable with Subpart B (general applicability, including applicability of state and local laws).
4. Subpart B is not exclusive (additional Subparts of 45 CFR 46 can apply to research that is under the applicability of Subpart B).

B. Definitions:

The following key definitions are provided at §46.202 and are in addition to the definitions provided at §46.102:

1. ***Dead fetus:*** A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
2. ***Delivery:*** Complete separation of the fetus from the woman by expulsion, extraction, or any other means.
3. ***Fetus:*** The product of conception from implantation until delivery.
4. ***Neonate:*** A newborn.
5. ***Nonviable neonate:*** A neonate after delivery that, although living, is not viable.
6. ***Pregnancy:*** The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
7. ***Secretary*****:** The Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
8. ***Viable***: As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

C. Review by the IRB

The UCCS IRB will review human subject research covered by Subpart B and approve only human subject research which satisfies the conditions of all applicable sections of this subpart. In doing so, the UCCS IRB will document specific findings when research involves one or more of the following:

1. Pregnant Women or Fetuses (see section F)
2. Neonates (see section G)
3. (After Delivery) Placenta, the Dead Fetus, or Fetal Material (see section H)

The UCCS IRB requires that investigators plan for the inclusion of these populations as early in the protocol planning process as possible. The UCCS IRB also requires that all submissions specify the inclusion of pregnant women, fetuses, and/or neonates. When completing the IRB New Submission application, the addendum for research involving pregnant women/fetuses/neonates must also be completed and submitted to be taken into consideration during the IRB review.

Protocols targeting pregnant women, human fetuses, and/or neonates as research subjects may be reviewed by a designated IRB reviewer or it may be reviewed at a convened IRB meeting in which a designated pregnant women/human fetuses/neonates' representative or consultant is present.

D. Exempt Review

The exemptions at 45 CFR 46.101(b) may be applied to research involving pregnant women.

E. Expedited Review

Expedited review is acceptable for pregnant women, fetuses, and/or neonates when the research presents no more than minimal risk to subjects and the involvement of human subjects falls in one or more expedited categories provided under 45 CFR 46.110.

F. Conditions/Findings Required for Involvement of Pregnant Women or Fetuses:

The UCCS IRB will determine and document that all of the following conditions required under 45 CFR 46.204 (a-j) have been met in order to approve research targeting pregnant women or fetuses.

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accordance with the informed consent provisions of subpart A of this part;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accordance with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;
6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accordance with the provisions of subpart D of this part;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

G. Conditions/Findings Required for Involvement of Neonates:

1. ***Neonates of Uncertain Viability and Nonviable Neonates:***
   The IRB will determine and document that the 4 conditions under 45 CFR 46.205(a)(1-4), as provided below, have been met.
   AND
   For research involving, or which could involve, neonates of uncertain viability, the IRB will determine and document in their minutes that the 2 conditions under 45 CFR 46.205(b)(1)(i-ii) have been met AND that legally informed consent is required in accordance with 45 CFR 46.205(b)(2).
   AND/OR
   For research involving, or which could involve, nonviable neonates, the IRB will determine and document in their minutes that the 5 conditions under 45 CFR 46.205(c)(1-5) have been met.

   45 CFR 46.205 Research Involving Neonates.

a. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
   1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
   2. Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
   3. Individuals engaged in the research will have no part in determining the viability of a neonate.
   4. The requirements of paragraph (b) or (c) of this section have been met as applicable.

b. Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:
   1. The IRB determines and documents that:
      i. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, **OR**
      ii. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research;
      AND

   2. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accordance with subpart A of this part (45 CFR 46 Subpart A), except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

c. Nonviable neonates. After delivery nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:
   i. Vital functions of the neonate will not be artificially maintained;
   ii. The research will not terminate the heartbeat or respiration of the neonate;
   iii. There will be no added risk to the neonate resulting from the research;
   iv. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
   v. The legally effective informed consent of both parents of the neonate is obtained in accordance with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

H. Neonates of Certain Viability:

The IRB will determine and document that only viable neonates will be included in research in accordance with 45 CFR 46 Subparts A and D (children), as per 45 CFR 46.205(d):
45 CFR 46.205(d)

- (d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D.

I. Conditions/Findings Required for Research Involving, after delivery, the placenta, the dead fetus or fetal material:

The IRB applies the following conditions upon any research involving, after delivery, the placenta, the dead fetus, or fetal material:

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

J. Research NOT Otherwise Approvable

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, will require HHS review. Consult with the IRB if research is believed to fit in 45 CFR 46.207.

K. Additional Items of Concern:

1. Pregnant Women Who are not the Target of the Study Population:
   When research targets a wide population that will include women of childbearing potential, there is the possibility of pregnancy, coincidental to subject selection.
   In the IRB application, the researcher should describe the conditions and requirements (if any) for (1) inclusion of pregnant women; (2) exclusion of pregnant women; or (3) women of childbearing potential who may become study participants.
   The IRB should consider the following issues:
   a. Does the IRB application or research protocol define any conditions under which pregnant women or women of childbearing potential who may be encountered during study enrollment can be included or excluded?
   b. Does the consent form for treatment and intervention studies describe any known risks to the pregnant or lactating woman (or to the fetus or neonate if the woman is or becomes pregnant)? These risks and the steps to be taken to minimize them should be discussed in the IRB application and in the consent form.
   c. Should researchers advise participants to avoid pregnancy or nursing for a time during or following the research? Is it appropriate to advise the subjects to notify the researcher immediately should they become pregnant?

2. Basic Ethical Principles and Concerns
   a. Inclusion of women in studies should be the norm, not the exception.
   b. The fetus is considered a vulnerable research subject and deserves special protection from harm.
   c. The decision-making authority for fetal risk is ordinarily with the pregnant or potentially-pregnant woman; this authority should not be displaced elsewhere for research participation.
   d. Under-representation of women in research has led to a systematic lack of data about drugs and treatments with them, displacing the "experiment" to the uncontrolled setting of clinical use; this creates scientific and justice concerns.
   e. In the case of studies of new therapies - especially for diseases with poor standard therapy options - the systematic exclusion of women may be unjustly denying them access to benefits of research participation.

3. Consent Signature Requirements
   The **mother's consent** is required when the research holds:
   - the prospect of direct benefit to the pregnant woman, or
   - the prospect of a direct benefit both to the pregnant woman and the fetus, or
   - no prospect of benefit for the woman nor the fetus but risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;

   Consent from the mother and father is required (unless the father is absent, incompetent, unknown or the pregnancy resulted from rape/incest) when the research holds out the prospect of **direct benefit solely to the fetus**.

Special Topics: XXV. Research with Prisoners		
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University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of human subjects research projects, including prisoner research. With this in mind, the IRB at UCCS requires that ***ALL research targeting prisoners*** is reviewed according to Subpart C of 45 CFR 46.301-306 of 45 CFR 46.301-306. Typically, research involving prisoners will be reviewed at a convened IRB meeting except when the research deals with preexisting de-identified data, or when the risk level is unchanged in a Continuing Review (CR) or Request for Change (ROC).

When completing the IRB New Submission application, the addendum for research involving prisoners must also be completed and submitted to be taken into consideration during the IRB review.

Resources:

1. Prisoner Research: OHRP Guidance (2003)
2. Prisoner Research Certification
3. IRB Resources – Prisoners as Subjects Checklist

A. Applicability

The UCCS IRB applies 45 CFR 46 Subpart C (Special Protections for Prisoners) to research involving prisoners, including situations where a human subject becomes a prisoner after the research has commenced. If a human subject **becomes a prisoner** during a study, it is crucial that the IRB is contacted immediately because additional review is necessary to comply with 45 CFR 46 Subpart C.

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable. [45 CFR 46.302].

“In accordance with the above regulatory language, concerns regarding coercion apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become prisoners after they become enrolled in the research. In the latter situation, it is unlikely that review of the research and the consent document contemplated the constraints imposed by incarceration.” – OHRP Guidance May 23, 2003

When the IRB reviews study protocols that will involve the use of prisoners as participants, a prisoner representative may be asked to participate in several types of these reviews:

1. Initial;
2. Continuing review (renewal);
3. Requests for changes; **or**
4. Adverse events, etc.

In order for the IRB to approve a study, there are seven conditions (described below) that must be met; in addition, the research must fit into one of four categories (described below). A checklist may be used to help facilitate this process.

NOTE – Minimal risk with respect to prisoners is different from that used in Subparts A, B, and D [46.303(d)]. (See below)

B. Definitions:

The following key definitions are provided at §46.303 and are in addition to definitions provided at §46.102:

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (adapted from 45 CFR 46.102).

C. Exempt Review

Exemptions do not apply to prisoner research EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners. 45 CFR 46.105(b)(2)

D. Expedited and Full IRB Review

Protocols involving prisoners as human subjects typically will be reviewed at a convened IRB meeting in which a designated prisoner representative is present. Except when the research deals with preexisting de-identified data, or when the risk level is unchanged in a Continuing Review or Request for Change.

For research not able to be reviewed as expedited, the IRB committee will consider the 7 conditions of approval which will be documented. When required, a letter of certification will be provided to the Office for Human Research Protections (OHRP) for Health and Human Services (HHS) funded research.

The IRB will determine if the research falls under one of the four categories listed in 46.306(a)(2):

(i.) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; (**NOTE:** Category (i) and (ii) must be no more than minimal risk 46.303(d))

(ii.) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; (**NOTE:** Category (i) and (ii) must be no more than minimal risk 46.303(d))

(iii.) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or (**NOTE:**

HHS Secretarial consultation is required for all category (iii) HHS funded research (this may take several months for review.))

(iv.) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research. (**NOTE:** HHS Secretarial consultation is required for all category (iii) HHS funded research (may take several months for review.))

E. Additional Items of Concern:

When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must determine, in addition to other requirements under 45 CFR 46 Subpart A, **seven additional findings** under 45 CFR 46.305(a), as follows:

(1) The research under review represents one of the categories of research permissible under §46.306(a)(2);
(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
(3) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides, to the IRB, justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
(5) The information is presented in language which is understandable to the subject population;
(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
(7) Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

F. Certification Letter to OHRP for HHS Funded Research ONLY

- A certification letter must be submitted to OHRP for all HHS funded projects involving prisoners. A certification letter approval from OHRP must be received before a research study can commence. Specific DHHS epidemiology research may be eligible for a waiver.
- The IRB administrative support will manage the certification letter to OHRP for HHS funded research involving prisoners. The letter will be on UCCS letter head and signed by the Signatory Official for UCCS. The letter should contain required information from OHRP guidance “How to Prepare a Prisoner Certification Letter to OHRP”.

A. Students as Human Research Participants

The involvement of UCCS students or subordinates (i.e., employees, lower ranking individuals in military, etc.) as human research participants may occur in the social and behavioral sciences. Although federal regulations do not explicitly state that students/subordinates are a vulnerable population, their involvement may present special concerns to researchers and the IRB.

1. Potential concerns include:

    a. Underage Students: Minors (students under 18 years of age) may be included in the human research participant pool provided there is additional "appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law" (see 45 CFR 46.408).

    b. Students who are 18 years or older: May participate in IRB approved research conducted by faculty or their advisees, provided consent is obtained according to 45 CFR 46.116.

    c. Potential for Student Coercion: Student participation in faculty research can raise questions regarding the student's ability to exercise free choice because of the possibility that grades, or other important factors may be perceived to be affected by the student's decision to participate. To protect against coercion, faculty/investigators should advertise for research participants generally (e.g., through human research participant pools or notices posted in the school) rather than personally recruit individual students, or require students enrolled in their classes to participate in their research. Faculty researchers must add safeguards to ensure that prospective students who become research participants do not experience adverse consequences if they decline or withdraw from the faculty research study.

    d. Potential for Subordinate Coercion: Subordinate participation (i.e., employees, lower ranking individuals in military, etc.) in investigator research can raise concerns regarding the subordinate's ability to exercise free choice. When sending recruitment letters, the investigator should ensure the potential subjects do not feel pressured into participating in the research for fear of job loss, delayed promotion, or other influences from the supervisor or superior officer. Additional safeguards must be added to ensure that potential subjects do not experience adverse consequences if they decline or withdraw from the research study.

    e. Requiring Research Participation: Requiring participation in research for course credit or extra credit is controversial. Students are to be given the choice of equitable alternative activities (e.g., write a brief research paper, attend faculty research colloquia) rather than only participating in faculty research for course extra credit. Students who choose to participate in studies should be given several studies to choose from and the studies must

not involve more than minimal risk. Students should be able to withdraw from the study at any time without losing the extra credit or experiencing any other consequences.

2. Should you invite your own students or subordinates to participate in your research study, please pay attention to the following:
    - The research must present no more than minimal risk to subjects.
    - The recruitment should involve only indirect methods such as being recruited through the posting of an IRB approved flyers/ads or through IRB approved communications sent out to a larger group.
    - Consent should be conducted by a third party. For example, if the investigator wants to administer pre- and post-tests to determine the efficacy of a particular curriculum, the necessary consent forms could be obtained, and the tests administered by a colleague at times when the investigator is not present. A graduate teaching assistant in the class in which the subjects are enrolled **does not** qualify as a third party for collecting data on behalf of the investigator.
    - If the research is conducted within a classroom setting, the instructor should be blinded to the identity of the participants and data cannot be analyzed until final grades have been posted.

Special Topics: XXVII. International Research		
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University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of human subjects research projects, including international research. With this in mind, the Institutional Review Board (IRB) at UCCS requires that **ALL** research involving human subjects conducted outside the United States or territories be reviewed. UCCS Principal Investigator (PI) or Co-PI must not be in contradiction with ethical principles established in the Declaration of Helsinki, the *Belmont Report*, or Federal regulations 45 CFR 46.

This SOP is intended to help define the requirements for PI's or faculty advisors conducting human subject research in international settings, and to provide guidelines for the IRB regarding the review of these types of studies. These guidelines may be in addition to items found in an IRB review not involving international research participants.

A. PI Responsibilities when Conducting International Research

In general, international research using human subjects must adhere to the UCCS IRB SOP's as well as the laws and regulations of the host country, institution, or community. It is the responsibility of the PI and the PI's faculty advisor to comply with this SOP.

It is the responsibility of the PI to have sufficient knowledge of local laws and customs related to human subject research (e.g., how research is typically conducted in the host country, how participants may be recruited, and how the consent process works). Local laws can be accessed at https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html.

General PI responsibilities:

1. When completing the IRB New Submission application, the addendum for research involving prisoners must also be completed and submitted to be taken into consideration during the IRB review.
2. Determine if there is a local IRB, ethics boards, or community leader, etc. which reviews research, and to obtain local approval and follow local requirements in addition to Federal regulations.
3. A local review may be required. (See OHRP International Compilation of Human Research Standards). If a local review is performed, provide a copy of the approval letter along with your UCCS IRB application.
4. If a local review is not available, then the IRB may ask for a "**consultant**" who is knowledgeable about the locale. In some cases, this person may be a UCCS faculty member, or it may be someone in the location of the research. This person will be asked to review the research proposal and highlight concerns they may have about conflicts with local customs, regulations, translation, or qualifications of the research team. This review will be provided as part of the IRB application. The required documentation is attached as Appendix A of this SOP.
    a. It is the responsibility of the PI to find a qualified person who is willing to act as a consultant to the UCCS IRB. A qualified person should be aware of local norms affecting your research and should have no conflicts of interest in reviewing your study (e.g., the "consultant" should not be a part of your research team or be funding your study). **Your IRB application**

should provide who the consultant is, why this individual is qualified to review your study, and disclose any conflicts of interest.

5. Responsible for providing an informed consent in English and the language of the intended research population. In some cases, the PI may be required to provide a certification from a translator stating that the English version matches the foreign language.
6. In some cases, it may be appropriate for the IRB to waive some elements of consent required by 45 CFR 46.116 and 45 CFR 46.117. If such a request is made, the PI must include in the IRB application an explanation of cultural norms or conditions that justify the waiver (e.g., societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the research, etc.).
7. In a few cases, permission from the host country may not be needed if the PI is recruiting participants outside an institution (i.e., known person to the investigator, snowball sampling) where there is not one to secure a letter of access. The IRB will have the final authority to determine if the PI must have a letter of access in the initial IRB review.

B. Appendix A: Local Review or Consultant Letter for Research Outside the United States

UNIVERSITY OF COLORADO COLORADO SPRINGS

Institutional Review Board

Local Review or Consultant Letter for Research Outside the United States

Background and Instructions for Investigators

Federal regulations requiring independent review of research involving human research participants extend to research that occurs outside the United States. These regulations also indicate that the review should be conducted by (or include) individuals who are familiar with the norms of the community in which the research is being conducted.

Federal regulations provide different ways to meet this requirement. One possibility is for an investigator to have his or her research reviewed by an IRB, Ethical Review Committee, or the equivalent in the country in which the research is being conducted. In this case, you can provide a copy of the letter of approval from this committee in lieu of the Local Review Letter described below. In most cases, the project will still need to be reviewed by the UCCS IRB, who will rely in part on the review by the host country's board.

Alternatively, the requirement for local review can be met through the use of a "consultant" to the UCCS IRB who is knowledgeable about the locale in which the research is being done. In some cases, this person may be a UCCS faculty member, but in many cases it will be someone in the location of the research. This person will be asked to review your research protocol and highlight any concerns he or she may have about conflicts with local norms or practices, translation, or qualifications of the research team. This information will then be used as part of the UCCS IRB's review process.

According to the regulations, this consultant may need to be actively involved in the UCCS IRB discussion (either in person or by teleconference) if the study involves higher levels of risk. But for most studies, it would be sufficient to have this information provided to the committee using the attached Local Review Letter (Appendix A).

It is your responsibility as PI to find a qualified person who is willing to act as a consultant to the UCCS IRB. A qualified person should be aware of local norms affecting your research, and should have no conflicts of interest in reviewing your study (for example, the consultant should not be part of your research team, funding the study, or benefiting from the research). **In your application to the UCCS IRB, you should indicate who this consultant is, why he or she is qualified to review your study, and disclose any conflicts of interest that may exist.**

You should also provide the consultant with the attached Local Review form and instructions; if desired, you may complete the information in the first two paragraphs of page 1 and the first item on page 2 of the form. The form itself should be on the letterhead of the consultant if possible, and normally should be delivered directly to the UCCS IRB office. Ideally this could be done using word processing software; if you instead print the form for the individual to complete by hand, please adjust the spacing to allow plenty of room for the consultant's comments.

UNIVERSITY OF COLORADO COLORADO SPRINGS

Institutional Review Board

Local/Consultant Review Letter for Research Outside the United States

Instructions for Local Review Consultant

Greetings from the University of Colorado Colorado Springs. At our university, we have a requirement that all research which involves living people must be reviewed by our Institutional Review Board (IRB). The committee is responsible for making sure the proposed research is safe for those who participate, that participation is voluntary, and that the research raises no ethical concerns.

We are asking for your help in this process. One of our researchers has proposed a study in a location that none of the committee members knows well. Because the committee is unable to evaluate the safety and appropriateness of the proposed research, we are asking for help in reviewing the study.

More specifically, we are asking that you review the researchers' intended study and complete the attached form. Please let the committee know of any concerns you might have about the study, or any suggestions you have that might improve the study. These don't have to be big concerns—we'd also like to know about less serious issues you may have. Please use as much room and as many pages as you like. The committee will then work with the researcher to find ways to solve any concerns with the study.

If possible, we would appreciate it if you transfer the form onto your own stationery, or attach a business card or something else that indicates that it was you who completed the form.

Once you have completed the form, we would prefer that you send it back directly to the Institutional Review Board, rather than giving it to the researcher. It would speed up the process if you could send the form to us by e-mail at irb@uccs.edu. If this is not possible, please mail it to "Institutional Review Board, University of Colorado Colorado Springs, 1420 Austin Bluffs Park Way, UOP, Suite 202, Colorado Springs, CO USA 80918."

Thank you very much for your help.

[Local Contact or Consultant Letterhead If Available]

Local/Consultant Review Letter

[Date]

Institutional Review Board
University of Colorado Colorado Springs
UOP, Suite 202
1420 Austin Bluffs Parkway
Colorado Springs, CO USA 80918

Dear Committee members:

I have reviewed [**name of PI**]'s protocol, **[title of research protocol],** with regard to its conformance with local customs, research regulations, and research traditions in **[name of country].** My expertise in **[name of country]** is due to my **[list experience, education, etc. that supports your expertise]**.

I understand that [**name of PI**] proposes to **[brief description of research activities to take place in country].**

Please check one:

_____ I have no concerns about this research being conducted in **[name of country/locale]**, and agree that this protocol meets locally acceptable standards of research.

_____ I have the following concerns regarding how well this study conforms to local customs and research methods: **[please list concerns].**

Please check one:

_____ I have no reservations about the qualifications of the research staff (including translators, transcribers, or others) to conduct this research.

_____ I have the following questions regarding the qualifications of the researcher or research staff to conduct this research. **[please list concerns].**

I understand that the researcher intends to translate consent forms and other research materials into the following languages or dialects: **[PI should include list of languages].**

Please check one:

_____ I believe that this list of languages is sufficient.

_____ I believe that this list of languages is not sufficient. **[please list concerns, in particular include any additional languages or dialects that should be included].**

Please check one:

_____ I have no concerns about the researcher's plan for explaining the study to participants and for getting their voluntary consent to participate.

_____ I have the following concerns regarding how the researcher plans to explain the study and obtain consent for participation. **[please list concerns].**

Do you believe that this study is risky enough that you should be personally involved (such as by telephone) in the Institutional Review Board's discussion of this study? ___Yes ___ No

Other comments or suggestions:

[If you have any other comments about this study that you believe would aid the Institutional Review Board in its review of this study, please add them here.]

Sincerely,

[Name, title and agency/institution of reviewer; please include email contact information if applicable]

Please return this form to the Institutional Review Board at the address above, or email as an attachment to irb@uccs.edu.

Special Topics: XXVIII. Student/Classroom Research Projects		
Number	**Effective Date**	**Page**
SOP# 28	**10/01/2022**	**1 of 4**

The University of Colorado Colorado Springs (UCCS) requires that all research involving human subjects conducted by faculty, staff, or students affiliated with the university, be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its federal status as an Exempt, an Expedited, or a Full review project. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB.

Learning how to conduct ethical research is an important part of a student's educational experience. Some research projects assigned for coursework do not meet the definition of human subject research and may not require IRB approval. If there is any question whether a course project meets the definition of human subject research, then it should be submitted to the IRB for review and assessment.

The IRB further requires that all student research activities are supervised by a faculty member; however, some types of student research activities may not require IRB review above and beyond faculty supervision. UCCS supports a wide variety of both undergraduate and graduate student research projects using human subjects – from course-related research exercises to dissertation studies. This document is intended to clarify IRB procedures related to classroom research projects performed by students.

A. Definitions:

1. ***Classroom Research Project:*** Any observation of or intervention with human subjects by a student as part of a course that is designed to develop or contribute to a student learning research and data gathering skills, where the intent is to collect data (e.g., learning how to interview, how to administer an IQ test, or conducting an interview). Classroom research projects are limited to those projects that do not meet the definition of human subjects research.

2. ***Generalizable Knowledge:*** Information that is collected or gathered to draw general conclusions; inform policy, inform professional knowledge in a discipline; or generalize outcomes beyond a specific group, entity, or institution being studied. As a rule, if you plan on presenting outside the classroom or department, the information would be considered generalizable knowledge.

3. ***Human research participant:*** A living individual from whom an investigator (whether professional or student) conducting research obtains data through the following methods: (i) an intervention, interacting with the individual and using, studying, or analyzing the information or biospecimens, or (ii) Obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens (adapted from 45 CFR 46.102)

4. ***Research:*** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the development of generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration quality improvement activities and service programs may include research activities and require IRB review. The following activities are deemed not to be research:

a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, support, requested, ordered, required, or authorized by a public health authority.
c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
d. Authorized, operation activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
(adapted from 45 CFR 46.102)

5. ***Vulnerable Populations:*** For the purposes of classroom research may include: pregnant women, fetuses, children, prisoners, persons at high risk of incarceration or deportation, individuals with impaired decision-making capacity, or economically disadvantaged persons. Projects involving such subjects **require IRB review** and submission of a protocol for approval prior to beginning the research.

B. Human Subjects Research and Course Projects

Some research projects assigned for coursework do not meet the definition of human subject research and may not require IRB approval. Course projects that **DO NOT** require IRB review and approval are limited to projects that do not meet the definition of human subject research.

Classroom research projects are not required to be submitted to the IRB for review unless the project meets the definition of human subject research. The responsibility for the initial determination as to whether an activity constitutes human subjects research rests with the faculty member/advisor/mentor. The faculty member should make this determination based on the definitions of "human subject" and "research" as detailed above in Section A. Since UCCS will hold them responsible if the determination is not correct, faculty members are urged to request a confirmation that the activity does not constitute human subjects research from the IRB office if there is any uncertainty. Informal requests may be made by phone or email and must include sufficient documentation of the activity to support a determination. Informal requests represent the opinion of the IRB office personnel and are not formal endorsements of the project as Non-human Subject Research. If the faculty member would like a formal determination that research does not meet the definition of human subject research, an application must be submitted for review and assessment.

It is the responsibility of the faculty member, department, and college/school to ensure that all activities conducted in the classroom that involve interaction with the public are conducted in accordance with ethical principles. The UCCS IRB adheres to the basic ethical principles from the *Belmont Report*. The IRB is available as a resource to help faculty develop appropriate class resources, but the college/school is ultimately responsible for their conduct.

Faculty and Students who undertake projects meeting the definition of human subjects research without submitting their work for IRB approval must understand that data procured for the purposes of 'course work' may not under any circumstances then be used for research. There is no after-the-data collection IRB application/retroactive review allowed because the intended use has now changed.

If at the conception of student classroom activity the instructor or student is aware or expects that the primary data gathered by the student will be used to develop or contribute to generalizable knowledge (e.g. thesis/dissertations or presented outside the classroom, except for general campus research days, i.e., Mountain Lion Research Day), the activity must be reviewed by the UCCS IRB **prior** to initiation. Projects presented at campus research days should include a disclaimer indicating that it is a classroom project and not research. Failure to obtain IRB review may be considered non-compliance.

Faculty and Students, who publish their classroom projects involving human subjects via any vehicle (e.g. thesis/dissertation, blogs, and/or posters presented outside the classroom), must first have had IRB approval before primary data is collected.

NO retroactive approval is available.

In making a determination of whether or not a classroom research project requires IRB review, the faculty member should err on the side of caution and contact the IRB office for assistance. The faculty member is responsible for communicating to students the ethics of human subjects research, for ensuring the protection of human subjects and that a process is in place for obtaining voluntary informed consent from research subjects, and for monitoring the students' progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the project, and document the determination that the project does not meet the definition of human subject research in consultation with their faculty. If the project does meet the definition of human subject research, then the project will need to be submitted to the IRB for review.

In summary, if the classroom assignment involves systematic data collection and if there is any intent to develop or contribute to generalizable knowledge (i.e., publish or otherwise report data outside of the classroom/department), then the assignment is most likely research and should be submitted for review by the IRB. Additionally, all projects that involve vulnerable populations require IRB review and submission of a protocol for approval prior to beginning the research.

C. Individual Research Projects Conducted by Students

Senior theses, Capstone projects, undergraduate research projects, master's and advance degree research, and similar exercises must be independently submitted to the IRB for review. Students must also have a faculty mentor identified on any human subject research project.

D. Theses and Dissertations

Theses and dissertation research activities are considered to meet the federal definition of human subject research and must be submitted for review by the IRB by the student researcher. However, when students conduct research as part of a course of study, a faculty member ultimately is responsible for the protection of the subjects, even if the student is the primary researcher and actually directs the project. Faculty mentors assume the responsibility for students engaged in independent research, and course instructors are responsible for research that is conducted as part of a course.

Students may not serve as Principal Investigators without a Faculty Advisor. They must have a faculty sponsor who fulfills the principal investigator criteria and who will be responsible for the conduct of the study and serve as a faculty mentor on the study. The mentor is responsible for ensuring that the student appropriately completes the required documents for submission to the IRB for review. In

particular, faculty and students should understand their responsibilities as a principal investigator as described in IRB SOP XXI. Responsibilities of the Principal Investigator.

Special Topics: XXIX. Department of Defense and Military Research		
Number	**Effective Date**	**Page**
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University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of human subjects research projects, including Department of Defense (DoD) projects. A DoD project is one which: is funded by a DoD organization; involves collaboration/cooperation with a DoD organization; takes place on a DoD site; uses DoD assets or facilities; or involves DoD personnel (unless the inclusion of those personnel is incidental in the study as DoD personnel are *not* the targeted recruitment demographic).

With this in mind, human subjects research involving the DoD may need to meet additional requirements which may address, but are not limited to, how subjects are recruited, submission of researcher qualification, the appointment of an outside research monitor, and the review & approval of the protocol by the DoD *in addition to* review & approval by the UCCS IRB.

This SOP is intended to help guide PIs or faculty advisors conducting human subject research involving the DoD, and to provide guidelines for the IRB regarding the review of these types of studies. These guidelines may be in addition to items found in an IRB review not involving the DoD.

DoD organizations include, but are not limited to:

- Air Force
- Air Force Academy
- Army
- Army Corps of Engineers
- Coast Guard
- Coast Guard Academy
- Defense Advanced Research Projects Agency (DARPA)
- Defense Intelligence Agency
- Marine Corps
- Military Academy (West Point)
- Missile Defense Agency
- National Geospatial-Intelligence Agency
- National Guard
- National Security Agency
- National War College
- Naval Academy
- Navy
- Office of Naval Research
- Pentagon Force Protection Agency
- Tricare Health System
- U.S. Naval Observatory

A. Responsibilities

Research involving human subjects must adhere to the UCCS IRB SOPs as well as those in the Department of Defense Instruction on human subjects research (DoDI 3216.02). It is the responsibility of the PI and (when applicable) the PI's faculty advisor to understand and comply with these guidelines. The DoD has some human subjects research requirements which are unique to DoD. Examples of issues which are unique to the DoD include research involving classified military information, or when research involves the recruitment of military personnel:

"Superiors of Service members (e.g., unit officers, senior NCOs, and equivalent civilians) in the chain of command shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as human subjects. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session." (DoDI 3216.02.e(1)(c))

General PI responsibilities:

- Provide letters of access to population under study.
- Provide appropriate military IRB approval (if necessary) prior to UCCS IRB approval, unless military IRB requires prior UCCS IRB approval. If this is the case, then a contingent UCCS IRB approval can be given.

B. Resources

Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

You can find further information about working with specific military branches by following these links:

- **Air Force**
- **Army**
- **Coast Guard**
- **Navy**
- **Marine Corps**

Special Topics: XXX. Use of Social Media and other Internet Resources		
Number	**Effective Date**	**Page**
SOP# 30	**10/01/2022**	**1 of 5**

University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of research projects involving human subjects, including research using social media and the Internet as a tool and venue. To date, the Office of Human Research Protections (OHRP) and Common Rule agencies have not issued formal regulations 45 CFR Part 46 or guidance addressing the ethical issues related to the use of social media and other Internet resources for human subjects.

With this in mind, the Institutional Review Board (IRB) at UCCS will use this SOP, 45 CFR Part 46, guidance from the Secretary's Advisory Committee on Human Research Protections (SACHRP), and other resources to review research using social media and other Internet resources. It should be noted that the SACHRP items do not replace OHRP regulations.

As the nature of research involving these technologies continues to evolve, it is not possible to identify every possible circumstance or type of research activity that may involve the use of social media and the Internet. We encourage you to refer to this document as you design your research study, and to contact the IRB office at irb@uccs.edu if you have specific questions.

A. Definitions

1. ***Engaged web-based research (active):*** Research that actively engages the site or community. Some examples include game or role playing or manipulating the environment with the intent to assess reactions or responses.

2. ***Interaction:*** Includes communication, or interpersonal contact between the investigator and human research participant. The interaction can include, for example, interviews, focus groups, dialogue across a LISTSERVE or newsgroup, or any exchange via social media. Social media sites would include, but are not limited to, Twitter, Snapchat, Facebook, Instagram, Pinterest, or internet blog sites.

3. ***Intervention:*** Both physical procedures by which information or biospecimens are gathered (e.g., education program, drug treatment, venipuncture) and manipulations of the human research participant (e.g., exercise program, diet therapy) or the human research participant's environment (e.g., music, room light) that are performed for research purposes (adapted from 45 CFR 46.102).

   Manipulations of internet environments may include testing of different website interfaces, provision of different responses to web queries, recording Internet-based activities or behaviors for subsequent analysis, or may be through something as simple as the presence of the researcher.

4. ***Non-Intrusive web-based research (passive):*** Research that involves data collection techniques that are observational in nature. There is no direct contact with human subjects about whom data is being collected. Some examples include public Twitter feeds, public Facebook profiles or postings, information from public/open chat rooms, etc. Depending on the Terms and Conditions of the site, it might not be permissible to conduct data collection methods (i.e., scrapping, crawl, cache content).

5. ***Social media/other Internet sites or communities:*** Web or mobile-device based services that provide ways for users to interact, such as social networking sites, blogs, discussion groups, or other information sharing services that support messaging, email, video posting comments, etc.

B. Applicability

Internet research includes both the Internet as a tool for research and as a locale or venue in which the research is conducted. There are multiple forms of Internet research and a wide range of Internet research where human subjects may be involved.

Below are some examples of social media and other Internet resources. Please note this is not an inclusive list.

- Twitter and other socially-mediated communities or communication technologies
- Chatrooms
- LISTSERVs
- Online Communities (including online games)
- Virtual Worlds
- Websites

C. Types of Research and Guidelines

1. Non-Intrusive web-based research (passive) as defined above

Guidelines for this type of research can vary, depending on access restrictions placed on the information desired.

Restrictions on accessing information:

If there are restrictions on accessing information or the social media or other Internet site has published restrictive provisions (i.e., terms of access, terms of service, terms and policies), there is an expectation of privacy and the PI should contact the IRB before conducting the research. Depending on the methodology and circumstance, it is possible that an IRB approval will be required. Restrictions could include having to request access to the site/data; the PI having to belong to, be invited to, or invite others to a particular interest or friend group; or if the PI seeks access when role playing or recruits individuals who have restricted access. Ensure that a description of consent procedures and how the consent will be documented are included in the IRB application. The PI should ensure that the published privacy/confidentiality policy permits the research to be conducted.

No restrictions on accessing information:

If the social media or other Internet site has no restrictions on accessing information (e.g., information available on a public website, blog, chat room, etc.), the following is recommended: (*Please note that this could include sites containing information that (by law) is considered "public," information based sites where information is posted for the purpose of sharing with the public, open access repositories, and discussion fora that are freely accessible to any individual with Internet access that do not involve restrictive provisions (i.e., terms of access, terms of service, terms and policies) that limit the use of the information for research.)*

- The PI should follow the published terms of service of the site; if there is no policy the site could be considered public.
- The PI should ensure that all information on the individuals is de-identified in how the data are

recorded (i.e., paraphrasing and no using direct quotes, no use of screen prints, do not identify or record usernames, etc.). If circumstances require that individuals be identified, the reasoning should be explained in the IRB application in order for the IRB to evaluate the impact to the risk/benefit of the participants.

- PI's should not elicit information from other sources to establish the identity of individuals that use pseudonyms to conceal their identity.
- In some cases, this research will not be considered human subjects research, but it is recommended caution be used and an IRB application be submitted should there be any question about its being research. There are emerging ethical sensitivities in this area.

2. Engaged web-based research (active) as defined above

This type of research involves interaction and/or intervention of the environment and is considered human subjects research. Some examples include game or role playing or manipulating the environment with the intent to assess reaction or responses. The PI must submit an application before conducting the research.

The PI should provide the below additional information when submitting an IRB application (excluding survey tools such as SurveyMonkey):

- Identify how the actions of the research may impact the site or community.
- Explain if there is an expectation of privacy on the site or community (see the definition of privacy for examples).
- Explain if vulnerable populations such as children will be targeted, especially on communities/sites that use pseudonyms.
- Explain safeguards in place to ensure screening for children, prisoners, and other vulnerable populations, especially if the platform lends itself to vulnerable populations participating.
- Explain if there is any potential or increased harm to participants in conducting the research.
- Explain how confidentiality will be protected (see the definition of confidentiality above).
- Indicate how subjects' consent will be obtained, or explain why not applicable.
- Indicate how anonymity of data will be obtained or explain why not applicable.
- Provide an example of what the prospective subjects will see (i.e. a "screen shot").
- Ensure that the site's published terms of service permit the research to be conducted. If there is no mention of research, the PI should have due diligence and contact the administration of the site to inquire. Should the site not respond, the matter will be reviewed by the IRB on a case-by-case basis.

3. Using social media for recruiting

Utilizing social media involves interaction and/or intervention of the environment and is considered human subjects research. Recruitment tools include web ads, Twitter streams, Facebook posts on personal feeds, blog postings, YouTube videos, and push methods. The PI must submit an application before conducting the research. Additionally, the following should be considered:

- The consent should always be independent from the recruitment and should be part of the research process.
- The PI should clarify in the recruitment statement that data is only collected once enrollment in the research study has occurred.
- The PI should ensure that the criteria for equitable selection of participants and sample selection is justified. This could be difficult since the respondent population is not under the control of the PI.

- The PI should ensure safeguards are in place to screen for children, prisoners, and other vulnerable populations.

4. **Use of Amazon Mechanical Turk for recruiting**
   The use of Amazon Mechanical Turk for recruiting purposes continues to grow. The compensation for tasks completed through Mechanical Turk is typically very small, usually less than $1. When using Mechanical Turk for recruitment, the same considerations for participants are the same as any other human subjects research. Additionally, the following should be considered:
   - Inform the potential participant if compensation is contingent on certain conditions.
   - Make sure that the complexity of the task and expected time to complete the task is reasonable and communicated clearly in the consent process.
   - Take appropriate steps to close research to prevent unnecessary responses even if the project is only on hold.

   Note – Data collected using this tool resides on the Amazon servers and no assurances can be made with regards to its use for purposes unrelated to research. For this reason, it is advised to collect data using third party survey software with known policies for data security and anonymity.

D. Additional Considerations

1. **Terms and conditions of use of social media and other software**
   PIs should be aware of any research related restrictions for the use of social media/site where they intend to conduct the research. Restrictions can be found where the policies are located and could be called terms of access, terms of service, terms and policies, or something similar. Failure to understand and obtain the appropriate permissions could result in consequences that could include loss of data, reputational harm to the PI or institution, or legal action. Neither UCCS nor the IRB can take responsibility for ensuring that the terms of service for conducting research on sites have been met.

2. **Confidentiality**
   Confidentiality refers to how information obtained from individuals is protected. Two potential sources of breach of confidentiality with electronic data include:
   a. Inadvertent disclosure: The use of computers and the Internet to obtain data, store, analyze, and communicate research data increases the likelihood of inadvertent disclosure of that data. Example: Identifiable research data being inadvertently sent to entire LISTSERVs.
   b. Deliberate attempts to gain access to research data (hacking): Level of security should be directly related to the sensitivity of the data and the likelihood of outside interest in the data.

   The best defense against a breach of confidentiality is multiple layers of security. To protect against security breaches, the use of controlled access privileges, firewalls, encryption, and limited Internet access on computers, as well as adequate physical security for computer equipment storing sensitive data should be in place.

3. **Privacy**
   Privacy refers to individuals' right to have control over access to themselves and their information. Privacy concerns arise in research on Internet activity and generally relate to whether such activity is identifiable and constitutes public or private behavior.
   Expectation of privacy:

- Consent should be obtained to use data from online communities with an expectation of privacy (i.e., participants in a chat room expect privacy and do not expect their activity to be studied by researchers).
- If a page is marked private then there is an expectation of privacy, or if a page/site requires you to request to belong then there is an expectation of privacy. Examples would include private groups within Facebook or LinkedIn.
- If a PI is studying a site where anyone can join; for example, the UCCS Facebook page the expectation of privacy may not be as great and statements could be considered in a public setting.
- Use of pseudonyms (screen names, handles, etc.) does not mean that they are anonymous. Online identities in online communities may be as important to them as their actual identity, and thus, need to be protected as much as actual identities. These personas and their reputations can usually be traced back to real individuals.

The PI should consider provisions for remote locking of devices or remote destruction of data in the event of a lost device.

4. Security of data and informed consent

Collecting data via the Internet can increase potential risks due to the involvement of third party sites, the risk of third party interception when transmitting data across a network, and the inability of ensuring that data is completely destroyed once the work is complete. The PI should inform the participants of the potential risks in the informed consent document. The informed consent should indicate that confidentiality will be kept to the degree permitted by the technology being used, but it is not possible to make guarantees regarding the interception of data being sent via the internet by any third parties.

It is important to remember that no social media or Internet site can provide absolute anonymity, confidentiality, or privacy. It is up to the PI to understand the privacy and data security information for intended sites, including how the data is transmitted and maintained. The data collected online may be stored on servers out of your control and data might be stored for a much longer time period on a server.

5. Affiliation with UCCS

For information regarding creating a social media page, please reference the UCCS Social Media Policy located at http://www.uccs.edu/socialmedia/social-media-policy.html.

6. Crowdfunding/Crowdsourcing

For information regarding the use of social media for crowdfunding and/or crowdsourcing, please reference the UCCS Crowdfunding/Crowdsourcing Policy (100-013) located at https://www.uccs.edu/compliance/sites/compliance/files/inline-files/100-013.pdf.

Special Topics: XXXI. Lab Certification (CLIA)		
Number	**Effective Date**	**Page**
SOP# 31	**10/01/2022**	**1 of 2**

University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of research projects involving human subjects. To date, the Office of Human Research Protections (OHRP) and Common Rule agencies have not issued formal regulations 45 CFR Part 46 or guidance addressing the ethical issues related to circumstances in which Clinical Laboratory Improvement Amendment (CLIA) certification is required for research laboratories, as well as the responsibilities of the researcher and the Institutional Review Board (IRB) related to certification.

A. Definitions:

Clinical Laboratory Improvement Amendment (CLIA): CLIA applies to, and requires certification of, all facilities that perform any tests on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" (see 42 U.S.C. §263(a)).

B. CLIA Examples:

An example of a non-patient-specific result is "10 out of 30 participants were positive for gene X." The result in this example is a summary of the group data, and is not indicative of an individual's health. An example of a patient-specific result would be "participant A was positive for gene X" in which the result is specific to participant A.

Examples:	**Does CLIA apply?**
1) A study subject is asked to take a urine-pregnancy test during the study visit to determine eligibility. The subject is given the results of the test.	Yes
2) The laboratory reports patient-specific test results to the study coordinator, who uses the results to assign the patients to the **treatment arm** of the study.	Yes
3) A laboratory is conducting research to evaluate a new test method. Specimens are collected and tested in a laboratory. Only summary results are provided by the laboratory to the principal investigator.	No

If results of lab tests will be reported back to the research subjects, a copy of the CLIA certificate for the lab analyzing the test should be provided to the IRB.

C. Responsibilities:

1. Researchers are responsible for complying with the CLIA requirements, when applicable:
   - Deciding whether their laboratories require certification
   - Obtaining and maintaining certification, as necessary

2. The UCCS Institutional Review Board (IRB) does not play any role in the implementation and enforcement of CLIA requirements at UCCS.
   - IRB approval is not conditional upon obtaining CLIA certification, even when CLIA certification is required.
   - However, the IRB carefully considers all aspects of a researcher's plan to return specific research laboratory results to individual research subjects before granting IRB approval for the plan. This includes consideration of the two issues underlying the CLIA regulations:
     - Information about the validity and reliability of the analysis.
     - Information about the provisions to ensuring that the correct results will be returned to the correct individual.

3. Privacy Board review may be required if using PHI or resources from a HIPAA covered entity on campus.

4. CLIA laboratory certification requirement. CLIA applies to, and requires certification of, all facilities that perform any tests on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings".

5. Applicability to research labs. CLIA certification is not required for "research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients."

6. The source of funding for the lab or the research is irrelevant. That is, CLIA requirements do apply to research studies and laboratories whether or not they are federally funded, if they are performing laboratory tests that meet the criteria described in Section C(3).

7. Implementation and enforcement. CLIA is implemented and enforced by the Centers for Medicare & Medicaid Services (CMS), which is part of the federal Department of Health & Human Services (HHS).

8. Relationship with FDA approval. Laboratory certification and FDA approval of a lab test are not the same, nor are they a substitute for each other.
   - The purpose of the CLIA program is to ensure accurate and reliable test results.
   - The purpose of the FDA approval program is to ensure that laboratory tests involving FDA-regulated devices or biologics are reasonably safe and effective.
   - The two agencies' regulatory schemes are different in focus, scope and purpose, but they are intended to be complementary.

D. Resources:

1. Centers for Medicare & Medicaid Services Research Testing and CLIA - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html
2. 42 CFR 493 - https://www.law.cornell.edu/cfr/text/42/part-493
3. Colorado Department of Public Health and Environment CLIA - https://www.colorado.gov/pacific/cdphe/clia-clinical-laboratory-improvement-amendments

Special Topics XXXII: IRB Policy for NIH Funded Clinical Trial Compliance		
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In 2016, NIH launched a multi-faceted effort to enhance its stewardship over clinical trials. The goal of this effort is to encourage advances in the design conduct, and oversight of clinical trials while evaluating the entire research enterprise to a new level of transparency and accountability.

University of Colorado Colorado Springs (UCCS) faculty, staff, and students conduct a diverse array of human subjects research projects, including projects that qualify as a clinical trial. With this in mind, the Institutional Review Board (IRB) at UCCS requires that all research that qualifies as a clinical trial meet the training and reporting requirements as set forth by the NIH for NIH-funded clinical trials. The requirements can be found in in the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" and the "Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials."

A. Definitions:

1. ***Clinical Trial:*** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. (adapted from the Notice of Revised NIH Definition of "Clinical Trial")

   In summary, if the answers to all the below questions are yes, the project meets the definition of a clinical trial:
   - Does the study involve human participants?
   - Are the participants prospectively assigned to an intervention?
   - Is the study designed to evaluate the effect of the intervention on the participants?
   - Is the effect being evaluated a health-related biomedical or behavioral outcome?

2. ***Intervention:*** For the purposes of this SOP, an intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. (adapted from the Notice of Revised NIH Definition of "Clinical Trial")

   Examples include:
   - drugs/small molecules/compounds;
   - biologics;
   - devices;
   - procedures (e.g., surgical techniques);
   - delivery systems (e.g., telemedicine, face-to-face interviews);
   - strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits);
   - treatment strategies;
   - prevention strategies;
   - and diagnostic strategies.

Depending on the study, a non-UCCS (external) IRB review may be required. Please contact the IRB as soon as possible to explore the use of an external IRB. Relatedly, if an external IRB is necessary, additional costs may be incurred.

3. ***Health-related biomedical or behavioral outcome:*** For the purposes of this SOP, this is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. (adapted from the Notice of Revised NIH Definition of "Clinical Trial")

   Examples include:
   - positive or negative changes in physiological or biological parameters (e.g., improvement of lung capacity, gene expression);
   - positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers, reading comprehension and/or information retention);
   - positive or negative changes to disease processes;
   - positive or negative changes to health-related behaviors; and
   - positive or negative changes to quality of life.

B. Good Clinical Practice (GCP) Training Requirement

The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in GCP.

UCCS makes this training available through the Collaborative IRB Training Initiative (CITI) training, which must be completed before a protocol will be reviewed by the IRB. Most studies at UCCS should be able to take the GCP – Social and Behavioral Research Practices for Clinical Research. If you are unsure of the course to take, please contact composp@uccs.edu.

UCCS expectation for fulfilling NIH GCP requirements:

- All study team members involved in the design, conduct, recording, or reporting of an active NIH-funded clinical trial must complete GCP through a qualifying training provider (e.g., CITI);
- Administrative Staff on an NIH-funded clinical trial are not required to complete GCP, unless directed to do so by the principal investigator on a project or per unit-specific (e.g., clinical trial support unit) business process;
- The study team member is responsible for obtaining a GCP training displaying the course completion date, and providing that certificate upon request of the research sponsor or the institutional review board (IRB);
- GCP training must be renewed every three (3) years upon initial certification expiration, as long as the study team member is involved on an active clinical trial. Most studies at UCCS should be able to take the GCP- Social and Behavioral Research Practices for Clinical Research. See the training documents below to learn how to sign up.

C. Reporting Requirements on ClinicalTrials.gov

All NIH-funded clinical trials are expected to register and submit results information to ClinicalTrials.gov, as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications and contract proposals submitted on or after 1/18/2017. ClinicalTrials.gov is a public website designed by NIH and hosted by the National Library of Medicine. For reporting and compliance purposes with ClinicalTrials.gov, the Principal Investigator will be designated as the Responsible Party.

ClinicalTrials.gov registration and reporting requirements include the following:

- Registration – The study must be registered on ClinicalTrials.gov within 21 days after the first subject is enrolled. Registration information includes descriptive information, recruitment information, location and contact information, and administrative data. UCCS currently has an institution account and PRS administrator. Please register under the institution. For more information contact the IRB.
- Updates – The information in the clinical trial records must be updated at least once every 12 months.
- Results – The study results must be reported on ClinicalTrials.gov within 1 year of the final collection of data. Per 42 CFR 11.10(a), the final collection for a clinical trial is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. Results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.

Note – Registration with ClinicalTrials.gov is the responsibility of the Principal Investigator. The NTC number (or ClinicalTrials.gov identifier) received upon registration will need to be reported to the IRB once received. The NTC number is a unique identification code given to each clinical study when it is registered on ClinicalTrials.gov. Please submit the UCCS IRB protocol number and the NTC number to the IRB via email at irb@uccs.edu.

D. Current IRB Responsibilities and Strategy

Current IRB responsibilities for NIH Clinical Trials include:

- Include required language in consent form: "This trial will be registered and may report results on www.ClinicalTrials.gov or some other Federally sponsored site that is publicly available."
- Remind investigators about GCP training requirement (but IRB does not track).
- Remind Investigators about ClinicalTrials.gov registration and to report the NCT number to the IRB.
- Assist investigators with Single IRB processes.

UCCS current strategy for NIH Single IRB requirements are:

- Default position is to cede oversight to an external IRB, either a commercial IRB or another academic partner.
- Fees for external IRBs must be included in the proposal budget.

E. Additional Resources:

- National Institutes of Health, Office of Extramural Research. Frequently asked questions for NIH Clinical Trial Definition. https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm.

- National Institutes of Health, Office of Extramural Research. NIH Definition of Clinical Trial Case Studies. https://grants.nih.gov/policy/clinical-trials/case-studies.htm.
- National Institutes of Health, Office of Extramural Research. NIH Clinical Trials for Grants and Contracts. https://grants.nih.gov/policy/clinical-trials.htm.
- CFR 42 Part 11 – Clinical Trials Registration and Results Information Submission. https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol1/xml/CFR-2016-title42-vol1-part11.xml.

Special Topics XXXIII: Research Involving Existing or Secondary Data		
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The University of Colorado Colorado Springs (UCCS) requires that all research involving human subjects conducted by faculty, staff, or students affiliated with the university, be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its Federal status as an Exempt, an Expedited, or a Full review project. This document, along with the Decision Charts, is to assist Principal Investigators (PI) in determining when their research uses only existing or secondary data about living individuals, if their project using existing or secondary data requires IRB approval, or if their project is eligible for certification of exclusion from IRB review.

A. Resources

1. Existing or Secondary Data Decision Chart

2. New Application for IRB Review

B. Definitions:

1. ***Anonymized Data:*** It is no longer possible for data to be linked to the private information. For de-identified data, the key to decipher the code (if applicable) no longer exists.

2. ***Anonymous Data:*** Data originally collected without identifiers.

3. ***De-identified (or Coded) Data:*** The Privacy Rule allows for a data set to be de-identified by removing all elements that could be used to directly identify the individual or by using a code system to replace all identifying information. Should the code system be utilized, a key to decipher the code must exist that allows the direct linkage of the identifying information to the private information. This code cannot be accessible by the PI. If the code is accessible by the PI, an IRB review is required.

4. ***Existing (or secondary) data:*** Specimens and/or data that were collected prior to the protocol being submitted to the IRB. Another common way of stating this would be that the materials were "on the shelf" (or in the freezer) at the time the protocol was written. This data could be provided by another source or already be in the PI's possession.

5. ***Human Subject:*** A living individual from whom a PI (whether professional or student) conducting research obtains data through the following methods: (i) an intervention, interacting with the individual, or (ii) collecting identifiable private or protected health information regardless of its source. (adapted from 45 CFR 46.102)

6. ***Private Information:*** Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical record or student record information) that may identify the individual. (adapted from 45 CFR 46.102)

7. ***Research:*** A systematic investigation, including research development, testing, and evaluation, designed to develop or to contribute to the development of generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. (adapted from 45 CFR 46.102)

8. ***Restricted Access Data***: Data that must have appropriate confidentiality protections in place per a formal data use agreement between UCCS and the data provider. Please note that any agreements requiring signature must be directed to the Office of Sponsored Programs and Research Integrity (OSPRI) at osp@uccs.edu. OSPRI will negotiate the terms of the agreement on behalf of UCCS.

C. Secondary Data Analysis that May Require Review by the IRB

1. Anonymous, de-identified, or non-public data:

   If the entity providing the data is NOT involved in the design, conduct, or reporting of the research (including sharing of any authorship rights), the use of the following types of non-publicly available datasets do not constitute federally-regulated human subjects research, and, therefore, do not require any further action with the IRB:

   a. Anonymized datasets; or
   b. De-identified datasets with private coded information when the PI has no access to the code key or identifying information.

2. Non-public, identifiable data where the PI did not record or retain identifiers:

   If a there was use of a dataset that contains private, identifiable information, but the PI or any member of the research team do not record or retain any identifiable information that directly or indirectly links to private information, the project may be eligible for IRB exemption. PIs are required to submit a new application for IRB review.

   When completing the application, PIs should include detailed information in the data monitoring section that clearly describes the steps taken to ensure the dataset cannot be linked to private information, the process for de-identifying the data, and the plan for final disposition of the identifying information.

3. Non-public, identifiable data where the PI had access to and recorded identifiers:

   If the PI, any member of the research team, or their collaborators use non-publicly available data and have access to and intend to use the private identifiable information about living humans, the project is considered human subjects research and PIs are required to submit a new application for IRB review.Written Agreements for Restricted Access of Licensed Data

PIs are not able to negotiate and sign data use agreements themselves. If a PI must sign an agreement in order to obtain data, please contact the Office of Sponsored Programs and Research Integrity (OSPRI) at osp@uccs.edu. OSPRI will negotiate the terms of the agreement on behalf of UCCS.

D. NIH Data Sharing Requirement

As of January 25, 2023, data sharing is required for some NIH funded grants. (See our NIH Data Management and Sharing Plan webpage). The IRB will need to have your approved data management sharing plan (DMSP) on file with your approved IRB application. There are some restrictions on the type and manner in which data can be shared, which extend beyond NIH policy, including UCCS policies, state laws, and human subjects research protections. We advise you to contact OSPRI staff early in the process for help determining if your DMSP is feasible.

E. HIPAA Protected Data

Secondary data sources may include HIPAA protected data, especially if the data are from any of the following sources:

- Accessing or collecting information from a medical record
- Adding information to the hospital or clinical record
- Creating or collecting information as part of health care
- Using information collected from the study to make health care decisions

Secondary data from UCCS covered entities will be reviewed in accordance with SOP XIX. HIPAA data from outside entities should be treated in accordance with that entities' HIPAA policies and in compliance with UCCS policies and procedures. For questions, contact the IRB or Privacy Board.

F. FERPA Protected Data

FERPA data include educational records of any kind that may personally identify a student, such as name, address, ID number, or another personal or indirect identifier. In addition, a record is identifiable if it includes "other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty." For more information about FERPA please click here.
If your research involves PII or FERPA, approval from the Office of the Registrar will be required in order to be able to obtain the data (prior to submission of your IRB application). The approval received from the Office of the Registrar will need to be submitted with your IRB application. Additionally, training might be required. You may contact the Office of Registrar at 719-255-3361 or email registrar@uccs.edu to determine what needs to be done.

G. Secondary Data Analysis that does not Require Review by the IRB

No further action with the IRB is necessary if there is use of the following public data types, as they do not constitute federally regulated human subjects research:

1. Data not about living people. For example, if the data is collected from historical archives, death records, or historical records of deceased people.

2. Publicly available data that contains identifiable data but not private information. This would be data found on unrestricted websites, in publications, in individual public records, or obtained through a Freedom of Information Act request.

   Additionally, to reduce burdens on PIs the IRB does not require review of studies involving the analysis of data held by these organizations unless a project merges multiple data sets and in so

doing enables the identification of individuals whose data is analyzed. A project that merges public data sets with other datasets may enable identification of individuals and requires IRB review.

a. Inter-University Consortium for Political and Social Research (ICPSR)
b. U.S. Bureau of the Census
c. National Center for Health Statistics
d. National Center for Education Statistics
e. National Election Studies

Note – Although IRB review is not required, it remains the responsibility of the researcher to ensure that the data are obtained under conditions allowed by the data provider. Additionally, it should be noted that many publications require an IRB approval/review letter for publication. If there is the possibility of publication, you may wish to obtain IRB approval. Retroactive approval will not be provided.

Applicable Regulations/Guidance:

45 CFR 46.102; National Institutes of Health, Office of Extramural Research. Frequently asked questions from applicants, Feb. 2010. http://grants.nih.gov/grants/policy/hs/faqs_aps_definitions.htm.

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, 2003, http://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf.

Family Educational Rights and Privacy Act of 1974 (FERPA), 1974, https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html.

A. Ethical Considerations

Federal regulations and commentaries offer guidance about payments and incentives but set no strict limits. Thus, the Principal Investigators and the local IRBs must decide how much payment is too much or not enough. There are two ways in which compensation can be problematic:

Undue influence: An offer of excessive or inappropriate reward is made in order to obtain compliance. For example, a researcher might offer a month's salary to students for one-day participation in study to test the effects of an investigational drug with potentially serious side effects. Because the level of compensation could induce subjects to participate against their better judgment, this offer might present undue influence.

Coercion: An overt or implicit threat of harm/negative consequences is intentionally presented by one person to another in order to obtain compliance. Compensation for research is not coercive in and of itself, since it does not involve a threat of harm. However, compensation can create potentially coercive situations, as when a third party is paid for another subject's participation, and that third party can exert coercion over the subject in order to obtain payment. For example, payment to a parent for a child's participation or incentives paid to a doctor or nurse for research recruitment could create coercion.

Once an investigator decides to pay a research participant, several points need to be considered. First and foremost, participant payment raises ethical issues pertaining to the requirement for voluntary participation and the individual's ability to make informed choices about research that are based on the real risks and benefits of participation, not solely on the financial incentives. Both the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) caution against undue inducement. By federal regulation and guidance, payment to research subjects is not considered a benefit of participation, but is instead compensation for time and inconvenience, or a recruitment incentive.

B. Amount of Payment

There are no hard and fast rules about how much participants should or should not be paid. Participants should be paid enough to make up for their time and inconvenience. Participants should not view research participation as a way to earn a living or regularly supplement their income. Large payments can suggest this possibility and can be coercive. (Restrictions may apply for clinical studies that bill insurance, see section G).

1. Amount of payment

The amount of payment should be commensurate with the time taken to participate, the level of risk involved, and the type of task(s) involved.

When appropriate, follow an hourly wage model, where payments are structured on a scale on par with hourly wages for unskilled jobs in the location where the research will take place. For the current Colorado minimum wage, see the Department of Labor and Employment website.

However, in some cases, an hourly range is clearly not appropriate. A half-hour spent running on a treadmill is not comparable to a half-hour taking an online survey. In these cases, it will be beneficial to consider overall effort/exertion rather than time. For these task-oriented payments, be cautious as you consider amounts greater than $100, as there may be undue influence introduced by these larger sums.

2. Timing of payment

Participants should be paid in a timely manner. It is best practice to pay participants at the time of participation or as soon as possible thereafter. However, prorated payments are acceptable, especially for studies requiring multiple contacts or phases.

a. Prorating payment

UCCS investigators are encouraged to implement a prorated system of payment for studies involving several tasks or office visits. By structuring payments this way, subjects who do not finish the study are paid in proportion to the part completed. While a small bonus for completion might be acceptable, large bonuses or withholding of large payments until the end of the study typically are not.

b. When is prorating not appropriate?

Prorated payment may not be appropriate for all research activities. As 45 CFR 46.116(a) requires that participants' voluntary refusal to participate or discontinue participation involve no penalty, the UCCS IRB/OHRPP may require full payment for subjects' partial completion of surveys or questionnaires or for "inadequate" participation in group discussions.

C. Methods of Payment and Reimbursement

1. Method of payment

Investigators can pay participants by various methods including cash, check, or gift card. When determining the method of payment, consider factors such as:

- The characteristics of the subject population (Are they likely to have bank accounts? Can they easily cash checks? What type of gift card would be best for the group?);
- University processes that need to be followed;
- The amount of payment (i.e., large sums are best not paid in cash); and
- The study procedures (internet surveys should not require a face-to-face interaction in order to provide payment).

2. Restrictions on Types of Payment

- Do not provide subjects with private industry sponsor’s advertising materials (i.e., items containing the sponsor’s name, logo) as a method of payment.
- Do not provide or allow payment in the form of a coupon good for a discount on the purchase price of the test article once it has been approved for marketing. These items may sometimes be

provided in addition to payment, but not as the sole form of payment.

3. **Reimbursement of Expenses**
   Investigators often wish to and are encouraged to provide reimbursement for parking, transportation and childcare costs for research-related visits (with the possible exception of the legal considerations for "clinical studies" described in section G). Actual reimbursement may require that participants provide copies of the receipts. These costs can, and often should, be added to adjust the hourly amount paid to subjects (see "amount of payment").

D. Departmental Procedures for Requesting Payment for Research Participants

UCCS departments may provide payments to research participants in the form of a request for direct payment, from petty cash, as a gift card, or as a cash advance. Additional information is available in the PSC Procedural Statement: Study Subject Payments.

E. Investigator Responsibilities

1. **IRB Application details**
   UCCS investigators must include the following information in their IRB application:
   - A description of all plans to pay subjects:
     - The amounts of any financial inducement, payment, services or other non-cash benefits;
     - Reimbursement for travel and other expenses, such as parking, transportation, lost wages, childcare;
     - The timing and method of disbursement; and
     - The conditions, if any, which the participants must fulfill in order to receive either full or partial payment.
   - If payment will differ for different groups of subjects, then clearly describe all of the above for each group.
   - For research involving minors, specify whether the payment is provided directly to the subjects or to their parent or legal guardian.

2. **Consent form details**
   - Within the Compensation section of the informed consent, the following details should be provided in the consent form by the researcher:
     - The amount of payment, including a description of any pro-rating or completion bonuses (which, as stated above) may not be so large as to exert an undue influence;
     - The method of payment (i.e., in cash or by check, or with a gift card);
     - The timing of payment (i.e., whether subjects are paid immediately or, for example, after a delay of four to six weeks) and
     - Any conditions that the subject must fulfill in order to be paid (i.e., provide receipts, provide Social Security Numbers (SSN) via a W-9 form if paid by check).
     - The fact that participants will have to provide their Social Security Numbers via a W-9 form if required.

3. Researcher will ensure compliance with UCCS payment procedures referenced in section D.

The IRB is not able to provide guidance related to University processes about how to pay research participants. Your department administrative support should be able to assist with the process.

Note – if researcher must collect SSNs, they must adhere to university policies governing the storage and security of this information. For resources regarding this type of data, see CU System OIT policy or CU System SSN Verification and Use policy.

F. UCCS IRB/OHRPP Responsibility

During its review, the UCCS IRB/OHRPP will ensure that:

- Payment offered for participation in research, monetary or otherwise, does not constitute undue influence.
- Payment offered is reasonable, given the complexity and the inconvenience of the study and the subject population.
- Payment is made on a schedule appropriate to the length or intensity of the study.
- Where appropriate, ensure that participants are compensated proportionally to their participation, when their participation is incomplete.
- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- The payment described in the protocol, the recruitment documents and the consent form are consistent and complete.

The UCCS IRB/OHRPP may request justification for payment amounts from the investigator in order to assess the appropriateness of the proposed payment plan. The UCCS IRB/OHRPP may refer payment considerations for studies that bill insurance to the Office of Campus Compliance, Legal Counsel or other offices to ensure that they do not conflict with the legal, contract or other requirements.

G. Legal Considerations for Clinical Studies that Bill Insurance

In addition to ethical considerations, there are also legal considerations governed by Federal and State Fraud and Abuse statutes that come into play for the subset of clinical studies that bill medical insurance providers, including government payers. That is, some arrangements to reimburse travel, lodging, or per diem expenses may be interpreted as unlawful inducements if associated with the delivery of standard of care services billed to a third-party payer (e.g., Medicare or private insurance).

While such arrangements may be acceptable, any such proposed arrangements should first be vetted with the UCCS Office of Sponsored Programs and Research Integrity (OSPRI). This vetting must occur before making any offers to the research participants or making any reimbursement proposals to the sponsor to reimburse travel, lodging, or per diem expenses.

By way of example, if you know when designing the study that participant safety might necessitate that a subject does not drive on the day of participation, then you need to be prepared to make reasonable accommodations. If the subject does not have someone reliable to drive him or her home that day or if the person lives far away, it would be prudent for the study team to help make travel and/or lodging arrangements if needed. This situation would need to be vetted as described above and then described appropriately in the consent form. For example, in the consent form, the section “Procedures” should include information like, “You must refrain from driving the day of participation. Because of this you

must make arrangements to have a relative or friend drive you home or the research staff can arrange a taxi ride home and/or make hotel accommodations for you if you live too far away." In "Risks and Discomforts?" you should describe the risks associated with participation and specify that because of those risks, participants cannot drive that day.

On the other hand, if something unforeseen comes up during a study and it becomes important to make travel or lodging arrangements for a particular subject's safety, you should talk with OSPRI and the IRB as described above and then submit an Unanticipated Event Form to irb@uccs.edu describing the reason for the deviation from the approved protocol.

Special Topics: XXXV: Review of Quality Assurance/Quality Improvement Projects		
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Quality Assurance and Quality Improvement (QA/QI) projects are those which are designed to evaluate and improve processes, performance, or standards of care. In most cases, these projects do not constitute research and fall outside of the IRB's purview. However, some of these projects can and do involve research, especially when they utilize human subjects. An IRB member or staff will review projects to determine if they qualify as QA/QI projects or are subject to review based on the categories of human subjects research as defined in 45 CFR 46.

QA/QI projects generally consist of the following:

- Intent is to improve processes, performance, or standards of care.
- Measure system level benefits and outcomes.
- Pose minimal risk.
- Distribution of results is immediate and local.

Additionally:

- All proposals for QA/QI projects must be submitted to the UCCS IRB via electronic application (https://uccs.my.irbmanager.com). No proposals will be accepted without being submitted electronically.
- For student proposals, the faculty advisor, mentor, designee, etc. must review and electronically sign the student's application; otherwise, it will not be accepted.
- If any of the project personnel have a conflict of interest (COI), it must be declared and explained on the QA/QI application. In some cases, a signed COI management plan will also be requested.
- Project leads are responsible for the conduct of all personnel on the project

Resources:

1. IRB resources – QA/QI Checklist

A. Initial Review of QA/QI Applications

All proposed student (undergraduate and graduate) QA/QI projects should be reviewed prior to the activity beginning. Faculty and staff, while not required, are highly encouraged to use this process as well, especially for externally funded work or projects that will be published. IRB staff will conduct an initial review of proposals to assess if the project is truly QA/QI or if it is human subjects research. Projects deemed to be research will be sent on for further review to an IRB reviewer. In some cases, applicants may be asked to provide more detailed responses in a full application. In these instances, the review will be conducted as outlined previously in theses SOPs.

When the project involves campus HIPAA protected data, the proposal will be referred to the Privacy Board for additional review and approval. In these instances, the project cannot start without both reviews having been completed. Please note that if you are conducting a project at an outside entity, they may also have a review process and/or policy which you must also follow.

B. Notification of Review

Once the proposal has been reviewed and deemed to satisfy the definitions of a QA/QI project, the applicant will be notified in writing that the review is complete and that the project may commence. Projects will not have an expiration date but will be subject to check-ins at **3-year** intervals.

Special Topics: XXXVI: Creation and Use of Research Repositories and Databases		
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The creation and/or use of research repositories, or databases, which house data or biospecimens about living individuals requires IRB approval, as they meet the definition of research in 45 CFR 46. Many of these repositories may be subject to other regulations such as HIPAA, especially if data is collected through campus clinics, or FERPA, if using student data.

A. IRB Review of Repository or Database Creation

All proposed research repositories and databases to be created from data or biospecimens from living individuals should be reviewed by the IRB via the online application before the collection of any data or specimens. These applications will be reviewed and processed in accordance with the policies and processes previously laid out in this SOP (see sections IX through XV).

B. Requirements for Approval of a Repository or Database

- Designated data manager with no ties to a particular study associated with the repository, who will act as good faith broker and disseminate data appropriately.
- Data management plan using appropriate IT approved storage and transfer platforms (HIPAA compliant where applicable).
- Consent forms must contain a time limit for storage and usage of data.
- Consent forms should include clear areas of usage and types of research to be conducted with the data.
- Access plan for researchers who will use the database (i.e., who is allowed to request data and for what purposes) – must include verification of IRB approval in the process.

C. IRB Review of Proposals Utilizing Data or Biospecimens from an UCCS Research Repository

All proposed research utilizing data or biospecimens from any UCCS research repository, or any other repository, which contains information about living subjects requires IRB review. Applications for these proposals are made through the online application and reviewed and processed in accordance with the policies and processes previously laid out in this SOP (see sections IX through XV).

Special Topics: XXXVII: Department of Energy Funded or Focused Human Subjects Research		
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Human subjects research funded by the Department of Energy (DOE), or which utilizes DOE sites or personnel for human subjects research are regulated by 45 CFR Part 46, 10 CFR part 745, and DOE Order 443.1C. PIs with projects receiving or seeking funding from DOE should ensure those protocols meet DOE HSR requirements.

DOE Requirements are the following:

(1) No HSR conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) of compliance and approval by the cognizant Institutional Review Board (IRB) in accordance with 10 CFR Part 745.103.
(2) Informed consent will be documented or waived in accordance with 10 CFR Part 745.117.
(3) HSR involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, or if authorized by the DOE and/or NNSA HSP Program Manager, other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.
(4) HSR that involves DOE Federal and/or contractor employees must first be reviewed and approved by the appropriate DOE IRB (the DOE site IRB or one of the Central DOE IRBs), or if deemed more fitting by the Federally assured DOE site or Headquarters, other appropriate IRB of record, in accordance with an IAA or MOU negotiated between the DOE site or Headquarters and the organization responsible for IRB review.
(5) Research that uses social media data must be submitted to the appropriate IRB for HSR review and determination.
(6) Research that involves the study of humans in a systematically modified environment must be submitted to the appropriate IRB for HSR review and determination.
(7)Classified and unclassified HSR that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.
(8) All exempt HSR determinations must be made by the appropriate IRB and/or IRB office.
(9) In order for a DOE IRB to vote on a new or amended protocol that requires full board review, there must be a minimum of five members present, including a scientist, a nonscientist, and an unaffiliated member.
(10) Personally identifiable information collected and/or used during HSR projects must be protected in accordance with the requirements of DOEOrder 206.1, Department of Energy Privacy Program, current version.
(11) If applicable, Federally funded HSR must comply with the requirements of the Paperwork Reduction Act.

(12) It is Departmental policy that Human Terrain Mapping (HTM), defined in paragraph 8.r., is managed as HSR and is subject to this Order.

(a) HTM projects, conducted with DOE funding, at DOE sites/institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, must be strictly limited to only those projects involving the analysis and modeling of de-identified data.

(b) Statements of work for HTM projects must be submitted to the HSP Program Manager (and when an NNSA element is involved, the NNSA HSP Program Manager), for DOE Headquarters review and approval prior to initiation. If the project is to be conducted by or for the intelligence community, the Office of Intelligence must also review and approve it prior to initiation. The HSP Program Manager(s) and the Office of Intelligence must engage the recognized DOE site IRB, and as needed, the principal investigator (PI) and/or sponsor, in clarifying whether the proposed project is HTM and if so, that the data to be used will be de-identified. Additionally, the PI will be asked to provide written verification that only de-identified HTM data (as defined in paragraph 8.g.) will be used.

(c) The recognized DOE site IRB (or in the case of HSR funded through SIPP, the Central DOE IRB-Classified) is the only entity authorized to determine whether the HTM data received by the PI after project initiation meets DOE criteria for de-identification. If the DOE site does not have a designated site IRB, then the Central DOE IRB(s) must be the responsible IRB.

(d) All projects funded by other entities, including HTM activities, must comply with the applicable DOE O 481.1E, Strategic Partnership Projects [Formerly Known as Work for Others (Non-Department of Energy Funded Work)], current version, or DOE O 484.1, Reimbursable Work for the Department of Homeland Security, current version.

(e) In a case where the sponsor requests assistance in the de-identification of HTM data prior to using the data and/or re-identification of the data following completion of the project, DOE sites may provide such services under a separate contract and/or task order with the sponsor by following the appropriate DOE standard operating procedure approved by the DOE IO.1

There are additional requirements for Classified HSR, however, at this time UCCS is unable to meet requirements for Classified research.

If you have questions please contact IRB@uccs.edu.