
**University of Colorado Colorado Springs**

# Researcher Manual for IRB Submission

**October 2019**

# Table of Contents

## What is the purpose of this manual?

This document is designed to guide you through policies and procedures related to the conduct of human research that are specific to the University of Colorado Colorado Springs (UCCS).

General information regarding human research protections, relevant federal regulations, and guidance is incorporated into the required human protections training. For additional information see below: "What training is required to conduct human research?"

## What training is required to conduct human subject research?

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or UCCS policies.

All members of the research team must provide verification of online human subjects training through the Collaborative Institutional Training Initiative (CITI) and other training required by the UCCS IRB. This includes members of the research team engaged in human subject research or data analysis. Members of the research team who have not completed human research protection training may not take part in aspects of the research that involve human participants. No protocol will be reviewed if the investigator and the research team have not successfully completed the basic or refresher training within the last three years. If you have questions regarding who need training, please contact the IRB office at irb@uccs.edu.

Additionally, if the study is funded by NIH and meets the definition of a clinical trial, Good Clinical Practice (GCP) Training is required for all personnel including PIs, Co-PIs, and Faculty Advisors (if applicable). You can learn how to register for the required GCP Training on the IRB website.

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.

The CITI site can be accessed at http://www.citiprogram.org. Current information about training requirements can be accessed on the IRB website. Both trainings are valid for a three-year period, after which time the training must be repeated.

## How do I submit new human research to the IRB?

1. Complete the electronic "IRB New Application" through IRBManager. Click here to access and complete.

2. Answer all questions and complete all Addendums if research involves Children, Pregnant Women/Fetuses/Neonates, Prisoners, or International Travel.
3. Attach all supporting documentation. Templates are available on the IRB website.
4. Keep electronic copies of ALL submitted documents in case revisions are required.

*Note: Faculty advisors must review and digitally sign student protocols. Faculty advisors are indicated on the application as such, and **not** as co-investigators.*

FAQs and other guidance documents are available here to assist you while completing the application. If you need additional assistance, you may contact the IRB at any time.

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.

## *How can I ensure a successful IRB application?*


- Read and follow the directions. Re-read to make sure everything is completed.
- Answer all questions on applicable addendums if research involves Children, Pregnant Women/Fetuses/Neonates, Prisoners, or International Travel.
- Make sure all your procedures are crystal clear. If someone outside your field of study cannot understand what you want to do, neither can the IRB reviewer. For example:
    - Not clear: The participant will get blood work taken once a month.
    - Clear: The participant will report to the clinic at a time assigned by the coordinator, having fasted for at least 12 hours, and will have three test tubes of blood collected (totaling three tablespoons). The following plasma variables will be taken: albumin, serum, ferritin, etc.
- Ensure all personnel involved with the study have completed CITI training and that it is current (within 3 years), or the study will not be approved until all required training is complete. The CITI site can be accessed at http://www.citiprogram.org.
- If you are a student, make sure you enter the correct faculty advisor information. The FA must sign off on your application before it will be processed. Please note that they cannot be added to your application until they have logged into IRBManager at least once.
- Make sure all your surveys or questionnaires are submitted with the application.
- Make sure your numbers (i.e., sample size), compensation, and time commitment are consistent across all documents.

- Explain any jargon or acronyms used (e.g., Most IRB reviewers know what PTSD is, but they do not know what ACHNE stands for).
- If you are using ads or flyers for recruitment, make sure they contain all of the following:
    - That participants are being asked to participate in research,
    - The name and institution of the researcher,
    - Purpose of the research,
    - Inclusion or exclusion criteria,
    - Brief statement of procedures,
    - Time commitment,
    - Compensation,
    - Location of research,
    - The researcher's contact number or UCCS email, and
    - There is no emphasis (bold, underline, etc.) to any financial benefit.
- State risks and benefits to the participants. Do not understate risks. All studies entail at least some risk (e.g. annoyance, frustration).
- If you need a letter of access to a population or site, make sure it is submitted with the application. At minimum, this should be a scanned letter that is dated with an original signature from an authorizing official. Otherwise, you will be asked for one.
- Make sure all the elements of consent are included and they are clear. Do not remove anything that is already on the UCCS template.
- Make sure the consent or assent form is written at the level for which it is intended. All consents should not be written over an 8th grade level. Use short words and short sentences. The readability calculator utilized by the IRB reviewers is the readability statistics proofing option within Microsoft Word. If a third-party readability calculator is utilized, make sure to use the Flesch-Kinkaid formula to determine the readability.

## *How do I create a consent document?*


Use the templates available on the IRB Website to create a consent document. There are two templates available depending on the type of consent required, paper or electronic. Additional information is available in the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs)

Note that all consent documents must contain ***all of the required information*** and any additional appropriate elements of informed consent disclosure. The templates are drafted to include all required elements of informed consent that are stated in both DHHS and FDA regulations, as well as the additional elements as recommended by DHHS. Note that additional information regarding the consent forms can be found in Appendix A of this document.

The 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". DO NOT use language copied from the protocol. Avoid technical jargon. Also, include information about what will happen during the study and information regarding the approximate amount of time required to participate in the study. If participants will be screened, describe screening procedures and major inclusion/exclusion criteria.

Consent forms will be stamped with an approval stamp and expiration date following IRB review and approval.

## *Am I able to screen or determine eligibility without consent?*

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

> (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
>
> (2) The investigator will obtain identifiable private 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.

## *When is child assent required?*

Taking into account 45 CFR 46.408(a), UCCS's IRB typically requires researchers to obtain written assent from all subjects between the ages of 6 and 18 (or age of consent when the research is taking place) unless a clear justification of waiver or alteration of assent is provided and approved. Use the templates available on the IRB Website to create an assent document. Additional information is available in the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs)

## *How long can I expect for the review to take?*

Researchers are typically contacted within five to ten business days after receipt of an IRB application by the IRB office. This contact *may* be the approval of the protocol, a request for additional information about the protocol, or a request for revisions in the protocol materials. Note that the IRB makes every effort to provide timely responses, but some reviews may take longer. Additionally, timely reviews may be dependent upon IRB member and staff workload. A flowchart of the new IRB application review process is available in Appendix B.

Protocols that qualify for exempt review usually are approved as quickly as possible. Exemption can only be determined by the IRB. ***PIs cannot make a determination of exemption themselves***. Expedited reviews may take up to 20 business days after receipt by 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 at least ***ten business days*** prior to the scheduled IRB meeting. The IRB will make every effort to review the protocol at the next monthly 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 that meeting dates may change depending on the availability of a quorum.

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 review within 20 business days after a communication from the IRB may cause the IRB application to be closed. If closed, the PI will be required to submit a new IRB protocol application.

## *What are the general criteria used to review protocols?*

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits.
- Selection of participants is equitable.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative.
- Required elements of informed consent are present.
- When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.
- Whenever appropriate, there are provisions to protect the privacy of participants and to maintain the confidentiality of data.
- When some or all of the participants are vulnerable research participants, additional safeguards have been included in the study to protect the rights and welfare of these participants.

## *What are the different regulatory classifications that research activities may fall under?*

Submitted activities may fall under one of the following four regulatory classifications:

- Not Human Research: Activities must meet the organizational definition of human research to fall under IRB oversight. Activities that do not meet this definition are not subject to IRB oversight. Review the IRB Office's Human Subject Worksheet (Available in Appendix C) for reference. Additional flowcharts are available to assist in determining if the activities meet the UCCS definition of human research in Appendix D and

Appendix E. Contact the IRB Office in cases where it is unclear whether an activity is human research. For a written determination, submit a "New IRB Application" to irb@uccs.edu.

- Exempt: Certain categories of human research which may be exempt from further review still require initial IRB review. ***It is the responsibility of the UCCS IRB, not the investigator, to determine whether human research is exempt from further IRB review.*** Examples of exempt research may include review of existing data, documents, or records (if the information is recorded in such a manner that participants cannot be identified and the data is not collected via intervention or interaction with the participants).
- Expedited Review: Certain categories of non-exempt human research may qualify for review using the expedited procedure, meaning the project may be approved by a single designated IRB reviewer, rather than the convened board. This would include research that poses only minimal risk to adult human participants and does not involve vulnerable populations.
- Full Review: Non-Exempt human research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB. Research involving more than minimal risk and/or vulnerable participants must undergo a Full IRB review. Vulnerable subjects include children under 18 years of age, prisoners, pregnant women, mentally/cognitively impaired persons, economically/educationally disadvantaged persons, and any subjects likely to be vulnerable to coercion or undue influence.

## *What are the decisions the IRB can make when reviewing proposed research?*


The IRB may approve research, require modifications to the research to secure approval, table research, or disapprove research. Another option would be for the application to be returned without review if it is found to be incomplete.

- Approval: Made when all criteria for approval are met.
- Application Approved with Changes: Made when IRB members require specific modifications to ensure human subjects' protection before approval can be finalized.
- Tabled: Made when the IRB determines that the board is unable to approve research (or when there is a loss of quorum) and the IRB may suggest modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing. When taking this action, the IRB automatically schedules the research for review at the next meeting.
- Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

## What will happen after IRB review?

The IRB will provide a written decision indicating that the IRB has approved the human research, requires modifications, or has disapproved the human research.

- If the IRB has approved the human research: The human research may commence once all other organizational approvals have been met. IRB approval usually lasts for a specified period of time which is noted in the approval letter.
- If the IRB requires modifications: Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you choose not to make the required modifications, please inform the IRB by emailing irb@uccs.edu.
- If the IRB disapproves the human research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at a scheduled IRB meeting (see IRB website for the monthly meeting dates).

## What are my obligations after IRB approval?

- Submit "Request for Continuing Review" (Renewal) forms at least ***10 business days*** before the expiration date for all applicable protocols indicated in the approval letter from the IRB.
- Notify the IRB when the research is complete by emailing irb@uccs.edu.
- Report any Conflict of Interest (COI) or perceived Conflict of Interest to the IRB when the protocol is submitted, or if there is a newly identified COI.
- Conduct research in an ethical and appropriate manner, refraining from research misconduct activities, which include, but are not limited to: plagiarism, falsification, fabrication, and other forms of misrepresentation of ideas, and other serious deviations from accepted practices in proposing, carrying out, reviewing, or reporting results from research.
- Report any suspected research misconduct to the Research Integrity Officer.
- Adhere to all policies and procedures set forth by UCCS and by the IRB as well as all applicable local, state, and federal regulations. Report any changes in research activity related to the project, including additional personnel.
- The PI must provide the IRB with all protocol and consent form amendments and revisions. The IRB must approve these changes prior to their implementation. Submit changes using a copy of the "Request for Change" form to the IRB.
- All advertisements recruiting study participants must receive prior approval by the IRB.

- The PI must promptly inform the IRB of all adverse and serious adverse events to participants (within 5 days of the researcher becoming aware of the occurrence).
- When your study has been approved, it may be assigned an expiration date. If you need to continue your project past the expiration date, you will need to request the project be renewed (at least ten business dates before the expiration date). Submit a copy of the "Request for Continuing Review" (Renewal) form to the IRB at least 10 business days prior to your expiration date.
- If you are a student, please note that it is required to include the IRB approval letter to the library when you submit the dissertation/thesis.
- Once you have completed your study/research, keep all records including signed consent documents on record for 3 years after the conclusion of your study.
- If the research is sponsored by NIH, registration and reporting of the clinical trial at ClinicalTrials.gov is required. Additional information is available on the IRB website. Additional information is available in Special Topics: XXXII IRB Policy for NIH Funded Clinical Trial Compliance of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

Failure to comply with these responsibilities may result in suspension or termination of the IRB approved protocol, and possible disciplinary action.

## *How do I submit a Request for Change?*

Complete the "Request for Change" form in IRBManager. Click here to access your protocols and submit the request. Detailed instructions are available on the IRB website. Attach any required supplemental documents to your application. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

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 in writing to the IRB Office on the "Request for Change" form.

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.

## *How do I submit a "Request for Continuing Review" (Renewal)?*

Complete the "Request for Continuing Review" (Renewal) Form in IRBManager. Click here to access your protocols and submit the request. Detailed instructions are available on the IRB website. Attach any supplemental documents to the application. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

All human research may be subject to continuing review of research based on the level of risk as assessed by the IRB at the time of initial review. If the project is expected to continue past the expiration date, then the investigator must submit a "Request for Continuing Review" (Renewal) form to the IRB office at least ***10 business days before the study expires***.

Research studies that do not require annual reviews, must request any changes to the research proposal via submission of a Request for Change to the IRB for review before implementation.

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 expedited 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.

We must receive a "Request for Continuing Review" (Renewal) form prior to the expiration date in the approval letter. If we do not, you may be restricted from using any data collected after the expiration date.

## *What if I recruit more subjects than I have approval for?*

With IRB approval, you are approved for the number of subjects that are listed in the application. If you oversample (recruit more than indicated in the application), you will be required to submit a "Request for Change" form and an Unanticipated Event/Deviation form to justify the increased sample size. The forms are available on the IRB Website. Depending on the circumstances, it is possible that additional information will be requested as well.

## *How do I close out a study?*

Studies can be closed by either sending an email to irb@uccs.edu indicating that the study is complete, or logging in to IRBManager and completing the Continuing Review/Renewal application. Maintain all study documents (especially signed consent forms) for ***three years*** after the close of the study or after funding has ended (whichever is longer).

## *What do I do if I need to continue a study after it has already ended?*

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 interest of individual participants 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 the continuing review application within ten business days of the expiration may not provide adequate time to review the request and result in non-compliance. Should this occur, it will be handled by the IRB Chairperson or delegate.

If the investigator with an expired protocol is actively pursuing a 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 participants can be made. Even if such a request is approved, enrollment of new participants is not permitted.

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

## *How long do I keep records?*

Maintain your human research records, including signed and dated consent documents for at least ***three years*** after completion of the research.

If your human subject research is sponsored contact the sponsor before disposing of human research records.

## *How will IRB approval work if I am conducting research with an investigator at another university?*

The UCCS IRB office may defer its responsibilities to another IRB with a current Federal-Wide Assurance (FWA) to act as the IRB of record for studies to be conducted by, or with the assistance of UCCS personnel. Currently the UCCS IRB will not serve as the IRB of record for another institution. These agreements will require fully executed IRB Institutional Authorization Agreements (IAA) and should outline the basic responsibilities of each institution engaging in the reliance. Please contact the UCCS IRB office at 719-255-3044 with any questions.

## *What if I am conducting research with a non-UCCS researcher that is not working at a university?*

The UCCS IRB office may extend the UCCS Federal-Wide Assurance (FWA) to non-UCCS researchers who are not working at an institution with a current FWA.

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

- A UCCS employee or student is the Principal Investigator (PI) who is primarily responsible for the design and oversight of the research protocol;
- The outside investigator is assisting the PI;
- The outside investigator is not employed by, or a student of, an institution regularly engaged in human subject research or has their own FWA; and
- 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. Please contact the UCCS IRB office at 719-255-3044 for a template of the IIA or with any questions.

## *What if the research is being conducted within a school district?*

Typically, school districts have their own policies and procedures with regards to conducting research within their district. Please see the "Research with Local School Districts" document on the IRB Website for additional information for working with local school districts.

## *What if my research involves protected health information (PHI) and is subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA)?*

The majority of colleges, schools, centers, and departments within the University of Colorado Colorado Springs ***do not*** function as covered medical entities under HIPAA. The University of Colorado is a covered entity that has chosen hybrid status. Therefore, certain areas of the University ***must*** comply directly with HIPAA. The UCCS HealthCircle Clinics are considered 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.*** If you have questions about how HIPAA may impact human subjects research contact Privacy Board at Comply@uccs.edu.

## *What if my research involves personally identifiable information (PII) or FERPA data?*

FERPA data includes 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 visit http://www.uccs.edu/registrar/ferpa-the-family-educational-rights-and-privacy-act.html.

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.

## *What if I am using social media or other Internet resources in my protocol?*

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.

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

The required information varies based on the purpose of using social media (i.e., for recruiting only, using MTurk, engaging participants, etc.). In order to fully understand the requirements, the researcher should review Special Topics: XXX. Use of Social Media and other Internet Resources of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

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.

## *How do I determine if my student/classroom research project needs IRB approval?*

Some research projects assigned for coursework do not meet the definition of human subject research and may not require IRB approval. Classroom research projects are not required to be submitted to the IRB for review unless the project meets the definition of human subject research (A living individual about whom an investigator conducting research obtains either data through

intervention or interaction with the individual or identifiable private information). IRB approval is also required if there is an intent to add to generalizable knowledge. As a rule, if you plan on presenting outside the classroom or department, the information would be considered generalizable knowledge.

The responsibility for the initial determination as to whether an activity constitutes human subjects research rests with the faculty member/advisor/mentor. 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. Additional information can be found in Special Topics: XXVIII. Student/Classroom Research Projects of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

## *How do I manage research conducted internationally?*

It is the responsibility of the PI to have sufficient knowledge of local laws or customs related to human subject research (i.e. 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.

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. Additionally, depending on the location, it is possible that the IRB will require a local review or review by a "consultant" who is knowledgeable about the locale. If required, it can be found as Appendix A to Special Topics: XXVII. International Research of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

## *What is considered an appropriate incentive in research?*

Incentives that are provided in research should be appropriate and researchers must take great care to ensure there is no undue influence on participation. For research requiring participants to undergo a minor inconvenience or discomfort, no payment or a modest payment amount is usually adequate. Participants are often compensated based on the complexity of the study, the type and number of procedures to be performed, the amount of time involved, any travel required, and the anticipated level of discomfort or inconvenience. With this in mind, researchers need to justify the payment amount to the IRB based on these variables. The ethical principal of justice should be kept in mind while determining the payment amount.
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 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.

- Lotteries and raffles present ethical concerns as it may violate the principle of justice and create concerns of undue influence if the prize is large as compared to the amount of participation in the study. They should be avoided.

You may also elect to compensate research participants' parking while visiting UCCS. If you choose to do this, you should include this information in your Informed Consent document as well as your IRB application. Upon request, Parking offers coupon codes for parking, usually at the department level. Go through your research support personnel to see if a system is already in place or reach out directly to Parking to discuss individual researcher parking needs if you believe you'll be getting many off-campus participants.

Additionally, off-campus research participants have several free options available apart from walking.

- If a participant would like to bike, they may do so. There are several bike racks available around campus. A map of bike racks can be found here. Visitors are not required to register their bike, but they may wish to discuss the bike's presence with Parking. It is **strongly advised** that participants lock their bikes before leaving it anywhere on campus.
- Participants can park in the 500 series lots around campus for free and take the shuttle or walk to different parts of campus. A printable map is available here.

## *Is it possible to conduct research involving my own students or subordinates?*

The involvement of the investigator's students or subordinates (i.e., employees, lower ranking individuals in military, etc.) as human research participants may occur in the social and behavioral sciences. However, care should be taken to eliminate or reduce the risk of undue influence or coercion by the investigator which affects student/subordinate participation in research. No matter how well intentioned the investigator, students/subordinates may feel compelled to participate, believing that failure to do so will negatively affect their grades/review and the attitude of the investigator toward them. For this reason, the IRB generally will not permit an investigator to use his/her own students or subordinates as subjects in the investigator's research project. Attention should be given to whether they are being solicited because they are a convenient and accessible sample, rather than as a representative sample for the research inquiry.

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 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 was 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.

Additional information is available in Special Topics: XXVI. Subordinates as Human Research Participants of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

## *What if I want to provide diagnostic test results to participants?*

If you are considering providing diagnostic test results to participants or use test results to alter care, there are things that should be considered in advance such as the Clinical Laboratory Improvement Amendments of 1998 (CLIA). Additional information is available in Special Topics: XXXI. Lab Certification (CLIA) of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

## *What reporting requirements do I have if my research meets the definition of a clinical trial?*

A clinical trial is defined as 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.

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.

If your research meets the definition of a clinical trial, **and** is funded by a Common Rule Agency or the NIH you have additional reporting requirements:

- For each clinical trial conducted or supported by a Federal department or agency (per 45 CFR 46.116(h)) 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 trail on a publicly available Federal web site that will be established as a repository for such informed consent forms. These are currently: https://clinicaltrials.gov/ct2/manage-recs & https://www.regulations.gov/docket?D=HHS-OPHS-2018-0021

- The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.
- For research sponsored by NIH, registration and reporting of the clinical trial at ClinicalTrials.gov is required **within 21 days of the enrollment of the first participant.** Additional information is available on the IRB website as well as in Special Topics: XXXII IRB Policy for NIH Funded Clinical Trial Compliance of the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs).

## *How do I get additional information and answers to questions?*

This document and the policies and procedures for the Human Research Protection Program are available on the IRB website.

If you have any questions or concerns, about the Human Research Protection Program, contact the IRB Office at:

Research Compliance Program Director
1867 Austin Bluffs Parkway
UOP, Suite 202
Phone: 719-255-3903
irb@uccs.edu

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contacting the IRB Office, follow the directions in the "UCCS Research Misconduct Procedures."

## *Appendix A: Elements of Informed Consent (45 CFR 46.116)*

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 the Exempt review section in the University of Colorado Colorado Springs IRB Standard Operating Procedures (SOPs) 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(a):*

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 purpose 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/or 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 who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject; and
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.
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    i) 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

ii) 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(b):*

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

a. ***If the risk profile of any research-related interventions is not well known:*** 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 child bearing potential or pregnant women, and the risk profile of any research interventions or interactions on embryos and fetuses is not well known:*** 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:*** 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:*** 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:*** Consequences of a participant's decision to withdraw from the research and the procedures for an orderly termination of participation must be provided.
f. ***Unless significant new findings during the course of the research which may relate to the participant's willingness to continue participation are unlikely:*** 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 will be provided to the participant.
g. ***Unless the approximate number of participants involved in the study is not important to a decision to take part in the research:*** Approximate number of participants involved in the study must be provided.
h. ***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.
i. ***If clinically relevant research results are expected***: A statement regarding whether clinically relevant research results, including the individual research results, will be disclosed to subjects, and if so, under what conditions.

j. ***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) must be disclosed.

## *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 regulatory citations from 45 CFR 46. Please note that the New IRB Application takes these elements into consideration when requesting a waiver of informed consent.

### *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.*

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that ***both*** of the following conditions are met:

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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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.

**NOTE**: 45 CFR 46.116(e) for waiver of some elements or all elements of informed consent is *not used frequently* since the situation deals with specialized government programs. Additionally, 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 F, and refused to consent, an IRB cannot waive or alter consent for the storage, maintenance, or secondary research use of the identifiable private information or biospecimens.

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

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents **ALL** of the following:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration;

4. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation; and
5. 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.

***Modification of the Informed Consent Document:***

The consent document must be revised 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.

***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. Also, HIPAA requirements will still apply, if applicable.

***Posting of Clinical Trial Consent Form***

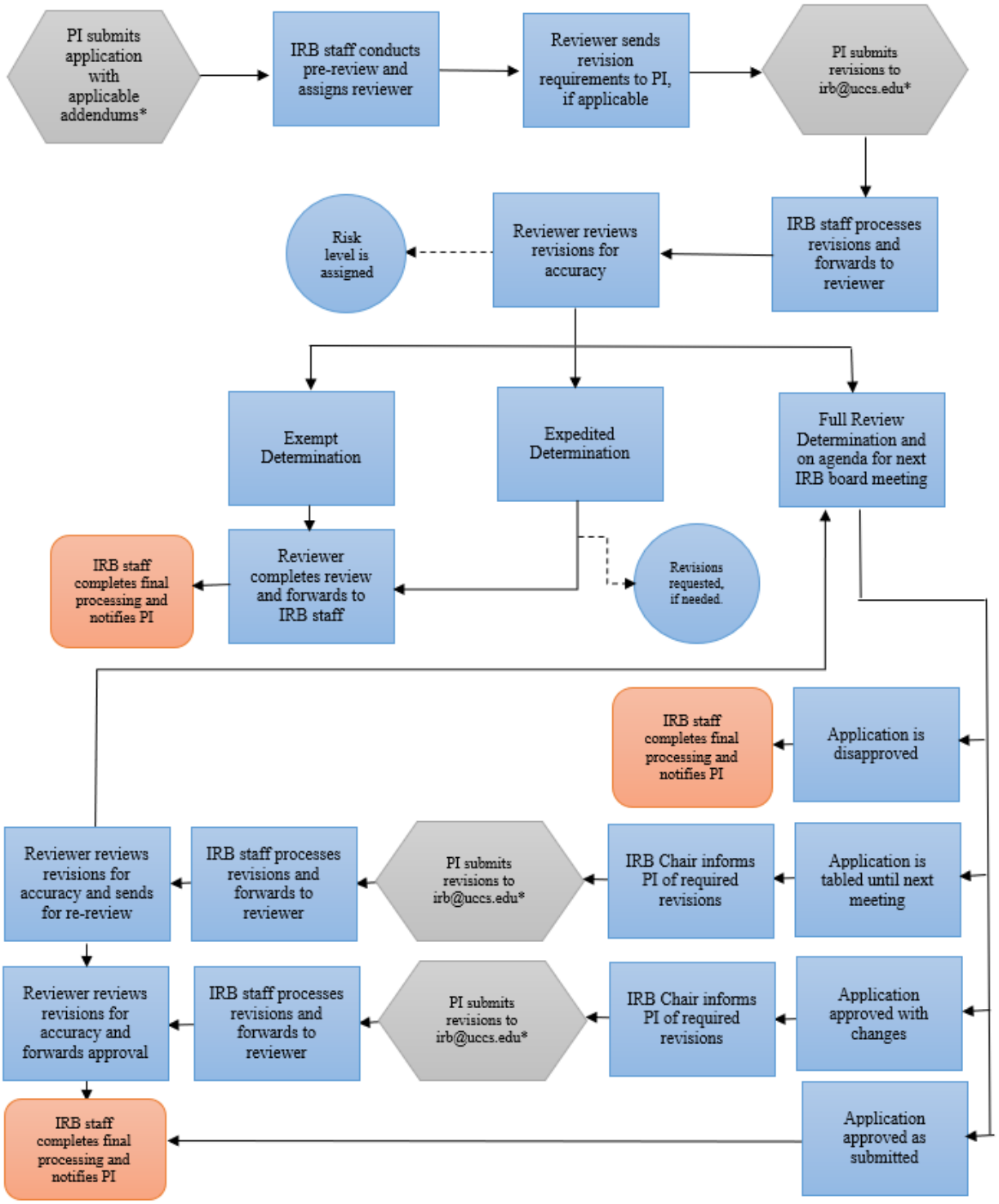
For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects ***must*** be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available "Federal Web" site that will 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 the "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.

## *Appendix B: New IRB Application Review Process*

** If the PI is a student, the application must be submitted through the faculty advisor*



# *Appendix C: Human Subject Worksheet*

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. The purpose of this worksheet is to provide support for individuals in determining whether an activity is human research or how it is regulated. This worksheet may be used for your benefit and does not need to be completed, submitted, or retained.

| | |
|---|---|
| **1** | **Research as Defined by DHHS Regulations** (Check if **"Yes"**.) |
| ☐ | Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.) |
| ☐ | Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.) |
| ☐ | Is the systematic investigation designed to develop or contribute to knowledge? (Designed: Observable behaviors used to develop or contribute to knowledge. Develop: To form the basis for a future contribution. Contribute: To result in. Knowledge: Truths, fact, information.) |
| ☐ | Is the knowledge that the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable; Disseminated. |
| **2** | **Human Subject under DHHS Regulations** (Check if **"Yes"**.) |
| ☐ | Is the investigator conducting the Research gathering data about *living* individuals, including biospecimens |
| **3** | **Human Subject Under DHHS Regulations** (Check if **"Yes"**.) |
| ☐ | Will the investigator gather that data through either of the following mechanisms (Specify which mechanism(s) apply):<br>☐ Physical procedures or manipulations of those individuals or their environment for research purposes , including biospecimens("intervention").<br>☐ Communication or interpersonal contact with the individuals. ("interaction"). |
| **4** | **Human Subject Under DHHS Regulations** (Check if **"Yes"**). |
| ☐ | Will the investigator gather data that is either? (Specify which category(s) apply):<br>☐ The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information").<br>☐ Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. "Private information"). |
| ☐ | Can the individuals' identified be readily ascertained or associated with the information by the investigator (i.e. "identifiable information")? |
| **If all items are checked under 1,2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations** | |
| **5** | **Human Research Under FDA Regulations** (Check if **"Yes"**.) |
| ☐ | Does the activity involve any of the following? (Check all that apply)<br>☐ In the United States: The use of a drug[i] in one or more persons other than use of an approved drug in the course of medical practice.<br>☐ In the United States: the use of a device[ii] in one or more persons that evaluates the safety or effectiveness of that device.<br>☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[iii].<br>☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[iv]. |
| **If "Yes", the activity is Human Research under FDA regulations*** | |
| **If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under UCCS policy.** | |

[i] The term "drug" means:
- (A) Articles recognized in the official United States Pharmacopoeia, Official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) Articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
- (D) Articles intended for use as a component of any article specified in clause (A), (B), or (C)

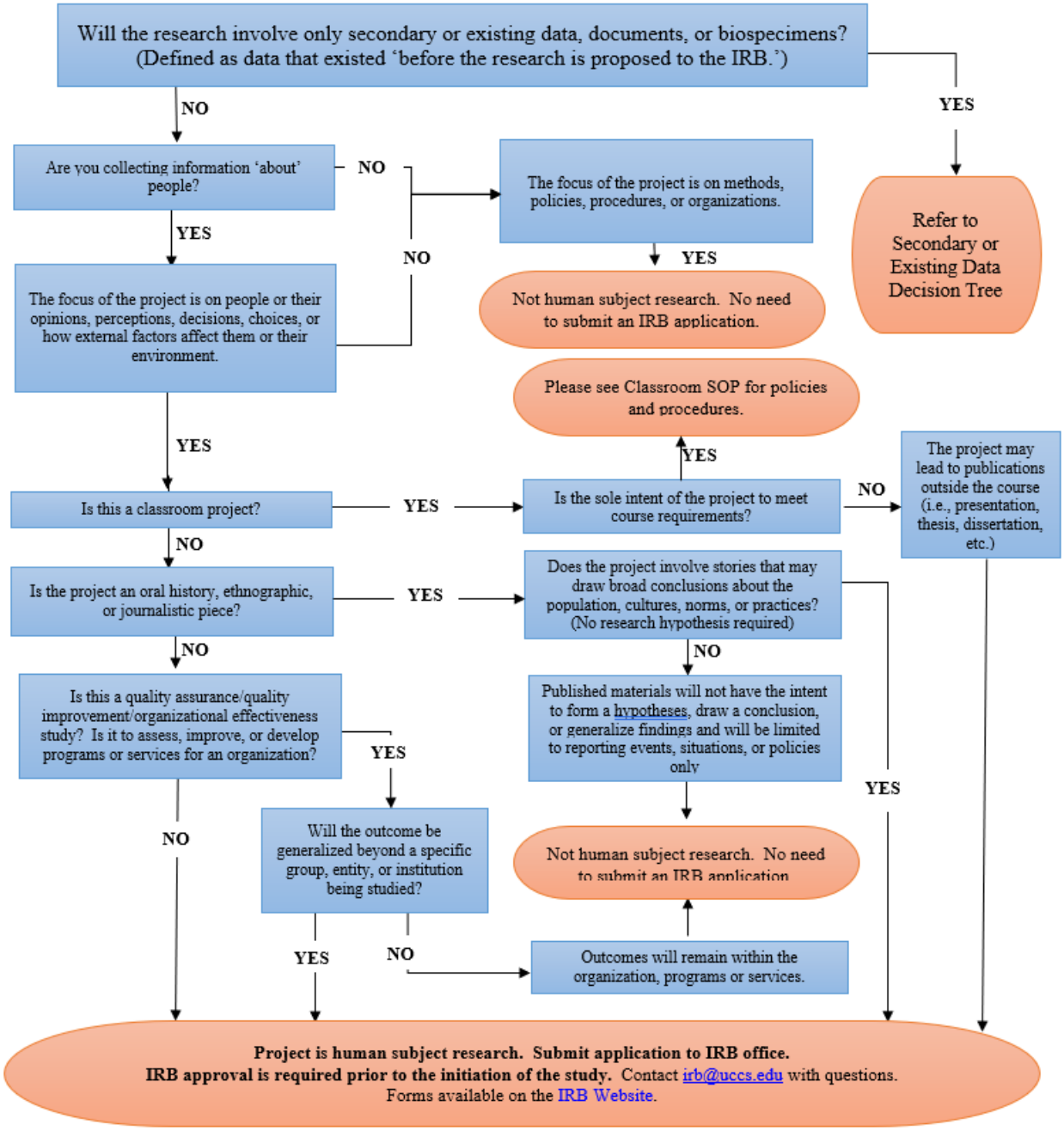
[ii] The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or relate article, including any component, part or accessory, which is:
- (1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[iii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[iv] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

* Review of FDA covered research may need to occur by an outside IRB. Contact us with questions irb@uccs.edu

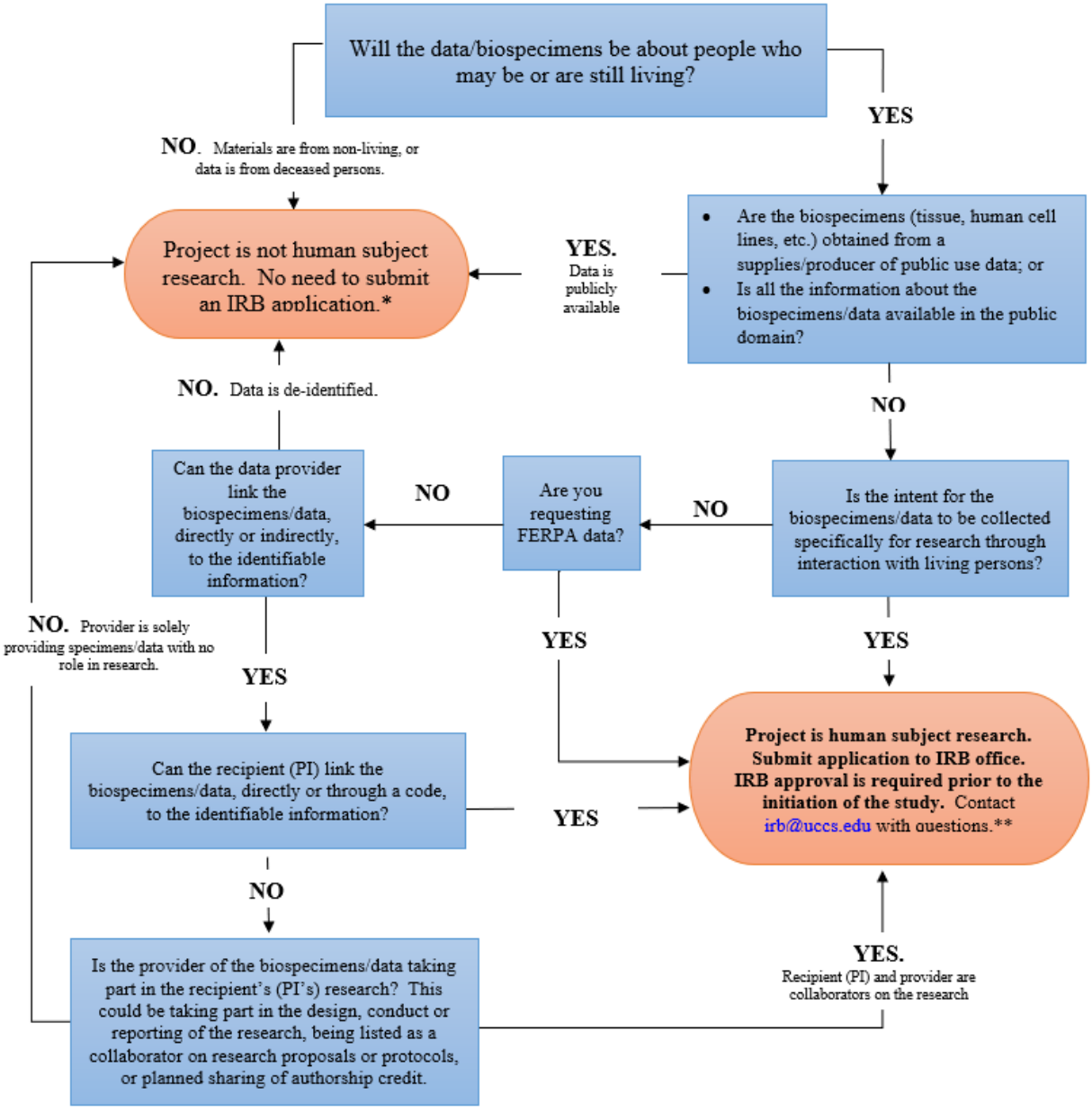
## *Appendix D: Does Your Project Require a UCCS New IRB Application?*



## *Appendix E: Secondary or Existing Data Decision Tree*

* If a PI is needing a signed 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.

** Forms available at the IRB Website.



## *Appendix F: Quality Assessment/Quality Improvement Decision Tree*

* If an approval is required to publish, it is a requirement to submit an IRB application prior to initiation of the project. No retroactive approvals are provided.
** Forms available at the IRB Website.