Hello Researcher:

Please use the following flowcharts and checklists to help you determine when your research may require a review by the Institutional Review Board (IRB).

Please note that these flowcharts and checklists are from the IRB Researcher Manual.

Other helpful resources may be found on the IRB website- https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb:

1. IRB Researcher Manual
2. A Dozen Tips for a Successful IRB Application
3. Research with Local School Districts
4. IRB Research Summary Instructions (provides guides for sections of the IRB application)
5. IRB Standard Operating Procedures (SOPs)

If you have questions about your specific research project, please feel free to contact us at IRB@uccs.edu. We would be happy to help.

Sincerely,

The Staff of the Office of Sponsored Programs and Research Integrity
(719) 255-3903 (voice) (719) 255-3706 (fax) irb@uccs.edu
Does Your Project Require a UCCS New IRB Application?

Will the research involve only secondary or existing data, documents, or biospecimens? (Defined as data that existed ‘before the research is proposed to the IRB.’)

- **NO**
  - Are you interacting with, or collecting information from or about people?
    - **NO**
      - The focus of the project is on methods, policies, procedures, or organizations.
    - **YES**
      - Refer to Secondary or Existing Data Decision Tree

- **YES**
  - The focus of the project is on people or their opinions, perceptions, decisions, choices, or how external factors affect them or their environment.
    - **NO**
      - Not human subject research. No need to submit an IRB application.
    - **YES**
      - Is this a classroom project?
        - **NO**
          - Is this an oral history, ethnographic, or journalistic piece?
            - **NO**
              - Is the project a quality assurance/quality improvement/organizational effectiveness study? Is it to assess, improve, or develop programs or services for an organization?
                - **NO**
                  - Will the outcome be generalized beyond a specific group, entity, or institution being studied?
                    - **NO**
                      - Outcomes will remain within the organization, programs or services.
                    - **YES**
                      - Project is human subject research. Submit application to IRB office.

- **YES**
  - The focus of the project is on people or their opinions, perceptions, decisions, choices, or how external factors affect them or their environment.
    - **YES**
      - Is the sole intent of the project to meet course requirements?
        - **NO**
          - Does the project involves stories that may draw broad conclusions about the population, cultures, norms, or practices? (No research hypothesis required)
            - **NO**
              - Published materials will not have the intent to form a hypotheses, draw a conclusion, or generalize findings and will be limited to reporting events, situations, or policies only
            - **YES**
              - Not human subject research. No need to submit an IRB application.
        - **YES**
          - The project may lead to publications outside the course (i.e., presentation, thesis, dissertation, etc.)
            - **NO**
              - Please see Classroom SOP for policies and procedures.
            - **YES**
              - Project is human subject research. Submit application to IRB office.

IRB approval is required prior to the initiation of the study. Contact irb@uccs.edu with questions. Forms available at https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb
Does Your Research Involving Secondary or Existing Data or Biological Specimens Require Review by UCCS IRB?*

Will the data/biospecimens be about people who may be or are still living?

NO. Materials are from non-living, or data is from deceased persons.

Project is not human subject research. No need to submit an IRB application.*

NO. Data is de-identified.

Can the data provider link the biospecimens/data, directly or indirectly, to the identifiable information?

NO

Can the recipient (PI) link the biospecimens/data, directly or through a code, to the identifiable information?

YES

Project is human subject research. Submit application to IRB office. IRB approval is required prior to the initiation of the study. Contact irb@uccs.edu with questions.**

YES

Are you requesting FERPA data?

NO

Was the intent for the biospecimens/data to be collected specifically for research through interaction with living persons?

NO

Is the provider of the biospecimens/data taking part in the recipient’s (PI’s) research? This could be taking part in the design, conduct or reporting of the research, being listed as a collaborator on research proposals or protocols, or planned sharing of authorship credit.

YES

Is the provider of the biospecimens/data taking part in the recipient’s (PI’s) research? This could be taking part in the design, conduct or reporting of the research, being listed as a collaborator on research proposals or protocols, or planned sharing of authorship credit.

NO

Are the biospecimens (tissue, human cell lines, etc.) obtained from a supply/producer of public use data; or

Is all the information about the biospecimens/data available in the public domain with no password required?

NO

Data is all publicly available

YES

* If an approval is required to publish, it is a requirement to submit an IRB application. No retroactive approvals will be provided. 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 https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb
Is your project Research or Quality Assessment/Quality Improvement?*

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?

**NO**
IRB review is likely required to address FDA requirements. Contact the IRB for guidance.

**YES**
Will the project involve testing an experimental drug, device (including medical software or assays) or biologic?

**NO**
IRB review is likely required. Contact the IRB for guidance.

**YES**
Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?

**NO**
IRB review is likely required. Contact the IRB for guidance.

**YES**
Will the results of the project be published, presented or disseminated outside the institution conducting it?

**NO**
This project appears to constitute QA/QI. Further IRB review is not required. Ensure that all those associated with the project are aware that it is ongoing.*

**YES**
Will the project occur regardless of whether individuals conducting it may benefit professionally from it?

**NO**
The project does not appear to fit the definition of QA/QI. Contact the IRB for guidance.

**YES**
Will the results of the project be published, presented or disseminated outside the institution conducting it?

**NO**
IRB review is likely required. Contact the IRB for guidance.

**YES**
This project appears to constitute QA/QI and does not fit the federal definition of research. Further IRB review is not required. Ensure that all those associated with the project are aware that it is ongoing. In future publications/presentations, it is recommended you refer to this as QA/QI and not as research.

Adopted with permission from the University of Wisconsin Health Sciences IRB.

* 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 will be provided.

** Forms available at https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb
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 individual in determining whether an activity is Human Subject Research or how it is regulated. This worksheet is to be used and does not need to be completed, submitted, or retained.

<table>
<thead>
<tr>
<th>1</th>
<th>Research as Defined by DHHS Regulations (Check if “Yes”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)</td>
</tr>
<tr>
<td>☐</td>
<td>Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)</td>
</tr>
<tr>
<td>☐</td>
<td>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.)</td>
</tr>
<tr>
<td>☐</td>
<td>Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>2</th>
<th>Human Subject under DHHS Regulations (Check if “Yes”)</th>
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</thead>
<tbody>
<tr>
<td>☐</td>
<td>Is the investigator conducting the Research gathering data about living individuals, including biospecimens.</td>
</tr>
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</table>

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<tr>
<th>3</th>
<th>Human Subject Under DHHS Regulations (Check if “Yes”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Will the investigator gather that data through either of the following mechanisms (Specify which mechanism(s) apply): Physical procedures or manipulations of those individuals or their environment for research purposes, including biospecimens (&quot;intervention&quot;). Communication or interpersonal contact with the individuals. (&quot;interaction&quot;).</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>4</th>
<th>Human Subject Under DHHS Regulations (Check if “Yes”).</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Will the investigator gather data that is either? (Specify which category(s) apply): 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”). 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”).</td>
</tr>
<tr>
<td>☐</td>
<td>Can the individuals' identities be readily ascertain or associated with the information by the investigator (i.e. &quot;identifiable information&quot;)?</td>
</tr>
</tbody>
</table>

If any items are checked under 1, 2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations.

<table>
<thead>
<tr>
<th>5</th>
<th>Human Research Under FDA Regulations (Check if “Yes”).</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Does the activity involve any of the following? (Check all that apply) In the United States: The use of a drug in one or more persons other than use of an approved drug in the course of medical practice. In the United States: the use of a device in one or more persons that evaluates the safety or effectiveness of that device. Data regarding subjects or control subjects submitted to or held for inspection by FDA.</td>
</tr>
<tr>
<td>☐</td>
<td>Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA.</td>
</tr>
</tbody>
</table>

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.

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1 The term “drug” means:
   (A) Articles recognized in the official United States Pharmacopeia, Official Homoeopathic Pharmacopeia 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) 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 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.

2 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:
   (A) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, and
   (B) 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
   (C) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its 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.

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

PI submits application with applicable addendums → IRB staff conducts pre-review and assigns reviewer → Reviewer sends revision requirements to PI, if applicable → PI submits revisions to irb@uccs.edu*

Risk level is assigned

Reviewer reviews revisions for accuracy → IRB staff processes revisions and forwards to reviewer

Exempt Determination

Reviewer completes review and forwards to IRB staff → IRB staff completes final processing and notifies PI

Expedited Determination

Reviewer reviews revisions for accuracy → IRB staff completes final processing and notifies PI

Full Review Determination and on agenda for next IRB board meeting

Revisions requested, if needed.

Application is disapproved

IRB staff completes final processing and notifies PI

Application is tabled until next meeting

IRB Chair informs PI of required revisions

Application approved with changes

IRB Chair informs PI of required revisions

Application approved as submitted

* If the PI is a student, the application must be submitted via the faculty advisor's email address.