

# IRB Application Worksheet

## About This Worksheet

This worksheet mirrors the questions you will answer in Cayuse Human Ethics (HE), the online system UCA uses for IRB submissions. Use it for two purposes: (1) to draft and refine your application offline, especially when your department has its own internal review process before Cayuse submission, and (2) as a learning tool to think carefully about how your study protects the people who participate in it.

An IRB application is not a bureaucratic hurdle. It is an opportunity to describe your research in a way that puts participant safety, dignity, and informed choice at the center. Take your time with each section. The clearer and more thoughtful your responses, the smoother your review will be.

## How to Use This Document

Required sections are marked clearly. Some sections only apply to certain kinds of studies, and those are marked with a yellow banner explaining when to complete them. Light purple boxes throughout the document offer guidance to help you understand what each question is really asking. Once your draft is complete and any internal departmental review is done, you (or your PI) will transfer your responses into Cayuse HE for formal submission.

## Required vs. Conditional Sections

### Everyone completes the following:

- Project Personnel
- Basic Information
- Review Level / Category
- Study Design
- Study Selection
- Study Procedures
- Participant Protection

### **IMPORTANT!**

**If you are relying on another institution's IRB:** you generally only need to provide the external IRB's approved documents, letters of permission, and information about external collaborators. Contact the UCA Office of Research Integrity and Compliance (ORIC) before you begin.

### Complete these sections only if applicable:

- **Study Products** — if your study involves drugs, biologics, devices, diagnostics, supplements, or food additives
- **International Research** — if any research activities occur outside the United States
- **HIPAA** — if your study involves protected health information collected or shared by a covered entity
- **Data and Safety Monitoring** — if your study poses greater than minimal risk or has a formal monitoring plan

# 1. Project Personnel

Tell us who is involved in this research, what role each person plays, and confirm that everyone has the training they need. The IRB needs to know who is responsible for what.

## \* Principal Investigator (PI) / Project Director affiliation

*The PI is the person primarily responsible for the ethical conduct and oversight of the study. If you are a student, your faculty mentor is the PI of record.*

- Faculty
- Student (list faculty mentor as PI below)
- Staff
- Other

## \* Principal Investigator / Project Director

Name:

---

Department / Organization:

---

UCA email and phone:

---

## \* Primary Contact (if different from PI)

*The primary contact receives study communications and can edit the submission. For student projects, this is often the student researcher.*

Name, role, email, phone:

---

---

## Co-Investigators, Student Co-Investigators, and Other Personnel

*List everyone who will interact with participants, handle data, or otherwise be engaged in the research. For each person, give name, role on the study, department, and email.*

---

---

---

---

**\* CITI Training Documentation**

*All study personnel must complete the CITI **Research Investigators** course before the IRB will approve your study. Externally funded projects also require the **Conflicts of Interest** course; NIH or NSF funding additionally requires the **Responsible Conduct of Research** course. You will upload these certificates in Cayuse. List the names of personnel whose certificates you will need to attach:*

---

---

---

**\* Conflict of Interest (COI)**

*A COI exists when personal, professional, or financial interests could influence (or appear to influence) someone's professional judgment on this project. Most student projects have no COI, but be honest if one exists.*

Do any project personnel have a COI related to this project?

Yes

No

If yes, list the person(s) and disclose the nature of the COI:

---

---

---

## 2. Basic Information

This section establishes the where, when, and what of your project, plus a few questions that decide which other sections you will need to complete.

### \* Performance / Project / Study Site(s)

*List every place your research will happen. This includes physical locations (a UCA classroom, a community center, a hospital), geographic areas (a school district, a city), and digital platforms (Qualtrics, Zoom, a public Facebook group).*

---

---

---

### \* External Sites

Will research be conducted at any non-UCA sites within the U.S.?

- Yes
- No

*If yes, you will need a letter of permission from each site or, in some cases, a formal reliance agreement. Talk with ORIC early if your study involves another institution that has its own IRB.*

### IRB Oversight Arrangements

If multiple sites are involved, indicate how IRB oversight is organized (check one):

- Each site conducts its own IRB review or provides a letter of permission
- UCA is the Reviewing IRB (IRB of Record) for other sites
- UCA is Relying on an External IRB
- Multi-site study, UCA is IRB of Record for all sites
- Multi-site study, UCA is Relying on an External IRB

**\* External Collaborators**

Will any researchers not affiliated with UCA conduct research activities?

- Yes
- No

If yes, list each external collaborator, their institution, and their role in the study:

---

---

---

*External collaborators may need their own training documentation, letters of permission, or reliance agreements. Plan to upload these in Cayuse.*

**\* International Sites**

Will any research activities occur at non-U.S. sites?

- Yes
- No

**⚠ If you answered Yes here, you must also complete the International Research section.**

**\* Project Type**

- Activities Without a Plan to Conduct Research Involving Human Subjects (use if you need a formal IRB determination, e.g., for a creative URC project)
- Research Study Involving Human Subjects (most common)
- 118 Determination / Just-in-Time (only for external grant funding situations; consult OGSR first)
- Clinical Trial
- Single Patient, Treatment Use, or Continued Access Drug/Device Study
- Emergency or Compassionate Use of Investigational Drug or Device

*Most UCA student and faculty projects are **Research Study Involving Human Subjects**. The federal definition of research is a systematic investigation designed to develop or contribute to generalizable knowledge. Surveys, interviews, focus groups, program evaluations, and analyses of existing data all typically qualify.*

**\* Study Dates**

Anticipated start date:

---

Anticipated end date:

*Do not begin recruiting or collecting data until you have IRB approval. Build review time into your start date. Review can take anywhere between a week or a month depending on the level of review.*

**\* Funding**

Does this project have funding or in-kind support (or will it potentially)?

Yes

No

If applying for URC funding, check here:

Applying for URC funding

If yes, briefly describe the funding source:

---

**Other Research Compliance Considerations**

Does your research involve any of the following? Check all that apply:

IACUC (live vertebrate animals)

IBC (biological agents, toxins, or hazardous materials)

RSC (radioactive materials or radiation-producing devices)

Export Control (foreign collaboration, international travel, etc.)

FERPA (student educational records)

Additional question for FERPA:

- What type of student data? (e.g., coursework, grades, GPAs, etc.)
- How are you collecting the student data?

Please Note: Post approval, you may be advised to contact [Ms. Amber Hall](#) in the IR office to discuss any projects that involve collecting data that is protected under FERPA. She has give the final approval before you can start

### 3. Review Level / Category

This reflects your best professional judgment about which level of review fits your study. The final determination is made by ORIC and the IRB, but your input helps with workflow and shows that you have thought carefully about the level of risk involved.

#### The Three Review Levels

***Exempt** applies to certain low-risk research (some surveys, observation of public behavior, use of de-identified existing data, normal educational practices). Exempt does not mean exempt from IRB review, just exempt from the more intensive review process.*

***Expedited** applies to research that is no more than minimal risk and fits one of the federal expedited categories. Most behavioral and social science research falls here.*

***Full Board** applies to research that is more than minimal risk, or that involves vulnerable populations or sensitive topics in ways that require careful collective review.*

**Minimal risk** means the probability and magnitude of harm or discomfort are not greater than what people ordinarily encounter in daily life or during routine examinations.

#### \* Proposed Review Level

- Exempt Review
- Expedited Review
- Full Board Review

## Exempt Review Categories

- A. Educational Research in Normal Settings
- B. Surveys, Tests, Interviews, and Behavioral Observation (Anonymous or Low-Risk)
- C. Benign Behavioral Interventions with Adult Consent
- D. Secondary Research with Existing Data/Specimens
- E. Federal Program Evaluation Research
- F. Food and Taste Studies

Important Note: **Generally, targeting a vulnerable population does not qualify for an exempt review;** however, for children:

- Category A may apply.
- Category B may apply to children in two circumstances: 1) when the research involves the use of standardized educational tests and 2) when the research involves observation of public behavior when the investigator(s) **do not** participate in the activities being observed. Survey and interview procedures do not apply to children.

•  
**If your research involves deception:** Category C only applies if participants prospectively agree to participate in research where they will be unaware of or misled about the nature or purposes of the research.

**If you will be audio/video/photographing participants for any reason:** Your study will need to undergo an expedited review at minimum, even if there is a procedure in place to destroy the data.

## Expedited Review Categories

If you selected Expedited, check all categories that apply to your study:

- A. Clinical studies of drugs or medical devices (specific conditions apply)
- B. Collection of blood samples within specified limits
- C. Prospective collection of biological specimens by noninvasive means
- D. Noninvasive data collection procedures routinely used in clinical practice
- E. Research using existing materials, data, documents, records, or specimens
- F. Voice, video, digital, or image recordings collected for research
- G. Behavioral or social research (surveys, interviews, focus groups, observation, etc.)
- H. Continuing review of previously approved research with minimal remaining activity
- I. Continuing review of other minimal risk research

*Tip: Most behavioral and social science studies at UCA fall under **Category G** (surveys, interviews, focus groups, oral histories) or **Category E** (analyzing existing data or records).*

## When Full Board Review May Be Required

Full Board Review is required when participant identification or responses could reasonably place them at risk of criminal or civil liability, financial harm, damage to employability, or stigmatization (unless adequate protections are in place); when the research involves classified information; when research involves a vulnerable population; or when the research presents more than minimal risk. In those cases, you must apply for Full Board Review:

- A. International Research
  - B. Research Involving Prisoners (Subpart C)
  - C. Privacy and Confidentiality Risks
  - D. Physical Risks Beyond Normal Experience
  - E. Psychological/Social Manipulation
  - F. Sensitive Information Probing
  - G. Vulnerable Population Risks
  - H. Complex Interventions
  - I. Data and Privacy Concerns
  - J. Regulatory Requirements
  - K. Institutional Factors
- **When in doubt, choose full review.** It's better to err on the side of caution when participant safety is involved.
  - **Research not previously reviewed that involves ANY of the checked categories above typically requires full board review**
  - **Even if research appears to fit exempt or expedited categories,** it may still require full review if it involves more than minimal risk, meets any of the above criteria, or is complex.

## 4. Study Design

This is where you tell the story of your research. Treat this section as your chance to help the reviewer understand what you want to learn, why it matters, and how you will go about it.

**\* Has a protocol document been issued by a Lead Site or Sponsor?**

Yes

No

*This usually applies only to industry-sponsored clinical trials. Most student and faculty research at UCA answers No here.*

**\* Study Background**

*Provide the background and rationale for your study. What does the existing literature tell us? What gap or question are you addressing? Two or three paragraphs is usually enough. Write so a smart non-expert can follow.*

---

---

---

---

---

---

---

---

---

---

**\* Hypothesis**

*State your hypothesis. For exploratory or qualitative studies, you may instead state your guiding research question(s).*

---

---

---

---

**\* Objectives**

*What specifically do you want to accomplish? Objectives are the concrete, measurable things your study will do. List them as a short, numbered list when possible.*

---

---

---

---

---

---

---

---

---

---

**\* Study Design**

*Describe the overall approach. Is it prospective or retrospective? Quantitative, qualitative, or mixed methods? Experimental, quasi-experimental, observational, descriptive? If you have multiple groups, arms, or populations, describe each.*

---

---

---

---

---

---

---

---

---

---

**\* Outcome Measures**

*What will you measure to answer your research question? Be specific about variables, instruments, and how you will define each outcome.*

---

---

---

---

---

---

**\* Inclusion Criteria**

*Who is eligible to participate, and why? Be specific (age range, status, characteristics).*

---

---

---

---

**\* Exclusion Criteria**

*Who will be excluded, and why? Make sure your exclusions are scientifically and ethically justified, not arbitrary.*

---

---

---

---

## 5. Study Selection

Tell us who your participants are, how many you expect to enroll, and whether any vulnerable populations are involved.

### \* Enrollment at UCA

Number of participants to be enrolled at UCA:

---

### \* Total Study Enrollment

Total number across all sites:

---

### \* Ages

*Indicate the age range. If you have multiple distinct populations (for example, parents and their children), list each range separately.*

---

---

## Vulnerable Populations

Vulnerable populations require additional protections. You are knowingly including a vulnerable population if participants will belong to that group at any point during the study and you will know they belong to it.

### Vulnerable Populations Knowingly Included

- Fetuses
- Pregnant women
- Neonates (birth to less than 1 month)
- Children (under 18, including infants)
- Prisoners
- Cognitively impaired adults
- Other (specify below)
- None of the above

If Other, specify:

---

**\* Necessity of Inclusion**

*For each vulnerable population included, explain why their inclusion is appropriate, whether the risk to them is minimal or greater, the prospect of direct benefit, and whether generalizable knowledge about their condition may be gained.*

---

---

---

---

---

**\* Special Arrangements**

*Describe any additional measures you will take to protect the rights and welfare of these populations (modified consent, additional safeguards, advocates, etc.).*

---

---

---

---

---

**\* Excluded Vulnerable Populations**

Will any vulnerable populations be deliberately excluded?

Yes

No

If yes, list which populations will be excluded and justify the exclusion:

---

---

---

*Exclusion must be consistent with principles of equitable recruitment. Excluding pregnant women or children just because they feel like extra paperwork is not adequate justification.*

## 6. Study Procedures

Walk us through exactly what will happen, from the moment you identify a potential participant to the moment you store the final dataset.

### \* Recruitment Process

*Where, when, and how will you find and approach potential participants? What materials will you use (flyers, emails, social media posts, classroom announcements, scripts)? Plan to upload copies of all recruitment materials in Cayuse.*

---

---

---

---

---

---

---

---

### \* Compensation

Will participants be compensated in any way?

Yes

No

If yes, describe the amount, method, timing, and any pro-rating for partial completion:

---

---

---

*Compensation should be fair but not so large that it becomes coercive (where someone might participate against their better judgment because they cannot afford to refuse).*



### \* Participant Duration

How long will each participant be involved? How many visits or sessions? What is the overall study timeline?

---

---

---

---

### Study Instruments

*Plan to upload all surveys, interview guides, scales, questionnaires, and other instruments you will use. List them here so you remember to attach them in Cayuse.*

---

---

---

### Data and Specimens

#### \* Identifiable Data or Specimens

Will the project collect or use materials recorded in a way that could identify individuals (directly or through a code linked to the key)?

Yes

No

#### Demographic Data Collected

Check all that apply:

- |   |  |
|---|--|
| <input type="checkbox"/> Name                   | <input type="checkbox"/> Job title             |
| <input type="checkbox"/> Marital status         | <input type="checkbox"/> Name of employer      |
| <input type="checkbox"/> Social Security number | <input type="checkbox"/> Type of employer      |
| <input type="checkbox"/> Income                 | <input type="checkbox"/> Age or date of birth  |
| <input type="checkbox"/> Physical address       | <input type="checkbox"/> Sex                   |
| <input type="checkbox"/> Email address          | <input type="checkbox"/> Gender                |
| <input type="checkbox"/> Phone number           | <input type="checkbox"/> Race or ethnicity     |
|   | <input type="checkbox"/> Other (specify here): |

---

None of the above

**\* Use of Demographic Information**

*Briefly explain how each piece of demographic information will be used. Only collect what you actually need. Collecting data you will not use is bad practice and increases participant risk.*

---

---

---

---

**\* Participant Data Protection**

*How will you protect privacy and confidentiality? If you cannot maintain confidentiality (for example, in a focus group where participants know each other), say so clearly.*

---

---

---

---

---

**\* Collection and Handling**

*Where and how will data or specimens be stored? What additional information will be associated with them? How long will you keep them? Who handles transmission, and how is data transported?*

---

---

---

---

---

---

---

**\* Data and Specimen Security**

*Concrete safeguards: password-protected files, encrypted drives, locked filing cabinets, separation of identifiers from data, restricted access lists, and so on.*

---

---

---

---

**\* Physical UCA Location for Records**

Building and room number where records can be accessed if needed (required even for digital projects):

---

---

**\* Sharing Results with Subjects**

Will study results or individual results be shared with subjects or their providers?

Yes

No

If yes, describe what will be shared and how, including any plan for handling incidental findings:

---

---

---

If laboratory results will be shared, is the lab CLIA certified?

Yes

No

N/A

**\* Data and Specimen Banking and Future Research**

Will any data or specimens be used for future research beyond this project?

Yes

No

**\* Data Analysis**

*Describe your analysis plan, including statistical procedures, software, power analysis (if applicable), and any quality control steps for the collected data.*

---

---

---

---

---

## 7. Participant Protection

This is the heart of the IRB application. Show us that you have thought seriously about what could go wrong for participants and how you have planned to prevent or minimize harm.

### \* Potential Risks

*Be honest and specific. Consider physical, psychological, social, legal, and economic risks, as well as time and effort burdens. The risk of a confidentiality breach is common to almost all studies. Describe each risk's probability, magnitude, duration, and reversibility. If risks to a fetus or to non-participants are possible, address those too.*

---

---

---

---

---

---

---

---

---

---

### \* Potential Benefits

*Describe potential benefits to participants (if any) and to society. Be honest. Much behavioral research offers no **direct** benefit to participants, and that is okay to say so. Do not overstate benefits to justify risk.*

---

---

---

---

---

### \* Data and Safety Monitoring

Does this project pose greater than minimal risk, or include a Data and Safety Monitoring Plan or Board?

Yes

No

► **If you answered Yes, also complete the Data and Safety Monitoring section later in this worksheet.**

**\* Deception**

Will deception be used as a method of data gathering?

Yes

No

If yes, justify the use of deception:

---

---

---

---

*Deception is permitted only when the research could not be done otherwise, the deception will not place participants at more than minimal risk, and participants are debriefed afterward. Plan to upload your debriefing script in Cayuse.*

**\* Subject Privacy and Confidentiality**

*Privacy is about how you approach participants and conduct sessions (private rooms, no overheard conversations). Confidentiality is about how you protect their data afterward. Address both.*

---

---

---

---

---

## Informed Consent

### \* Waivers or Alterations to Informed Consent

Will any part of this project involve a waiver or alteration of informed consent?

Yes

No

### \* Consent Process

*Walk us through how you will obtain consent. When? Where? In what format (paper, electronic, verbal)? How will you make sure participants actually understand what they are agreeing to? If vulnerable populations are involved, address consent for them specifically. Plan to upload your consent and assent forms in Cayuse.*

---

---

---

---

---

---

---

---

---

---

## HIPAA Screening

Two questions determine whether you need to complete the full HIPAA section:

**\* Does this project involve collecting or accessing health information AND one or more of the 18 HIPAA identifiers?**

Yes

No

**\* Does this project involve obtaining, using, or releasing PHI by a Covered Entity?**

Yes

No

**► IF you answered Yes to BOTH questions, also complete the HIPAA section later in this worksheet.**

## Conditional Section: Study Products

① This section applies if your study involves drugs, biologics, devices, diagnostics, supplements, or food additives. Otherwise, skip to the next section.

### \* Study Product Type

- Drug
- Biologic
- Food
- Cosmetic
- Device
- Surgical implant or prosthetic
- Dental device
- Electronic wearable device
- Electronic product that emits radiation
- Mobile medical application
- Software or algorithm (including AI/ML)
- Other device
- Other

### \* Device Description

*Name each device, describe its purpose, and explain whether it is intended to diagnose, treat, or prevent disease, or to affect bodily structure or function.*

---

---

---

---

---

---

---

---

**\* Device FDA Approval Status**

*Possible answers include: FDA approved; Investigational device requiring an IDE (provide IDE number and holder); IDE exempt (cite the exemption under 21 CFR 812); or not subject to regulation under 21 CFR 812 (explain why).*

---

---

---

---

---

**\* Non-Significant Risk (NSR) Determination**

Are you requesting a Non-Significant Risk determination for any device?

- Yes
- No

**Device Documentation**

*Plan to upload risk documentation, instructions for use or instruction manuals, and any FDA approval or exemption documentation in Cayuse.*

## Conditional Section: International Research

① This section applies if your study involves drugs, biologics, devices, diagnostics, supplements, or food additives. Otherwise, skip to the next section.

### \* Justification of International Setting

*Why does this research need to happen in this international location? Address both the scientific and ethical justification.*

---

---

---

---

---

### \* International Locations

List all cities and countries where research will occur:

---

---

---

### \* International Collaborators

*For each collaborating site, list the name, role (performance site, data center, etc.), the people involved, their qualifications, and what they will do.*

---

---

---

---

---

---

---

**\* Data and Specimen Access**

Which institutions or governments will have access to the data, and at what level (anonymous, coded, identifiable)?

---

---

---

---

**\* International Oversight Requirements**

*What local permissions are required? Will you obtain approval from a local IRB or ethics committee, or get input from someone with knowledge of the study site?*

---

---

---

---

---

**\* Applicability to Local Context**

*How does this research address an important question for the host community or country? What is the standard of care available locally compared to in the U.S.?*

---

---

---

---

---

**\* Community Consultation**

*Describe your knowledge of the local community and any consultation you have done (or plan to do) about the consent process, study instruments, and cultural appropriateness.*

---

---

---

---

---

**\* Literacy and Translation**

*Describe the literacy level of the population, how you will maximize participants' understanding of consent, and how documents will be translated and verified for cultural appropriateness.*

---

---

---

---

---

**Status of Women**

*If the status of women in the location differs from the U.S., explain how you will ensure women's voluntary participation and respect their autonomy to consent.*

---

---

---

---

---

**Clarification of Research vs. Treatment**

*How will you make sure participants understand that this is research, not just treatment? What is your plan for continued access to effective interventions after the study ends?*

---

---

---

---

---

**Additional Documentation**

*Upload any additional documentation related to International Research, as applicable.*

## Conditional Section: HIPAA

① This section applies if your study involves protected health information (PHI) collected, used, or shared by a Covered Entity. Otherwise, skip to the next section.

**Protected Health Information (PHI)** means health information combined with one or more of the 18 HIPAA identifiers. Even projects that are Not Human Subjects Research can have HIPAA obligations if PHI is being used by a Covered Entity.

### \* Health Information Collected

*If not described elsewhere, list the specific health information you will collect.*

---

---

---

---

---

### \* HIPAA Identifiers Collected

Check all that apply:

- |  |   |
|--|---|
| <input type="checkbox"/> Patient or participant names  | <input type="checkbox"/> Certificate or license numbers                               |
| <input type="checkbox"/> Geographic subdivisions smaller than a state                          | <input type="checkbox"/> Device identifiers and serial numbers                        |
| <input type="checkbox"/> Age information for those over 89                                     | <input type="checkbox"/> Vehicle identifiers (including license plates)               |
| <input type="checkbox"/> All elements of dates (except year) directly related to an individual | <input type="checkbox"/> Web URLs   |
| <input type="checkbox"/> Telephone numbers   | <input type="checkbox"/> IP addresses   |
| <input type="checkbox"/> Fax numbers   | <input type="checkbox"/> Biometric identifiers (fingerprints, voiceprints)            |
| <input type="checkbox"/> Email addresses   | <input type="checkbox"/> Full-face photographs or comparable images                   |
| <input type="checkbox"/> Social Security numbers   | <input type="checkbox"/> Genetic test results   |
| <input type="checkbox"/> Medical record numbers  | <input type="checkbox"/> Any other unique identifying number, characteristic, or code |
| <input type="checkbox"/> Account numbers   | <input type="checkbox"/> Health plan beneficiary numbers                              |
| <input type="checkbox"/> None of the above   |   |

## Waiver or Alteration of HIPAA Authorization

### \* Are you requesting a waiver or alteration?

Yes

No

### Type of Waiver or Alteration

Partial Waiver (waiver for part of the project; full authorization required for the rest)

Full Waiver (waiver for all access, use, and creation of records containing PHI as described)

Alteration of Authorization (removal of some, but not all, required elements)

### \* Description and Justification

*Explain what waiver or alteration you are requesting and why the project could not practicably be conducted without it. Be specific about what PHI you need and why standard authorization is not feasible.*

---

---

---

---

---

---

---

---

---

---

### \* Sharing of PHI

Will UCA receive PHI from or share PHI with any outside entities?

Yes

No

If yes, describe what PHI will be shared, who is receiving it, and under what authorization (Limited Data Set with DUA, subject authorization, waiver, etc.):

---

---

---

---

---

---

**\* Protection of PHI**

*Describe how PHI will be protected from improper use or disclosure during storage, use, and transfer.*

---

---

---

---

---

**Storage and Maintenance of Identifiers**

*After the project ends, will identifiers be destroyed, de-identified, or maintained for future research in a repository?*

---

---

---

---

**Additional Documentation**

*Upload any additional documentation related to HIPAA Authorization, as applicable.*

## Conditional Section: Data and Safety Monitoring

① This section applies if your study poses greater than minimal risk OR includes a formal Data and Safety Monitoring Plan or Board. Otherwise, skip to the next section.

**\* Has a DSMP or Charter been issued by the Lead Site or Sponsor?**

Yes

No

**\* Study Monitor**

Indicate the entity that will monitor the study data for safety. Check all that apply:

Investigator

Monitor independent of the study team (e.g., sponsor's medical monitor)

Data Safety Monitoring Board or Committee (DSMB/C)

**\* Monitor or DSMB/C Information**

*For each monitor or board member, provide name, credentials, role, expertise, and title/organization. If unknown, describe the expertise of anticipated members.*

---

---

---

---

---

---

---

---

**\* Objectivity of the Monitoring Entity**

*How will the monitor's objectivity be ensured? If the investigator is the monitor, verify absence of conflict of interest. If the monitor is from the sponsor, confirm they are not directly involved in conducting or analyzing the study.*

---

---

---

---

---

---

---

---

**\* Roles and Responsibilities for Data Gathering and Monitoring**

*Who records the data? Who verifies its accuracy and how? Who confirms protocol adherence? Who evaluates events to determine if they represent unanticipated problems?*

---

---

---

---

---

---

---

---

---

---

**\* Monitored Information and Reporting**

*What data and events will be monitored and reported? How will reports be submitted, how often, and within what timeframe (especially for unanticipated problems involving risks)?*

---

---

---

---

---

---

---

---

---

---

**\* Frequency of Monitoring and Reporting**

---

---

---

---

---

---

---

---

---

---

**\* Evaluation Methods**

*How will the monitor evaluate the data and events (statistical analysis, etc.)? For DSMB/C monitoring, describe meeting structure, format, and quorum.*

---

---

---

---

---

---

---

---

---

---

**\* Criteria and Response to Findings**

*What stopping rules, protocol changes, or other actions will be triggered by monitoring findings?*

---

---

---

---

---

**\* Communicating Findings**

---

---

---

---

**\* Confidentiality of Data Provided to Monitors**

---

---

---

---

# Attachments Checklist

When you transfer your application to Cayuse HE, you will need to upload supporting documents. Use this checklist to gather them ahead of time. Not every item applies to every study.

## Project Personnel

- CITI training certificates for all study personnel (if not already in their Cayuse profiles)

## Basic Information

- Training documentation for external collaborators
- Letters of permission or reliance agreements (IIA, IAA, MOU, etc.) for external sites

## Study Procedures

- Recruitment materials (flyers, advertisements, scripts, social media posts, emails)
- Study instruments (surveys, interview guides, scales, questionnaires)

## Study Products (if applicable)

- Risk documentation
- Instructions for use or instruction manuals
- FDA approval or IDE exemption documentation

## Participant Protection

- Informed consent forms
- Assent forms (for research with minors)
- Short forms or supplemental consent documents
- Debriefing script (if deception is used)

## International Research (if applicable)

- Local IRB or ethics committee approvals
- Translated consent and study documents
- Letters of permission from international sites

**HIPAA (if applicable)**

- Data use agreements
- Authorization forms
- Additional HIPAA documentation

**Data and Safety Monitoring (if applicable)**

- DSMP document or DSMB/C charter

**Questions?** Contact the UCA Office of Research Integrity and Compliance (ORIC). We are here to help you design a study that protects participants and produces good science. Reach out early, especially if your project involves vulnerable populations, sensitive topics, external sites, international research, or PHI.