

# Regulatory Mastery Training Series: Unlocking the IRB Approval Process



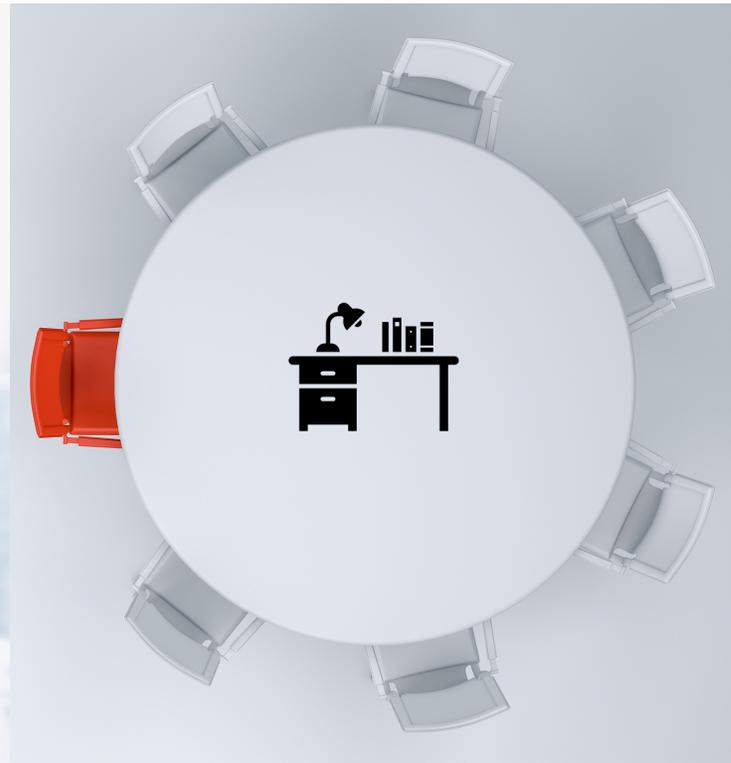
UtahStateUniversity

*February 26, 2025*

*Dr. Breanna Studenka, IRB Vice Chair & Associate  
Professor of Kinesiology & Health Science*

*Nicole Vouvalis, Executive Director of Human  
Research Protections*

# The Institutional Review Board



# The Human Research Protection Program

## VP for Research

Responsible for overseeing all aspects of USU's Human Subjects Research portfolio & ensuring appropriate access to resources for a well-functioning Human Research Protection Program (HRPP)



### Human Research Protections Office

Manages the day-to-day aspects of implementing and overseeing the HRPP, including:

- Researcher training
- Coordination with COI, IBC, ICOI, SPO processes
- Receiving complaints, concerns, and questions from research participants

### The IRB

Reviews all proposed human subjects research at Utah State University according to:

- Established ethical standards,
- Policies & procedures, and
- Best practices

### Researchers

Responsible for carrying out and overseeing research with human participants in a manner that:

- Complies with the terms of IRB's review,
- Ensures adequate resources and training for the safe conduct of the research, and
- Takes proactive steps to ensure the health, safety, and well-being of research participants

# Utah State University IRB Review Standards

**Utah State University's Institutional Review Board conducts its reviews according to two prevailing ethical standards:**

## **The Belmont Report**

- Respect for Persons
- Justice
- Beneficence

## **45 C.F.R. 46 (The Common Rule)**

- Subpart A: General Review standards
- Subparts C, D: Vulnerable Population Requirements

# The Pre-Review Phase

## Study Personnel

### USU Personnel

Please enter all of the USU study personnel to the list below by clicking "Add Info" or "Add a Line." You may double check that they have completed CITI training [at this link](#); unless this is a Non-Human Subjects Research Determination, do not submit your protocol until all staff are CITI trained.

 Columns

 Add Line

|  |  | USU PERSONNEL NAME           | USU RESEARCHER ROLE    | USU PERSONNEL EMAIL       | USU DEPARTMENT             | CITI TRAINING DATE |
|--|--|------------------------------|------------------------|---------------------------|----------------------------|--------------------|
|   |   | Vouvalis, Nicole             | Principal Investigator | nicole.vouvalis@usu.edu   | Institutional Review Board | 1/24/2028          |
|  |  | Sisneros-Kidd, Abigail Maryn | USU Co-Investigator    | abby.sisneroskidd@usu.edu | Institutional Review Board | N/A                |

Does this project involve a Non-USU Investigator?

Yes

No

# The Pre-Review Phase

## Informed Consent Form

Study Title: Justice in IRB Reviews Under DEI Bans

Principal Investigator: Nicole Vouvalis

Institution: Utah State University

## Introduction

You are invited to participate in a process that federally mandates its survey should take approximately more about how IRBs are meeting

## Study Procedures

If you agree to participate, you will

1. Complete a brief survey re making or have made to c
2. Indicate whether you would a second survey to list contact information to receive the results.

## Risks and Discomforts

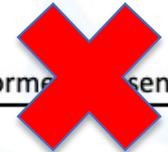
The risks involved in this study are minimal. You may experience mild fatigue or emotional discomfort from participating in the activities. If you feel uncomfortable at any time, you may take a break or stop participating. All questions have a "prefer not to respond" option, and so you may functionally skip any question by making that selection. |



You are invited to participate ...

Justice in IRB Reviews Under DEI Bans

Informed Consent



Page 1 of 1  
Protocol #  
IRB Exemption Date:  
Consent Document Expires:

✓ Done

encouraged to use. [Access them here](#). Outdated templates will not be required information for this project. Then, upload your informed each successful upload.

cess. Please provide the information for your debrief in your informed



lies often causes study

# The Pre-Review Phase

1. Funding Principal Investigator does not match protocol Principal Investigator
2. Principal Investigator has an expired protocol that was not renewed or closed in a timely manner
3. A student thesis or dissertation is marked, but no evidence of committee approval or agreement has been provided
4. A Non-USU Researcher will work on this project, but they have not provided CITI Training
5. Another researcher has initialed the Conflicts and Assurances section's requirements, but the PI must review and agree to those terms

## Basic Information

### Principal Investigator

Please list the person who will be the PI on this project. If that is not you, make sure you add yourself under Personnel on the next page with Full Access, or protocol.

Vouvalis, Nicole

### Department

Institutional Review Board

### Protocol Title



Justice Considerations in IRB Review under DEI Bans

Please select your anticipated start date for this research, taking care to allow ample time for IRB review.



March 12, 2025

### Is this research externally funded?

- Yes
- No
- There is internal funding (e.g. Office of Research Seed Grant; College funding; AES) for this project
- There is external funding that did not move through Sponsored Programs
- This research is funded by the Center for Growth and Opportunity

### Will this project be used, in part or whole, for a thesis or dissertation project?

- Yes
- No

Please indicate what type of review or action you are requesting. When you make a selection, more information about the type of review

- Non-Human Subjects Research Determination
- Exempt Review
- Expedited or Convened IRB Review
- Reliance on Another IRB's Review
- I am uncertain, and would like the IRB to categorize my submission appropriately

# Initiating the Review Process

## Two Regulatory Considerations:

- External Funding
- Review Type

## Revised Exemption Categories

"Exempt Review" is the "lowest" of the three levels of review available for human subjects research. It does not mean that it is exempt altogether from IRB review, but rather, that the project is exempt from many of the requirements that the IRB must meet for the approval of Expedited and Full Board submissions. Below, you will find detailed information about the exemption categories available at Utah State University. Please select the exemption you are interested in learning more about. Exemption categories can be combined within a research project, but for a project to be Exempt, **all aspects** of the project must fall within one (or more) of the exemption categories. As a reminder, no research project that is greater than minimal risk can be reviewed as Exempt.

Exemption 1: Educational Research ▾

Exemption 2: Interviews, Surveys, Public Observations, and Educational Tests ▾

Exemption 3: Benign Behavioral Interventions (Former Public Officials Exemption) ▾

Exemption 4: Secondary Data Use ▾

Exemption 5: Federal Demonstration Projects ▾

Exemption 6: Taste & Food Quality/Consumer Acceptance Studies ▾

# Summary of 45 CFR 46.101: Categories of Exemption

Available at [irb.usu.edu/basics](http://irb.usu.edu/basics)



## Study Personnel

### USU Personnel

Please enter all of your USU study personnel to the list below by clicking "Add Info" or "Add a Line." You may double check that they have completed CITI training [at this link](#); unless this is a Non-Human Subjects Research Determination, do not submit your protocol until all staff are CITI trained.

[Columns](#) [+ Add Line](#)

|  |  | USU PERSONNEL NAME           | USU RESEARCHER ROLE    | USU PERSONNEL EMAIL       | USU DEPARTMENT             | CITI TR DATE |
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|  |  | Vouvalis, Nicole             | Principal Investigator | nicole.vouvalis@usu.edu   | Institutional Review Board | 1/24/2       |
|  |  | Sisneros-Kidd, Abigail Maryn | USU Co-Investigator    | abby.sisneroskidd@usu.edu | Institutional Review Board | N/A          |

### Does this project involve a Non-USU Investigator?

Yes

No

Select all of the activities your Non-USU colleagues will engage in. Only researchers who meet the definition of an "investigator" need to be listed on your protocol. The activities listed below are activities that make an individual an "investigator."

- Interaction or intervention (including online intervention) with living people participating in this study
- Obtain, study, analyze, or interpret identifiable information about participants in this study
- Actively recruit participants into this study
- Obtain informed consent under this study (this includes being a resource to answer questions for potential participants about the study)
- Interface with the IRB regarding this study
- Other
- None of the above

### Non-USU Personnel

Enter all of your external study personnel to the list below by clicking "Add Info" or "Add a Line."

# Initiating the Review Process

## Two Regulatory Considerations:

- External Researcher Agreements
- Appropriate Training

## Project Overview

Provide an overview (or a brief abstract) for this study. The overview/abstract must include at least the following information:

1. The purpose of the study
2. The research questions, hypotheses, or themes this study will explore.
3. The "gap" or "problem" relevant to the discipline that this study will address.
4. How the study design will generate the information needed to address the research questions, hypotheses, or themes identified above.



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1. The purpose of this study is to determine in which ways local perception of the UN affects the success of their peacekeeping missions.
2. The research questions will explore any interaction they've had with UN peacekeepers, either directly or indirectly. It will ask about the frequency of these interactions, experience in these interactions, what they believe the purpose of the mission is, if they believe the DRC can achieve long term stability, if they would like to see more or less involvement from the UN, etc. The hypothesis of the study is that the better a local perception is, the more successful the mission is. Because the UN has been in the DRC for over a decade and is in the process of withdrawal despite the ongoing conflict, this creates unique circumstances and perceptions. This survey will explore if more interaction with peacekeepers improves the perception of the UN and the mission.
3. The "gap" is that we don't know how important local perception of the UN is in regards to the success of their missions.
4. This study will generate real life experiences and perceptions between peacekeepers and the locals in the communities that they are serving in. It will give new real-world insight that can't be gathered by research information that is already provided online. This will ultimately contribute to either confirming or disproving my hypothesis.

**Upload a proposal here.** Proposals are required for all Expedited and Convened IRB protocols, and for some Exempt protocols. If this study:

- is any review type other than exempt;
- has been proposed to an external funding source;
- is a dissertation/thesis project; or
- has been funded internally

You must provide the proposal that you submitted via that process, rather than a modified one for IRB purposes. The IRB is required to ensure that this protocol matches that project.

A proposal should, at a minimum, cover the following topics: background/literature review, research questions, target population (including a justification for the use of a vulnerable population, if applicable), methods/procedures, data handling, limitations, analysis plans, and relevant appendices or references. It is generally very difficult to communicate these items to a reviewer in fewer than three pages. Failure to address these items sufficiently may result in your protocol being returned by the reviewer for their inability to make required findings.

[POLS 4990 Design .pdf](#)

[Replace](#)

Will any portion of this project be completed outside of the United States or in another jurisdiction that is sovereign, such as a territory or sovereign indigenous lands?

Yes

No

Specify each country, territory, or distinct cultural location where this research project will take place.

Please be specific - Canada, for example, has laws that are variable between provinces, so if you know that your research will take place entirely within Alberta, please say Alberta, Canada.

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# Substance of the Review

## 45 CFR 46.111(a):

“In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied...

(1) Risks to subjects are minimized by using procedures that are consistent with sound research design”

# Substance of the Review: Sound Scientific Design

- Does the proposal clearly demonstrate knowledge of the current state of this field?
- Has the research team provided adequate background information about the currently-proposed research, with appropriate references?
- Are the research questions or hypotheses clearly stated and reasonable in light of the background provided?
- If the study team anticipates null hypotheses, is there scientific benefit that outweighs risks to participants?
- Is the research methodology clear and soundly designed?
- Does the proposed methodology permit the hypotheses or research questions to be addressed?
- Does the proposed study move some aspect of this field forward?

## Project Overview

Provide an overview (or a brief abstract) for this study. The overview/abstract must include at least the following information:

1. The purpose of the study
2. The research questions, hypotheses, or themes this study will explore.
3. The "gap" or "problem" relevant to the discipline that this study will address.
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[POLS 4990 Design .pdf](#)

[Replace](#)

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Please be specific - Canada, for example, has laws that are variable between provinces, so if you know that your research will take place entirely within Alberta, please say Alberta, Canada.

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# Substance of the Review

## 45 CFR 46.103(d):

“Certification is required when the research is supported by a Federal department or agency and not otherwise waived or exempted. ... For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research.”

## 45 CFR 46.101(f) – (i):

“When research takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances... the department ... may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy... provided the alternative procedures are consistent with the Belmont Report.”

## Study Participants

A participant is a living individual about whom an investigator conducting research obtains:

- 1) data or specimens through intervention or interaction with the individual; or
- 2) identifiable private information or specimens.

**All participants must be described in this section.**

Identifying all participants can sometimes be complex, so please contact the [Human Research Protections Office](#) if you would like assistance (i.e. in the case of "secondary participants" or existing data).

Below, add a row for each distinct population that will be involved in your study. Select "+Add Line" (or "+Add Info") to add a new row, and complete the information requested for each distinct population. You can add as many distinct populations as will be involved in your study.

Download All

Columns

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|  | POPULATION DESCRIPTION                         | INCLUSION CRITERIA   | EXCLUSION CRITERIA  | POPULATION NUMBERS | STATUS |
|--|--|--|---|--------------------|--------|
|  | IRB or Human Research Protection professionals | Over the age of 18, working in a human research protection or IRB or research compliance office in the United States | Anyone who has worked in the position for fewer than three months | 75                 | N      |

Describe the study team's existing relationship to the participants who are targeted for recruitment into this study.

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No existing relationship.

How many participants do you anticipate will begin this study?

?

100

How many participants do you anticipate will complete this study?

?

20

Will the research team offer compensation to any of the participants?

Compensation is any item of value given in exchange for the participant's time or effort with your study procedures.

Yes

No

# Substance of the Review – Study Participants

45 CFR 46 requires the following with regard to study participants:

- Equitable selection of subjects - 111(a)(3)
- Assessment of whether subjects are already undergoing procedures for diagnostic or treatment purposes which might address RQs – 111.(a)(1)(ii)
- “particular cognizance” wrt subjects who are vulnerable to coercion or undue influence – 111(a)(3)
- “additional safeguards” for participants vulnerable to coercion or undue influence – 111(b)

## Study Participants

A participant is a living individual about whom an investigator conducting research obtains:

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How many participants do you anticipate will complete this study?



20

Will the research team offer compensation to any of the participants?

Compensation is any item of value given in exchange for the participant's time or effort with your study procedures.

Yes

No

# Substance of the Review – Study Participants

45 CFR 46 permits screening prior to informed consent where:

- “an investigator will obtain information for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without informed consent.”

Separately: we are looking for consistency!

## Study Procedures

Provide a complete, step-by-step description of the study procedures.

This field should detail everything from the point of obtaining informed consent to the end of the study.

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Step One:

Step Two:

Step Three:

Step Four:

Step Five:

Please specify your anticipated end dates for the items below. These dates will be used to set the expiration date for your informed consent documents (if applicable) and your protocol, so be certain to keep this information up-to-date as your work progresses.

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|  | PARTICIPANTS COMPLETE | STUDY COMPLETE   |
|--|-----------------------|------------------|
|  | December 6, 2025      | December 9, 2025 |

What measures will be taken to ensure participant privacy during the study? Consider procedures from recruitment through the end of the participant's involvement in the study.

Privacy means the extent to which participants have control over what they share, with whom they share it, and in what kinds of spaces. Do not address confidentiality of the data - that will be addressed later.

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1) Participant will not be asked to provide their name.

2) Any questions that would provide an identifying factor (age, nationality, gender) will be optional.

Will there be any email communications with participants during the course of this study? This includes email communications regarding recruitment, informed consent, data collection, compensation, scheduling, etc.

?

Yes

No

# Substance of the Review – Procedures

45 CFR 46 requires the following with regard to study procedures:

- Risks to subjects are minimized by using **procedures** that are consistent with sound research design – 111(a)(1)
- Risks to subjects are minimized by using **procedures** already being performed... - 111(a)(1)

45 CFR 46.116 (Informed Consent):

- In seeking informed consent, the following information shall be provided... “a description of the **procedures** to be followed”
- Alternative **procedures** that might be advantageous to the subject
- A statement that a particular **procedure** may carry risks to the subject

# Substance of the Review: Procedures

- Based on the procedures outlined in the proposal and protocol, are you very clear on what participants will be asked to do?
- Do you have all of the relevant data collection and intervention materials?
- Are the materials being utilized with participants limited to what is appropriate to address the research questions?
- Are there alternative procedures that participants should consider before enrolling in this study?
- Are there existing procedures being completed with this participant pool that could be utilized in this study?
- Are the inclusion and exclusion criteria appropriate for the safety and wellbeing of the populations who will be asked to complete this study's procedures?
- Are the questionnaires and data collection sheets tied to the research questions and analyses identified in the proposal?
- Do the measures go beyond the identified research questions?

## Risks & Benefits

**Describe the reasonably foreseeable risks of harm, discomforts, and/or hazards to participants and others associated with this study.** Loss of confidentiality is a risk in nearly all research where data about people are collected or used, and should nearly always be contemplated as a research related risk.



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Loss of confidentiality is a risk. Questions may invoke discomfort if recalling on previous events is triggering for subject.

**Other than for loss of confidentiality concerns, how will your study team work to avoid or mitigate foreseeable risks?** This field should address all other risks identified above.

If your only foreseeable risk is loss of confidentiality, you may simply state "Loss of confidentiality concerns are addressed in the Confidentiality section, below. There are no other foreseeable risks associated with this protocol."

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To avoid the risk of discomfort when reflecting on events when answering a question, all open ended questions will be optional.

**Is it likely that the study procedures will yield risks that are currently not easily identified or stated?**



- Yes  
 No

**What is the level of risk that you believe applies to this study?**

Bear in mind that the risk determination is ultimately made by the IRB, but your assessment is factored into that determination.

**Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- This study meets the definition of Minimal Risk  
 This study does not meet the definition of Minimal Risk

**Describe how and when monitoring of the study will take place to detect harms to the participants.**

This is distinct from risk mitigation, above. Risk mitigation is proactive steps the study team will take to mitigate anticipated risks. Monitoring includes steps the research team will take to determine whether risks are occurring at the frequency and intensity that are expected, and that reasonable steps are occurring to timely address any unanticipated risks that may occur.

# Substance of the Review – Risks & Benefits

The IRB must find and document that the benefits outweigh the risks of the research.

The regulations assume that there are risks associated with research participation.

# Substance of the Review: Risks

- What is the level of risk associated with this protocol?
- Could disclosure of the participants' responses outside of the research reasonably place them at risk of civil or criminal liability, or be damaging to their financial standing, employability, educational advancement, or reputation?
- Could disclosure of the participants' responses outside of the research reasonably place them at risk of damaging their insurability, or might their responses be stigmatizing?
- Are the risks identified in the protocol complete, based on your experience in this field and/or in working with this population? Should other risks be identified?
- Does the study team's description of how and when monitoring will occur seem reasonable for the detection of harms to participants?
- Does the list of benefits appear to be complete, based on your experience in this field and/or in working with this population?
- Do the benefits of this research (both direct and indirect) outweigh the risks to participants?

## Confidentiality

### Does this project involve identifiable information or specimens?

Identifiable means that the identity of the living person "is or may readily be ascertained." Some examples include:

- Email addresses
- Telephone numbers
- Recordings (audio or video) or images
- Codes linking back to an identity that the research team *could* access (regardless of whether the research team *will* access it)
- Transcriptions that have not been scrubbed of identifying information



Yes

No

### Explain where the data, information, or biospecimens will be housed *during the data collection process*.

Outline applicable confidentiality safeguards associated with that initial data storage mechanism(s).

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Data will be collected through Qualtrics. Qualtrics encrypts all data to ensure security as well as having access control and complying to industry standards.

**After the data, information, or biospecimens have been obtained by the research team, what will happen to prepare for and begin use/analysis?** *Be sure to include how data will be moved from a temporary collection site to longer-term storage, what will be removed or coded, what will be deleted or maintained, and what storage repositories will be utilized.*

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Following data collection, data will be transferred to a Microsoft spreadsheet, only accessible by me. Only responses that I deem as irrelevant will be removed from this.

**Describe the extent to which confidentiality will be maintained during the study, and after it has ended. What steps will you take, if any, to protect participants' identities at each of those time points?**

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Confidentiality will be maintained during the study by not asking for a specific name and making any questions in which the response would be an identifying factor optional. Following data collection, this research will not be published, ensuring confidentiality.

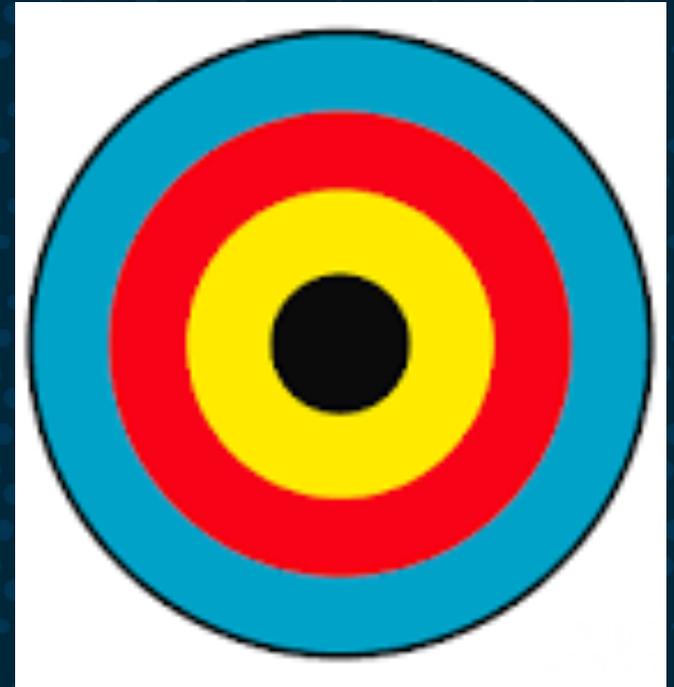
# Substance of the Review – Confidentiality

Confidentiality is a key consideration in IRB approval.

Confidentiality safeguards are governed by both the IRB's assessment of the appropriate level of confidentiality, as well as USU requirements on data storage and sharing.

# Substance of the Review: Confidentiality

- Consider the data collected in this study. Has the study team described protections that are appropriate for the level of confidentiality this information requires?
- Has the study team disclosed the extent to which participants' confidentiality will be maintained in the informed consent document?
- Could disclosure of the participants' responses outside of the research reasonably place them at risk of damaging their insurability, or might their responses be stigmatizing?
- If so, reasonable and appropriate protections must be implemented so that the risk of breach of confidentiality is no more than minimal. What are those protections?



## Informed Consent

Describe the amount of time and the circumstances available to participants between learning about the study and agreeing to participate in the study. Explain how that interim time permits participants to make informed and uninfluenced decisions regarding their participation in the study.

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I plan to have this survey available for between 1-2 weeks, giving participants time to review the brief summary provided and decide whether or not they want to take the survey. They can also stop taking the survey at any time if they decide in the middle of the process that they no longer want to participate.

Describe any special characteristics regarding your anticipated participant population that might impact the IRB's assessment of the manner and language in which informed consent documentation is presented. The IRB is required to find that the informed consent documentation is presented in a manner and language that is easily understandable to the participants likely to engage with the study.

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Because French is the official language of the DRC and is widely spoken there, the survey and informed consent documentation will be in French.

For participants (or parents, LARs, etc.) who do not speak or read English, translated documents are required. Hover over the question mark below to learn more about translation requirements.

In this field, please describe the additional measures that are in place to ensure that the non-English speakers or readers in your study are able to ask questions, register concerns, or withdraw.



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There will not be a space within the survey to ask questions or address concerns, but all participants will have the option to withdraw at any point. By providing the survey in French, questions and concerns will be mitigated.

## Informed Consent Documents

The IRB has developed several templates for informed consent documentation that you are encouraged to use. [Access them here](#). Outdated templates will not be accepted - please be sure to use the most recently updated templates so that you capture all required information for this project. Then, upload your informed consent documentation below. You may upload as many as needed by clicking "Add Line" after each successful upload.

If you have requested an alteration of informed consent, you will usually need to have a debriefing process. Please provide the information for your debrief in your informed consent document, or as a separate attachment here.

The IRB **strongly recommends** using a **new template** to form your informed consent document for a **new study**. Using templates from older studies often causes study teams to miss a required element that may not have applied to a previous study, but which will apply to the present one.

# Substance of the Review – Informed Consent

Please attend our March 24 training on Informed Consent Waivers & Alterations!



# Resources

- [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research](#)
- [Categories of Exemption Summarized](#)
- [Expedited Review Categories](#)
- USU IRB [Standard Operating Procedures](#)
- USU IT [Data Handling Requirements](#)
- USU IRB Informed Consent Templates: [Informed Consent Documents](#)
- Request a Consultation – [Submission Form](#)
- Ask The IRB Slack – [Invite Link](#)



# Thank You!

Please use the feedback link on our home page (or scan this QR code) to request topics for Fall 2025 IRB trainings.

Upcoming Regulatory Mastery Training Series Sessions:

- March 24: Informed Consent Waivers & Alterations
- April 28: I'm Approved, Now What?

