
THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact
A Step-by-Step Guide
to Successful IRB Submissions
Human Subjects Protection Program (HSPP)
THE UNIVERSITY
OF ARIZONA

Fall 2022 HSPP Workshop Series

1. **Ethical & Regulatory Foundation of Human Subjects Research & IRB Review**
2. **A Step-by-Step Guide to Successful IRB Submissions (September)**
3. **Informed Consents & Waivers (October)**
4. **Let's Talk About Research Data (November)**
5. **Your Study is Approved, Now What? (December)**

HSPP Training Opportunities:
https://research.arizona.edu/compliance/human-subjects-protection-program/hspp-training/irb-training-opportunities

Agenda

- **HSPP Overview**
- **PI Eligibility**
- **Steps for Successful Submissions**
- **Training Requirements**
- **Preparing IRB Application Materials**
- **How to Submit in eIRB**
- **Summary & Tips**
- **Resources**
- **eIRB Submission Demonstration**

HSPP Overview

Research, Innovation & Impact

Human Subjects Protection Program (HSPP)

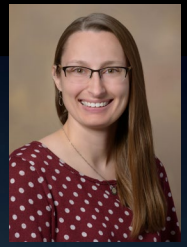
- Provides **oversight** of research activities involving human subjects.
- We work in **collaboration** with the research community to maintain ethical and compliant research practices at the University of Arizona.
- We provide **guidance** about ethical and regulatory issues to the Institutional Review Board (IRB).
- Provides **administrative support** to the IRB.
- The HSPP Team also **helps researchers** with their IRB applications.

https://research.arizona.edu/compliance/human-subjects-protection-program

The HSPP Team

Gina Fimbres-Leon Guerrero
IRB Intake Coordinator

Christine Melton-Lopez
HSPP Director

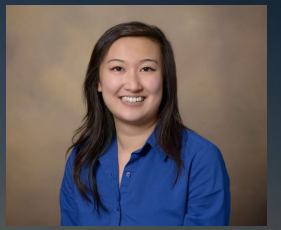


Chelsea Quinn
IRB Associate

Joanna Schrader
IRB Coordinator

Courtney Hammel
Assistant Director

Simona Janisch
Manager
Process Improvement
Reliance & Education



Tiffany Gin
IRB Associate

Jeff Homes
IRB Coordinator

Maria Acuna-Baltierra
IRB Associate

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Review Categories

- **Minimal Risk 2018** (not federally funded/unfunded, not greater than minimal risk)
- **Exempt** (federal/funded, fits into a specific **45CFR46.104** Exempt category)
- **Expedited** (federal/funded, fits into a specific **45CFR46.110** Expedited category)
- **Full Committee (greater than minimal risk)**

Minimal Risk
Probability and magnitude of harm or discomfort is **not greater than those encountered in daily life** or during routine physical or psychological exams.

IRB Review

❖ **Minimal Risk Submissions:**

- Reviewed by the **IRB Chair or Designee**.
- Includes **Minimal Risk 2018, Exempt, Expedited**, and **low-risk modifications to approved Full Committee projects** (for example staff change or minor edits that don't-increase-risk, etc.)

❖ **Greater than Minimal Risk Submissions:**

- Reviewed by the **Full Committee** on the **2nd & 4th Tuesday** of every month.
- Items for review must be submitted at least *two (2) weeks* prior to the meeting.
- The application must be complete, with all revisions complete *one (1) week* prior to the meeting.

How long does IRB review usually take?

- **Personal changes/deferrals/closures** ~ 1 week
- **Modifications/continuing reviews** ~ 2-3 weeks
- **New projects** ~3-4 weeks
- **We recommend submitting new projects 2 months before approval is needed.**

- Pre-review starts when **the submission is complete & ready for review.**
- **Incomplete submissions**, the **need for multiple Clarification Requests** and **delayed study team responses** can significantly add to the review timeline.

PI Eligibility

Who Can be a UA Principal Investigator?

Have a minimum of 0.50 FTE as a University of Arizona employee.

Eligible to be a PI:

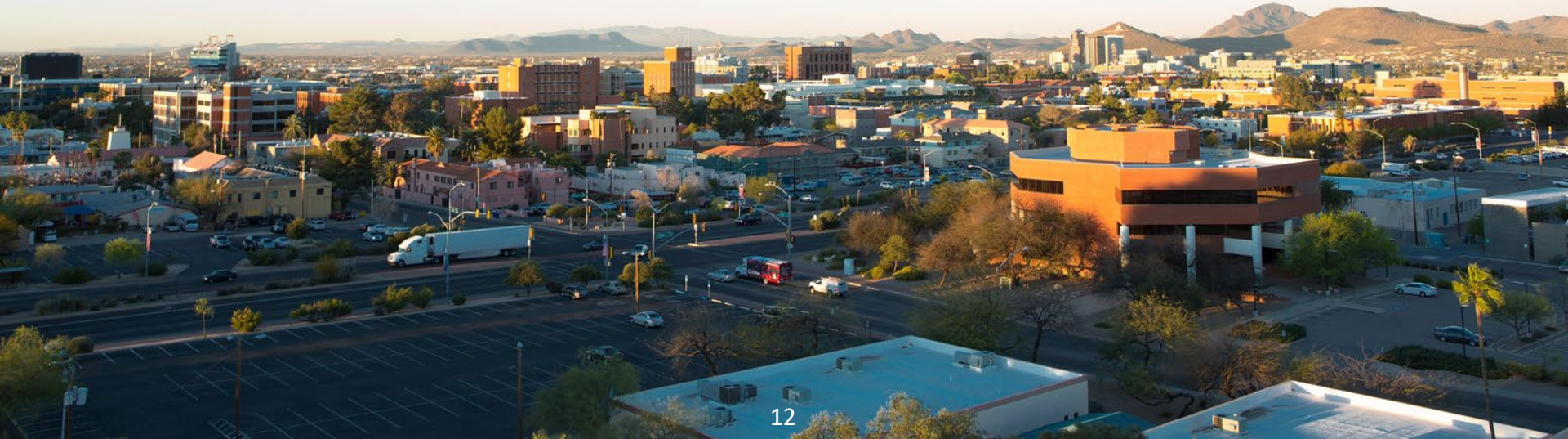
- Tenured/Tenure Eligible Faculty
- Continuing/Continuing Eligible
- Career track asst/assoc/full professors (including clinical, research, and professors of practice)
- Research Scientists
- Postdoctoral Fellows
- Directors, Chairs, Deans, Vice Presidents
- Librarians/Curators
- Affiliate or Clinical Faculty (DCC)

Need an Advisor/Co-Investigator:

- Research Associates
- Research Assistants
- Undergraduate and Graduate Students
- Medical School Residents
- Adjunct Faculty
- Visiting Faculty & Scholars (DCC)
- Emeritus Faculty (DCC)
- Other Designated Campus Colleagues

RII Principal Investigator Eligibility Webpage
https://research.arizona.edu/administration/getting-started/principal-investigator-project-director-co-principal
HSPP Guidance Document: PI Eligibility
https://research.arizona.edu/sites/default/files/PI%20Eligibility%20v2021-09.pdf

Steps for Successful Submissions



Steps for Successful Submissions

Step 1 Does your Project Require IRB Approval?

Step 2 Complete the Required Trainings

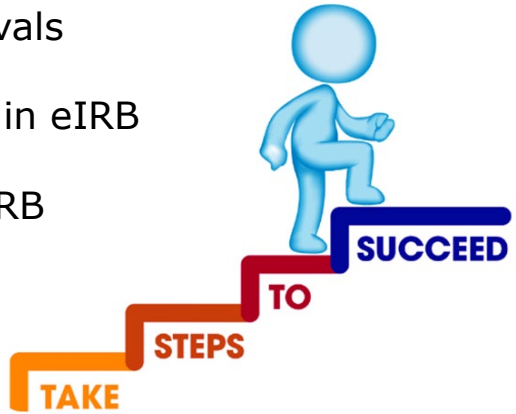
Step 3 Prepare Required Forms

Step 4 Obtain Required Approvals

Step 5 Obtain Additional Approvals

Step 6 Prepare the Submission in eIRB

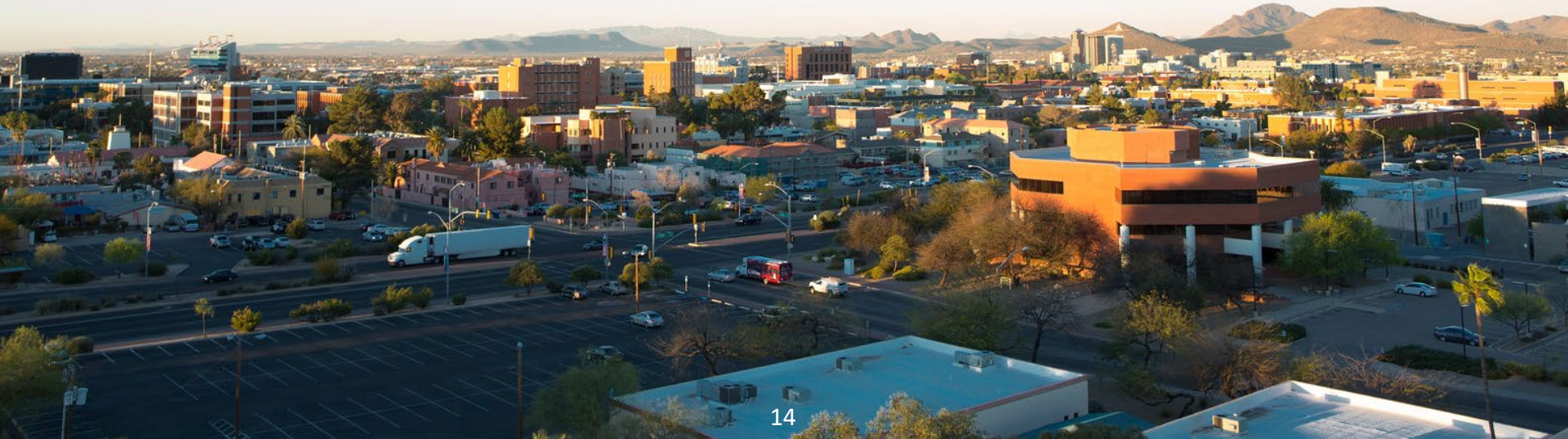
Step 7 Submit the Project in eIRB



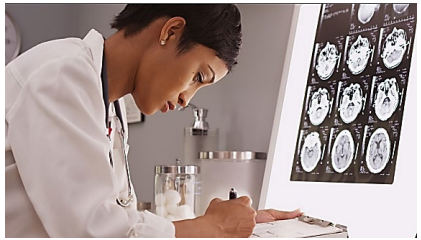
HSPP Getting Started Webpage

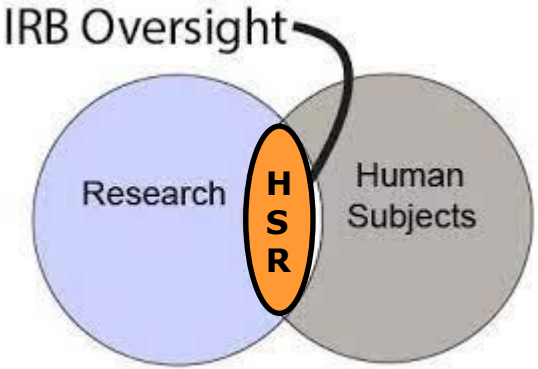
https://research.arizona.edu/compliance/human-subjects-protection-program/getting-started

Human Subjects Determination (Step 1)



Not every project needs IRB approval





If the activity **is "Research" or "Clinical Trial"**
and involves **"Human Subjects"**
the activity requires review and approval by the IRB.

HSPP Guidance: What is Human Research?
https://research.arizona.edu/sites/default/files/What%20is%20Human%20Research%20v2021-09.pdf

Does Your Project Need IRB Approval?

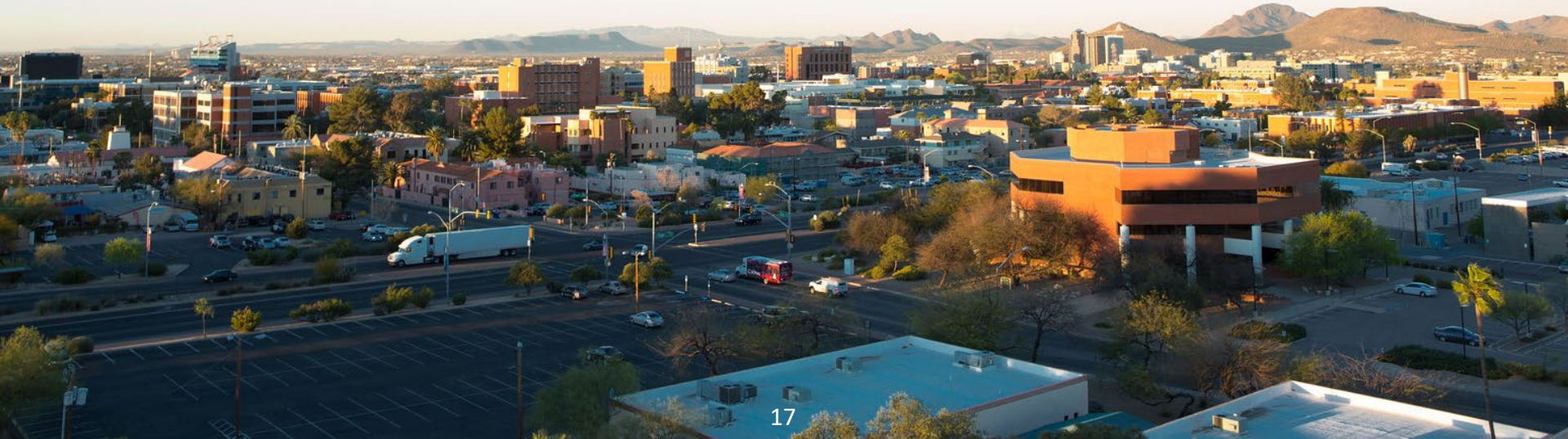
The **IRB Protocol for Determination of Human Research** can be used to decide if the project is Human Subjects Research.

https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index

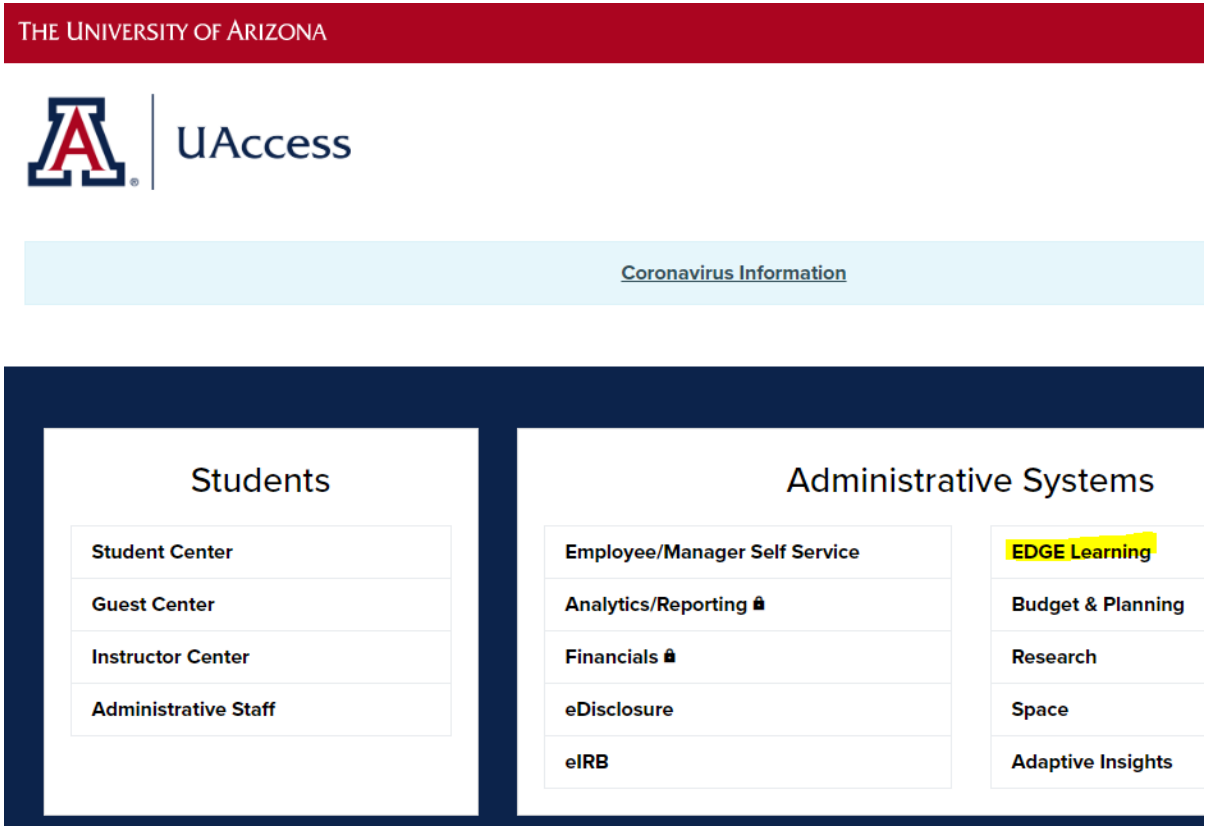
This form is **required** if the proposed study involves the following activities, and it is unclear whether these activities require IRB review:

- Access to electronic medical records **(EMR)**;
- Use or disclosure of Protected Health Information **(PHI)**;
- Requests for data or specimens from the Banner Clinical Research Data Warehouse **(CRDW)**;
- The project is or will be supported by **federal funds (i.e., NIH)** that involves people;
- The information will be used to support an application to the **FDA** or involves the use of a test article in a human;
- IRB certification for access to materials from **dbGap**; OR
- The project involves **Native American/Alaskan Native or indigenous populations**.

Training Requirements (Step 2)



Step 2: Complete Required Training



CITI PROGRAM

EDGE Learning
DEVELOP | GROW | ENGAGE

https://arizona.sabacloud.com/Saba/Web_spf/NA7P1PRD161/app/dashboard

Which Training is Required?

IRB: Biomedical Research Investigators

- FDA Regulated Research
- Medical Records Review

OR

IRB: Social & Behavioral Research Investigators

- Non-Medical Investigations
- Surveys & Interviews

Training for Unaffiliated Collaborators

Non-UA personnel including BH Staff:

Training is also required for individuals who are not affiliated with the University of Arizona but are conducting human research at the University of Arizona. This includes non-University of Arizona personnel and community partner researchers.

- CITI Human Research Training (i.e., BH CITI Training)
- OHRP Human Research Training
- Other Comparable Community Partnered Research Ethics Training

For more information about HSPP training requirements, including training requirements for outside investigators, visit the HSPP Training webpage: https://research.arizona.edu/compliance/human-subjects-protection-program/hspp-training

IRB: Native American Research Certification

- Both UA CITI training courses include the **Native American Module**, which is required training for all UA researchers.
- The Native American Module is also offered as free-standing training for non-UA affiliates and Collaborators.
- The Native American Research Certification must be completed for all projects that enroll Native Americans.

Additional Training

- For projects that involve **Banner Health** electronic medical records **(EMR)**, researchers must also complete the **annual UA HIPAA Privacy training.**
- If you are conducting a Clinical Trail or NIH funded research, **Good Clinical Practice (GCP)** training might also be needed (check with your department).
- **All researchers** are required to complete the **annual Conflict of Interest (COI) training**.

+

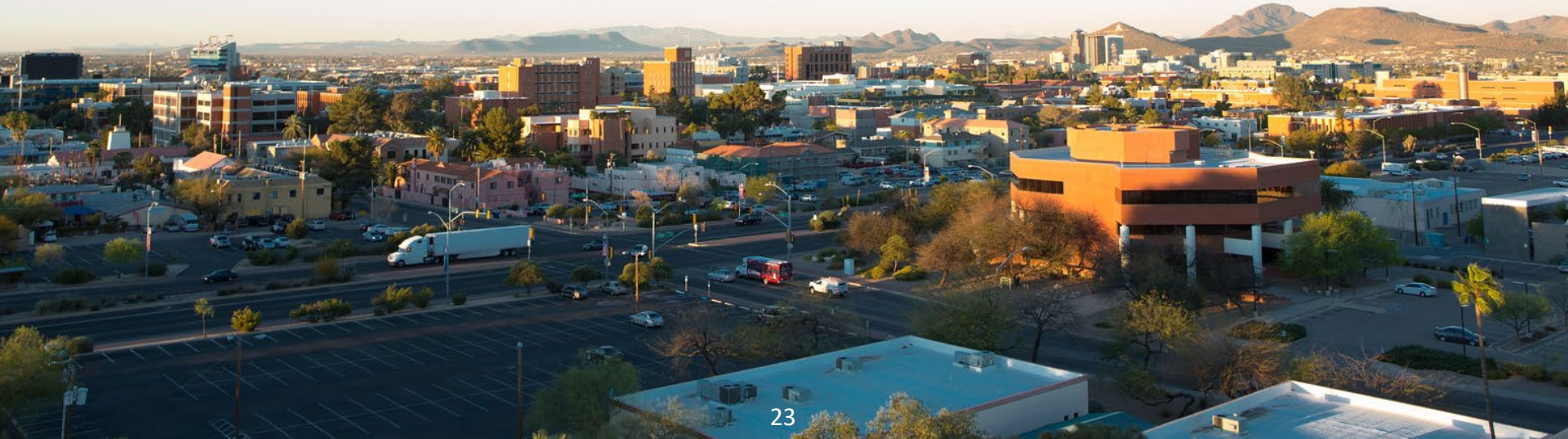
eDisclosure

All personnel listed in eIRB must **complete a COI Research Certification in eDisclosure for each study** they are listed on.

This requirement applies to **new projects** and when **adding new staff** to an existing protocol.

The study specific Research Certifications must be completed by all research personnel before the study is approved by the IRB.

Preparing the UA IRB Application (Steps 3-5)



Step 3: Prepare Required Forms

Complete the Appropriate IRB Protocol Form:

- IRB Protocol for **Human Research (v Sept 2022)**
- IRB Protocol for **Retrospective Data Review (v Aug 2022)**
- IRB Protocol for Projects Using **External IRBs (v Sept 2022)**

Important: The New versions of the protocols will be required after November 7, 2022

HSPP Forms: https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms

IRB Protocol for Human Research

1. **Background** (short, limit 1000 words)
2. **Lay Summary** (brief description of the proposed project)
3. **Purpose** (specifics aims, objectives, questions to be answered, etc.)
4. **Funding Information**
5. **Resources** Available to Conduct the Human Research
6. **Study Population** (number of subjects; race/gender/ethnicity; inclusion/exclusion criteria)
7. **Recruitment Methods**
8. **Diversity, Equity, and Inclusion**
9. **Consenting Process** (Consent document or Request for Waiver of Consent/PHI will need to be uploaded with the application)
10. **Research and Data Collection Procedures** (detail what will be done for research purposes only and what data elements will be collected; indicate total estimated time; amount, method, frequency and type of specimens being collected, etc.)
11. **Potential Benefits** to Subjects
12. **Risks to Subjects** and how risks are minimized.
13. **Cost**, **Compensation and Injury**
14. **Privacy of Subjects** & **Confidentiality of Data** (participants/data/samples; future use; repositories; storage; sharing)
15. **Additional Questions** (Injury; withdrawal; safety monitoring; Data Management Plans; and International research)

IRB Protocol for Retrospective Data Review

1. Background (short, limit 1000 words)
2. Lay Summary (brief description of the proposed project; this can be added to eIRB as well)
3. Purpose (specifics aims, objectives, questions to be answered, etc.)
4. Funding Information
5. Resources Available to Conduct the Human Research
6. Study Population (number of subjects; race/gender/ethnicity; inclusion/exclusion criteria)
7. **Number of Specimens/Records to be Reviewed Locally** (include date range)
8. Research and Data Collection Procedures (detail what will be done for research purposes only and what data elements will be collected; indicate total estimated time; amount/method/frequency and type of specimens being collected, etc.)
9. Potential Benefits to Subjects
10. Risks to Subjects
11. Privacy of Subjects & Confidentiality of Data (participants/data/samples; future use; repositories; storage; sharing)

IMPORTANT:

- Make sure to fully answer each question.
- If something is not applicable, write N/A and note why it is not applicable.
- Make sure that it's clear what is being done for research purposes vs. patient care/non-research event.
- Make sure that the date range for the retrospective data review is before the date of the IRB application.

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118 Request Form

Red text is instructional. Delete all red text prior to submitting this form.

118 Determinations are granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Funds may not be used to conduct research with human subjects until an IRB application has been reviewed and approved.

Basic Information	
Title of Study:	
Short Title:	
Principal Investigator Name:	
Principal Investigator's Department/Unit:	

1.0 Funding Information

Indicate the funding source for the project. Please list the name of the funder, and the institutional proposal number or award number, if available, that you received from Sponsored Projects. eIRB tip: For externally funded projects, the institutional proposal or award number provided must be linked in the "Study Funding Sources" section in eIRB.

☐ **Federal Funding**, including flow-through federal funding (i.e., NIH, NSF, DoD, etc.)	Name of funding source:
	Institutional Proposal or Award Number:
	Funding Agency Number:

2.0 118 Request Information

§46.118 Applications and proposals lacking definite plans for involvement of human subjects: Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under §46.101(i) or exempted under §46.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

1. **Explain why human subjects study information is not available at the time of this application.**

Items needed for approval, as applicable:

- Copy of the award/grant application
- Award/grant application number

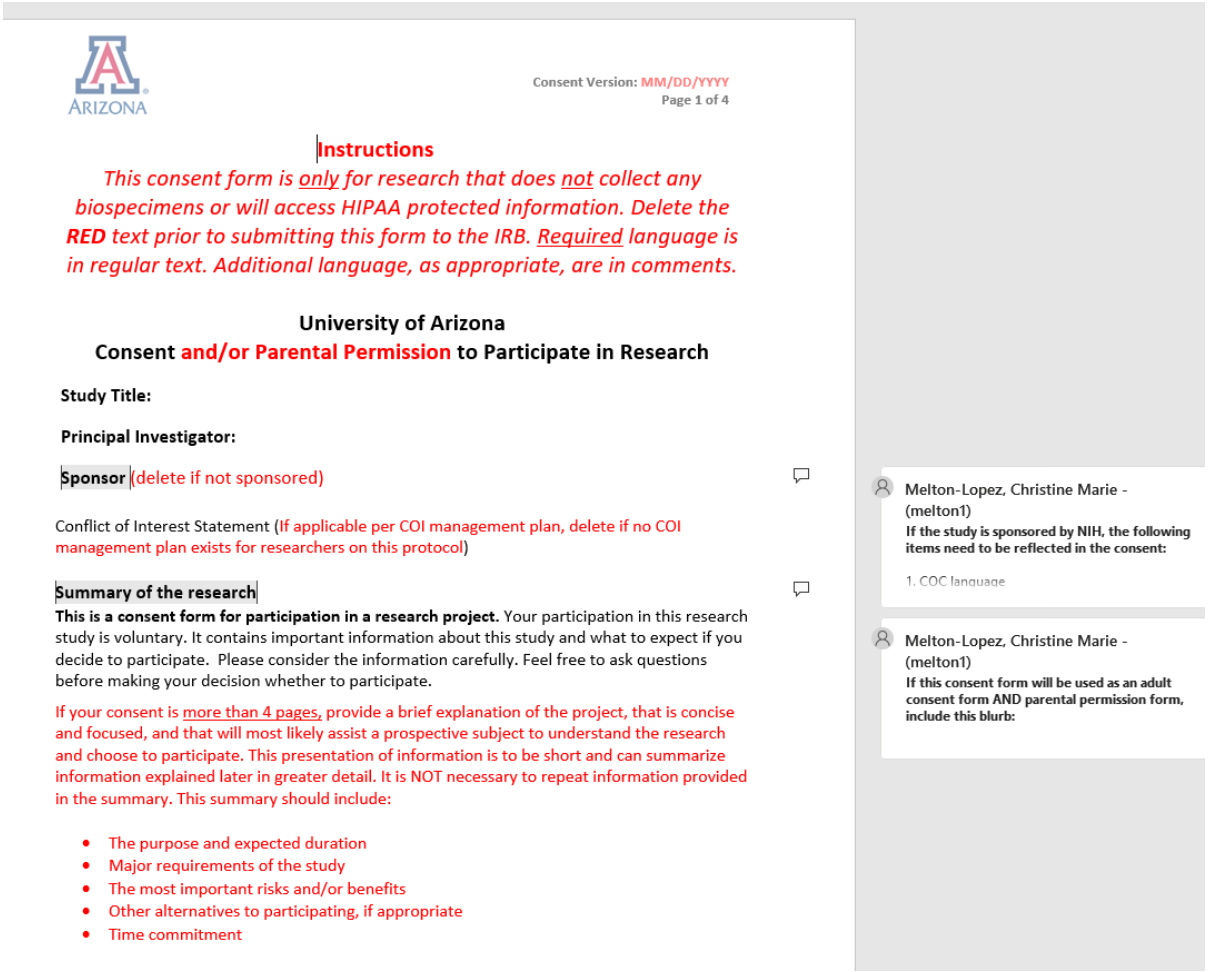
Informed Consent Forms

Use the Correct Consent Template(s):

- **Externally funded Social Behavioral** ICF/Parental permission (v. Sept 2022)
- **Internally funded/non-funded Social Behavioral** ICF/Parental permission (v. Sept 2021)
- **UA/Banner Medical** ICF/Parental permission (required for Banner; also includes Banner PHI) (v. Sept 2022)
- **Assent 8-12 yrs**
- **Assent 13-17 yrs**

*IRB can grant a Waiver of Assent for 7 yrs and under

https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates



ARIZONA

Consent Version: MM/DD/YYYY
Page 1 of 4

Instructions

*This consent form is only for research that does not collect any biospecimens or will access HIPAA protected information. Delete the **RED** text prior to submitting this form to the IRB. Required language is in regular text. Additional language, as appropriate, are in comments.*

University of Arizona
Consent and/or Parental Permission to Participate in Research

Study Title:

Principal Investigator:

Sponsor (delete if not sponsored)

Conflict of Interest Statement (If applicable per COI management plan, delete if no COI management plan exists for researchers on this protocol)

Summary of the research

This is a consent form for participation in a research project. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

If your consent is more than 4 pages, provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment

Melton-Lopez, Christine Marie - (melton1)
If the study is sponsored by NIH, the following items need to be reflected in the consent:

1. COC language

Melton-Lopez, Christine Marie - (melton1)
If this consent form will be used as an adult consent form AND parental permission form, include this blurb:

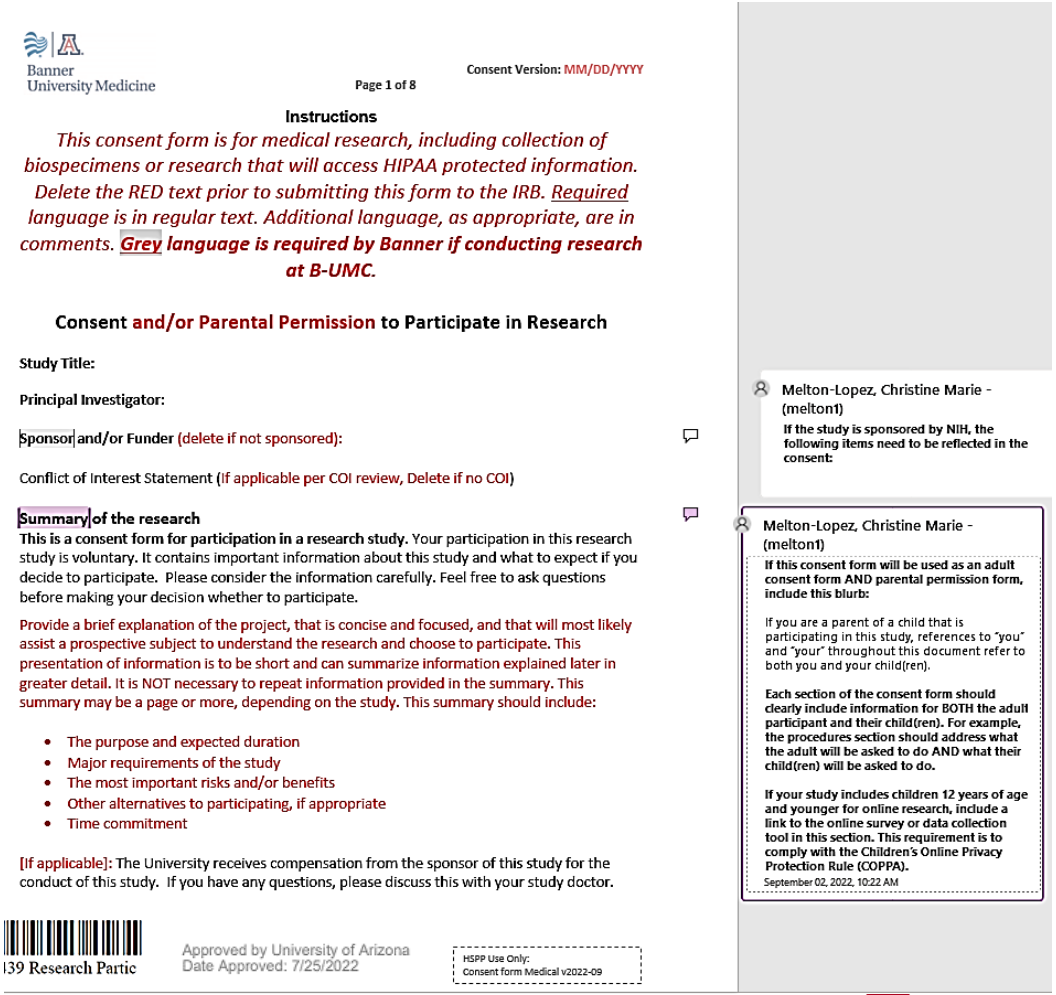
Externally Funded Social Behavioral ICF template

Required Parts:

- UA Logo
- Version Date
- Regular text
- Summary of the Research (>4pg ICF)

Customizable Parts:

- This form can be used as an adult consent or parental permission.
- Red text can be removed/replaced
- Insert side bar comments as applicable.



Banner University Medicine

Consent Version: MM/DD/YYYY

Page 1 of 8

Instructions

This consent form is for medical research, including collection of biospecimens or research that will access HIPAA protected information. Delete the RED text prior to submitting this form to the IRB. Required language is in regular text. Additional language, as appropriate, are in comments. Grey language is required by Banner if conducting research at B-UMC.

Consent and/or Parental Permission to Participate in Research

Study Title:

Principal Investigator:

Sponsor and/or Funder (delete if not sponsored):

Conflict of Interest Statement (If applicable per COI review, Delete if no COI)

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary may be a page or more, depending on the study. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment

[If applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

139 Research Partic

Approved by University of Arizona
Date Approved: 7/25/2022

HSPP Use Only:
Consent form Medical v2022-09

Melton-Lopez, Christine Marie - (melton1)

If the study is sponsored by NIH, the following items need to be reflected in the consent:

Melton-Lopez, Christine Marie - (melton1)

If this consent form will be used as an adult consent form AND parental permission form, include this blurb:

If you are a parent of a child that is participating in this study, references to "you" and "your" throughout this document refer to both you and your child(ren).

Each section of the consent form should clearly include information for BOTH the adult participant and their child(ren). For example, the procedures section should address what the adult will be asked to do AND what their child(ren) will be asked to do.

If your study includes children 12 years of age and younger for online research, include a link to the online survey or data collection tool in this section. This requirement is to comply with the Children's Online Privacy Protection Rule (COPPA).

September 02, 2022, 10:22 AM

UA Medical ICF/Parental Permission Template

Use this template for:

- Medical Research
- B-UMC Research
- When Biospecimens are involved
- When PHI is accessed

BH Required Parts:

- Banner Logo
- Barcode on pg1
- Banner Gray Language

Customizable Parts:

- Red text can be removed/replaced
- Insert side bar comments as applicable

Helpful Hints:

- Submit the ICF as a MSWord document.
- Keep the version date on top updated.
- After approval, the consent will be PDFd and the approval date will appear on the bottom of the page.

HSPP Appendices

Complete as Applicable:

- Appendix for **Children/Wards**
- Appendix for **Cognitively Impaired Individuals**
- Appendix for **Native Americans and Indigenous Populations**
- Appendix for **Prisoners**
- Appendix **for Pregnant Women, Neonates and Fetuses**
- Appendix **for Drugs**
- Appendix **for Devices**
- Appendix **for Multisite Research** (for each P-site that the UA IRB will oversee)
- Appendix for **Waiver or Alteration of Consent or PHI**
- Appendix for **Exception from Informed Consent** (planned Emergency research)

Step 4: Obtain Required Approvals

Required Approvals for Submission:

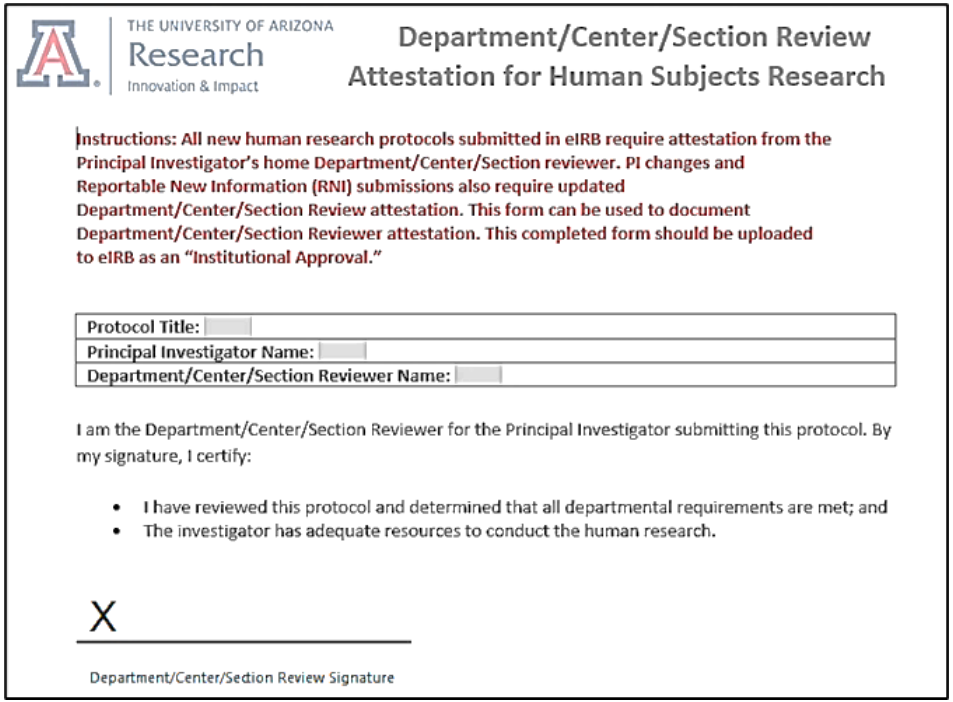
- **Department**/Center/Section Review Attestation
- **Scientific/Scholarly** Review Attestation
- **Advisor**/Co-Investigator Attestation (IF PI is a student or resident)
- **Responsible Physician** Attestation (IF PI is conducting medical procedures for which the PI is not certified/licensed)

To satisfy the requirements HSPP accepts the following:

- **HSPP Attestation Forms** uploaded to eIRB
- **Email** approvals uploaded to eIRB
- **Comment** added to the study page in eIRB

Please clearly identify who is approving for what. If the advisor is signing for both the Advisor and Scientific/Scholarly Reviewer, then indicate that by stating, for example,
"I approve as both the Advisor and Scientific/Scholarly Reviewer for project XYZ."

Department/Center Attestation



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Department/Center/Section Review Attestation for Human Subjects Research

Instructions: All new human research protocols submitted in eIRB require attestation from the Principal Investigator's home Department/Center/Section reviewer. PI changes and Reportable New Information (RNI) submissions also require updated Department/Center/Section Review attestation. This form can be used to document Department/Center/Section Reviewer attestation. This completed form should be uploaded to eIRB as an "Institutional Approval."

Protocol Title:
Principal Investigator Name:
Department/Center/Section Reviewer Name:

I am the Department/Center/Section Reviewer for the Principal Investigator submitting this protocol. By my signature, I certify:

- I have reviewed this protocol and determined that all departmental requirements are met; and
- The investigator has adequate resources to conduct the human research.

X _____

Department/Center/Section Review Signature

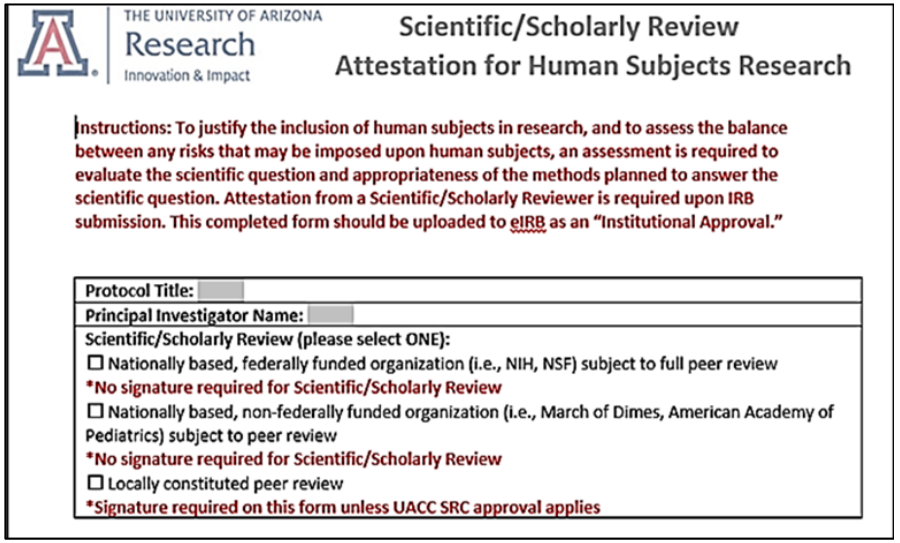
<u>Departmental signature is needed for:</u>

- All New Projects
- PI changes
- Reportable New Information (RNI)

<u>You can use:</u>

- The HSPP Attestation Form
- Email approval
- Comments logged in eIRB

Scientific/Scholarly Review Attestation



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Scientific/Scholarly Review Attestation for Human Subjects Research

Instructions: To justify the inclusion of human subjects in research, and to assess the balance between any risks that may be imposed upon human subjects, an assessment is required to evaluate the scientific question and appropriateness of the methods planned to answer the scientific question. Attestation from a Scientific/Scholarly Reviewer is required upon IRB submission. This completed form should be uploaded to eIRB as an "Institutional Approval."

Protocol Title:
Principal Investigator Name:
Scientific/Scholarly Review (please select ONE): ☐ Nationally based, federally funded organization (i.e., NIH, NSF) subject to full peer review ***No signature required for Scientific/Scholarly Review** ☐ Nationally based, non-federally funded organization (i.e., March of Dimes, American Academy of Pediatrics) subject to peer review ***No signature required for Scientific/Scholarly Review** ☐ Locally constituted peer review ***Signature required on this form unless UACC SRC approval applies**

If the project is nationally based, just check box 1 or 2 and upload the form in eIRB.

If the project is not nationally based, a local Scientific or Peer Review and a signature are required.

Locally Constituted Peer Review Attestation

When a locally constituted peer review is required, the local scientific/scholarly reviewer should consider the following:

- Is the rationale for the study clearly stated and is the rationale scientifically sound?
- Are the aims and corresponding hypothesis clearly stated?
- Is the primary outcome (and secondary outcomes, as appropriate) clearly defined?
- Are there adequate preliminary data in the literature (or from the investigator) to justify the proposed research?
- Has an adequate literature review been done to support this study?
- Is the question or hypothesis being tested providing important knowledge to the field?
- Is the design of the study appropriate for the questions that are posed?
- Have the validity and reliability of measures been established or are there methods proposed for establishing validity and reliability?
- Is the proposed subject population appropriate?
- Are statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?
- Are all the proposed tests or measurements requested necessary to answer the scientific question?
- Are the investigators well qualified to conduct this study?
- Is the proposed research novel and new?

I am the local scientific/scholarly reviewer for this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically sound. Furthermore, I believe that risks are adequately balanced, and the scientific question(s) and methods are appropriate.

X _____

Local Scientific/Scholarly Reviewer Signature

Advisor/Co-Investigator Attestation

Advisor/Co-I Attestation for Human Subjects Research

Instructions: Attestation from an Advisor/Co-I is required upon IRB submission when the Principal Investigator (PI) does not meet RII PI Eligibility. This form can be used to document Advisor/Co-I attestation. This completed form should be uploaded to eIRB as an "Institutional Approval." Note, the Advisor/Co-I providing attestation on this form must be the same Advisor/Co-I listed in eIRB for this protocol.

Protocol Title:	
Principal Investigator Name:	
Advisor/Co-I Name:	

I am the Advisor for the Principal Investigator submitting this protocol. By my signature, I certify that I have reviewed the protocol. Furthermore, I believe that the Principal Investigator has the necessary training, experience, and knowledge to conduct the research in a manner consistent with the regulations governing human subjects research and sound research principles. I acknowledge that I am acting as the Advisor and Co-Investigator on this protocol for the researcher. I agree to:

- Oversee and monitor the conduct of this research by communicating regularly with the Principal Investigator;
- Assist with the resolution of any problems or concerns encountered during the research; and
- Assure that the UA IRB is notified in the event of an adverse event or unanticipated problem.

I understand that as Advisor and Co-Investigator I am responsible for the conduct of this research.

X _____

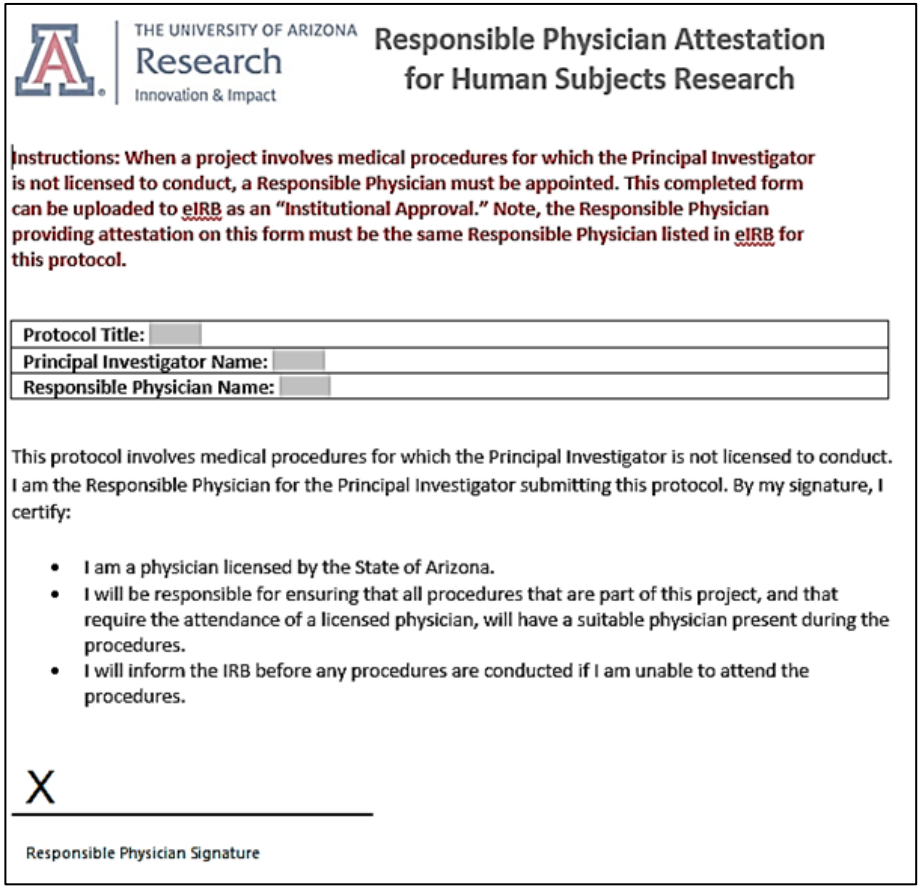
Advisor/Co-Investigator

<u>An Advisor/Co-Investigator needeeds to be added to the project when the PI does not meet PI eligibility, i.e.,:</u>

- Research Associate
- Research Assistant
- Undergraduate or Graduate Student
- Medical School Resident
- Adjunct Faculty
- Visiting Faculty & Scholars (DCC)
- Emeritus Faculty (DCC)
- Other Designated Campus Colleagues

If you are using an email to satisfy this requirement, make sure that all the information about what is being agreed to is listed.

Responsible Physician Attestation



THE UNIVERSITY OF ARIZONA Research Innovation & Impact

Responsible Physician Attestation for Human Subjects Research

Instructions: When a project involves medical procedures for which the Principal Investigator is not licensed to conduct, a Responsible Physician must be appointed. This completed form can be uploaded to eIRB as an "Institutional Approval." Note, the Responsible Physician providing attestation on this form must be the same Responsible Physician listed in eIRB for this protocol.

Protocol Title:	
Principal Investigator Name:	
Responsible Physician Name:	

This protocol involves medical procedures for which the Principal Investigator is not licensed to conduct. I am the Responsible Physician for the Principal Investigator submitting this protocol. By my signature, I certify:

- I am a physician licensed by the State of Arizona.
- I will be responsible for ensuring that all procedures that are part of this project, and that require the attendance of a licensed physician, will have a suitable physician present during the procedures.
- I will inform the IRB before any procedures are conducted if I am unable to attend the procedures.

X _____

Responsible Physician Signature

<u>When is a Responsible Physician Needed?</u>

- A Responsible Physician needs to be added to the study **when the PI is not licensed to conduct some of the study procedures**.
- **Upload a copy of the** Physician CV with the IRB application.
- The Responsible Physician must be **licensed in Arizona**.

Step 5: Obtain Additional Approvals

Additional approvals may be needed depending on the nature of your project.

The most common approvals include:

- **UAHS/RIA Feasibility Approval** if your project utilizes Banner resources.
- **UACC SRC Approval** for cancer-related projects.
- **CATS Research Center Approval** for projects using CATS facilities and resources
- **School District Approval** if your project will be conducted at a public school.
- **Tribal Approval** for projects on tribal land or involving a specific Native American tribe.
- **RLSS Radiation Safety Approval** if your project involves ionizing or non-ionizing radiation.
- **UA Travel Registry Number** if traveling outside of the US.
- **eDoc Number** if your project is industry-funded or has a single IRB mandate.

Please review the HSPP Guidance: Other Approvals Required for more information
https://research.arizona.edu/sites/default/files/Other%20Approvals%20Required%20v2021-11.pdf

UA & BH Collaboration

- **Research Projects:** RIA/UAHS Feasibility approval; UA/BH Medical Consent/PHI language; Honest Broker Data Requests; Banner Employee Addendum.
- **Non-Research Projects:** Non-Human Subjects Determination, Letter of Support from data owner, BH Non-Research Data Use Committee (NRDUC) Supplemental Questionnaire and Approval Letter, Case Report HIPAA Authorization.
- **Access to the Data Warehouse:** BH Cerner Data/CRDW; UA EPIC/CDW.
- **Banner Translation Services:** Translation by Cyracom required for all BH sites including projects conducted at BUMC-Tucson, South, and Phoenix.

IMPORTANT: All Projects conducted at Banner require IRB Approval AND Banner Approval before the study can take place.

For information about UA & Banner Health (BH) collaborative activities and requirements visit the HSPP website **https://research.arizona.edu/compliance/human-subjects-protection-program/collaborative-activities-banner-health**

How to Submit in eIRB (Step 6 & 7)

Step 6 Prepare the Submission in eIRB

DIRECT LINK to eIRB

https://eirb.arizona.edu/IRB

UAccess

Administrative Systems

Employee/Manager Self Service	EDGE Learning
Analytics/Reporting 🔒	Budget & Planning
Financials 🔒	Research
eDisclosure	Space
eIRB	Adaptive Insights

Log in with UA NetID & Password

HSPP Website
https://research.arizona.edu/compliance/human-subjects-protection-program/eirb-information

eIRB Information

The Human Subjects Protection Program (HSPP) has launched a new system, eIRB, designed to make submitting human research protocols easier and faster.

ACCESS EIRB

https://vimeopro.com/user43881429/university-of-arizona/video/398307344

Create a New Study, Upload Documents & Answer the Questions in the Smart Forms

SMART FORMS

Create New Study

- **Basic Study Information**
- Study Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Local Site Documents

Basic Study Information

1. * **Title of study:**

   Enter The Full Study Title; Make Sure it Matches the Grant/Funding so it can be easily matched.

2. * **Short title:**

   Abbreviated Title or Acronym for quick reference

3. * **Brief description:**

   Describe what the study is about, how long it will take, how many and what type of participants will be enrolled, anything else that provides a quick snapshot of the study and why it is being done.

Basic Study Information Continued

4. * **What kind of study is this?**
   - ○ Multi-site or Collaborative study
   - ● Single-site study

   Clear

5. * **Will an external IRB act as the IRB of record for this study?**

   ○ Yes ● No Clear

6. * **Local principal investigator:**

   Simona Janisch ···

7. * **Is the local PI a student or medical school resident investigator?**

   ○ Yes ● No Clear

If YES is checked, upload the Advisor Attestation with the application

Basic Study Information Continued

8. * Attach the protocol:

+ Add

	Document	Category	Date Modified	Document History
Update	Completed IRB Protocol Form.docx(0.01)	IRB Protocol	7/21/2022	History
Update	Sponsor Protocol if Applicable.docx(0.01)	IRB Protocol	7/21/2022	History

This is also where you can upload the Human Subjects Research Determination and the 118 Form

Study Funding Sources

Study Funding Sources

You can link the funding by IP/Award Number

* Select the funding proposals and/or awards related to this study:

ID	PI	Title	Prime Sponsor	Sponsor

1. Identify each external organization supplying funding for the study:

+ Add

It is very important to properly link the funding in eIRB before you submit the application

Award Number	PI	Title	Prime Sponsor	Sponsor	Project Status	Attachments
There are no items to display						

Local Study Team Members

Add Study Team Member

1. * **Study team member:**
   Courtney Hammel ···

2. **Role in research:** (check all that apply)
   - [x] Advisor
   - [x] Co-Investigator
   - [ ] Research Staff
   - [ ] Responsible Physician

If an Advisor is being added, check both Advisor and Co-I.

3. * **Is the team member involved in the consent process?**
   (●) Yes ( ) No Clear

Local Study Team Members

1. **Identify each additional person involved in the design, conduct, or reporting of the research:**

+ Add

This is where you add UA Affiliated Study Members from the drop-down menu

	Name	Roles	Financial Interest Review Status	Involved in Consent	E-mail	Phone
Update	Courtney Hammel	Co-Investigator	Pending Creation	yes	courtneyolson@arizona.edu	520/626-9034

This is where you add Collaborators like Banner staff and staff not affiliated with any outside institution.

2. **External team member information:**

+ Add

Name	Description
There are no items to display	

Upload the Human Subjects training verification for each Collaborator

Do Not Add Multisite Staff to this section

Study Scope

Study Scope

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?
   ○ Yes ● No Clear

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?
   ○ Yes ● No Clear

3. * Will you be using, collecting, or accessing biological specimens?
   ○ Yes ● No Clear

4. * Will you be using, collecting, or accessing clinical data?
   ● Yes ○ No Clear

5. * Will the data or specimens be stored in a repository?
   ○ Yes ● No Clear

6. * Will you enroll non-English speaking individuals?
   ● Yes ○ No Clear

If **Yes** is checked for **Q1** or **Q2** **additional Smart Forms** for **Drugs** or **Devices** will open.

Extra Drug & Device Smart Forms

Drugs

1. * **List all drugs, biologics, foods, and dietary supplements to be used in the study:**

+ Add

Generic Name	Brand Name	Attachment Name
There are no items to display		

2. * **Will the study be conducted under any IND numbers?**

○ Yes ○ No Clear

3. **Attach files:** (such as IND or other information that was not attached for a specific drug)

+ Add

Document	Category	Date Modified	Document History

Devices

1. * **Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

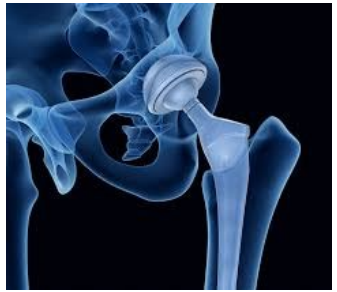
+ Add

Device	Humanitarian Use Device	Attachment Name	Device Exemptions	IDE/HDE Number
There are no items to display				

2. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)

+ Add

Document	Category	Date Modified	Document History



Local Research Locations

Local Research Locations

1. **Identify research locations where research activities will be conducted or overseen by the local investigator:**

+ Add

	Location	Contact	Phone	Email
Update	College of Medicine Phoenix			
Update	Online	HSPP	000-000-0000	vpr-irb@arizona.edu

Filter by Location Name | college of medicine

Location Name
College of Medicine Phoenix

Filter by Location Name | online

Location Name
Online

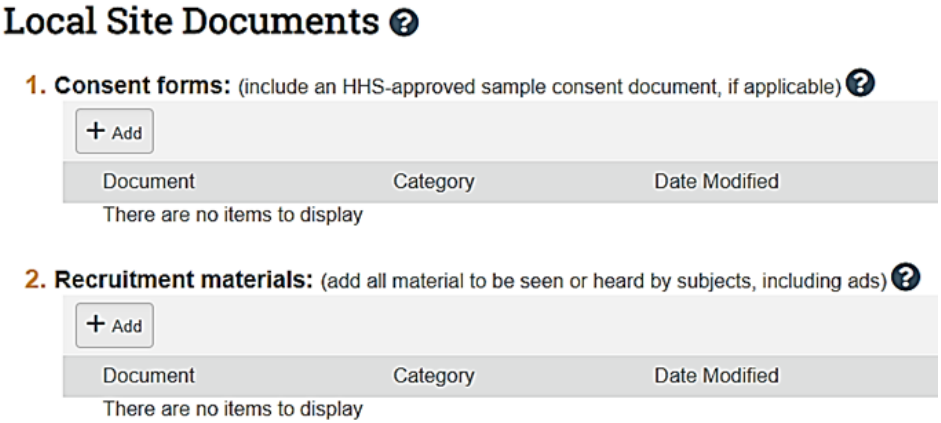
Select Research Location SEL

Filter by Location Name | university of arizona | Go | Clear

1-16 of 16

Location Name
University of Arizona Arthritis Center
University of Arizona Arthritis Center
University of Arizona Arthritis Center
University of Arizona Arthritis Center
University of Arizona Campus
University of Arizona Campus
University of Arizona Cancer Center
University of Arizona Cancer Prevention Research Office
University of Arizona Collaboratory
University of Arizona Collaboratory
University of Arizona College of Law
University of Arizona Family and Community Medicine Department
University of Arizona Family and Community Medicine Department
University of Arizona Health Sciences
University of Arizona Psychology Department
University of Arizona, Psychology Department

Local Site Documents



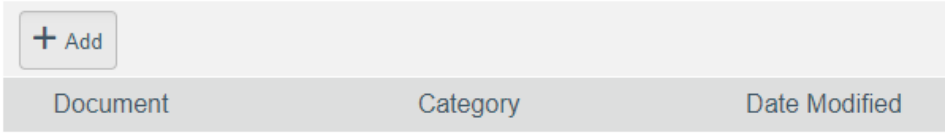
Consent Templates Updated September 2022

- **Externally funded Social Behavioral** ICF/Parental permission
- **UA Medical ICF**/Parental permission (required for Banner; also includes Banner PHI)

https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates

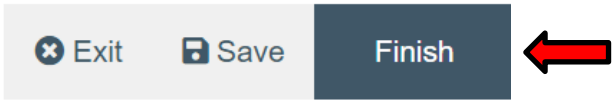
Local Site Documents Continued

3. **Other attachments:**



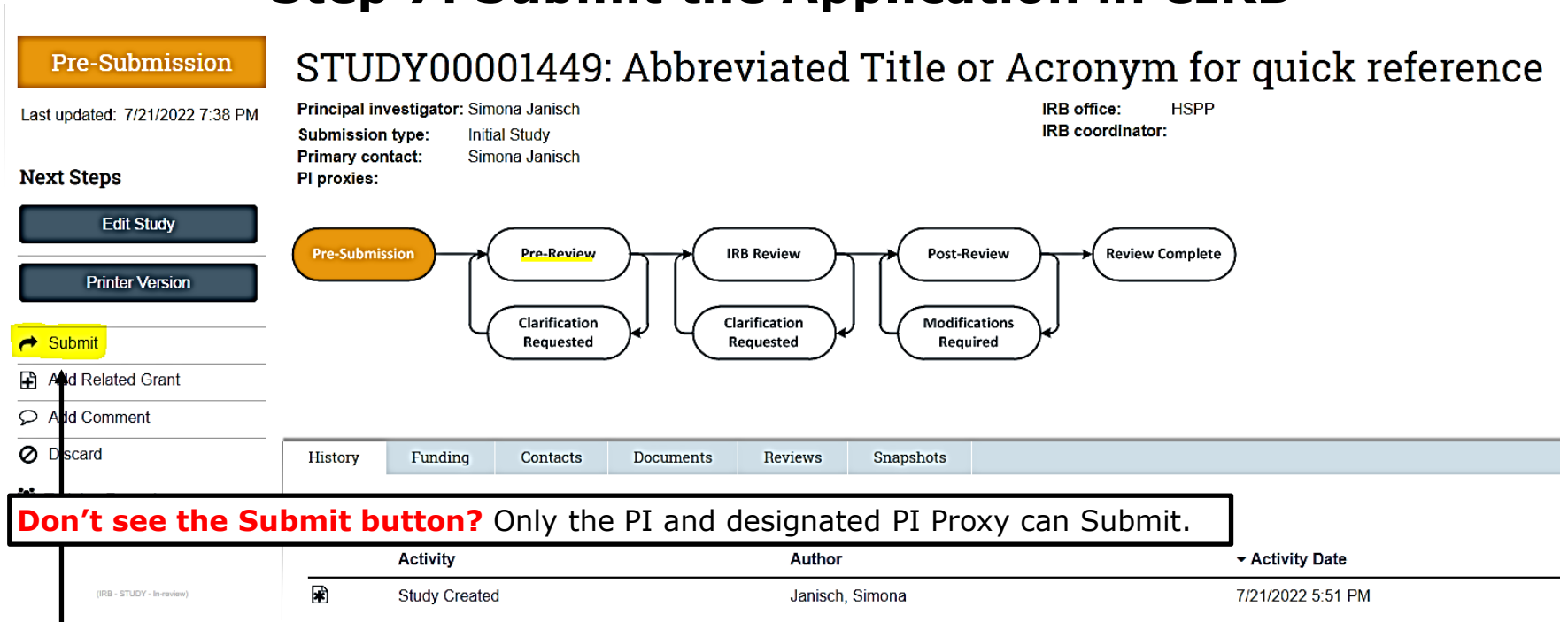
Upload all "Other" documents to this section including:

- PI CV or Bio-sketch
- Waiver of Consent/PHI
- RIA/UAHS Feasibility Approval email
- Departmental Approval (HSPP form or email)
- Scientific Review Approval (or Cancer Center SRC approval; HSPP form or email)
- Advisor Attestation CV (if PI is a student/resident)
- Responsible Physician Attestation & CV (if they are being added to the study)
- Site Authorizations (CATS, public schools, etc.)
- Data Collection Tools
- Participant Facing Materials
- HSPP Appendices (i.e., Children, Native American,… all that apply)



IMPORTANT: Clicking the FINISH button does not SUBMIT the application; Finish it takes you back to the study home page in eIRB.

Step 7: Submit the Application in eIRB



Don't see the Submit button? Only the PI and designated PI Proxy can Submit.

HSSP Handout : How to Add & Remove a PI Proxy
https://research.arizona.edu/sites/default/files/How%20to%20Add%20and%20Remove%20a%20PI%20Proxy%20in%20eIRB.pdf

Submit

IMPORTANT! Before you click "OK" below, please verify that the correct funding source is linked on the Study Funding Sources Smart Form. Linking the correct funding source has significant implications to the COI disclosure process. You CANNOT change the funding source after you click "OK" until after the submission is approved by the IRB.

By signing below you are verifying that:

- You certify that the information you provided in this submission is correct and complete.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with the Belmont Report and institutional requirements: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.
- You have read and acknowledge the HSPP guidance on Principal Investigator Responsibilities: https://research.arizona.edu/sites/default/files/Principal%20Investigator%20Responsibilities%20after%20IRB%20Approval%20v2021-09.pdf.
- You acknowledge it is the responsibility of the Principal Investigator (PI) to ensure the correct personnel are listed as an Investigator on the Sponsored Projects Institutional Proposal or Award for Sponsored research. All other personnel not listed on the Institutional Proposal or Award are responsible for ensuring that they have submitted all appropriate disclosures and are in compliance with the University's Conflicts of Interest and Commitment Policy: https://policy.arizona.edu/ethics-and-conduct/conflicts-interest-commitment-policy-interim.

Press OK to Submit

HSPP Guidance: PI Responsibilities
https://research.arizona.edu/sites/default/files/Principal%20Investigator%20Responsibilities%20after%20IRB%20Approval%20v2021-09.pdf

STUDY00001449: Abbreviated Title or Acronym for quick reference

Principal investigator: Simona Janisch
Submission type: Initial Study
Primary contact: Simona Janisch
PI proxies:

IRB office: HSPP
IRB coordinator:

Pre-Review Steps:

- **Completeness Check**
- **Triage**
- **Assigned** for pre-review

STUDY00001449: Abbreviated Title or Acronym for quick reference

Principal investigator: Simona Janisch
Submission type: Initial Study
Primary contact: Simona Janisch
PI proxies:

IRB office: HSPP
IRB coordinator: Simona Janisch

Summary & Helpful Tips

Tips for Success

1. Determine if you need IRB Review
2. Complete the appropriate training.
3. Use the most current forms and templates.
4. Fill out all-applicable forms and get all the required signatures.
5. Provide as much information as possible and be clear about what is being done for research purposes.
6. Address participant privacy and data confidentiality, protection, storage and future use.
7. Obtain additional approval and required signatures (RIA, Department, Scientific, etc.).
8. Upload everything into the correct place in eIRB.
9. Allow plenty of time for review.
10. Respond to Clarification Requests in a timely manner.

IMPORTANT: Research may NOT START until IRB approval is received!

Summary of New Project Requirements

The following forms and documents are typically needed for new project submissions:

- CV/Bio-sketch of the PI
- IRB Protocol form
- Informed Consent Form(s) or ICF Waiver
- Required Approvals
- Additional Approvals (as applicable)
- HSPP Appendices (as applicable)
- Data Collection Tools
- Recruitment Materials
- Participant/Study Materials

Resources

HSPP Resources

- **Getting Started Page:** https://research.arizona.edu/compliance/human-subjects-protection-program/getting-started
- **HSPP Forms:** https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms
- **Access to eIRB:** https://eirb.arizona.edu/IRB
- **eIRB 'How To" Videos and Manuals:** https://research.arizona.edu/compliance/human-subjects-protection-program/eirb-information
- **HSPP Guidance Documents:** https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers
- **Helpful Tips:** https://research.arizona.edu/compliance/human-subjects-protection-program/getting-started/top-10-tips

Contact Information

Simona Janisch

sjanisch@arizona.edu

***Gina* Fimbres- Leon Guerrero**

gjfimbres@arizona.edu

HSPP Departmental Email:
vpr-irb@arizona.edu

HSPP Webpage:

https://research.arizona.edu/compliance/human-subjects-protection-program

HSPP Office Hours

HSPP Virtual Office Hours
are held every other Thursday
from 10 am – 11 am.

No registration is required

Use this link to join :
https://arizona.zoom.us/j/86232995912

Remaining 2022 Dates

- September 29
- October 12
- October 27
- November 10
- November 24
- December 8
- December 22

Stay in the Loop

Subscribe to the HSPP listserv:

- Send a blank email to: list@list.arizona.edu
- In the subject line, enter: subscribe UA-IRB Firstname Lastname
- Delete any signature line and/or confidentiality statement that you may have in your e-mail.

Subscription Instructions: https://it.arizona.edu/documentation/how-subscribe-and-unsubscribe-list.

Demonstration