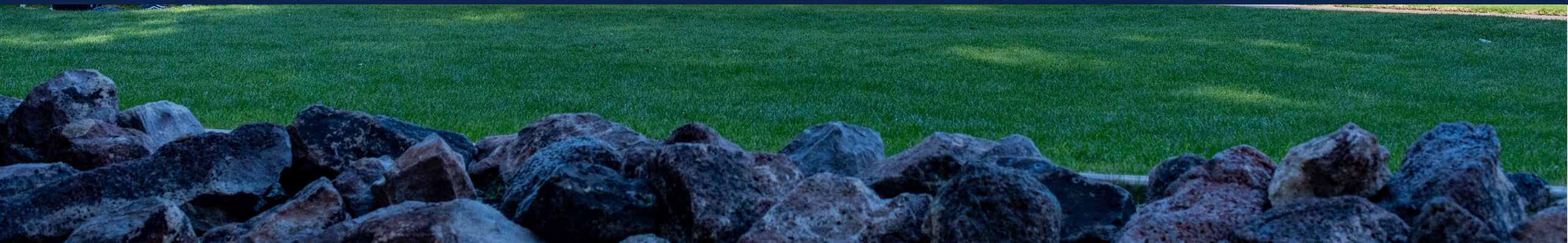
A Step-by-Step Guide to Successful IRB Submissions

Human Subjects Protection Program (HSPP)



TODAY'S PRESENTATION

AGENDA

- HSPP Overview
- Preparing IRB Application Materials
- How to Submit in eIRB
- Helpful Tips
- eIRB Submission Demonstration

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HSPP Overview

Human Subjects Protection Program (HSPP)

PURPOSE

Provide **regulatory and administrative support** to the Institutional Review Board (IRB)

Collaborate with research community to **maintain ethical and compliant** research practices

Provide **education, review and monitoring** for human research projects

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

REVIEW CATEGORIES

MINIMAL RISK 2018

Not federally funded/unfunded, not greater than minimal risk

EXEMPT

Federal/funded, fit into a specific Exempt category (45 CFR 46.104)

EXPEDITED

Federal/funded, fit into a specific Expedited category (45 CFR 46.110)

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

MINIMAL RISK SUBMISSIONS:

- Reviewed by Single IRB Chair or Designee
- Includes Minimal Risk 2018, Exempt, Expedited, and low-risk modifications to approved Full Committee projects

GREATER THAN MINIMAL RISK SUBMISSIONS:

- Reviewed by the Full Committee on the 2nd & 4th Tuesday of every month
- Items must be submitted at least 2 weeks prior to the meeting and finalized by 1 week before

HOW LONG DOES IRB REVIEW USUALLY TAKE?

- **Personal changes/deferrals/closures** ~ 1-2 weeks
- **Modifications/continuing reviews** ~ 2-3 weeks
- **New projects** ~ 3-4 weeks

*****We recommend submitting new projects at least 2 months before approval is needed*****

- Pre-Review starts when the submission is complete & ready for review.
- Incomplete submissions, multiple Clarification Requests, and delayed study team responses can significantly increase review time.

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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

See: HSPP Getting Started Webpage

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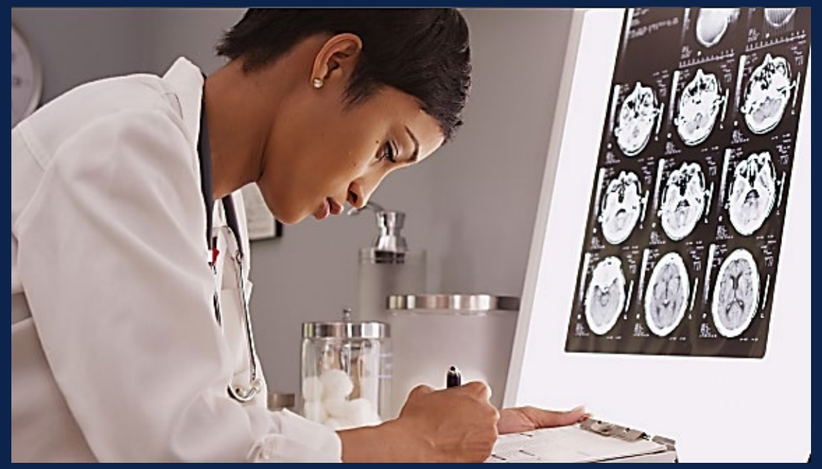
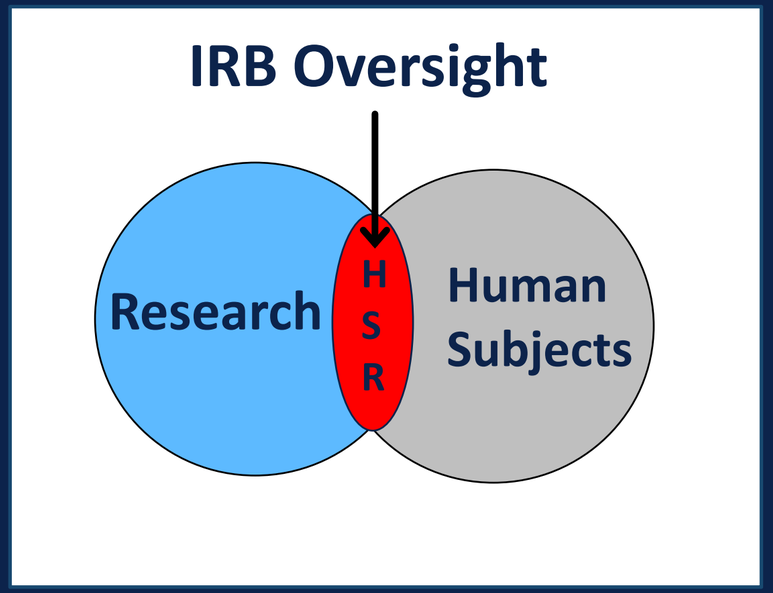
Does your Project Require IRB Approval? (Step 1)

Not every project needs IRB approval





If the activity is **“Research”** and involves **“Human Subjects”**
IRB review and approval is required

See: HSPP Guidance: What is Human Research?

IRB Protocol for Determination of Human Research

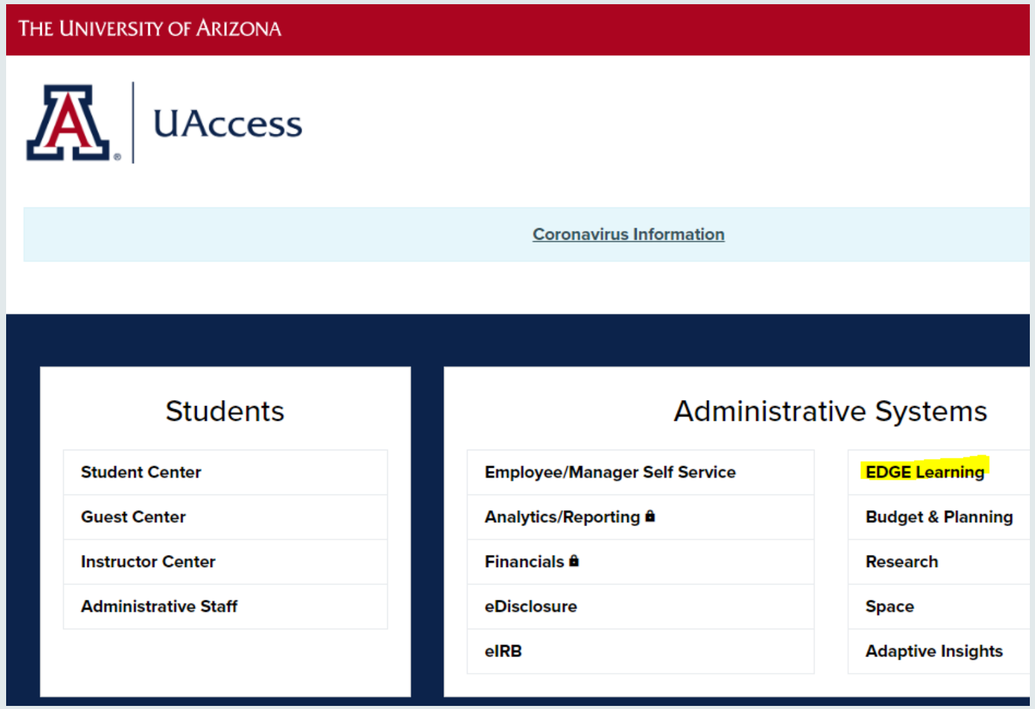
Required if the study involves any of the following activities, and it's unclear whether the activities require IRB review:

- Access to **EMR**
- Use or disclosure of **PHI**
- Requests from the Banner Clinical Research Data Warehouse (**CRDW**)
- The project will be supported by **federal funds (i.e., NIH)**
- Used to support an application to the **FDA** or involves a test article
- IRB certification for access to materials from **dbGap**; OR
- Involves **Native American** or Indigenous populations

Training Requirements (Step 2)

COMPLETE REQUIRED CITI TRAINING

Log in to EDGE Learning



CITI PROGRAM

EDGE Learning
DEVELOP | GROW | ENGAGE

All members of the research team need to complete training *before* conducting any activities involving human research.

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WHICH TRAINING IS REQUIRED?

IRB - Biomedical Research Investigators

- FDA-regulated research
- Medical records review

OR

IRB - Social & Behavioral Research Investigators

- Non-medical research
- Surveys & interviews

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Native American Research Module

- Both training courses include the Native American Research Module, which is required training for all University of Arizona researchers
- Also offered as free-standing training for non-UA affiliates and collaborators

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ADDITIONAL TRAINING

BANNER EMR

Researchers must also complete annual UA HIPAA Privacy Training

CLINICAL TRIALS OR NIH FUNDED

Good Clinical Practice (GCP) training might also be needed (check with your department)

ALL RESEARCHERS

Must complete the annual Conflict of Interest (COI) training and complete a COI Research Certification in eDisclosure

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TRAINING FOR UNAFFILIATED COLLABORATORS

e.g., Banner Staff not affiliated with the U of A *or* community partner researchers

ACCEPTED TRAINING:

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

See: Non-Affiliated Training Requirements

Preparing the UA IRB Application (Steps 3-5)

PREPARE REQUIRED FORMS

Complete the appropriate IRB Protocol Form

- IRB Protocol for Human Research (v Aug 2024)
- IRB Protocol for Retrospective Data Review (v Dec 2023)
- IRB Protocol for Projects Using External IRBs (v Dec 2023)

***Make sure you are using the current version!**

HSPP Forms webpage

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)
4. **Funding**
5. **Resources**
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. **Benefits** to Subjects
12. **Risks** and how risks are minimized
13. **Costs & Compensation**
14. **Privacy** of Subjects & **Confidentiality** of Data (future use; repositories; storage; sharing)
15. **Additional Questions** (Injury; Withdrawal; Safety Monitoring; Data Management Plan; and International Research)

IRB Protocol for Retrospective Data Review

For retrospective data review involving existing records, data abstraction, and analysis

- Background, Lay Summary, Purpose
- Funding
- Resources
- Study Population
- Number of Specimens/Records to be Reviewed Locally (include date range)
- Research and Data Collection Procedures
- Benefits & Risks
- Privacy & Confidentiality of Data

IRB Protocol for Projects Using External IRBs

For requests to cede IRB oversight to a non-UA IRB

- Funding
- Scope of Ceded Activities
- Recruitment Methods
- Consenting Process
- Privacy & Confidentiality

INFORMED CONSENT FORMS

Use the correct consent templates!

Download current templates from the HSPP website.

- Externally funded Social Behavioral ICF/Parental Permission (v. Dec 2023)
- Internally funded/non-funded Social Behavioral ICF/Parental Permission (v. Dec 2023)
- UA/Banner Medical ICF/Parental Permission (v. Dec 2023)

  * Required for Banner; also includes Banner PHI authorization language
- Assent Form (v Apr 2024)

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

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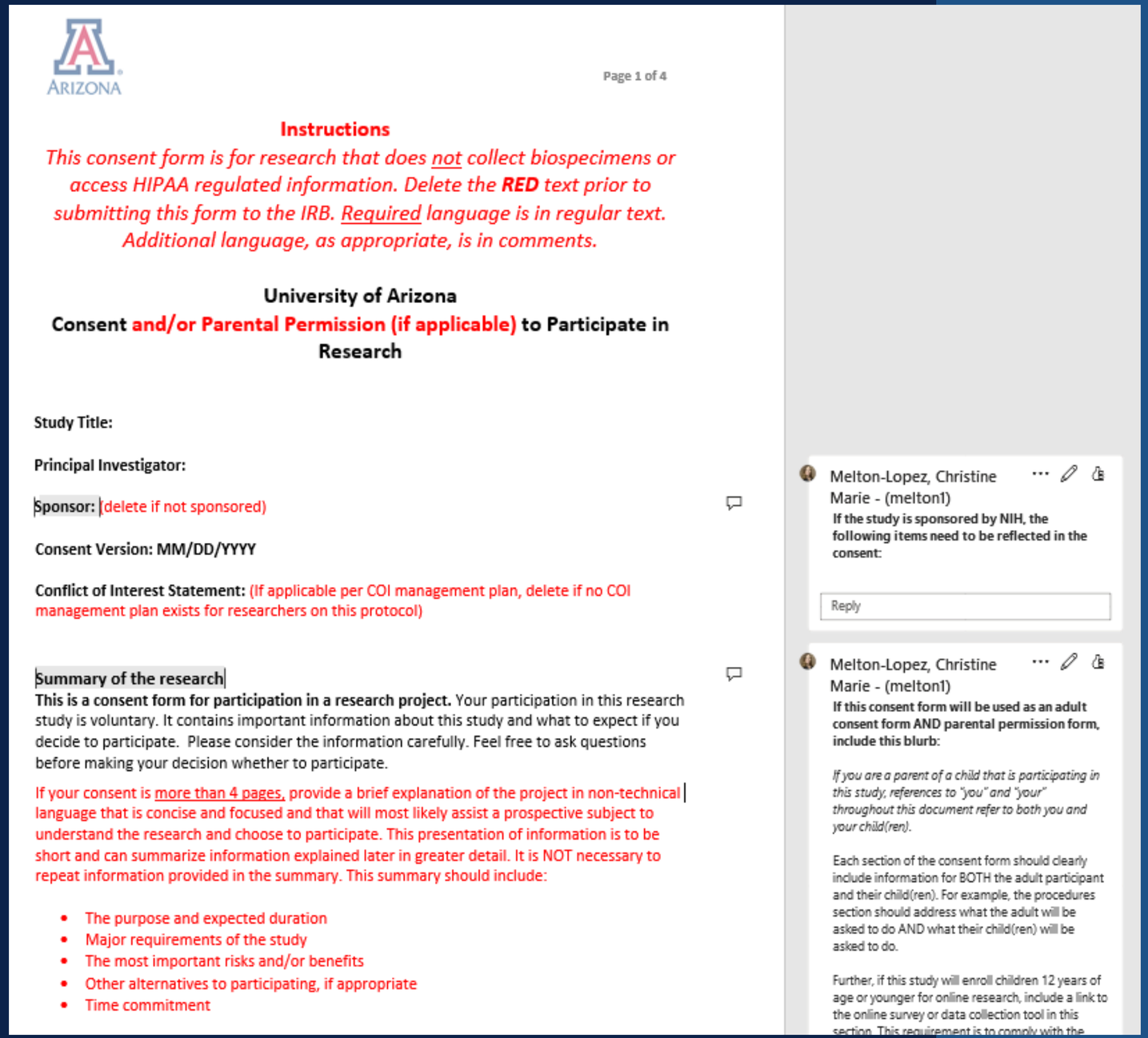

ARIZONA

Instructions

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

University of Arizona
Consent and/or Parental Permission (if applicable) to Participate in Research

Study Title:

Principal Investigator:

Sponsor: (delete if not sponsored)

Consent Version: MM/DD/YYYY

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 in non-technical language 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:

Reply

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.

Further, if this study will enroll children 12 years of age or 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

EXTERNALLY-FUNDED SOCIAL/BEHAVIORAL ICF TEMPLATE

Required:

- UA logo
- Consent version date
- Regular text
- Summary of the Research (if > 4 pages)

Customizable:

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

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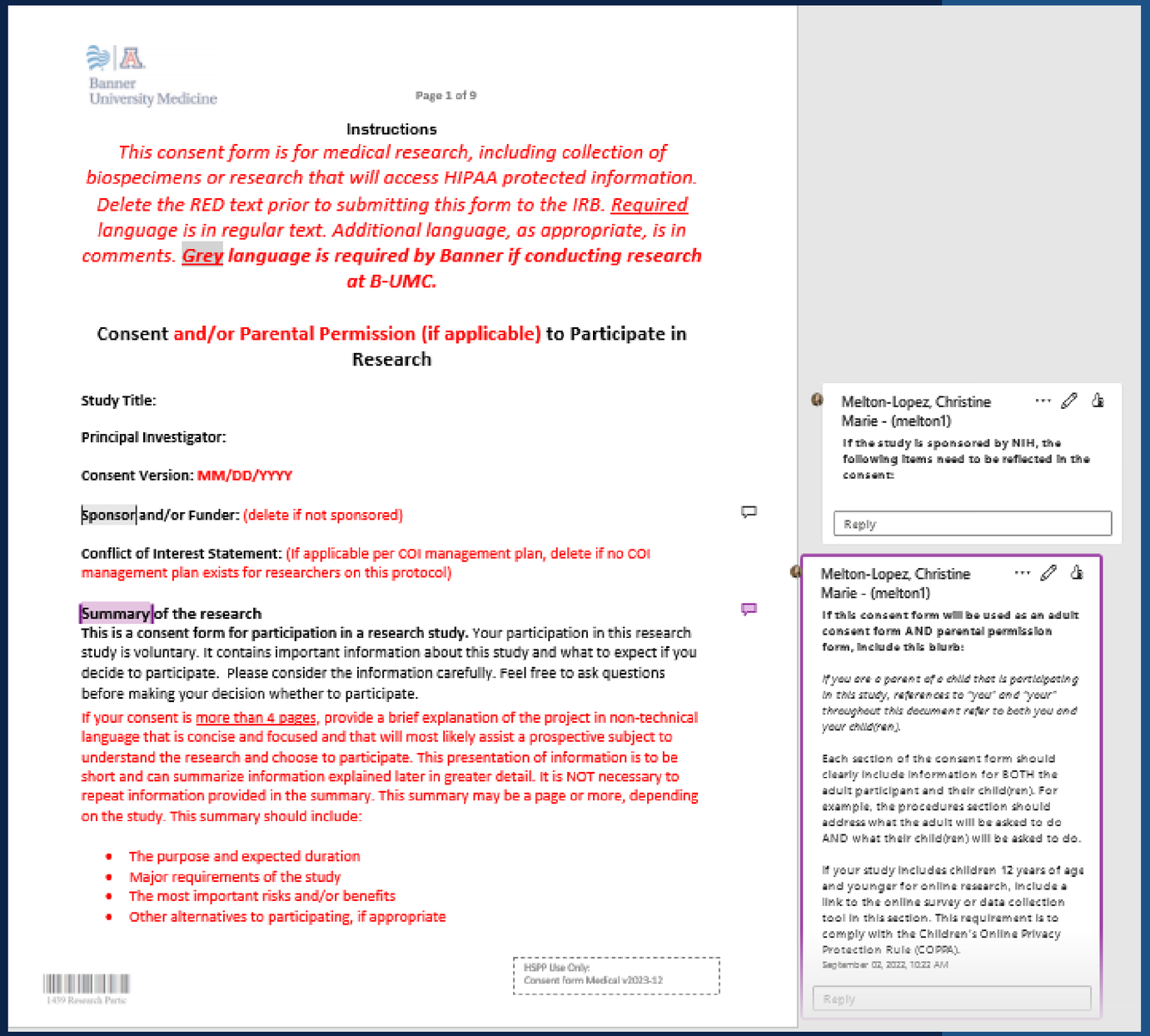
Banner
University Medicine

Page 1 of 9

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, is in comments. Grey language is required by Banner if conducting research at B-UMC.

Consent and/or Parental Permission (if applicable) to Participate in Research

Study Title:

Principal Investigator:

Consent Version: MM/DD/YYYY

Sponsor and/or Funder: (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 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.

If your consent is more than 4 pages, provide a brief explanation of the project in non-technical language 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

1439 Research Parac

HSPP Use Only:
Consent form Medical v2023-12

Melton-Lopez, Christine Marie - (melton1)

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

Reply

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

Reply

MEDICAL ICF/PARENTAL PERMISSION TEMPLATE

Use this template for:

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

Required by Banner:

- Banner logo
- Barcode on page 1
- Banner gray language

Customizable:

- Red text should be removed/replaced.
- Insert language from side bar comments as applicable.

Helpful Hints:

- Submit the ICF as a Word document.
- Keep the version date updated.
- After approval, the document will be converted into a PDF, and an approval date will appear in the footer.

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HSPP APPENDICES

All appendices are found on the **HSPP Forms webpage**. Complete as applicable:

- Appendix for Children/Wards
- Appendix for Cognitively Impaired Individuals
- Appendix for Pregnant Women, Neonates and Fetuses
- Appendix for Prisoners
- Appendix for Native Americans and Indigenous Populations
- Appendix for Drugs
- Appendix for Devices
- Appendix for Multi-Site Research (for each pSite that UA IRB will oversee)
- Appendix for Waiver or Alteration of Consent or PHI
- Appendix for Exception from Informed Consent (planned Emergency research)
- Appendix for Department of Defense (DoD) 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)

HSPP ACCEPTS THE FOLLOWING:

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

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.”

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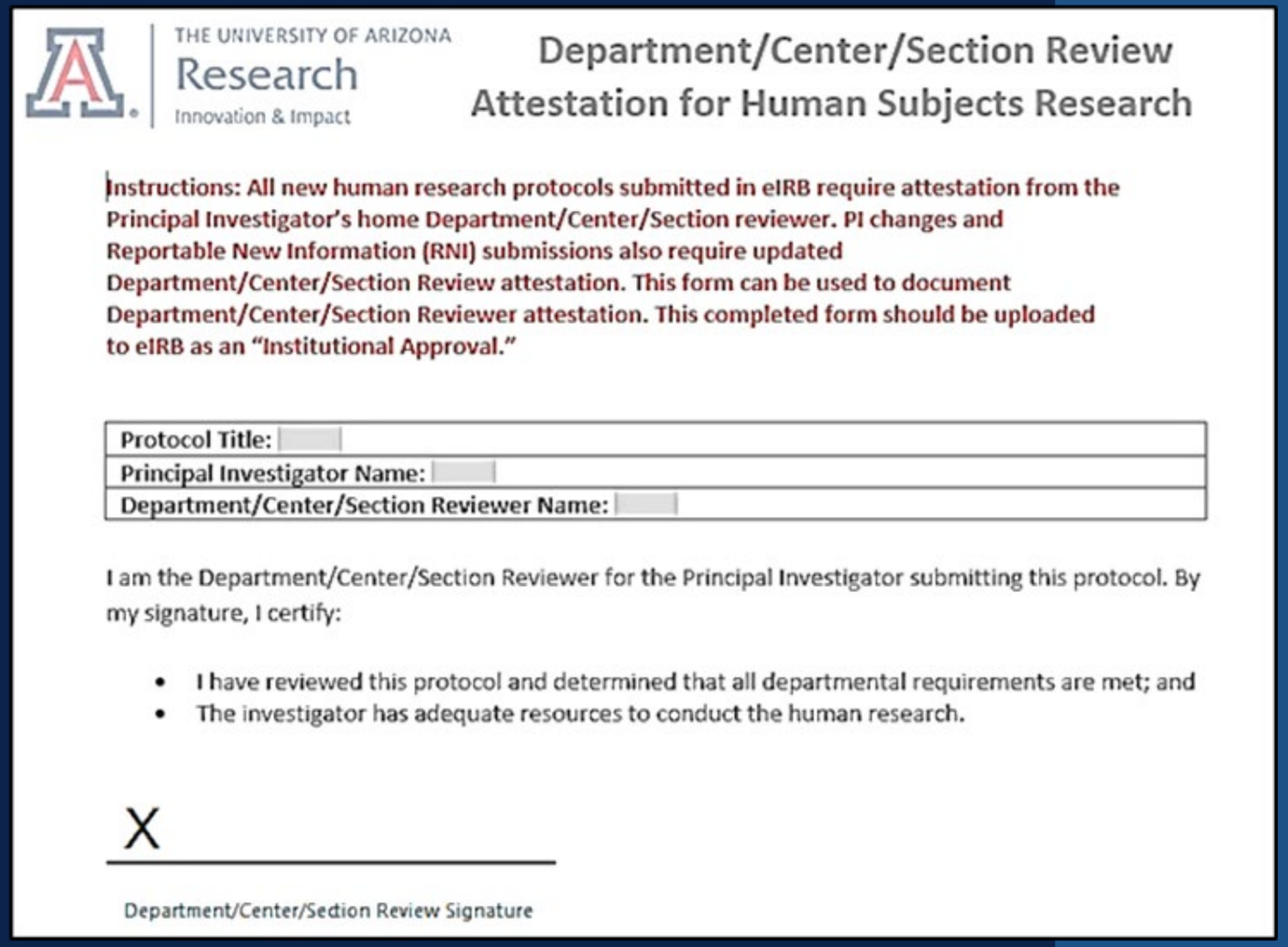
DEPARTMENT/CENTER ATTESTATION



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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

Departmental signature is needed for:

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

You can use:

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

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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 Locally Constituted Peer Review, Reviewer Name:

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/Peer Review and 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

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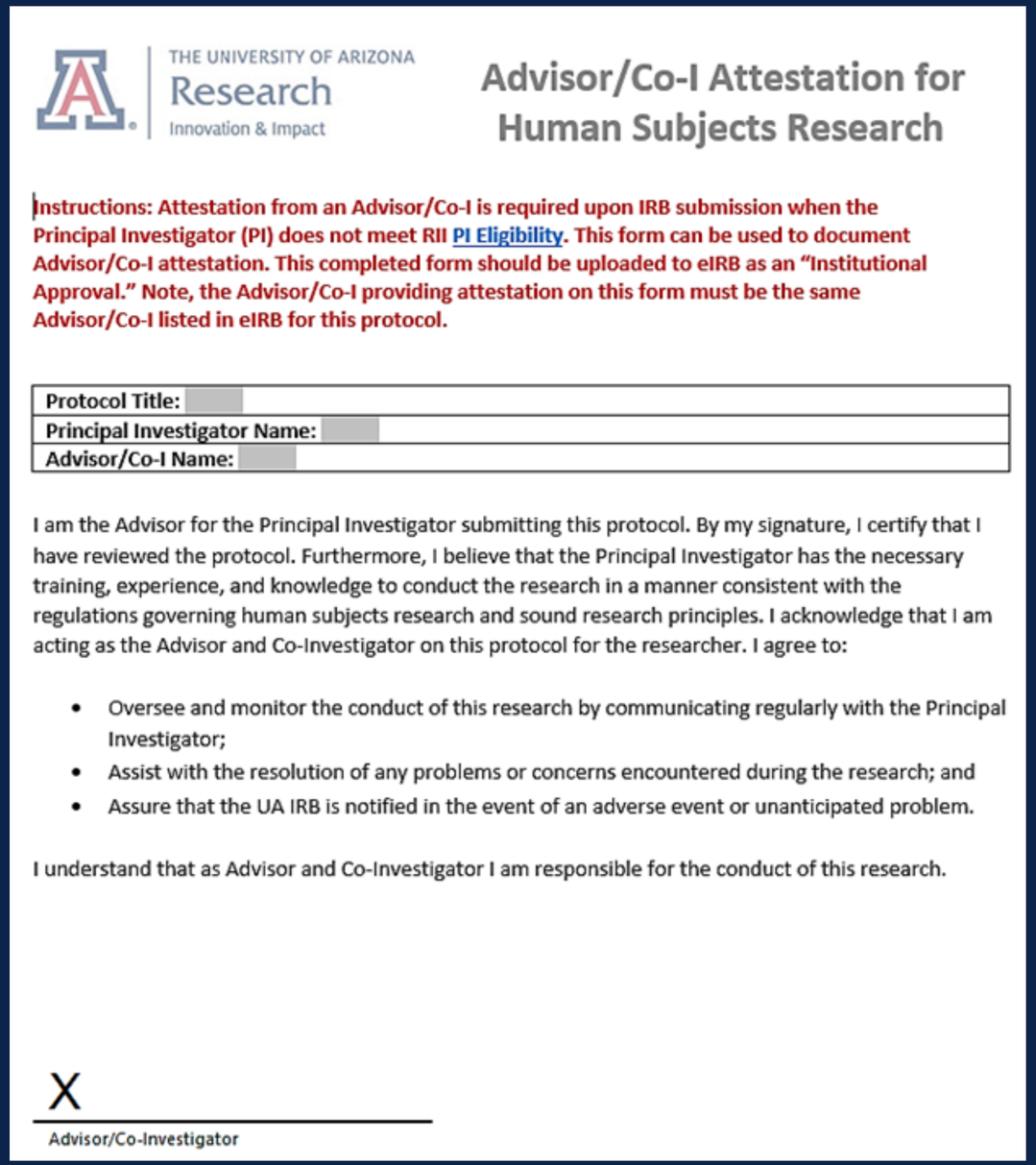

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Advisor/Co-I Attestation for Human Subjects Research

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

ADVISOR/CO-INVESTIGATOR ATTESTATION

Required for students and residents

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

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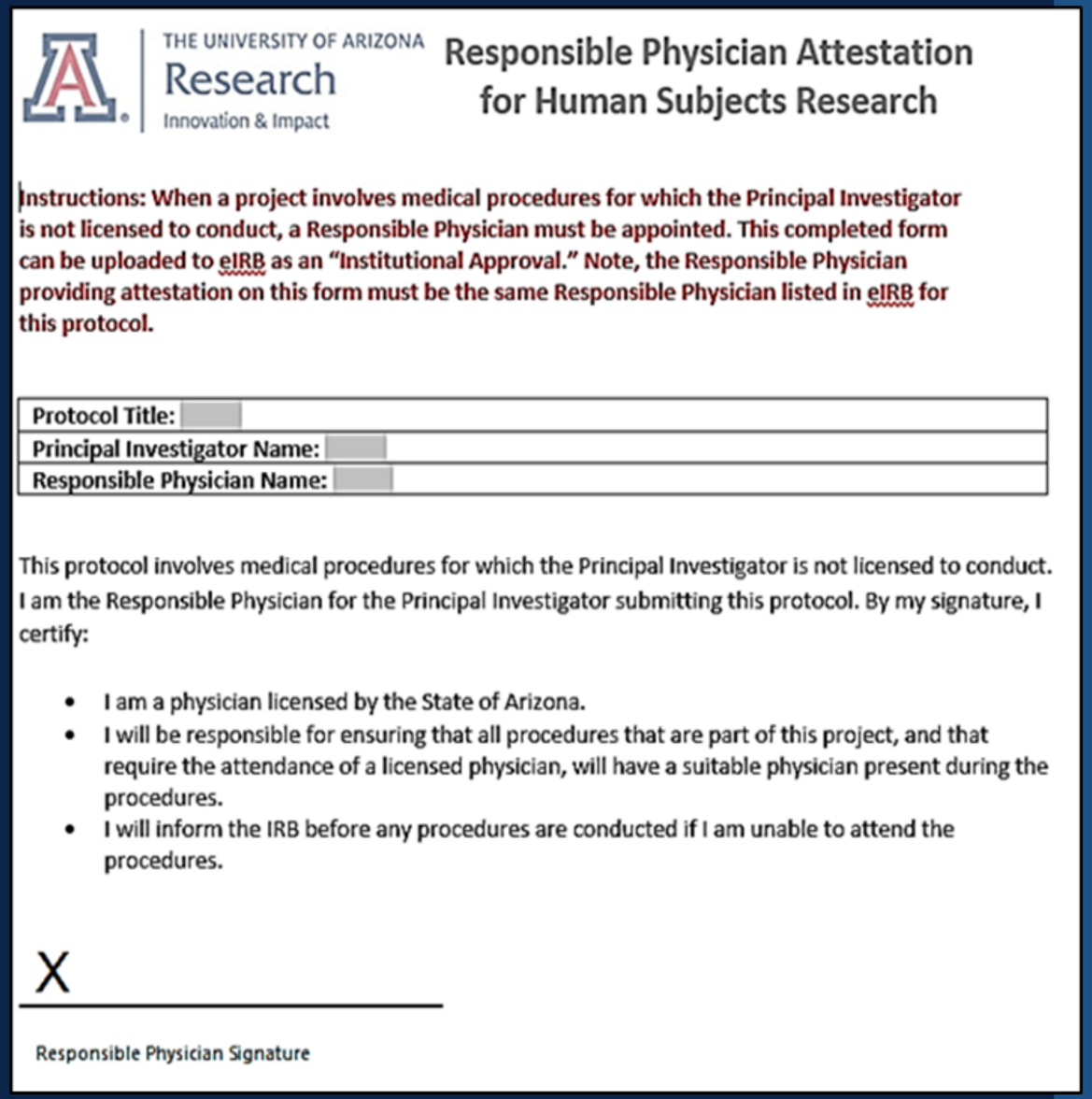

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Responsible Physician Attestation for Human Subjects Research

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

RESPONSIBLE PHYSICIAN (RP) ATTESTATION

When is a RP Needed?

- When a project involves medical procedures that the PI is not licensed to conduct
- Add the RP to the Local Study Team Members
- Submit a copy of the RP's CV
- RP must be licensed in the state of AZ

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STEP 5: OBTAIN ADDITIONAL APPROVALS

May be needed depending on the nature of your project

Common approvals:

- **UAHS/RAP Feasibility Approval:** if utilizing Banner resources
- **UACC SRC Approval:** for cancer-related projects
- **CATS Research Center Approval:** if using CATS facilities and resources
- **School District Approval:** if conducted at a public school
- **Tribal Approval:** for projects on tribal land or involving a specific Native American tribe
- **RLSS Radiation Safety Approval**
- **eDoc Number:** if industry-funded or has a single IRB mandate

Please review HSPP Guidance: Other Approvals Required for more information

COLLABORATION WITH BANNER

RESEARCH PROJECTS

RAP/UAHS Feasibility approval; UA/BH Medical Consent/PHI language; Honest Broker Data Requests; Banner Employee Addendum

NON-RESEARCH PROJECTS

IRB Protocol for Determination of Human Research Form and signed PI Attestation

ACCESS TO DATA WAREHOUSE

Banner Cerner data/CRDW; UA EPIC data/CDW

IMPORTANT! All projects conducted at Banner require IRB Approval AND Banner Approval before the activity may begin.

For information about UA & Banner collaborative activities and requirements, visit the HSPP website.

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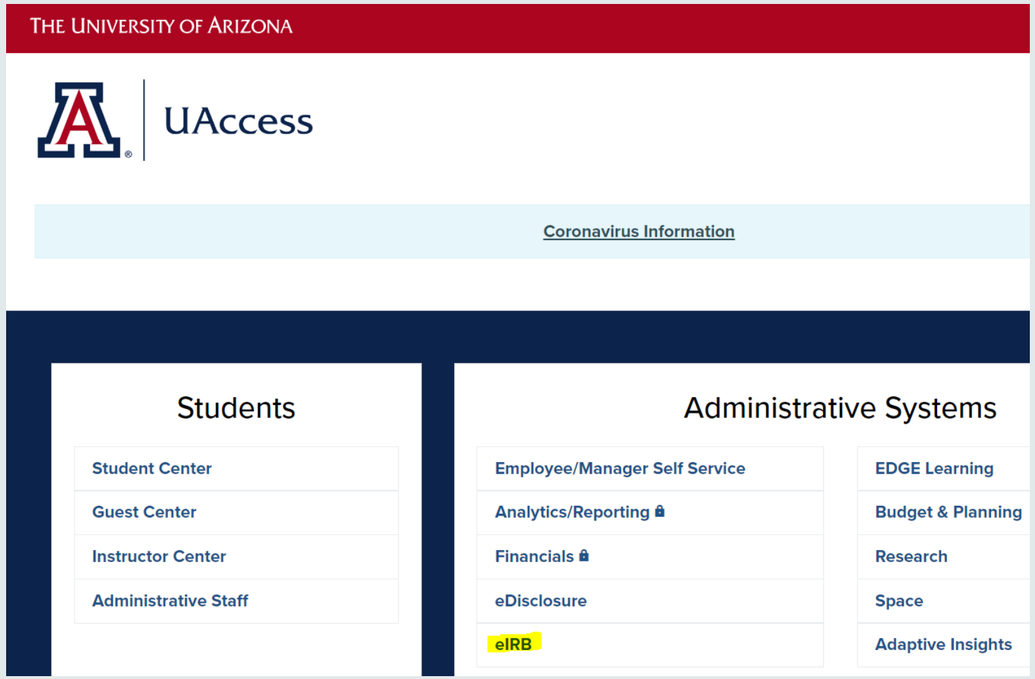
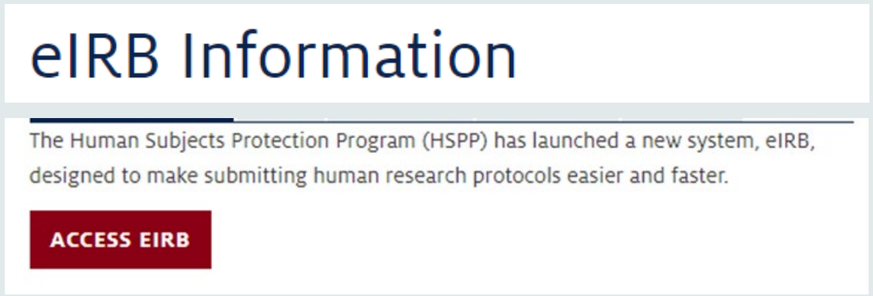
How to Submit in eIRB (Step 6 & 7)

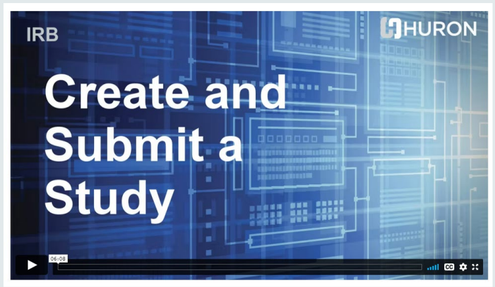
STEP 6: Prepare the Submission in eIRB

Log in to eIRB with your UA NetID and password



HSPP Website





How to Create and Submit a Single Site Submission

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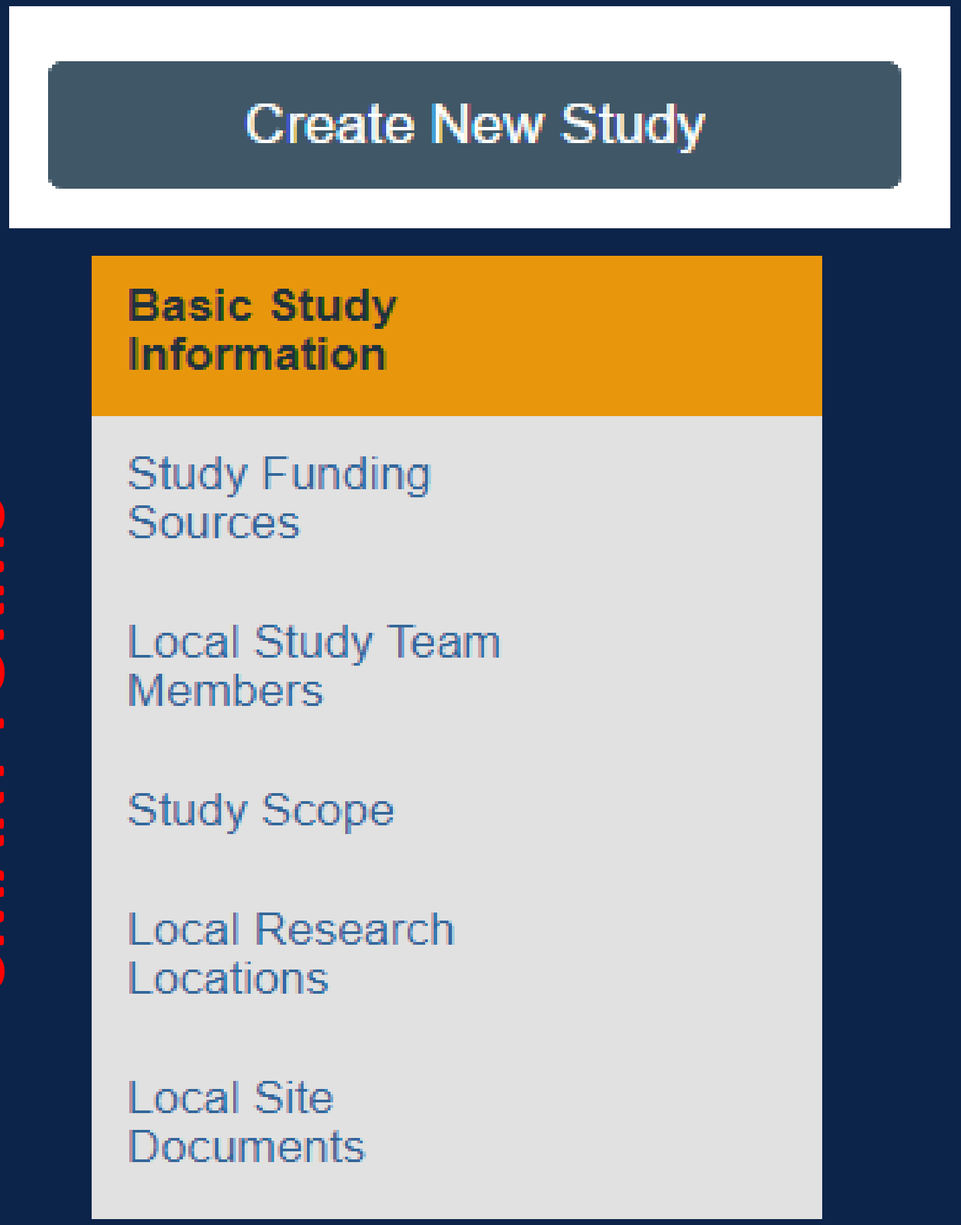
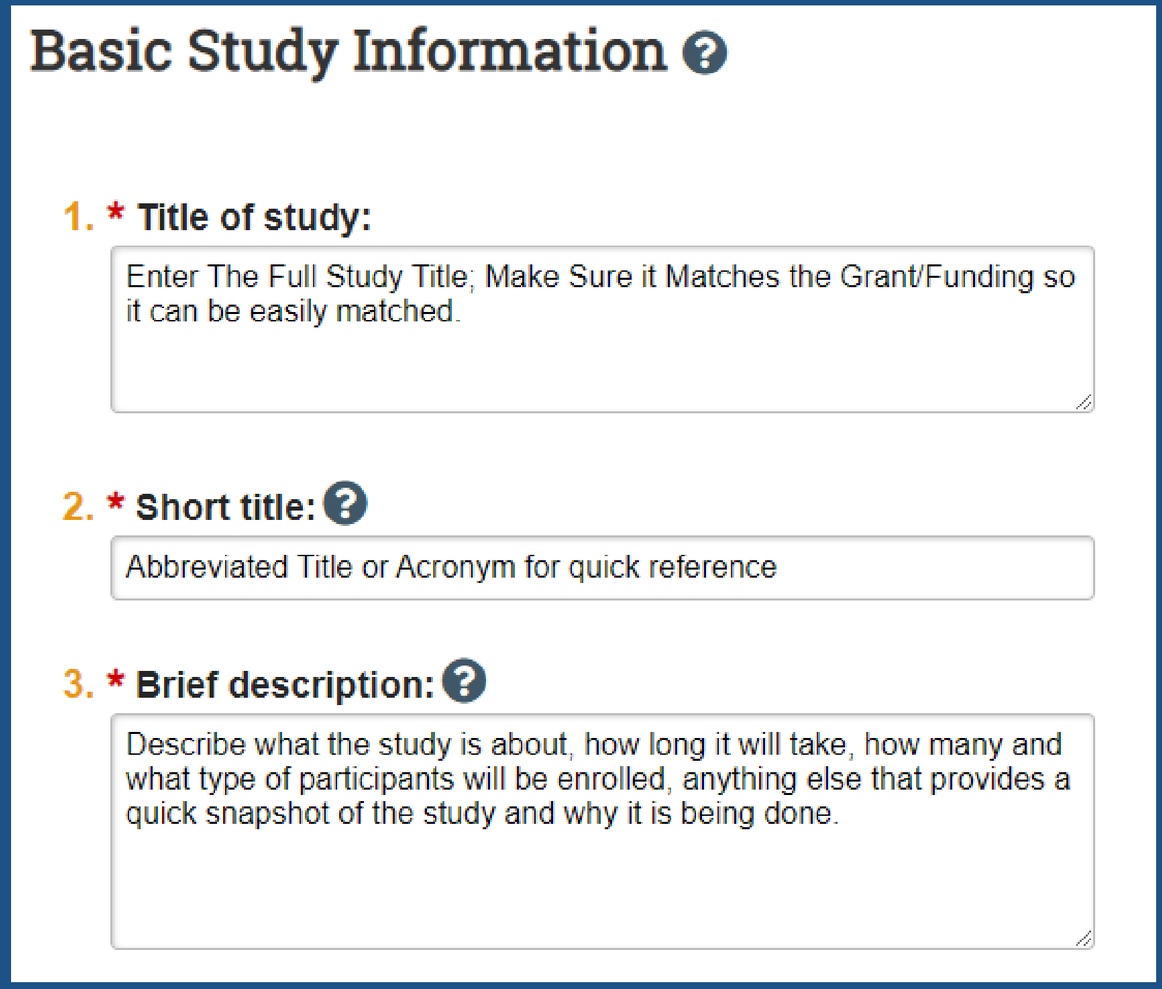
CREATE NEW STUDY, UPLOAD DOCUMENTS & ANSWER QUESTIONS IN SMART FORMS

SMART FORMS





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Basic Study Information

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

Basic Study Information

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

Study Funding Sources

Link the funding by UA Institutional Proposal/Award #

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

ID	PI	Title	Prime Sponsor	Sponsor

Study Funding Sources

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

+ Add

Very important to properly link funding in eIRB before you submit the application!

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

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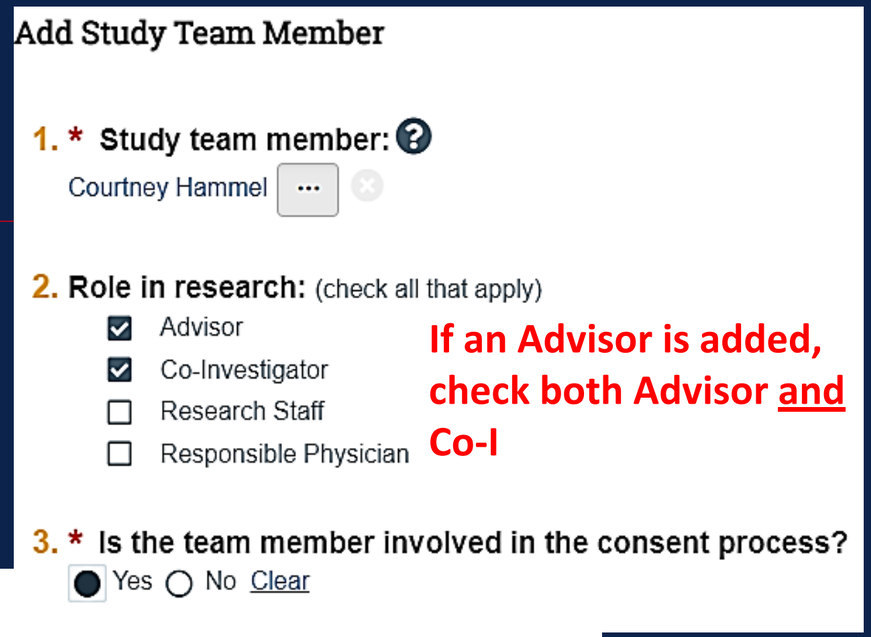
Local Study Team Members



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 personnel 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

2. External team member information:

For outside collaborators such as non-DCC Banner staff, upload Human Subjects training verification for each collaborator.

+ Add

Name	Description
There are no items to display	

For multi-site studies with outside institutions: Do NOT include information about team members at other institutions here. These individuals will be captured in the separate pSite.

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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** will open for **Drugs** and/or **Devices**

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

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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

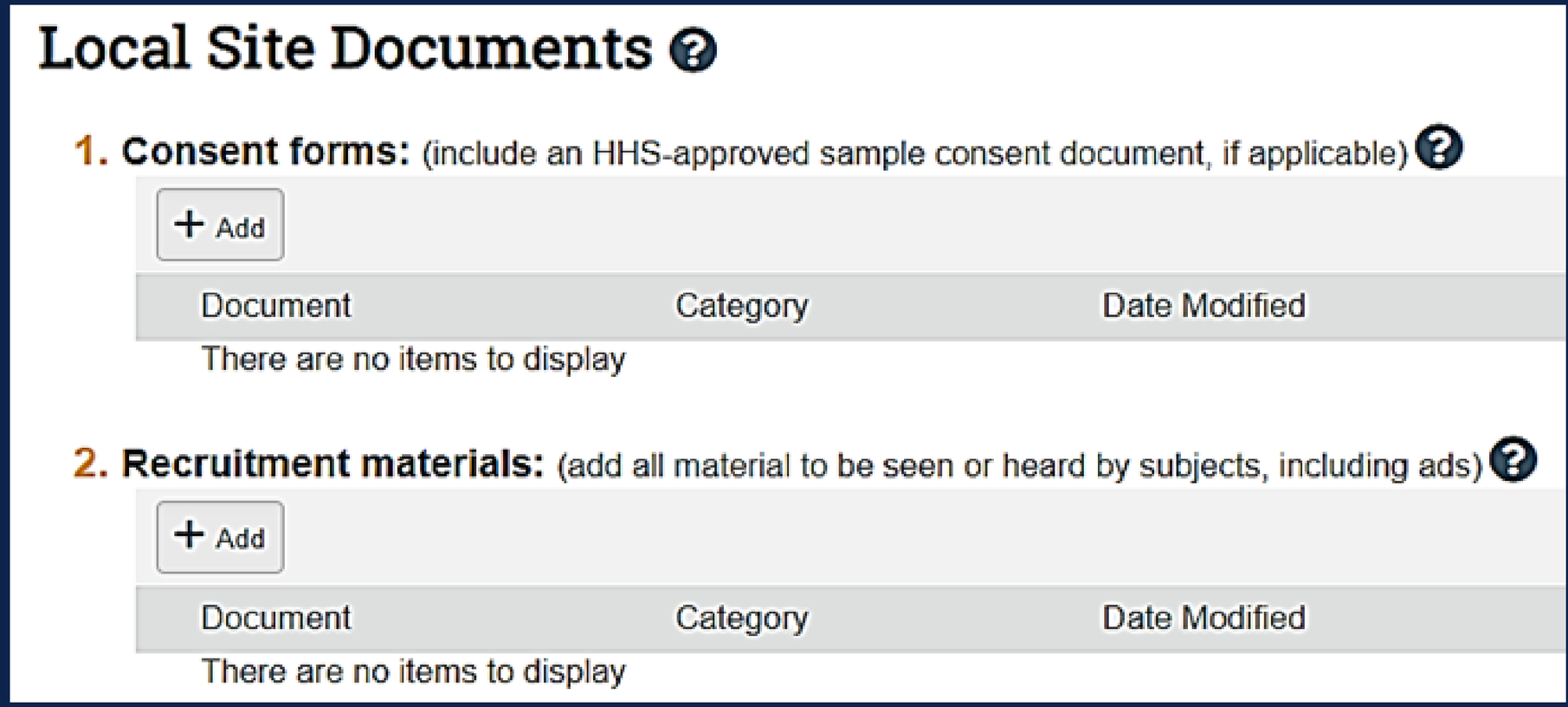
Filter by Location Name | university of arizona | Go | Clear

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

NOTE: only upload Word versions of consent forms and recruitment documents.



Local Site Documents

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

+ Add

Document	Category	Date Modified

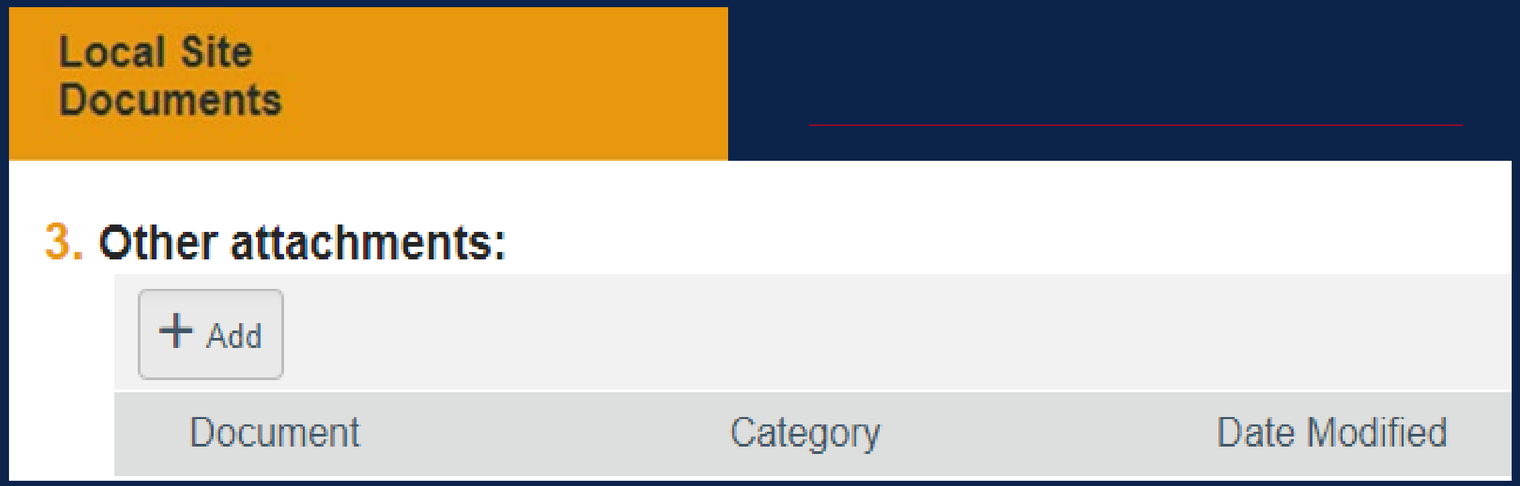
There are no items to display

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified

There are no items to display



Upload all other documents to this section including:

- PI CV or Resume
- Approvals & Attestations
- Site Authorizations (CATS, public schools, etc.)
- Data Collection Tools
- Participant Materials
- HSPP Appendices (e.g., Waiver of Consent/PHI)

IMPORTANT! Clicking the **FINISH** button does not **SUBMIT** the application. It takes you back to the study home page in eIRB.

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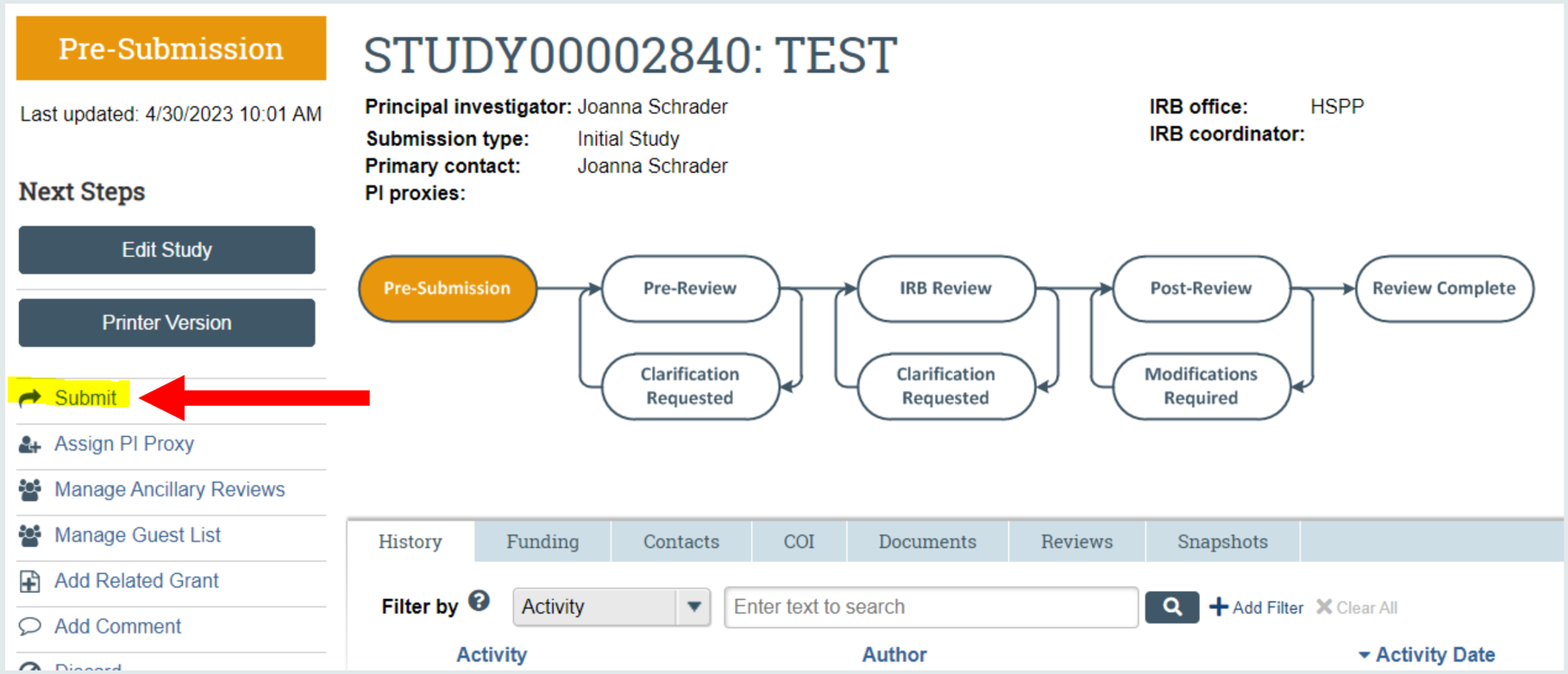
STEP 7: Submit Application In eIRB

Don’t see the Submit button? Only the PI and PI Proxy can submit.



HSSP Handout: How to Add & Remove a PI Proxy

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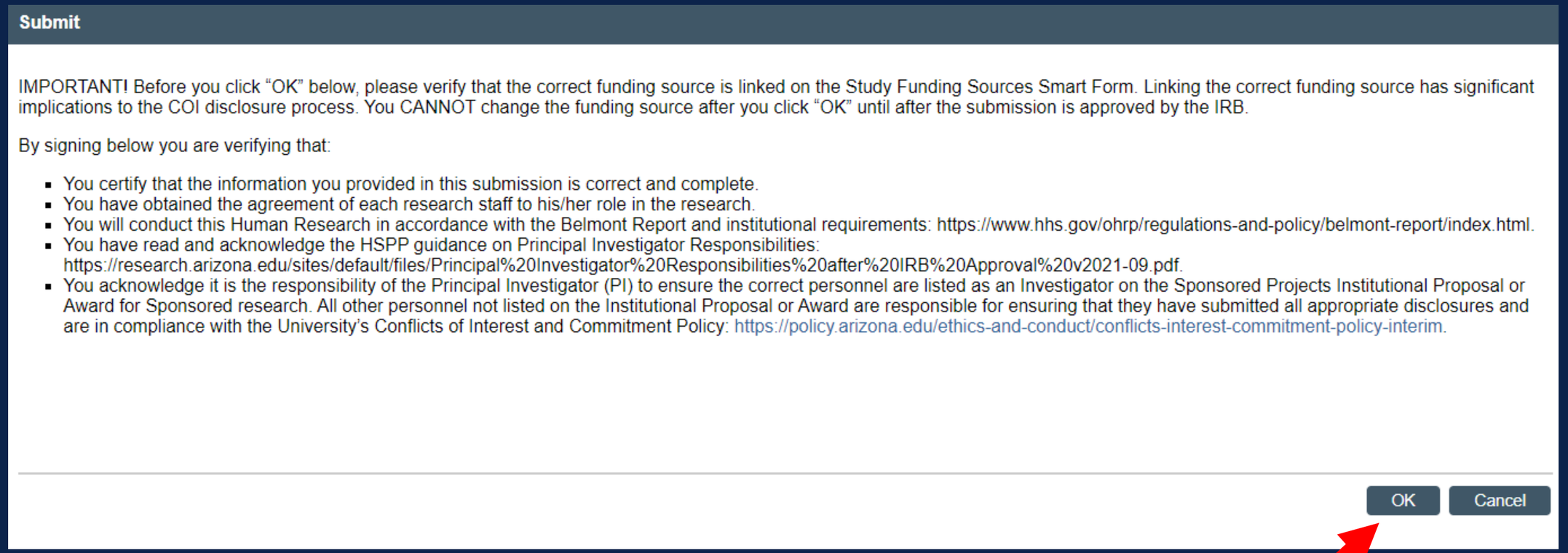

HSPP Guidance: PI Responsibilities

Click OK to Submit

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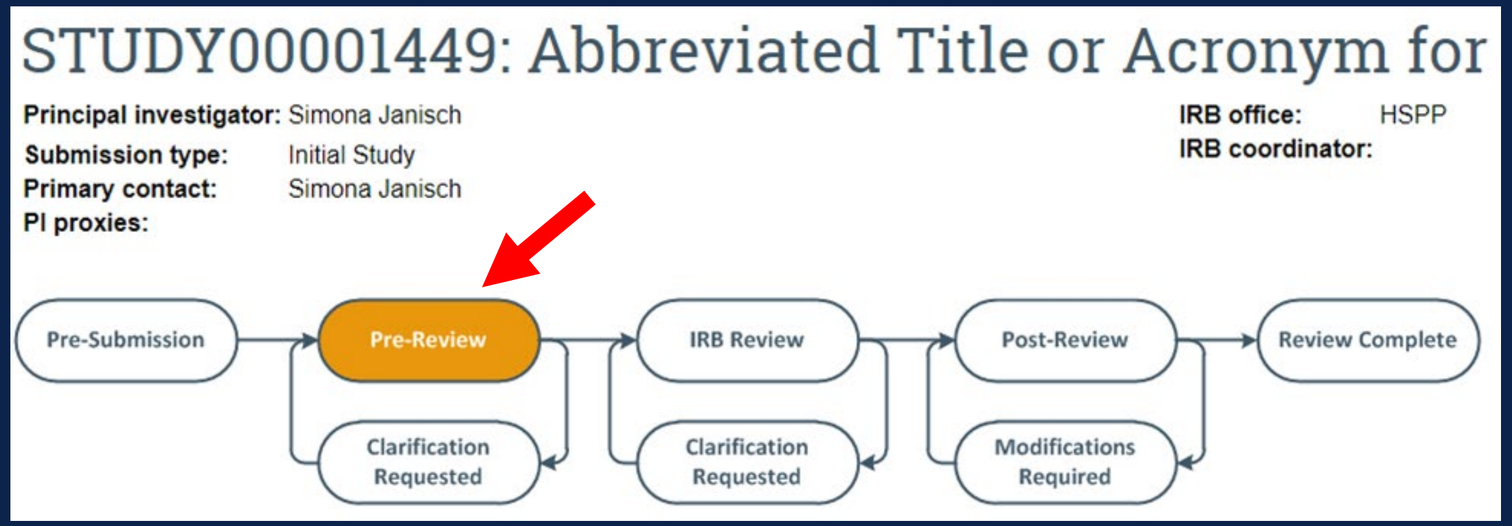
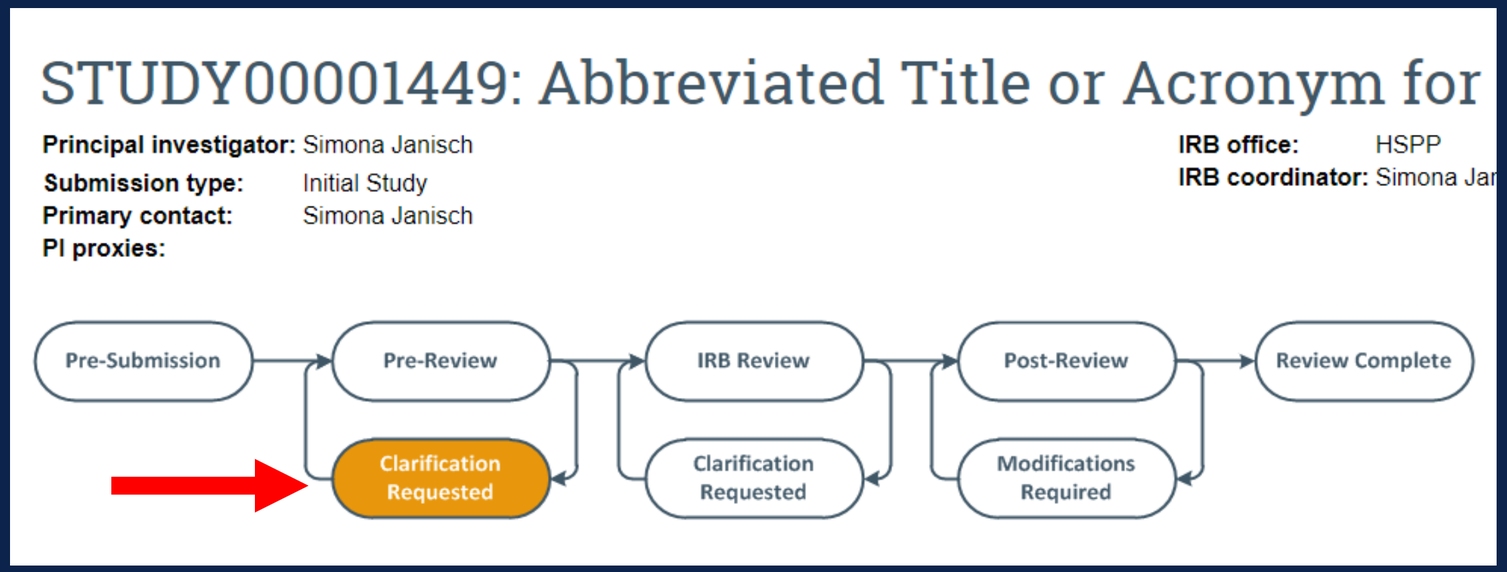


Pre-Review:

- ✓ Completeness Check (approvals, required forms, etc.), then
- ✓ Assigned for Review



Clarifications Requested:

- ✓ Returned to study team if reviewer has questions or requests changes
- ✓ Will receive an email notification

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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 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 approvals and required signatures (RAP, 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 begin until IRB approval is received!

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SUMMARY OF NEW PROJECT REQUIREMENTS

Typically needed for New Project submissions:

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

Resources

HSPP RESOURCES

- Getting Started Page
- HSPP Forms
- Access to eIRB
- eIRB ‘How To” Videos and Manuals
- HSPP Guidance Documents
- Helpful Tips

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HSPP VIRTUAL OFFICE HOURS

Every 1st & 3rd Thursday
from 10-11am

No registration is required.

Use this Zoom meeting link to join:
https://arizona.zoom.us/j/82630871478

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

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Human Subjects Protection Program (HSPP)

CONTACT INFORMATION

HSPP Department Email
vpr-irb@arizona.edu

HSPP Staff Directory

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

Demonstration