A Step-by-Step Guide to Successful IRB Submissions

Human Subjects Protection Program (HSPP)
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/hbpp-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
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
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.
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.**

**Important**

- 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](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](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](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
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](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

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
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.

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](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.
118 Request Form

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.

- **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(1) 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
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
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

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.
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 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):**

**Conflicts 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 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

**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

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
Scientific/Scholarly Review Attestation

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.

[Signature]
Advisor/Co-Investigator Attestation

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

- 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

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

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**When is a Responsible Physician Needed?**

- 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](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

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.

Log in with UA NetID & Password

https://vimeopro.com/user43881429/university-of-arizona/video/398307344
Create a New Study, Upload Documents & Answer the Questions in the Smart Forms

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

5. * Will an external IRB act as the IRB of record for this study?  
   - Yes  - No

6. * Local principal investigator:  
   - Simona Janisch

7. * Is the local PI a student or medical school resident investigator?  
   - Yes  - No

   If YES is checked, upload the Advisor Attestation with the application
8. *Attach the protocol:*

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed IRB Protocol Form.docx(0.01)</td>
<td>IRB Protocol</td>
<td>7/21/2022</td>
<td>History</td>
</tr>
<tr>
<td>Sponsor Protocol if Applicable.docx(0.01)</td>
<td>IRB Protocol</td>
<td>7/21/2022</td>
<td>History</td>
</tr>
</tbody>
</table>

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

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**Study Funding Sources**

**Study Funding Sources**

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

   *It is very important to properly link the funding in eIRB before you submit the application*
Add Study Team Member

1. * Study team member: 🌐
   - Courtney Hammel

2. Role in research: (check all that apply)
   - Advisor
   - 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: 🌐

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest Review Status</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Courtney Hammel</td>
<td>Co-Investigator</td>
<td>Pending Creation</td>
<td>yes</td>
<td><a href="mailto:courtneyolson@arizona.edu">courtneyolson@arizona.edu</a></td>
<td>520/626-9034</td>
</tr>
</tbody>
</table>

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

2. External team member information: 🌐

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
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</thead>
<tbody>
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   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**

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

<table>
<thead>
<tr>
<th>Location</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>College of Medicine Phoenix</td>
<td>HSPP</td>
<td>000-000-6000</td>
<td><a href="mailto:vpr-irb@arizona.edu">vpr-irb@arizona.edu</a></td>
</tr>
</tbody>
</table>

Filter by Location Name

- College of Medicine Phoenix
- Online
Local Site Documents

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

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

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
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

STUDY00001449: Abbreviated Title or Acronym for quick reference

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

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
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
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

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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