IRB Application – the Basics

GETTING STARTED
Is my project Human Subjects Research?

- **Research** is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

*The University of Arizona interprets generalizable to mean that results can be applied to the population at large.*

- **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.
Is my project Human Subjects Research?

- **Clinical Investigation** - Any experiment that involves a test article administered to one or more humans (except marketed drugs in the course of medical practice)

- **Test article** - Any drug (including biological product for human use), device, food/color additive, electrical product, or any other article subject to regulation

• Research, clinical research, clinical study, study, and clinical investigation are deemed synonymous
Is my project Human Subjects Research?

- Use the Determination of Human Research Form to determine if your proposed project meets the definition of human research.
- This form can be found on our Forms page [http://orcr.arizona.edu/hsp/forms](http://orcr.arizona.edu/hsp/forms).
- There are only certain circumstances in which we would need to see this form, please see the detailed list on page 1 of this document.
Your project is Human Subjects Research...

- Find the appropriate form for submission:
  - Visit our website: http://orcr.arizona.edu/hssp/forms (this link will take you straight to the forms section).
Types of submission:

- F200
- F203
- F204

These forms are found under “Application for IRB Protocols”, under the same link as the previous slide. Note: Only one form will be appropriate for your project.
The F200...

Used for **prospective** research.

Prospective investigators create and design the study, recruit subjects, and collect new data on subjects.

- Examples:
  - Surveys
  - Interventions
  - Interviews
  - Focus groups
  - Observation & interaction
  - General ongoing biological collection
The F203...

Used for **retrospective** research.

Retrospective - investigators review already existing data. Involves **no** interaction with subjects.

- **Examples:**
  - Medical records review
  - Retrospective biological analysis
  - Existing identifiable data
The F204...

Used for projects that will be **deferred** to another IRB.

Deferred- The University of Arizona IRB will not be the IRB of record. An outside IRB will take on this role.

• Examples:
  • Multi-center cooperative group research projects
  • UA researcher involved in an outside IRB-Approved study

*See “insider tip #6” for additional information on this form*
You have your form!

- Now what?
  - Download your form from our website and fill it out!
  - It’s never too early to initiate the process.
Insider Tips...

Insider tip #1
Follow the red text!

- Each application includes **red text** which is the **exact** information the IRB is looking for.
- Don’t forget to delete all red text before submission.

1) Background
   
   Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature).

2) Purpose
   
   This section should describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of the Human Research.

3) Lay Summary (approximately 400 words)
   
   Provide a brief description of the proposed research using terms that someone who is not familiar with the science or discipline can understand.

4) Resources available to conduct the Human Research
   
   Describe the resources (personnel, facilities, time, etc.) that are available to abstract and analyze data.
   
   Describe your process to ensure that all persons assisting with the study (e.g., school teachers or floor nurses) will receive appropriate training for their study-related duties and functions.

5) Study Population
   
   Provide a general description of the type of specimens and data needed to complete the proposed study (both locally and overall if multi-site). For more information, see HSPH Guidance, Enrollment and Accrual of Study Participants.

   If a power analysis is applicable to your study, include the planned number of subjects to be enrolled and projected total sample size accounting for attrition due to withdrawal, screen failures, etc.

   Provide the primary inclusion criteria and/or exclusion criteria, as applicable. Detailed criteria may reference the study protocol. See HSPH Guidance, Vulnerable Populations, to address criteria required for inclusion in the study.

   Complete and attach the relevant Appendix A, B or C if vulnerable populations (children, pregnant women, or prisoners) will be enrolled to address the relevant regulatory criteria.
Insider Tip #2

Don’t forget your additional documents!

- On the last page of every application is a list of additional “required items” and “other approvals as applicable” documents that are needed with your submission.
- As you could guess, “required” means you must submit it!
- Pay special attention to the appendices as your project may require specific regulatory documentation.

**Required Items:**
- F107: Verification of Human Subjects Training (VOTF)
- Current PI/Co-PI CVs or Resume, if not included with copy of grant application

**Other Approvals as applicable:**
- Appendix A - Children
- Appendix B - Drug/Device
- Appendix C - Multi Site Research
- Appendix D - Pregnant Women and Neonates
- Appendix E - Prisons
- Appendix F - Waiver of Consent/ PHI
- Certificate of Confidentiality
- Contract – complete or draft copy of contract including budget
- Data Collection Tools – surveys, questionnaires, diaries not included in the protocol, data abstraction form for records review
- Grant Application(s) – complete copy of grant, regardless of home institution or funding agency, and a copy of the Notice of Grant Award
- Other Approval letters (e.g., school districts, Tribe), other IRB approvals, etc.
- Protocol – including all amendments/revisions, sub- or extension studies
- Scientific Review Committee letter (for cancer related projects – AZCC SRC; other units as applicable if the unit has a scientific review committee)
- Site Authorizations for research purposes and/or access to administrative records/samples
  - External sites (such as schools, other hospitals or campuses, etc.)
  - B-UMG approval
Insider Tip #3
Where can I find the F107?

- The F107 is found on the same “forms” page, under “Additional Forms”.
- No, the F107 is not the same document as your “CITI Course Completion Certificate” (Note: we do not need your “CITI Course Completion Certificate” with your submission.)
Insider Tips...

Insider tip #4
Avoid your project being returned!

Every submission must have the following:

1. **Signatures** (PI, Advisor (if PI is a student or resident), Scientific Reviewer, and Department Review). These signatures must be obtained within 30 days of submission.

2. **Appendix F** *(if you wish to request any waivers in the consenting process). Note: Appendix F is always required with form F203.*

3. **Proper Approvals** in place, as necessary (SRC, Radiation, Global Initiative etc.).

4. No active administrative closures from the PI.

5. The most current version of the form—be sure to always download from our website.

*Subject to change*
Insider Tip #5
Consent writing help?

- See our consent templates section! ([http://orc.arizona.edu/hgap/forms](http://orc.arizona.edu/hgap/forms), under “Consent Templates”).
- Contains templates for consent and PHI (HIPAA) documents.
- Want to create your consent from scratch? Check out “C100: Elements of Consent”, to ensure your consent contains all necessary elements.
Insider Tips...

Insider tip #6
(this tip only applies to form F204, if this is not your form, proceed to the next slide)

Get a head start on your F204 submission!

- Download the institutional agreement (if necessary) and get a jumpstart on obtaining the required signature.

Download this form:

- Institutional Agreement Ceded Review - used when the UA IRB is deferring IRB oversight to another IRB.
Insider Tip #7
Guidance and Policies!

- These are meant to be followed - Read them!
- Our guidance and policies documents can help you plan your research.
- UA guidance documents are continuously being added and updated.
- Currently there are around 50 posted guidance documents posted on our website [http://orcr.arizona.edu/hspp/guidance](http://orcr.arizona.edu/hspp/guidance).
Insider Tips...

Insider tip #8
Join Our Listserv!

- For updates from the HSPP please sign-up for the HSPP listserv (http://orcr.arizona.edu/hssp/procedures).
Is the form and all additional documents ready to go?

- Submit your new project submission to our departmental email account: VPR-IRB@email.Arizona.edu.
- You will know the email went through if you receive an immediate “IRB Submission Receipt”.
- An IRB Associate will complete a “pre-review” on your submission, in which you will receive a reply for revisions- not to worry, 9 out of 10 submissions require revisions.
- Be prompt in your response! The faster you are, the faster the submission will go to the chair or committee for review!
- HSPP staff is not aware of deadlines. Please inform staff of any deadlines so we can work with you.
- Please note all revisions must be received within 30 days of the initial pre-review or as designated by your reviewer.
Checklist Items

Checklist Item #1

- Have you completed your CITI Training?

http://orcr.arizona.edu/hspptraining

- The CITI certification is valid for a four-year period, after which time refresher training must be completed.

- If you have completed CITI for another institution you will need to affiliate with the University of Arizona (UA) and complete any of the modules that are specific to the UA.
Checklist Item #2

- Is your project funded?

- All projects funded by an outside agency, must go through Sponsored Projects [http://rgw.arizona.edu/services/sponsored-projects-services](http://rgw.arizona.edu/services/sponsored-projects-services).

- The HSPP office needs either:
  - Proposal Development number, or
  - Institutional Proposal number

- This number allows us to link your human subjects application to Sponsored Projects
Checklist Items

Checklist Item #3

- Is your project Industry Sponsored? If so, the following fees apply:
  - Initial, Full Board – $2,500
  - Initial, Expedited – $1,000
  - Initial, Deferral to a Commercial IRB – $1,000
- Fees are applicable, regardless of whether the project is actually initiated.
- Investigators and/or departments are responsible for the payment of this fee regardless of reimbursement from the sponsor.
- For submitting payment, please see the Guidance on Fees
Checklist Item #4

- Are you traveling abroad to conduct your research?
- Please be sure to obtain travel authorization from Global Initiatives Office.
- For more information, please contact Global Initiatives
  https://global.arizona.edu/.
Checklist Items

Checklist Item #5

- Make sure to have your site authorizations in place!

- Banner - Required if using Banner facilities, data, and patients (see [http://research.ahsc.arizona.edu/](http://research.ahsc.arizona.edu/) for more details).

- SRC - Required for any projects using cancer patients or facilities.

- Radiation - Required regardless if the radiation device is approved and used as standard of care.

- School Approval - Research being conducted at a school requires approval from the district, principal, and teacher, if applicable.

- Private locations also require written site authorization.
Learn more about your IRB!

**Organizational Structure**

- **Senior Vice President for Research and Discovery**: Kimberly Espy, PhD
- **Institutional Official**: Jennifer Barton, PhD
- **IRB Director**: Mariette Marsh, MPA, CIP
- **IRB Manager**: Andi Encinas, CIP
- **IRB Coordinator (Full Committee)**: Alixx Encinas, MS
- **IRB Associates (Expedite and Exempt)**: Amber Abeyta, Gina Fimbres, and Christine Melton-Lopez
- **IRB Chairs**: Peter Lichtenthal, MD, Thomas Park, PhD, James Goodwin, PhD, Ida (Ki) Moore, DNP, and David Raichlen, PhD

**Office for the Responsible Conduct of Research**
Learn more about your IRB!

Who reviews projects for Banner - University Medical Center?

- The University of Arizona IRB reviews for all UA faculty, physicians, students, or staff
  - This includes Fellows and Residents

- Review is inclusive of the three Banner hospitals
  - Banner - University Medical Center Tucson
  - Banner - University Medical Center South Campus
  - Banner - University Medical Center Phoenix
Learn more about your IRB!

What are the types of review?

- **Exempt** (Chair approval)  ➔  low risk
- **Expedited** (Chair approval)  ➔  minimal risk (no more risk than everyday life)
- **Full Committee** (Committee Approval)  ➔  greater than minimal risk

- Level of review will be determined once the complete project is submitted to the HSPP.
- Chairs review anywhere from every day to once a week.
- Committee meets on the second and fourth Tuesday of every month.
You have your IRB Approval, now what?

Begin your research! But keep in mind…

- After your study is approved, any changes you wish to make must be submitted as an amendment prior to implementation.
- Exempt studies typically do not require amendments unless the change is increasing the risk. Review the Exempt Guidance for instances that would require an amendment.
- Expedited and Full Committee projects must have an annual renewal submitted and approved before the expiration date.
Confused? Want to talk?

- We love to talk to our investigators!
- Reach out to us – send an email to our departmental email
- Whenever you are on our website, our contact Information is always found on the right-hand side Under “HSPP Contact”.