IRB Boot Camp

Training aimed for those new to research and the IRB process at the University of Florida

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Learning Objectives

- Who is the IRB?
- Getting started with the IRB process and myIRB
- Research Review Types
- Strong IRB submissions and common mistakes
- Tracking Progress and Responding to Reviewers in myIRB
- Other IRB submission Types
- Contacting the IRB
- Additional Resources
Who is the IRB?

- Ethics Committee
  - The University of Florida Institutional Review Boards (IRBs) are charged with protecting the rights and welfare of participants in human subject research studies. UF IRBs review all research involving human subjects to ensure the welfare and rights of research participants are protected as mandated by federal and state laws, local policies, and ethical principles.

- UF IRBs:
  - IRB-01 - broad category of ‘medical’ research
  - IRB-02 - social, behavioral, and educational research
  - IRB-04 - Western IRB (Industry Sponsored)

- The IRB is one reviewing body of UF Research
  - Other Committees that Review Research
Special Guidance:

COVID-19 and Conducting Human Subjects Research

The University of Florida Institutional Review Boards (IRBs) are charged with protecting the rights and welfare of participants in clinical trials and other human subjects research studies. UF IRBs review all research involving human subjects to ensure the welfare and rights of research participants are protected as mandated by federal and state laws, local policies, and ethical principles. Faculty, staff, and students at the University of Florida, UF Health, and/or the North Florida/South Georgia Veteran's Health System (NF/SGVHS) must receive approval for any human subjects research from a UF IRB before conducting the research. This includes research conducted off-site by University faculty and staff when acting as University employees or in connection with their University affiliation. This website is aimed at any University of Florida faculty members, students, and/or staff members who conduct research with human subjects or assist in such studies. UF IRBs only review research from researchers who have a formal affiliation with UF, UF Health, or the NF/SGVHS.

Please submit your research to the relevant IRB Office below:

- IRB 01 — Gainesville HSC
- IRB 02 — Gainesville Campus
- WIRB
Getting Started

- Register for myIRB
  - Registration instructions
  - Remember to use VPN!
  - Researcher Manual: A step by step guide for myIRB.
  - UF myIRB Sandbox to practice IRB submissions
  - Contact myIRB Technical Assistance by email at myirbtech-l@lists.ufl.edu

- Required Training
  - IRB 803 training is required for all researchers and study staff
  - Other trainings that someone else might require you complete:
    - Good Clinical Practice
    - HIPAA Training
Approved Human Research Roles

What roles are staff eligible to do?

<table>
<thead>
<tr>
<th>Investigator type</th>
<th>Minimal Risk</th>
<th>Greater than Minimal Risk</th>
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<td>PI</td>
<td>Evaluating Adverse Events</td>
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<td>3. UF\Shands Students – Contingent on having a faculty mentor*</td>
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<td>a. Fellows &amp; Post Docs</td>
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<td>b. *Medical Residents</td>
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<td>c. *Medical Students at UF</td>
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<td>d. *Graduate Students at UF</td>
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<td>e. *Undergraduate Students enrolled at UF</td>
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<td>f. *High School Students enrolled at UF or within a UF sanctioned program (eg. CPet)</td>
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<td>4. External (non-UF or Shands) Faculty, Staff, or Students</td>
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<td>a. Volunteers (not faculty, staff or students of UF or Shands)</td>
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<td>b. *Visiting students currently enrolled at a non-UF college or university</td>
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<td>c. High School students (must be at least 16 years old)</td>
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Research Review Types

- Non-Human
- Exempt
- Data/Chart Review
- Expedited
- Full Board
- Tissue and/or Data Banks

Selecting the Requested Review Type
Non-Human

- Choose a non-human review if you are receiving *de-identified* samples or data for analysis.

- *The data cannot contain any of the HIPAA identifiers including dates.*

- If the data is coded or if the person giving you the data or samples has any identifiers a *Confidentiality Agreement* between the PI and the person supplying the data or samples is required.

- *A list of all variables is required* for the reviewer to determine if the data is de-identified or coded and if a confidentiality agreement is required.

- [Non-human Research Guideline](#)
Exempt

- Research team has contact with subjects or personally identifiable data, but risks to subjects are minimal. Typically either educational, observational, surveys, or data chart reviews. (Data/Chart reviews follow a different pathway in myIRB).

- Consent process may be required if there will be interactions with participants. For surveys, a waiver of documentation of consent is most often used. Upload waiver of documentation on top of survey on Data Collection page.

- Do not submit record reviews using this path.

- Exempt Submissions Guideline
Data/Chart Review

- Choose this review type if you are looking at records, data, or specimens. You can examine PHI with this review type. This review type branches down two paths: the exempt review and the expedited review. When you answer the questions, myIRB will present the appropriate path.

  - Exempt Data/Chart Review
    - Most record reviews will follow this path. You can access data, keep a link to the data, and work retrospectively and prospectively. You can include tissue samples that have no links to identifiers or are publicly available. HIPAA regulations do apply when keeping a link. The IRB will evaluate your de-identification plan when you do keep a link and the practicability of your request for a waiver.

  - Expedited Data/Chart Review
    - If you are working with identifiable tissue that is not publicly available, your record review will be approved under an expedited category.
Expedited

- Used for research involving no more than minimal risk, and for minor changes in approved research.

- Written informed consent may be required unless IRB approves a request to waive consent or documentation of consent.

- Common submissions include:
  - Collection of blood samples
  - Collection of other biological specimens for research purposes through noninvasive means
  - Collection of data through noninvasive procedures routinely used in clinical practice
  - Performing tasks that are little to no risk

- Expedited Submissions Guideline
Greater than minimal risk research. Includes not only experimental medical research (drugs/devices), but also research that collects identifiable information that could adversely affect the subject’s insurability, employability, reputation, etc if accidentally disclosed; psychological research that could adversely affect subject’s mental/emotional well being; etc.

Written informed consent

Common submissions include:

- Drug or device studies where a subject’s care is altered due to their participation
- Studies that involve the collection of sensitive information including drug use or sexual abuse
Tissue/Data Banks

- **The Banking Only** review type if for any local bank (tissue, data, future contact registries) and any non-local bank that is not part of another study (banking only).

- *At UF all local banks must be submitted as stand-alone projects, and must use this path.*

- Use the banking consent template.

- Banks kept externally can be added to another protocol. A Banking Consent Addendum can then be added to the consent.

- **Banks- Tissue, Data, Registries Guideline**
Strong IRB Submissions

- Protocol Document or Study Description (for exempt studies)
  - Clear recruitment strategy and study procedures.
  - Consider project feasibility.
- Informed Consent Forms
  - IRB-01 ICF Templates
  - IRB-02 ICF Templates
  - Tip: All consent documents should be written at an 8\textsuperscript{th} grade reading level. A Glossary of Lay Terms for Use in Informed Consent Forms is available
- Appropriately identify vulnerable populations
- Any and all participant-facing study materials must be submitted to the IRB for approval prior to implementation.
- Consistency throughout the study protocol, myIRB smartforms, and other study documents.
- myIRB Acceptability Standards
The status of the study will always show under “Current State” on the top left-hand corner.
Once your study has been submitted to the IRB office, the review process will begin. Your study could be in the State:

- **IRB Staff Review**: IRB staff pre-review process. You may receive questions you need to respond to before it moves past this state. No action is required by you when the study is in this state.

- **In Exempt Review**: Study has been assigned to an exempt reviewer. No action is required by you when the study is in this state.

- **In Expedited Review**: Study has been assigned to an expedited reviewer. No action is required by you when the study is in this state.

- **Assigned to IRB Meeting**: Study has been assigned to a meeting and reviewers. You may receive questions from the reviewers. In order to make changes you will need to contact the IRB office to request removal from agenda, and the IRB office will push the study back to you in a state you can edit.

- **Awaiting Correspondence**: The submission has been approved by a reviewer and is waiting for an IRB staff member to finalize the letter and documents. **Do not start study related activities until the state is changed to approved and you have received your approval letter.**
Responding to Reviewer Notes

- Edit Study to see notes and respond. Some notes require that you edit the smartforms with the requested changes, others might require information only. **Note:** The responses do not remain once the submission is approved. If a change is required, you must edit the study for the change to save.

- Options:
  - Information only
  - Change Requested Completed
  - Change Request Not Completed
Responding to Reviewer Notes

- To see all comments click “Next” at the top which will take you to the next smartform page with a reviewer comment.
- Check Hide/Show Errors to see if any pages have not been addressed.
- Note: The name assigned to the reviewer comment will be an IRB Office staff member, but the comment is often made by an IRB reviewer. This is done to keep reviewer comments anonymous.
Responding to Reviewer Notes

The History tab will often have attached documents with reviewer comments. Download the document and reply to each reviewer comment before resubmitting to the IRB.
Other IRB Submission Types

- **Revisions**
  - Federal regulations require that changes to IRB approved research may not occur without prior IRB review and approval, "no matter how minor" unless a change is required to eliminate an apparent immediate hazard to subjects.

- **Event Reporting**
  - Serious and Unexpected and Related or the Relationship is "more likely than not" adverse events must be reported to the IRB within 5 days of the PI becoming aware of the event. Again, this requirement includes both local and non-local adverse events.
  - **Major Protocol Deviations** have the potential to negatively impact: the rights and welfare of the research subject, subject safety (increase risks and/or decrease benefits to study subjects) the subject’s willingness to continue to participate in the study, or integrity of research data.

- **Regulatory Noncompliance**
- **Unanticipated Problem**
Other IRB Submission Types

- **Continuing Review**
  - An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year.
  - Tip: When reporting enrollment, review [Study Subject Definitions Guideline](#).

- **Status Report**
  - For minimal risk protocols approved under an “Expedited” category, in most instances the IRB will not require continuing review, but instead will require an every 3 year Status Report.
  - Continuing review has also been eliminated for research that has progressed to the point that it involves only data analysis or “accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.”

- **Study Closure**
  - [Closed or Closed to Accrual Studies](#)
  - [Retention of Signed Informed Consent Forms](#)
  - [Investigator Requirements for Retaining Research Data](#)
  - [Destruction of Data](#)
Contacting the IRB

- Contact us through our [website](#) or directly through myIRB.
- **IRB-01**
  - Peter Iafrate, Pharm.D, Chair
  - Telephone: (352) 273-9600
- **IRB-02**
  - Ira S. Fischler, PhD, Chair
  - Telephone: (352) 392-0433
- **IRB Education**
  - Tanya V. Aranca, IRB Educator
  - Telephone: (352) 273-9603
  - Email: [arancat08@ufl.edu](mailto:arancat08@ufl.edu)
Resources

- Investigator Guidelines
- IRB listserv
  - Newsletter
- Alphabetical Listing of IRB-01 Forms including: Confidentiality Agreement for Data and/or Specimens, Documentation Forms for Continuing Review for sIRB Studies Only (UF IRB of record), Emergency Use documents, and more.
- Single IRB (sIRB)
- Quality vs. Research
  - QIPR
- External Faculty Joining UF Guideline
- Documentation Tools including: Note to File Template, Data De-identification Attestation Templates, and more.
Questions?