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

irb.ufl.edu


UF Institutional Review Board
Protecting the rights and welfare of human research subjects
Search UF Web
COVID-19 Resources
IRB Home
myIRB
IRB–01
IRB–02
WIRB
sIRB
Contact Us
UF sIRB Request
University of Florida Federalwide Assurance
University of Florida IRB COVID–19 Response
Required Training for UF IRBs
Definition of a Human Subject Research
HIPAA Home
UF QI Program
Report Noncompliance
Web–Based Submission Tracking for Paper Studies
Research Data is Institutional Property
IRB Policies, Guidelines and Guidances
IRB Home
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 web site is aimed at any University of Florida faculty members, students, and/or staff members who conduct research with human subjects or assists in such studies. UF IRBs only review research from researchers who have a formal affiliation with UF, UF Health, or the NF/SGVHS.
Association for the Accreditation of Human Research Protection Programs, Inc.
Full Accreditation
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?

Investigator type	Minimal Risk					Greater than Minimal Risk				
	PI	Evaluating Adverse Events	EPIC EMR Access	Access to data	Obtain Consent	PI	Evaluating Adverse Events	EPIC EMR Access	Access to data	Obtain Consent
3. UF\Shands Students – Contingent on having a faculty mentor*.										
a. Fellows & Post Docs										
b. *Medical Residents										Case-by-case Basis
c. *Medical Students at UF										
d. *Graduate Students at UF										Case-by-case Basis
e. *Undergraduate Students enrolled at UF			Proof of HIPAA Training					Proof of HIPAA Training		
f. *High School Students enrolled at UF or within a UF sanctioned program (eg. CPet)										
4. External (non-UF or Shands) Faculty, Staff, or Students										
a. Volunteers (not faculty, staff or students of UF or Shands)			Proof of HIPAA Training					Proof of HIPAA Training		
b. +Visiting students currently enrolled at a non-UF college or university	Case-by-case Basis	Case-by-case Basis	Case-by-case Basis					Case-by-case Basis		
c. High School students (must be at least 16 years old)				De-Identified only					De-Identified only	

http://irb.ufl.edu/wp-content/uploads/Approved-Human-Research-Roles-Final.pdf

Data, Data, Data!

- HIPAA Identifiers
- **Private Health Information**
- **Anonymous** – identity of subjects is not known at any time
- **Coded** – per OHRP, identifying information has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens
- **De-identified** – research data/samples have been stripped on any and all identifiers (including dates and zip codes)

Make sure you are using the correct term when describing study procedures, data collection, and data analysis.

Research Review Types

- Many researchers chase after a particular approval. Instead, IRB is there to help you choose the most appropriate review type.
  - All minimal risk studies now submit status reports instead of continuing review.

- ***Only the IRB may make the final determination that proposed research meets the regulatory criteria.***
  - 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 (although, 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 and it must contain all elements of informed consent. Upload waiver of documentation on top of survey on Data Collection page.
  - No where in the regulations do they talk about “verbal consent”; instead you must obtain IRB approval for a waiver of documentation of consent
    - The consent process is still done but no one signs anything.
    - Common in anonymous online survey and studies that involve interviews only.
- ***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. Data/Chart Reviews 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.
- If obtaining or sharing a Limited Data Set outside the covered entity, you must request a Data Use Agreement (DUA). DUAs are handled by the Office of Clinical Research and are submitted for review via UFIRST: https://research.ufl.edu/ufirst.html

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
  - Preforming tasks that are little to no risk
- Expedited Submissions Guideline

Full Board

- 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

Study Title and Staff Smartform

- Please include a brief summary or abstract for your study.
- The Principal Investigator must have “Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations”
- Remember to check Approved Human Research Roles
  - Medical Residents and students are *required* to have a faculty mentor
- Pay attention to who is obtaining consent

A Template for Success

- Protocol Template or Study Description (for exempt studies)
  - Clear recruitment strategy and study procedures
  - Consider project feasibility
- Informed Consent Forms
  - IRB-01 ICF Templates
    - Standardized Text for Informed Consent Forms
  - IRB-02 ICF Templates
    - Checklist: http://irb.ufl.edu/irb02/informed-consent-instructions-procedures/chklist.html
    - Common Problems with informed consent: http://irb.ufl.edu/irb02/informed-consent-instructions-procedures/ifcprob.html
  - All consent documents should be written at an 8th grade reading level. A Glossary of Lay Terms for Use in Informed Consent Forms is available

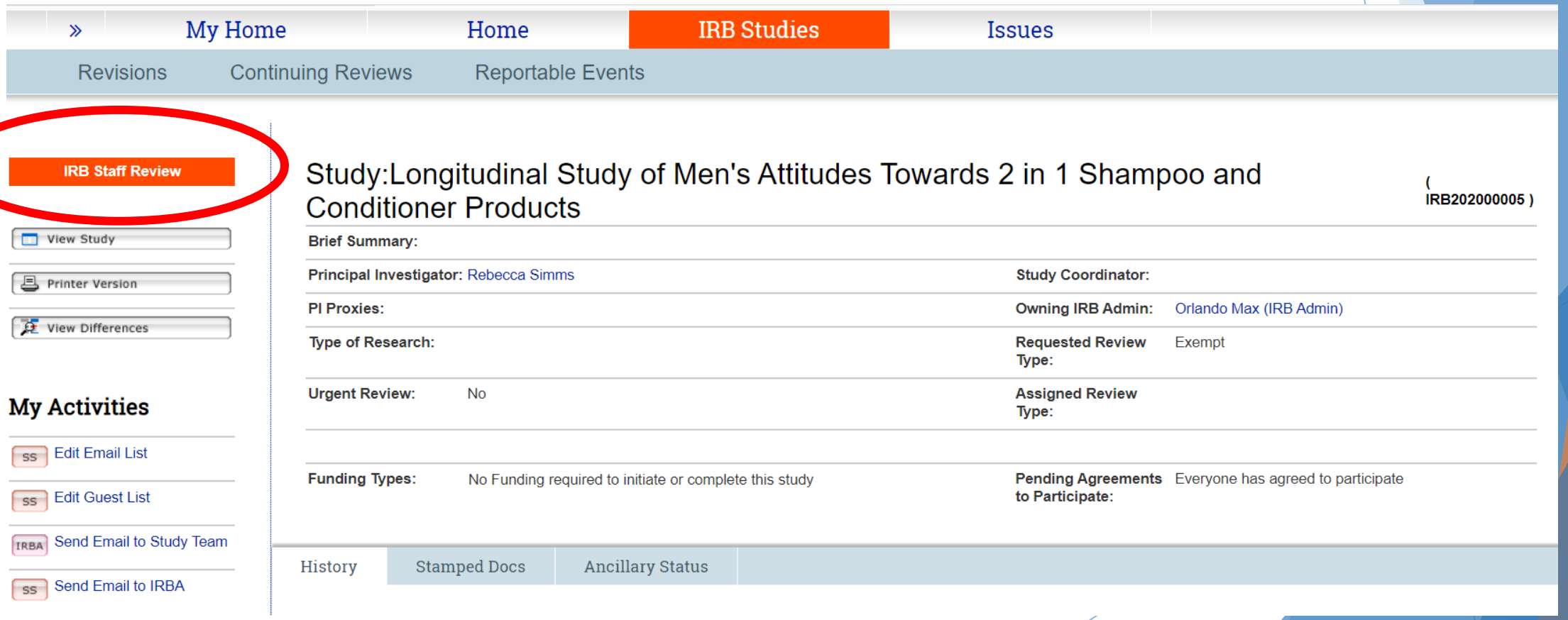
Incomplete and Inconsistent responses on myIRB Smartforms and Study Documents

- Read the questions answer them thoroughly and thoughtfully. *Be sure to answer the entire question in myIRB.*
- Avoid skipping questions in the Smartforms.
- Appropriately identify vulnerable populations
- Any and all participant-facing study materials must be submitted to the IRB for approval prior to implementation.
- myIRB Acceptability Standards
  - Make sure you are consistent throughout all study documents including but not limited to the protocol, ICF, myIRB smartforms, etc.
    - Enrollment numbers in your protocol should match Enrollment Details and your ICF.
    - Ages and inclusion/exclusion criteria should be the same in your protocol and on the Subject Description Smart Form.
    - Check your attachments before you submit.
    - Don’t get burned by “Copy and Paste”.

Questions so far?

Tracking Study Progress myIRB

- The status of the study will always show under “Current State” on the top left-hand corner.

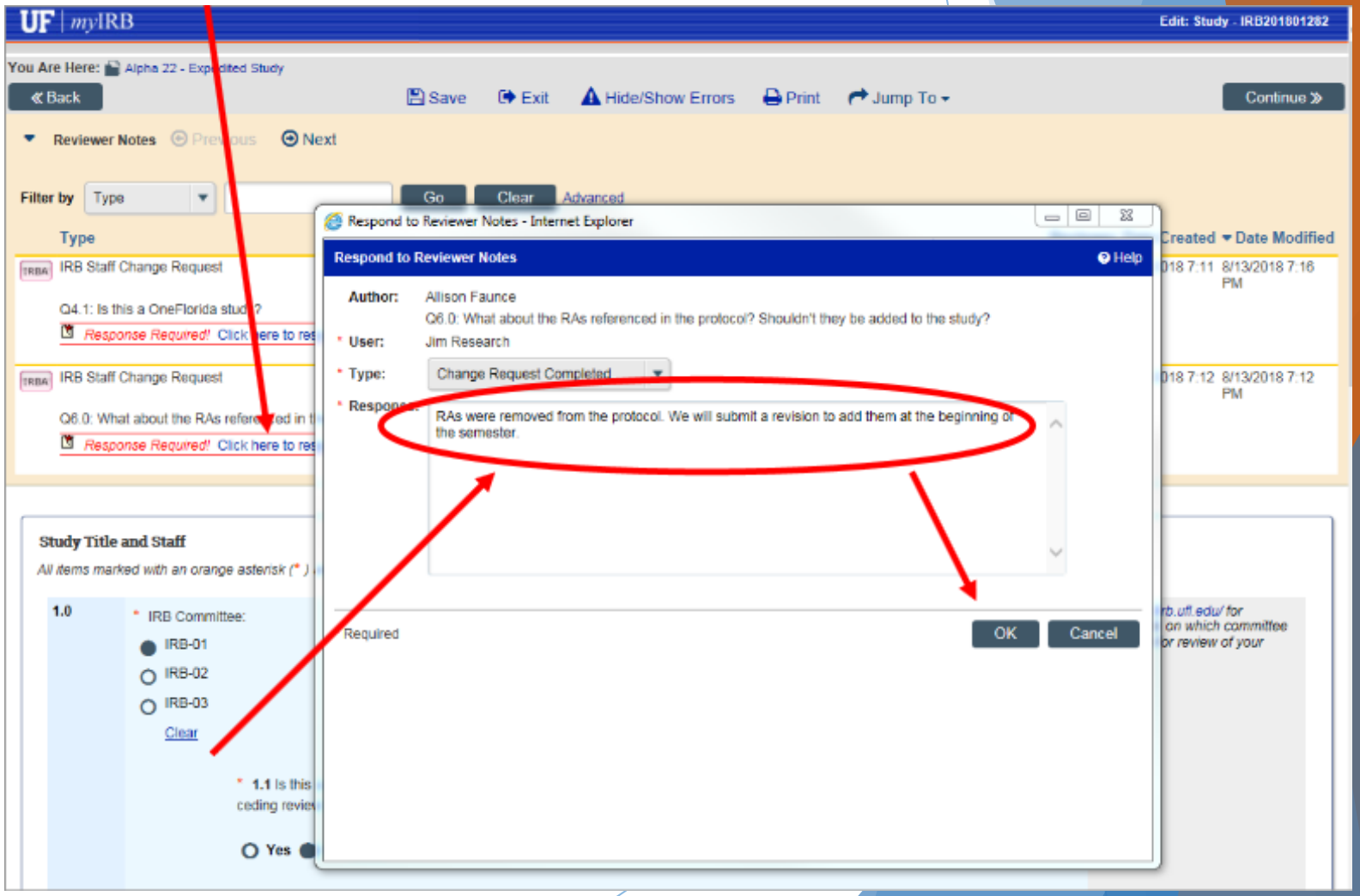


Tracking Study Progress myIRB

- 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.*

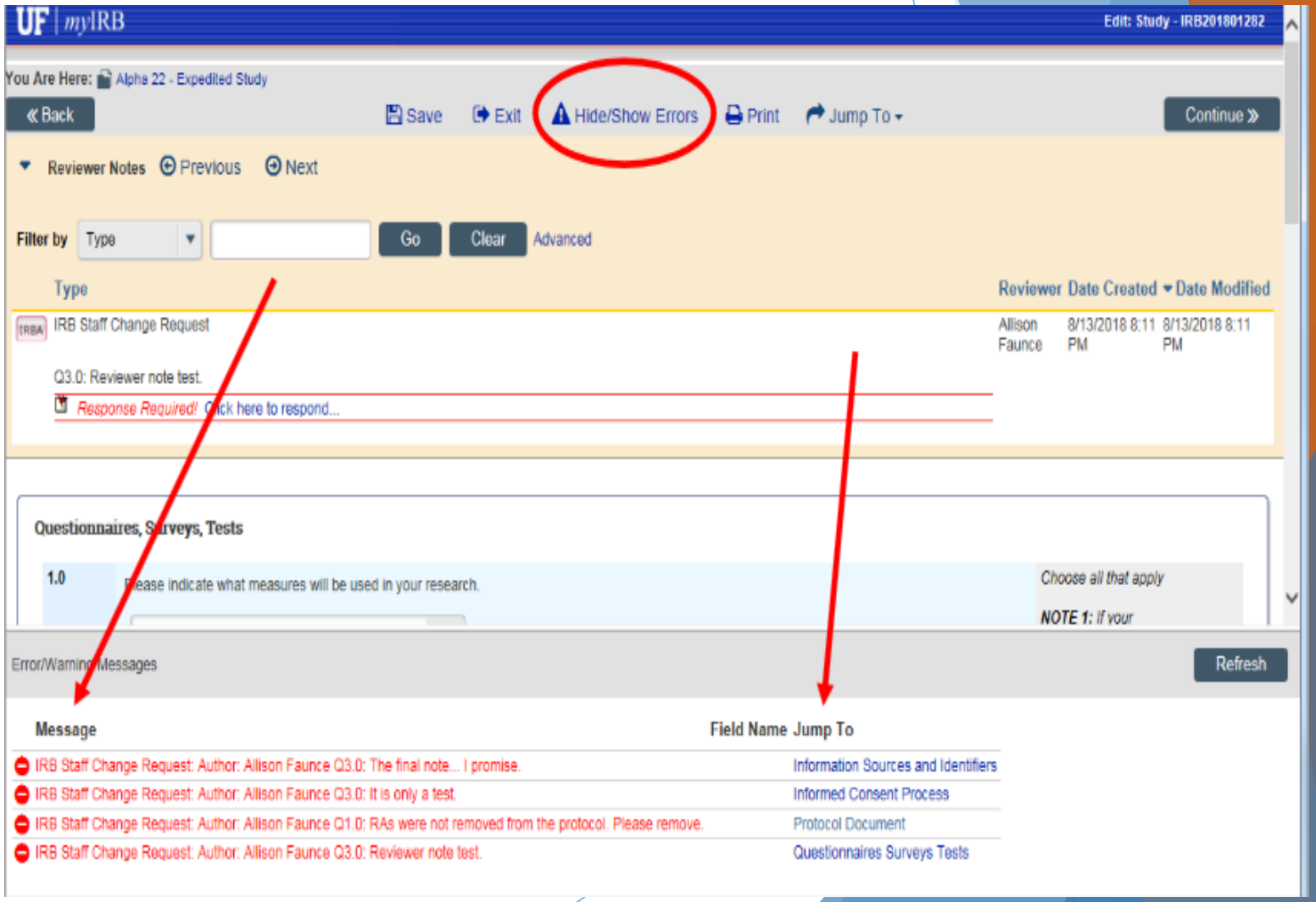
Responding to Reviewer Notes

- 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



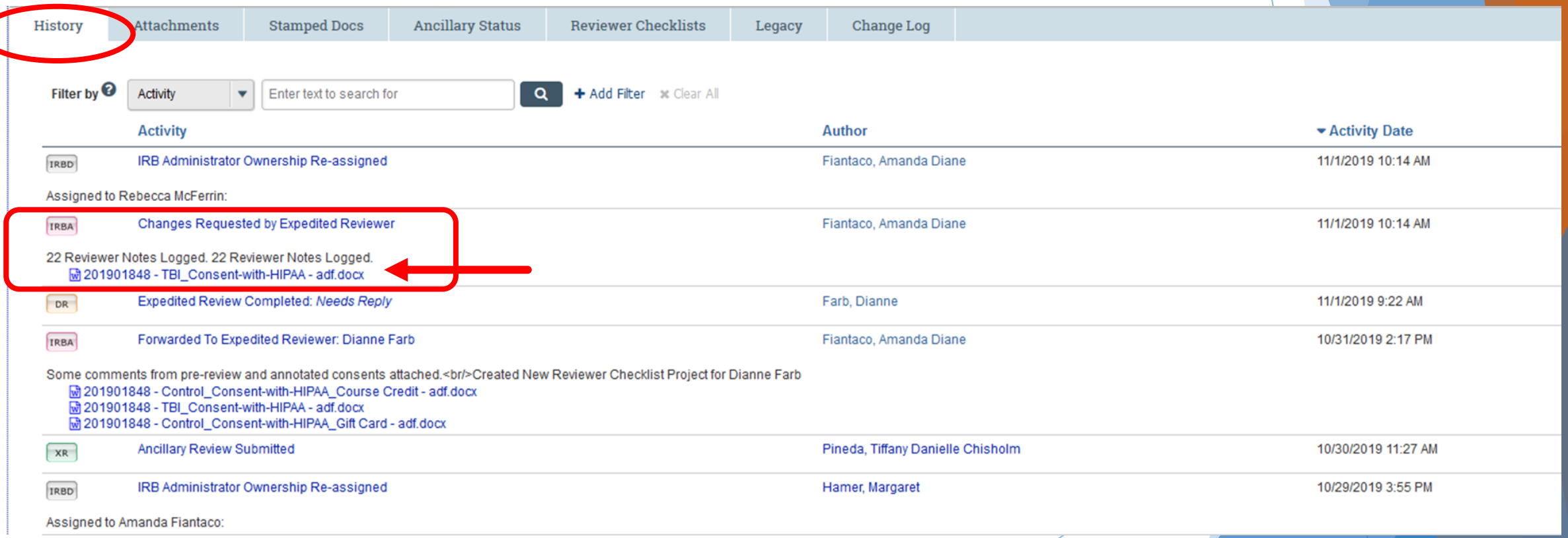
Responding to Reviewer Notes

- 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.

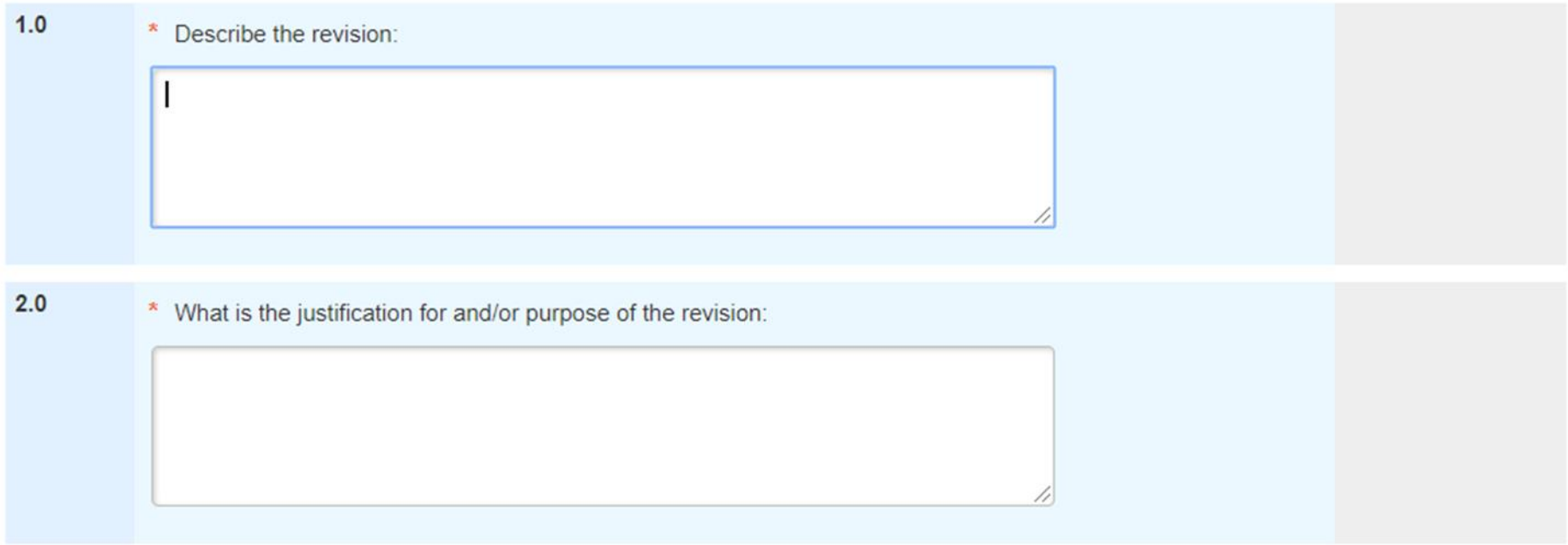


Responding to Reviewer Notes

- 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.



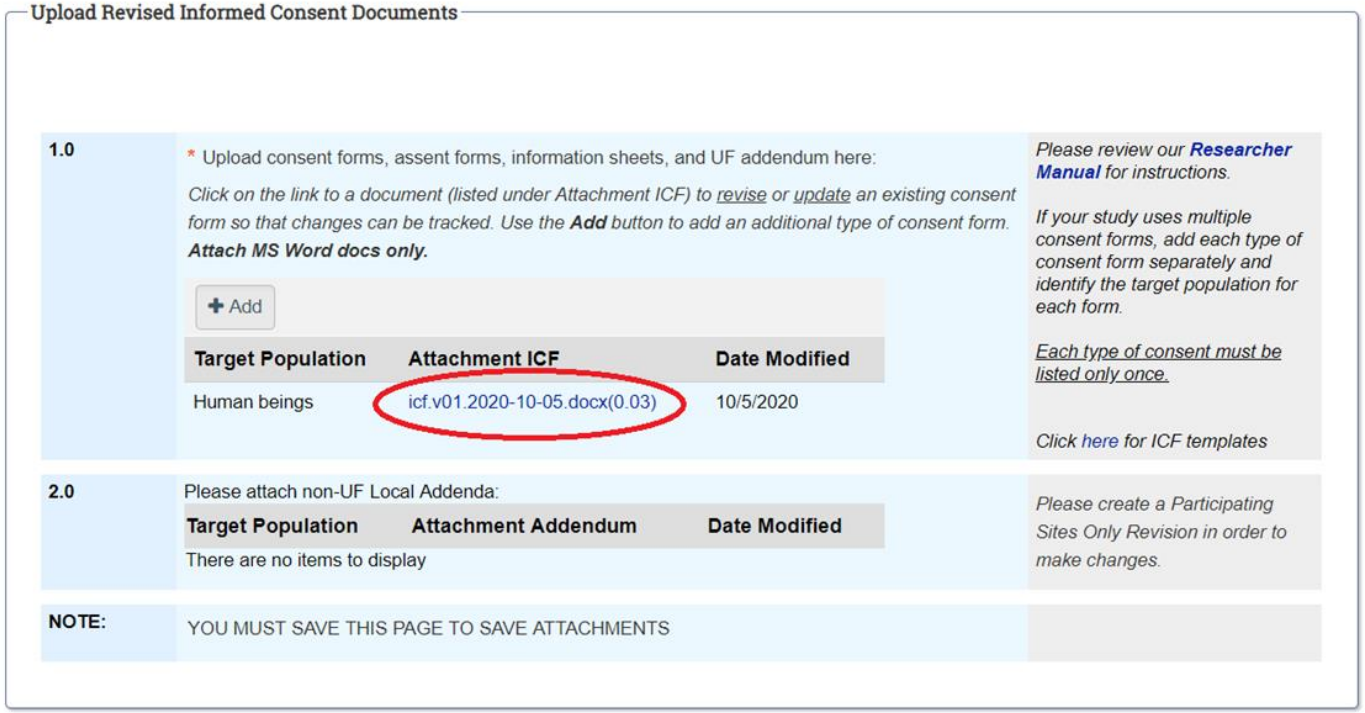
Other IRB Submission Types



- 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.
- Give a complete answer to these questions when submitting a revision.
  - Include a summary of protocol changes if applicable
  - Make sure you specify why these changes are being made

Updating documents in myIRB

- When revising consent forms, assent forms, and information sheets; click on the link to the document (listed under Attachment ICF, circled in red) to revise or update an existing consent form so that changes can be tracked. Only use the Add button to add an additional type of consent form. Be sure to attach MS Word docs only.
- Be sure to upload tracked changes (you can't track changes in PDFs)



Other IRB Submission Types

- 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

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
  - If your project ends up falling under the research category and needing IRB approval, be sure to update
- External Faculty Joining UF Guideline
- Documentation Tools including: Note to File Template, Data De-identification Attestation Templates, and more.

Questions?