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Submitting Research to the IRBs

A new semester often brings an influx of researchers and students wanting to submit their research proposals to one of the UF IRBs. All research proposals are submitted electronically in myIRB. The UF IRB website provides a plethora of information; however, it can be rather daunting at first. Here is a “quick-to-link” guide:

All research study staff (PIs, Co-Investigators, etc.) are required to register in myIRB (which may require the VPN download) and completion of required training (Currently, the training is not consistent for submitting research to any of the 3 IRBs; however, this will be changing in the near future. You will be advised.)

Who can serve as PI? Please read the UF policy regarding Principal Investigator and student roles in conducting research.

Please familiarize yourself with the myIRB electronic system by referring to the myIRB Researcher Manual.

Not sure if your study could be submitted for exempt review? Please refer to the guide for requesting the correct review type.

Do you know the research rules and regulations? No problem. Please refer to the IRB policies, guidelines and guidances.

This list of quick links is not exhaustive and it is not final. The website, forms, guidelines, etc. are updated as needed to better inform the research community. It is recommended that you routinely check the website for crucial updates. And please, do not hesitate to contact the IRB office if you have questions or need assistance.

Enrolling Subjects Who Do Not Speak or Read English

If you wish to obtain informed consent from a research subject who does not speak or read English, you must do one of the following. NOTE: simply using an interpreter is NOT sufficient.

1. If you are primarily seeking consent from subjects who do speak or read English, but unexpectedly want to enroll someone who does not speak or read English, you must:
   a. Extra “short form”: Use an IRB approved “short form” that is translated into the subject’s native language. The “short form” is a generic consent form that states general requirements required under the regulations such as the subject is being asked to participate in research, they can refuse to participate without penalty, contact information for the IRB, etc. Based on an analysis of the population of Gainesville, the IRB has already approved short forms in Spanish and Hindi (available on our website, see links below).
Enrolling Subjects Who Do Not Speak or Read English, continued:

b. Interpreter: Have a competent interpreter fluent in English and the subject’s native language.

c. Summary: The competent interpreter should present an IRB approved written summary of the protocol. The IRB approved Informed Consent Form written in English can serve as the written summary.

d. Researcher: A member of the research team who is approved by the IRB to obtain informed consent should participate in the process, answer questions, and seek informed consent.

e. Witness: A witness who is fluent in English and the subject’s native language must witness the informed consent discussion. The competent interpreter may serve as the witness.

f. If the subject gives consent to participate, the following must occur:

   i. The subject (or LAR) should sign and date the “short form”.

   ii. The witness should sign and date (a) the “short form” and (b) the IRB approved Informed Consent Form written in English.

   iii. The person obtaining consent should sign and date the IRB approved Informed Consent Form written in English.

   iv. Give the subject copies of the “short form” and the IRB approved Informed Consent Form written in English.

*We advise that you make a research note to file to document that the above process occurred.*

2. If you know that you will be seeking consent from subjects who do not speak or read English, you must:

   a. Have the Informed Consent Form translated into the native language by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.

   b. Have the translated consent approved by the IRB.

Helpful links:

- The IRB’s “Consenting Subjects Who Cannot Speak or Read English” Investigator Guideline.

What if you need a “short form” for a subject who speaks a language other than Spanish or Hindi?

- You will need to have the “short form” translated by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.


Obtain IRB approval: The IRB must review and approve this translated document. A minor revision will need to be submitted to your study. If this is the only change you make, the IRB should quickly review and approved the revision.
Reporting Unanticipated Problems

External auditors recently identified that our research community needs to be better informed about “Unanticipated Problems”. This is significant because researchers are required to promptly report “Unanticipated Problems” to the IRB.

Unanticipated Problems are any incident, experience, or outcome that meets all three of the following criteria:

1. Unexpected in terms of nature, severity, or frequency given (a) the research procedures and (b) the characteristics of the subjects being studied.
2. Related or possible related to participation in the research.
3. Suggests subjects or others are at a greater risk of harm (physical, physiological, economic, or social harm) than was previously known or recognized, even if no specific harm has yet occurred.

Examples include but are not limited to:

- Malfunctioning of research equipment that results or could result in risk to subjects or others.
- Breach of confidentiality, such as losing a laptop that stored subjects’ identifiable private information.
- Loss of research data, such as paper records lost or destroyed, or electronic records lost if a hard drive crashes.
- Incorrect labeling, dosing, or dispensing of study medication even if there is no indication of harm.
- Regular adverse events that are unexpected, related/possibly related, and place subjects or others at a greater risk of harm – regardless of the severity of the adverse event. Examples could include less serious adverse events that are occurring more frequently than anticipated, or are not described in the protocol or informed consent form.

Helpful links:

- This issue is described in greater detail in the IRB’s “Unanticipated Events Reporting” Investigator Guideline,
- IRB Policy HRP-112 “Reportable Events”.

What do you need to do if you identify an Unanticipated Problem?

- Any Unanticipated Problems that you identify must be promptly reported to the IRB via myIRB.
  - Please refer to the directions on how to do this on page 27 of the myIRB Researcher Manual or contact the IRB office for assistance.

You must also list the Unanticipated Problem on the Cumulative Adverse Event Table submitted with your future Continuing Reviews.
Subject Enrollment

Dr. Valentine is working on the continuing review for her retrospective chart review in myIRB. She entered “0” for enrollment because she reviewed 61 medical records, but she did not obtain informed consent or interact directly with subjects. Is she correct?

No, Dr. Valentine would not be correct because the IRB considers an enrolled subject as someone:

- Who has signed an Informed Consent Form, or
- Whose data you have collected, or
- Whose medical record you have reviewed (in the cases where consent is not required like a retrospective chart review). Every record you look at is an enrolled subject.

For more information regarding the factors to take into account when determining the total number of subjects you should enroll, what to do if you need more subjects, and what happens if you over-enroll can be found in the helpful Enrolling Study Subjects Investigator Guideline.

Annual myIRB Cleanup

Effective on February 22, 2018, all new studies that have been in the pre-submission state since 2016 will be administratively withdrawn by the myIRB IT team. This year there are a total of 268 studies:

- IRB-01: 140 studies
- IRB-02: 114 studies
- IRB-03: 14 studies

This administrative withdrawal of new studies that have never been submitted to the IRB is required for the following reasons:

- Studies sitting in pre-submission for over a year will not have any system updates incorporated within the SmartForms.
- These studies are included in metrics reporting.
- The study staff listed on the study may no longer be accurate.
- Attached documents such as protocols and ICFs may not be current which could result in regulatory non-compliance.

If you have a new study that has been in pre-submission since 2016, you can (a) submit the study, (b) do nothing and let it be administratively withdrawn, or (c) copy the study and submit the copy at a later time. (Instructions can be found on pages 54-56 of the myIRB Researcher Manual.)