Preparing IRB Submissions for Human Subjects Research

Tips for Preparing IRB Protocols

IRB Educational Session-Psychological Sciences

September 15, 2017

Research Compliance Services
Post Approval Monitor-Joan Levine, MPH, CIP
Objectives

You are ready to begin the submission process to the IRB—what do I need to know?

• Describe and give examples of the 3 levels of IRB review.
• Discuss the process for submitting a protocol to the IRB using the web-based application system-InfoEd.
• Protocol submission process; Forms and locations.

infoed.uconn.edu/ & InfoEd How to Guides
• Common pitfalls when completing forms/submitting to IRB. Tips for completing a submission.
Is your study human subjects research?

a. Is it research?

• *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

b. Is it human subjects research?

• 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.

If yes to both A and B, then you will need to submit your research to the IRB.
Collaborative Institutional Training Initiative (CITI)

The web-based training modules in CITI provide basic education on the history and ethical principles of research.

All researchers, including students who are working on the study and are considered “key personnel” must complete the online "CITI Training” course for the protection of human participants in research BEFORE the IRB will approve a study.

Research personnel must renew their training every three years.

Key personnel on studies considered to be clinical trials must also take Good Clinical Practice training. Also, available from CITI.
The National Science Foundation (NSF) requires the responsible conduct of research (RCR) training for all undergraduates, graduates, and post-doctoral fellows who conduct research supported by NSF funds.

The National Institutes of Health (NIH) requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, or dissertation research grant must receive RCR training. This requirement also applies to all faculty, including new faculty, mid-career faculty and senior faculty, and professional and scientific employees receiving funding from these sources. PIs are responsible for ensuring that each undergraduate student, graduate student and postdoctoral researcher who participates in their NSF or NIH funded research completes the training during the course of their participation in the project. These RCR modules can be accessed through the CITI training program.
InfoEd is the web based application system used to develop and submit research protocols to the IRB.

InfoEd sessions are offered on a regular basis.

The IRB strongly encourages all researchers to attend a session prior to submitting a protocol.

Students have access to all features in the InfoEd submission system. However, a faculty mentor must be listed as the Principal Investigator of the study. The PI is ultimately responsible for ensuring protection of human participants.

**Tips:** Before clicking submit, all studies that are unfunded must be routed to the department head and PI for sign off. For funded studies, routing must go to the PI. If you are unsure who your Department Head is, please contact RCS. There are some DHs who delegate this task to others.

**Don’t forget to click “submit”!!**
The Common Rule

Office for Human Research Protections (OHRP)-The “Common Rule” is the federal policy for the protection of human subjects in research. It was first published in 1991 and known as 45 CFR 46.

The Common Rule describes the detail of the IRB operations and the types of research that are subject to regulation.

There are 4 subparts for additional protections for pregnant women, human fetuses, and neonates, prisoners, and children.

UConn requires additional protections for students who take part in research.

Changes to the regulations have been approved by the previous administration. However, the changes are presently in review by the current administration.
Level of IRB Review

What level of review is my study?

Levels of IRB Review

Full Board
- More than “minimal risk” to subjects
- Not covered under other review categories
- Example: interventions involving physical or emotional discomfort or sensitive data

Expedited
- Not greater than minimal risk
- Fits one of the 9 Expedited Review Categories*
- Examples: Collection of biospecimens by noninvasive means, Research with existing documents/record collected for non-research purposes in which subjects are identifiable

Exempt
- Less than “minimal risk”
- Fits one of the 6 Exempt Categories*
- Example: Research with de-identified records, anonymous surveys

*Defined by federal regulation (45 CFR 46)
1. **Exempt research** is considered “less than minimal risk” and fits into one of six categories. Most of the research here at UConn falls under Category 2: anonymous survey research. These applications are accepted on a continual basis. The IRB Chair or designee reviews and approves. [IRB-5 Application and Protocol](#)

Examples: anonymous surveys collected through Qualtrics/Survey Monkey—many studies use Mechanical Turk, or the Psychology Participant Pool to collect data. The data are not linked to any identifiers.

2. **Expedited studies** involve no greater than minimal risk and fit into one of 9 categories. [IRB-1 Application and Protocol](#)

Examples: Survey research with identifiable data, focus groups, collection of data through non-invasive procedures or means (MRI, EEG, buccal swab), secondary data analyses of identifiable datasets. One IRB member reviews this research. Typically, an IRB member will review protocols at least once per week.
3. **Full committee research** is considered to be more than minimal risk. These studies include research that involves physical or psychological risks, or the collection of identifiable data considered to be sensitive in nature. The full board reviews these studies at a fully convened meeting. Meetings once every 3 weeks. Dates are listed on the IRB web-site. These protocols are due 3 weeks prior to the IRB meeting date. This provides time for a RCS member to pre-review the study to ensure all of the documents have been submitted, and for the IRB members to read through and be prepared for discussion during the meeting.

**IRB-1 Application and Protocol**

Examples: research with drugs/supplements, biologics, many devices protocols, research that includes psychological, physical, or legal risk.

At times, researchers are invited to the IRB meeting to clarify procedures.

* Call RCS prior to submitting your protocol to ensure that you are submitting under the correct category and have all necessary forms completed. *Common Finding-protocols submitted under incorrect category-exempt vs. expedited*
1. Risks to subjects are minimized

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
Forms

• Complete the IRB-1 or IRB-5 (if Exempt) electronic application in InfoEd.

• Complete the corresponding IRB-1 or IRB-5 Study Protocol and upload to InfoEd.

• Include an Appendix A form (personnel form) if you have additional “key personnel” that will be working on your study. Each person listed on Appendix A must complete the required CITI courses prior to IRB approval. If a person has not completed the training, this will hold up IRB approval. *Common Finding:* personnel have not completed CITI

• Please be sure that the protocols and other forms, such as the consent form, parental permission form, information sheet, etc., are the most recently updated forms that are on the IRB web-site. *Suggestion:* create folder on your computer with all necessary forms. *When complete, upload to InfoEd.*
• In your IRB-1 or IRB-5 Application or Protocol, please be sure to provide a response to each question.
• The IRB relies on the investigator to provide necessary information.
• When ready to submit your protocol, please check for completeness and accuracy.
• It may be helpful for someone to proofread the consent form. Are the procedures clear? If I were a participant, would I understand the research, how the data are stored in a confidential manner, the compensation, who to contact?
• Use an appropriate reading level in the consent form.
• Avoid jargon. If the proposal can’t be easily understood, then the IRB can’t adequately assess the required elements. Same for consent.
Common Findings During Initial Review

- Screening procedures are not clearly defined in protocol.
- Consider screening, if possible prior to consent. If doing so, complete the waiver questions in the consent section for screening.  
  Common Finding: not completing the waiver questions
- Inconsistencies between IRB protocol and consent form-incentives, privacy/confidentiality, procedures.
- Record retention-not consistent with regulations (3 years after study completion).
- Study measures-inconsistency between what is submitted, what is included in the protocol, and what is described in the consent form.
- Eligibility not clearly defined-or missing components.  For ex: not excluding people with certain conditions.  For ex: if MRI-must exclude those with metal in body, etc.
- More detailed description of procedures needed in the ICF.
- **Forgetting to click on submit!!!**
Tips when Preparing Protocols

Recruitment methods
Are you using recruitment material (flyers, Ads, emails, letters)? If yes, must include the following:

- A statement that includes “research”
- Title
- Purpose
- Major procedures. What is tested? Length of time to complete.
- Major inclusion/exclusion criteria.
- Benefits.
- Compensation.
- Location, contact information of SI and PI, Department.
- No bold statements, or compensation in CAPS.
Preparing Protocols cont.

• When using acronyms, please spell them out first. Also, provide clarification where needed when using scientific terminology.

• How are the data maintained? UITS guidelines-Data Security Assessment Form?

• Are there additional regulations to consider-FERPA, FDA? Are there other institutions involved in the research?

• Review practical guidance in the Researcher’s Guide section.
Other Regulations to Consider

Considerations for enrolling college students:

• FERPA considerations-

Definition: The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records.

FERPA restricts researchers’ access to student records without written permission from parents. However, within FERPA [20 U.S.C. 1232g(b)(1)(F)], there are conditions under which student records can be disclosed without parental consent: “Organizations conducting certain studies for or on behalf of the school”. Investigators must contact each institution and follow that institution’s FERPA policy, in addition to the requirements of UConn IRB. Finally, Protection of Pupil Rights Amendment (PPRA) outlines 8 categories of protected information for survey responses and requires that parents be afforded the right to inspect surveys before they are given to students (for more information on FERPA and PPRA, see the link at the end of this section).

**Contact the Privacy Officer at UConn if you plan on obtaining educational data from students at UConn or other schools. Rachel Krinsky-Rudnick rachel.krinsky@uconn.edu**
Research in Other Countries

- Research conducted in foreign countries remains under UConn purview and guidelines. Adjustments may be made to respect cultural differences, but standards for the protection of human subjects in research are not relaxed.

- The IRB may require the research study to be approved by the local equivalent board or group, with submission of documentation of approval.

- The IRB may seek guidance from the Office for Human Research Protections International Compilation of Human Subjects Protections or may contact OHRP to determine whether procedures by foreign institution afford equivalent protections to U.S. regulations.
Research with Other Institutions

• If your research will take place at another institution/facility, please include information that will be informative and helpful for the IRB reviewer.

• Agreements with Connecticut Children’s Medical Center (CCMC), Hartford Hospital (HH), and UConn Health (UCH).

**Call IRB first-this may save you a considerable amount of time when completing your submission.**
Informed Consent

How is consent going to be addressed in your study?

UConn RCS has templates on web-site for the Informed Consent Form, Information Sheet, & Parental Permission Form. There is required language in each.

- Signed consent
- Information Sheet-no signature. This requires a “Waiver of Signed Consent” (must meet 4 criteria).
- Parental Permission Form-minors cannot provide consent. This form is signed by the parent/s of the child. The IRB will determine if the child also signs (assents) this form. Age factors into this determination.
- Minors-a separate assent form (no signature)
- “Waiver of consent”-IRB determines a waiver under certain circumstances (screening).
Informed Consent Cont.

- Have you been trained on how to administer consent?
- How is privacy addressed during the consent process (referring to the individual-not data)?
- What safeguards are in place if you are enrolling vulnerable populations? How are you going to assent minors?
- Although the regulations do not require consent in research that is Exempt, UConn policy is to provide participants with an Information Sheet.

*Call the IRB office for guidance before you submit your protocol.*
Time Frames for Review

- For Exempt Review, allow 2-3 weeks for the IRB to take an initial look at the protocol. The IRB Chair delegated IRB staff to assume the review responsibility.
- For Expedited Review, allow 3-4 weeks for the IRB to take an initial look at the protocol. IRB staff conduct an administrative review followed by an IRB member who conducts a scientific review.
- For Full Board Review, allow 3 weeks as the IRB meetings take place every three weeks during much of the year. IRB staff conduct an administrative review followed by an IRB member who serves as primary reviewer. The full IRB also reviews the protocol.
- Overall, the IRB advises that researchers allow for an approximate 4 week approval process.
- Note that these time frames are approximate and depend upon the time of year. Protocols are reviewed in the order in which the IRB receives them.
• Issued in 1991
• Changes include focus of IRB review on higher risk research, less on lower risk procedures.
• Effective date: January 19, 2018
• Key changes that influence SBER:
  - Changes to consent-information must be presented to facilitate subject understanding of why or why not to participate. Could be detailed in a summary in the form
  - Continuing review not required if Expedited, “Limited Review (new)”, or open for data analyses and/or accessing follow-up clinical data in certain circumstances.
  - Establishes new Exempt categories based on level of risk-now 8 categories-benign behavioral interventions, storage, maintenance, & use of secondary use of identifiable private information & identifiable biospecimens-where “broad consent (prospective consent to unspecified future research)” is obtained
  - U.S. institution engaged in “cooperative research”—single IRB review-research in the U.S.-compliance date 2020, similar to NIH policy

2. Link to IRB help sessions, InfoEd sessions, IACUCC training, IRB forms workshops & other related IRB events: [http://research.uconn.edu/news/upcoming-events/](http://research.uconn.edu/news/upcoming-events/)


4. IRB web-site: [http://research.uconn.edu/irb/](http://research.uconn.edu/irb/)

5. UConn IRB CITI program how to page: [http://research.uconn.edu/irb/citi-training/](http://research.uconn.edu/irb/citi-training/)


8. FERPA UConn: [http://ferpa.uconn.edu/](http://ferpa.uconn.edu/)

9. InfoEd Support: Please email [ERA-support@uconn.edu](mailto:ERA-support@uconn.edu) or call 860-486-7944 to be connected to a member of the eRA Helpdesk support team. The help desk line is staffed Monday-Friday (except holidays) from 8:30 AM – 4:00 PM.
IRB Office

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