HRPP Newsletter

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In this issue:

Spring Semester 2016!

With the semester underway, the HRPP is bustling with activity as we move into what historically has been the IRB's busiest time of the year. February typically marks the beginning of this busy period with the number of submissions increasing significantly until April. We will do our best to provide efficient review turn-around times. In this issue we highlight ***ways researchers can help us to decrease review times*** both during this busy time and all year long. We understand how important timely review is to our research community and hope that by working together to increase understanding, we will continue to improve this vital service.

– HRPP Staff

Training Opportunities

The HRPP is continuing to provide training opportunities to the research community. Listed below are a variety of workshops hosted by the IRB. Registration is recommended.

Unable to attend a live training session?

Check out our Path to IRB Approval video. Recorded at last month's Responsible Conduct of Research (RCR) Lunch Series, this presentation targets how to write an application for IRB approval.

IRB 101 – An overview of IRB requirements and procedures designed for anyone interested in conducting human subjects research at the University of Tennessee, Knoxville.

IRB: Responding to Reviews – Learn how to respond in iMedRIS to requests for changes from the IRB.

IRB: Forms 2, 3, 4 and 7 – Learn how to modify an already approved study, request renewal of a study's approval, report problems to the IRB, and request closure of a completed study.

Tip of the Month: Top 10 Obstacles to IRB Approval

Delays in obtaining IRB approval are typically due to incomplete applications or insufficient consent forms. Understanding what the IRB needs and providing it in your submission can reduce the time required for review. Listed below are the issues most frequently resulting in requests for changes or additional information.

1. Application does not include all research team members (anyone conducting research procedures or having access to study data) in the Study Personnel, Contact Information and Credentials sections (items 3.2, 5.1 and 6.1). Include the Faculty Advisor in all of these sections if the PI is a student.

2. Incomplete descriptions of study procedures, recruitment procedures and procedures used to protect participant privacy and the confidentiality of participant information.
3. Not recognizing common risks and overstating benefits to participants.
4. Study materials not targeted to the participant population. Studies frequently propose participant materials written at a reading level much higher than the national average (7^{th}-8^{th} grade) when recruiting from the general population.
5. Confusing confidentiality and anonymity.
6. Consent forms missing required elements of informed consent.
7. Discrepancies between the application form, consent form and other study documents. Lack of consistent document titles or no titles. Missing documents.
8. Lacking awareness of the challenges involved in conducting research with vulnerable populations, different cultures and the potential for undue influence and coercion.
9. Application uses jargon, highly technical or discipline/field-specific language, unexplained acronyms or lacks clarity.
10. Not proofreading – typographical errors, disorganized information and lack of attention to detail.

How You Can Speed Up Your Study's IRB Review

Understanding a little about how IRBs work can help speed up the review time for your study. Consider the following when preparing to submit an IRB application.

- Understand that the IRB must have a clear understanding of your study before approving it. IRB reviewers must rely on the documented information provided in the submitted IRB application and study documents for clear, detailed information which leaves no room for ambiguity. Determinations cannot be made on assumptions such as when we *think* we know what a researcher describes, but are not certain.
- IRB reviewers come from varying backgrounds and may not be familiar with your academic discipline or field of research. Taking care to use simple lay language and providing thorough descriptions of concepts and detailed procedures reduces the need for additional requests for information.
- Ask questions and seek assistance.
    - Refer to our website or the help menu in iMedRIS for requirements, guidance and consent form samples, including the screen-by-screen instructions for the Form 1 Initial Application.
    - Consult with us about your research study. We can alert you to issues specific to your study before you submit an application which can reduce or eliminate additional requests for changes or information.
    - If questions arise while completing your application or even planning your research, contact our office. If we can't help, we will connect you with someone who can.
- Plan ahead and begin developing your application early. Time required for review and approval of a study depends on the type of research, the level of risk, and the complexity of ethical or technical questions that arise during review. Keep in mind the IRB reviews research involving human participants conducted by UT Knoxville and UTIA faculty, staff and students, hence the IRB has yet to experience a *slow* period.
- Follow the IRB Applications Step-By-Step guidance below.

IRB Applications Step-By-Step

Study Procedures

- Explain what procedures participants will perform and/or experience, plus their sequence and frequency. Identify when and where they will occur. Include any screening or follow-up procedures to be used.
- Describe the data that are being collected. If using records or data sets, identify the specific information or data points to be used for the research.
- Describe approximate duration, for both specific procedures/study visits and overall length of participation.
- Describe the setting and mode of administering data collection instruments or conducting interviews (e.g., telephone, in-person, computer based, group-setting).
- If the study evaluates existing procedures or includes a combination of existing procedures and research-specific procedures (e.g., study on existing curriculum activities that also interviews instructors about their experience), clearly distinguish between which procedures would occur even if the study were not conducted and the procedures solely conducted for the research.

Recruitment Procedures

- Explain how potential participants will be identified and how contact will be initiated to inform them of the study (in-person, phone, flyers, email, social media, etc.).
- State who will contact potential participants and identify any pre-existing relationship they may have with participants (instructor, supervisor, care provider, etc.).

Confidentiality and Privacy Procedures

- Privacy is a person's control over the extent, timing and circumstances of sharing him/herself (behaviorally, intellectually or physically). Describe how privacy of participants will be protected during data collection, particularly of sensitive information. For research involving internet surveys, are data secured via access controls (e.g., passwords, authentication, encryption)
- Describe how data will be collected: anonymously, with direct identifiers or indirect identifiers[i].
- Confidentiality pertains to the handling of identifiable information that is disclosed by a person in a relationship of trust with the expectation it will not be divulged without permission. Explain how identifiable data and research records (e.g., consent forms, participant payment information, participant correspondence) will be handled. If confidentiality is promised, describe all measures used to minimize the risk of disclosure such as:
    - storage and access to paper and electronic information (including security measures such as passcodes, authentication, encryption, etc.);
    - if data will be de-identified, how and when; and
    - if data will be coded and if a code key exists, if code key will be stored separate from data, who can access it and how long it will be kept.

Risks and Benefits

- Include all risks. Risks related to loss of privacy and confidentiality are the most common risks associated with social, behavioral and education research, yet they are rarely identified as such in IRB applications. Describe how risks will be minimized.
- Identify any probable benefits the research may present. Most research is unlikely to result in direct benefits to participants. A direct benefit is an outcome of the research that is directly advantageous to the participant. Survey research usually does not offer the direct benefits to participants who take them. However a study that investigates a new instructional method to teach algebra may present direct benefits to participants if the new method improves their comprehension of an algebraic concept.

Consent Documents

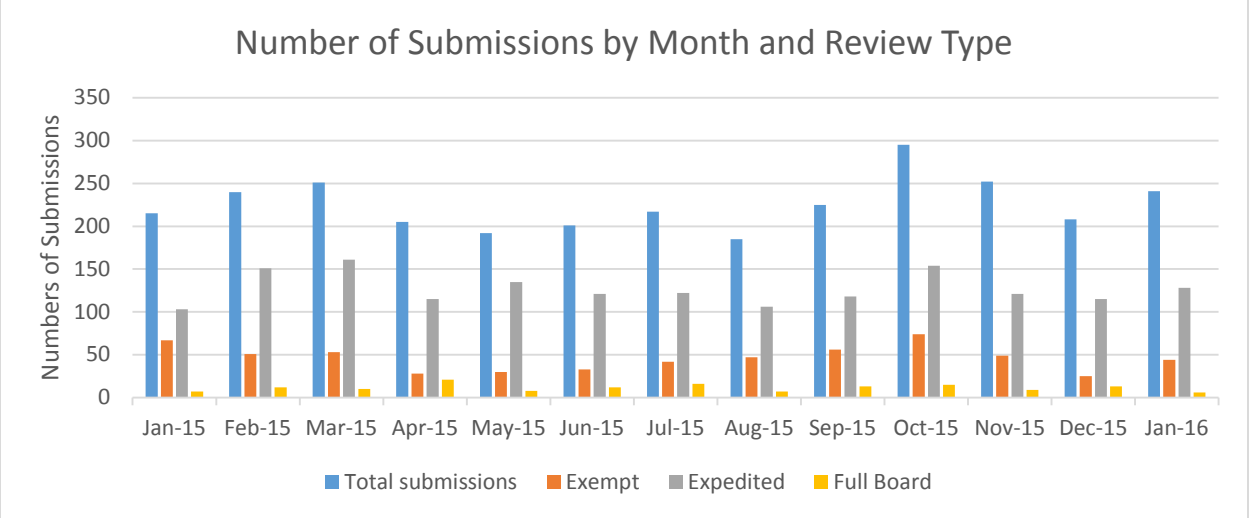
- Include the required elements of informed consent.
- Write the consent form using language appropriate to your participant population. We recommend writing consent forms in the 2nd person (*you*).
- Describe study procedures in a step-by-step manner in the order they will occur.
- Benefits from the research can never be guaranteed. Use *may occur* instead of *will occur* when writing about possible benefits.
- If a student is the study PI, include the Faculty Advisor's name and contact information.

Other

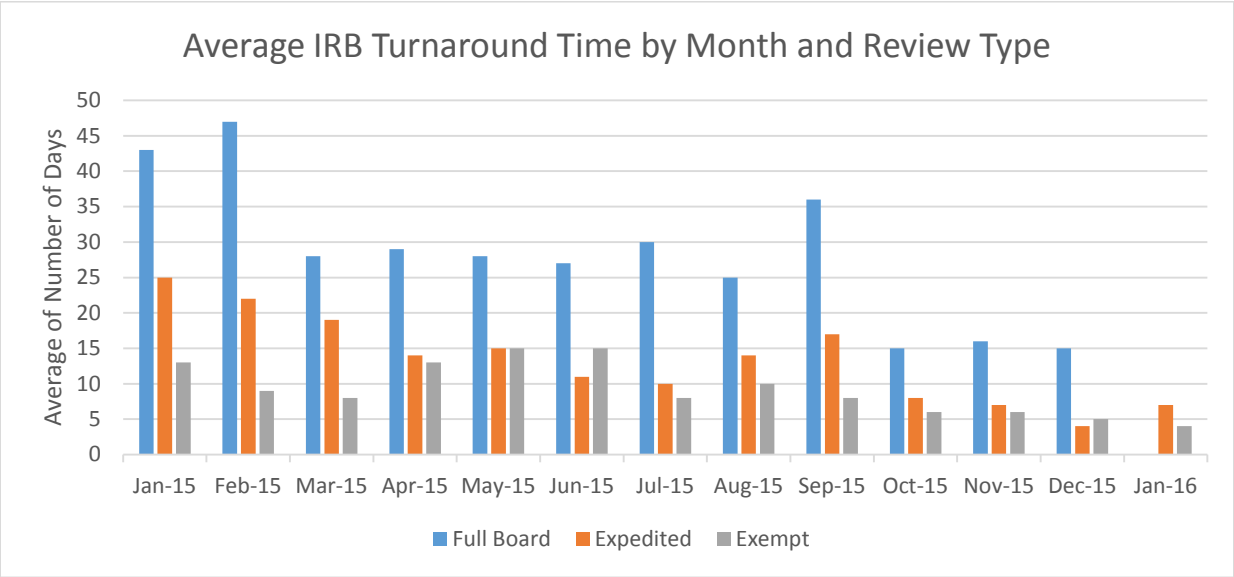
- Write all study materials to be shared with participants, including recruitment materials, and study instructions in a language appropriate to your participant population
- Submit a copy of all consent materials, recruitment materials, data collection instruments, site permission letters, IRB approvals from collaborating institutions, etc. with your IRB application.
- PROOFREAD!
- Have someone unfamiliar with your field read your entire application package for understandability, consistency and errors.

IRB Metrics Update

This first graph highlights the number of submissions received over the last year (January 2015-January 2016). A monthly average of 225 studies and associated requests has been submitted for that period. During the month of January 2016 the IRB received a total of 241 submissions.



The second graph, below, highlights the average review time per month. The IRB continues to strive to maximize the efficiency of review for full board, exempt and expedited categories. The average review turnaround time for all submissions during the month of January improved by more than two weeks—from 22 days in 2015 to 5 days in 2016—continuing the trend of significant reduction across all review types.



Contact Information

If you have questions or concerns, please don't hesitate to contact any of our team members.

[i] Indirect identifiers refer to information that when used together, or in conjunction with other information, may enable a reasonably informed and determined person to deduce the identity of individual research participants (e.g., a study on NFL quarterbacks).