Malone University HRC/IRB Frequently Asked Questions (FAQ) Page

Updated to accommodate the July-2018 adoption of the new Final Common Rule

How will IRB reviews change in 2018?

For the average researcher, very little about the HRC/IRB process will change. Some researchers will be pleasantly surprised when their proposals receive exemptions from further review instead of expedited reviews. However, because of the way the new guidelines are written, researchers will still need to file the appropriate paperwork in order for the HRC/IRB to make this determination.

Some researchers with ongoing projects will receive notifications that they need not apply for continuing reviews any more. This is due to the new guidelines associated with continuing reviews of low risk studies.

When a project involves stored data or biospecimens, where subjects are identifiable, broader consent forms can be used "up front" to obtain permissions for future uses of the information.

For projects using identifiable data where HIPAA applies, if *secondary* analyses are proposed, they can be exempted…provided the facility and files are protected under HIPAA.

For federally funded clinical trials, the researchers must propose a manner whereby the blank consent form will be publicly available (e.g., posted on a website).

Multi-site projects are generally supposed to be reviewed by a single IRB, with agreements being put in place with other institutions that they will accept that single IRB's review and determinations without re-reviewing a proposal.

Consent forms must include clear language about a project's aim and scope with descriptions of risks and benefits.

Understanding Consent Forms

A sample consent form is available at the HRC/IRB website. Please, use it to help construct the form for your study.

If your study is minimal risk (no more risk than everyday life) and the only link between the subject and the study would be the signed consent form, then request a "waiver of signed consent" in Section C, Item 6, of the HRC/IRB forms.

When requesting a waiver of signed consent, implied consent must still be sought. This means that the survey or study MUST include detailed enough instructions for the participants to:

(1) understand the purpose of the study and its scope;

(2) comprehend the potential risks and benefits of the study (if none, then state as much);

(3) understand how the data will be used;

(4) learn about contact information, so that s/he can contact researchers with questions; and

(5) understand that by completing the survey or study, s/he is giving consent for his/her responses/data to become part of the researchers data analysis.

When do I need to include a Debriefing Statement?

The easy answer is when, in Section B #15 of the HRC/IRB forms, you state you will include one. In this case, the Debriefing Statement should be included. The provision of a debriefing statement is usually dependent upon the type of research being conducted. Anonymous surveys do not usually need a Debriefing Statement because there is no one-on-one interaction and anonymity is assured. However, it can be very helpful to include one, even with an anonymous survey, because it provides an opportunity to remind the subject why the study is happening and it can provide contact information so that the participant can reach the researcher with any questions.

Debriefing Statements are particularly important when the research includes a face-to-face interview, biomedical intervention, or behavioral testing, because the interviewee might have follow-up questions. The Debriefing Statement should be provided with the research proposal sent to the IRB/HRC.

What date should be used for the Start of Research entry (Sec. B #17) on the IRB/HRC forms?

Data Collection should not start before the date of approval from the IRB/HRC. For less risky research (i.e.: research not involving sensitive populations, anonymous surveys for responsible adults, etc.), the IRB/HRC approval will usually be within 10-15 business days after submission to the IRB/HRC. Therefore, the data collection data should be an estimate based on the time to process the HRC/IRB proposal. Researchers can estimate this date and include the abbreviation for estimated (est.) for the date of beginning data collection in the space provided in Sec. B #17 – "*Earliest possible date when research subjects will first be involved*." Please note: It is a violation of IRB/HRC rules and Malone University Policy to begin data collection before IRB/HRC approval. Incomplete proposals (lacking a the survey, instructions, consent form, debriefing, and/or letters of permission from cooperating institutions) will be delayed.

When is Letter from an Outside Cooperating Organization necessary?

If data are to be collected from an outside organization (i.e.: from a specific school, school district, nursing home, hospital, or other discrete organization), approval from that organization is needed. For example, if the research involves the nurses at Mercy Medical Center, a Letter from Mercy as a Cooperating Organization is required. Alternatively, if the research is targeted toward nurses, in general, from different hospitals, then a Letter from an Outside Cooperating Organization is not needed (as when one simply sample from among one's nurse acquaintances), **unless** access to participants is through a specific organization or business (e.g., via a hospital staff member, employee bulletin board, or a professional organization). When applicable, the researcher is required to get approval, in the form of a written letter from a designated authorized person within that organization. The approval letter must accompany the application to the IRB/HRC. The absence of this approval letter will delay the proposed research and the start of data collection.

What is an "adverse event" or "unanticipated problem involving research subjects" and when do I need to report it/them to the HRC/IRB using Section E of the online forms?

According to the Office of Human Research Protections at the US Department of Health & Human Services, an adverse event is define in 21 CFR 312.30 as "any untoward occurrence (physical, psychological, economic, social, or legal) which affects a study subject" (e.g., any evidence in a subject that s/he has experienced a sign or symptom that is undesirable and is temporally linked to the research study). An adverse event need not be causally linked to a research study; a temporal relationship is sufficient for reporting.

An "unanticipated problem" is "Any incident, experience, or outcomes that meets all three criteria:

1. Unexpected
2. Related or possibly related to participation in research
3. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized
    - May be physical, psychological, economic, or social harm"

Source: OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events – January 15, 2007

Report any adverse event or unanticipated problem in your research to the HRC/IRB chair, immediately. Use the form in Section E of the HRC/IRB forms. It also helps, if you call the HRC/IRB chair in order to discuss the issue, so that she or he can provide guidance.