Instructions/Checklist for SED IRB Pre-Review

Proposed 7/15

Instructions

1. All documents and document file names need to include the PI’s name (Last Name, First Name) followed by a brief descriptor of the document (e.g. application, informed consent) and the date of submission (e.g. 2.12.12). Revisions should be labeled (e.g. Revision 1, Revision 2).

2. All documents should be in Word format to allow for ‘Track Changes’. The exceptions to this are any certificates, surveys, interview questions, and the signature page of the proposal application. These should be in PDF format.

3. Please be sure to visit the Institutional Review Board site (http://www.bu.edu/irb/) and use their materials for guidance (please see http://www.bu.edu/irb/guidance-and-faqs/submission-guidance/steps-to-submitting-a-new-irb-application/ ). Use the templates for consent and assent forms that they provide, adapting them where necessary to the specifics of your study (please see http://www.bu.edu/orc/forms/human-subjects/ ). You can find information about the CITI Program Human Subjects Training here (http://www.bu.edu/orc/training/human-subjects/citi-program/ ). You may also find helpful information on the frequently asked questions page (http://www.bu.edu/irb/guidance-and-faqs/faqs-definitions/faqs/ ). The materials on the IRB site, including the application forms, are frequently updated, so do not assume that the forms you or your faculty advisor downloaded months or even weeks ago are the most up-to-date forms. Go to the site and upload the newest materials.

4. The PI’s name and contact information should be listed on both the informed consent and any debriefing forms. PIs who are students must state this fact explicitly at the beginning of all consent forms and must list the name of their faculty supervisor. Student PIs must also include the name of their faculty supervisor in their list of study staff.

5. Please indicate if data is being collected anonymously and, if so, how the anonymous data will be stored. Be aware that anonymous data contains no identifiers OR codes that link to subject identity. If the data are not being collected anonymously, describe how you will protect the privacy of your participants.

6. If you are administering a survey online and asking potential participants to check a box indicating that they have read a consent form or description of the study, you must fill out the section of the proposal that says “Waiver of written documentation of informed consent.”

7. Review of materials will take up to 1 week (7 days) from the time that you submit to the SED IRB representative. Review may take longer over breaks, holidays, and the summer.

8. Once your documents are approved by the IRB, you will not be able to make any changes to forms (including adding or deleting questions, changing procedures, altering consent forms) without review by the IRB. You are required to use the approved documents.
Pre-Review Checklist

Attach only documents that apply to your particular study. Failure to provide all documents can result in a delay in processing your application. Send completed Pre-Review Checklist and all student materials to Dr. Jennifer Green at jggreen@bu.edu. For more information about specific IRB application materials, visit www.bu.edu/irb.

Consent Forms (check all that apply)

___ Adult consent
___ Parental consent (for child)
___ Child assent 7-11 year old
___ Child assent 12-17 year old
___ Screening consent (if participants are screened for eligibility to participate)
___ Other (specify) ______________________________________________________________________

Recruitment materials (Check all that apply)

___ Brochure
___ Flyers/ handouts
___ Radio ads
___ Internet posting
___ Email text
___ Recruitment letters
___ Screening forms
___ Other (specify) ______________________________________________________________________

Dissertation materials
(Please indicate in your IRB application if study is related to dissertation work)

___ Copy of dissertation prospectus (you may attach a draft, but are then required to submit the final proposal upon approval)

For school-based research (Check all that apply)

___ Letters of permission – these will typically be from administrators (e.g., superintendent, principal)
___ Copy of school or district policy regarding research conducted, or description of policy
Other Attachments (Check all that apply)

___ Grant or protocol (if your study is funded)
___ Human subjects training certificates for all investigators listed in Section A (unless posted on IRB website)
___ All surveys, questionnaires, data collection forms and other instruments that will be used in the study.
___ All consent and assent forms
___ Recruitment materials
___ HIPAA forms
___ Other letters of permission – If the study is being conducted at a site that is not part of SED it may be necessary to provide the IRB with a letter of permission from the person in charge of the site indicating that it is permissible to conduct research at that site. If the study is going to take place at an external site (i.e. church, clinic, etc.) proof of permission to conduct research at that site will be required.