

IRB Preparation Guidelines

This document contains information about the IRB review process conducted in the Psychology Department by the Pre-IRB Review Committee (PRC) and by the IRB at the University level. It provides both general and more specific guidelines for preparing new IRB protocols, modifications, annual renewals, and terminations.

- For help concerning the PRC review process:
 - Sarah Mason, PRC Coordinator at swmason@email.unc.edu (962-1404), Davie 325.
 - If Sarah is unavailable, contact Brigid Poole at bhpoole@email.unc.edu (843-8985).

- For help concerning the drafting of an IRB proposal, contact,
 - Jean-Louis Gariepy, Chair, PRC at lgariepy@email.unc.edu (962-2392)
 - For help concerning specific ethical concerns, please contact the IRB office directly at 966-3113.

The Departmental Pre-Review Process

The PRC reviews all IRB proposals prior to submission to IRB. Our department does this (1) to reduce the work load we impose on the IRB by screening proposals for avoidable errors, and (2) to prevent long delays in obtaining IRB approval. PRC has a cover sheet that you should complete prior to submitting your proposal to Sarah Mason (See URL for cover sheet below).

This cover sheet requires that you provide the following information:

- For all proposals: A brief Title, Date of submission, PI's signature.
- For renewals: Last year's IRB number and code, the basis upon which your proposal was reviewed (i. e., Exempt, Expedite, or Full review).
- If you are a Graduate student, obtain your supervisor's signature attesting that s/he has read your proposal and finds it error-free.
 - This form should be placed on top your proposal. You can download it from <http://psychology.unc.edu/research/IRB.html>

Researchers should give all IRB applications and one copy to Sarah Mason in Room 325 or place them in her mailbox. Sarah is a part-time employee. If she is not in her office, and you have an emergency, you may want to contact Brigid Poole in Room 206. A member of the PRC will contact you if there are significant issues or questions concerning your proposal and ask you to address them. When the local reviewer finds your proposal adequate, s/he will give it to Sarah who will submit it to the IRB. Please allow one to two weeks for PRC review. If you are pressed for time, please let Sarah know at the time of submission.

IRB Instructions and Forms

A detailed manual concerning IRB regulations and procedures is available from the office of Human Research Ethics at <http://research.unc.edu/ohre>.

This site also contains (under "Investigators/IRB forms") all the templates, in downloadable form, that you will need to prepare your IRB application (including forms for new proposals, protocol modifications, and renewals). **IRB FORMS CHANGE CONSTANTLY. YOU ARE THUS ADVISED TO DOWNLOAD ANY FORM FROM THE IRB WEBSITE AS YOU NEED THEM.** Investigators working with vulnerable populations who need HIPPA authorization will find the necessary form at the same location. Note that **IRB no longer accepts APPLICATIONS prepared on older forms.** Unless you are using the most recent forms currently on the OHRE website at the time of submission, IRB will not accept your proposal.

IMPORTANT NOTE: As of January, 2007, the IRB requires that at renewal time any modification approved during the year, calls for a complete rewrite of the original application that incorporates the approved modification(s). The renewal application form also requires a note to the IRB that your application contains modifications to the original application. Detailed instructions are contained on the renewal form.

CITI Accreditation

CITI accreditation is required for all types of Applications. All research personnel (PIs, RAs, Graduate and Undergraduate students) must be certified by CITI training prior to conducting research. Accreditation is obtained by completing online the Course in The Protection of Human Research Subjects at <https://www.citiprogram.org/default.asp>. Once this course is successfully

completed your certification may be downloaded within 48 hours from http://cfx3.research.unc.edu/training_comp/.

IMPORTANT NOTE: Although the IRB no longer requires you to append a copy of your CITI training, we strongly advise that you attach the certification to your proposal anyway. This may speed up the review process and avoid any confusion concerning your certification in cases when the CITI database has not been properly updated.

Users of the Psyc101 Participant Pool

All Investigators using the Psych 101 Participant Pool **must** use the Informed Consent letter prepared by Barbara Goldman. She prepared this template to insure that all information required by IRB of users of this population is properly included. All you have to do is fill in the appropriate information under each item and delete the information that does not apply to the specifics of your research. A template of this consent form can be found at <http://psychology.unc.edu/research/IRB.html>

- **Note:** Users of the Psych 101 pool are required to attach the text of the advertisement they post in Davie Hall to recruit potential subjects for their research.

PREPARATION INSTRUCTIONS: GENERAL

- Use a simple, descriptive title on your IRB application and your consent form. Your title does not need to match your grant title, if you have one.
- Use a readable font size and appropriate spacing. Check your spelling and grammar. The policy of the IRB office is that anything that will be read by the participants must be spelled correctly and must be grammatically correct. Consent documents, flyers, questionnaires, debriefing letters etc. will not be approved until they meet this standard. In the body of your application small typos may be hand-edited.
- You do not have to print consent forms on departmental or project letterhead. The new templates have a standard heading that identifies the university. You should use letterhead for letters of invitation.

- Write letters of invitation and consent forms at reading levels appropriate to the sample being recruited. Simpler is usually better. Avoid using jargon. Have a reader outside your area of expertise review your letters and forms to help spot such jargon.
- You **MUST** use a photocopy of the approved “stamped” consent forms for your participants.
- The OHRE website specifies the required elements of a consent, parent permission, and assent form. These are built into the templates provided by OHRE. You may, however, request a waiver of some of the elements. Alternative examples such as telephone scripts and letters to accompany surveys are also provided, along with the required elements.
- If warranted, include a list of resources (such as counseling agencies, hotlines, or websites) especially if you cannot provide individually -tailored information or assistance. For some projects, you may want to provide a listing of such resources to all participants even though you can provide more specific assistance to those whose need is apparent. You should indicate what services will be provided by the research team over and above the study itself if the researcher discovers something that merits further attention (e.g., possible developmental delay discovered in testing a child) if the testing or the sample makes this likely.

SPECIFIC PROCEDURES

1. Modifications

The instructions for the Modification form on the OHRE website presume **paper-based submissions, which are now required by the IRB.**

All changes, from a phone number on the consent form, new staff, or “old” staff leaving, and changes in measures, procedures, sample, etc. are called “modifications” and must be approved by the IRB.

1. Requests for modifications do **NOT** need local IRB review.
2. You do **NOT need to reformat** previously approved consent, parental permission, and child assent forms when making modifications.

Paper-based submissions, with the signed Modification form, should be submitted via campus mail **CB# 7097**, or dropped off at the **at renewal time to the IRB, Medical Building 52, Mason Farm Road, Chapel Hill, NC 27599-7097**

2. Changing Principal Investigator or Faculty Advisor

- A change of Principal Investigator or Faculty Advisor is considered a proposal modification that can be handled on an Expedited basis.
- The PI must submit a revised Application form, pages 1 and 2, with updated signatures. Retain outdated Application pages in IRB study file.
- The modification form should include the signatures of both incoming and outgoing PIs and/or FAs. If the outgoing PI or FA has left the university, the signature of the department chair, dean, or program director is required.
- As appropriate the PI should submit as part of the modification request **revised consent forms**, with updated contact information, i.e., new PI name, telephone number and email address.

3. Renewals

You should receive a renewal email from the IRB 60 days prior to expiration of your currently approved protocol. A follow-up email is sent 30 days prior to expiration.

Renewals are handled like new applications, unless the renewal form is used to close a study, that is, to terminate approval, or because the entire study is completed and no further data analysis is planned. NOTE: renewals keep the same number originally assigned to it by the IRB.

Just like forms for new proposals, renewal forms also change periodically on the OHRE website. PIs are thus advised to download a new form every time you need one.

If your research is terminated:

- Send the termination (called renewal or termination) form directly to the IRB, CB# 7097.

For continuing research:

- If you do NOT NEED to make any changes at the time of renewal, include a single copy of all the recruitment and consent materials you want to use for the upcoming year. DO NOT include another set of measures.

If there have been any modifications approved since the last review and your research is continuing, **the IRB requires a complete rewrite of the original application that incorporates the approved modification(s). The renewal application form also requires a note to the IRB that your application contains modifications to the original application.**

- Highlight the modifications by bolding, underlining, using italics, etc. Do *not* use yellow marker or highlighting that does not copy well.
- Unless you only plan to conduct analyses during the continuing period, include copies of consent documents and all recruitment materials to be used with subjects *in the upcoming approval period*. There is no need to include copies of other already approved documents (e.g., questionnaires, measures etc...) unless these have been modified.
- We suggest you include a copy of CITI certification for all personnel involved in the research. This letter can be printed at the following website: http://cfx3.research.unc.edu/training_comp/

Subjects Enrollment:

IRB still requires investigators to keep an exact count of the number of subjects enrolled in their study across successive years. Accordingly, the current Renewal form requires the following information.

- a. Total projected enrollment as approved by IRB
- b. Total number of subjects enrolled to date
- c. Number of subjects enrolled since last renewal
- d. Number to be enrolled in upcoming year

4. Established longitudinal studies with multiple, separate applications

For previously approved longitudinal studies where you prefer to submit new applications for different phases, you do not have to switch to the new templates. **This is the only exception to using the updated Renewals forms Behavioral IRB does make.** For example, you have separate protocols for infants/toddlers at 12 months, 18 months, 24 months, and 30 months, only the first of which is already approved. You will NOT need to switch over to the new templates for the 18-month-application, even if it is submitted as a NEW application after March 15, 2005. However, make sure you explain this decision in your application.

Prepared by Dr. Marilyn Hartman (2005)

Revised By Jean-Louis Gariépy and Brigid Poole (August 23, 2007)