

INSTRUCTIONS FOR PRINCIPAL INVESTIGATORS

Any person proposing to conduct research involving human subjects must prepare a project proposal for review by the IRB. The purpose of the proposal is to describe research purposes, procedures, and protections against risk so that the IRB can determine whether adequate protection of the rights and welfare of prospective research subjects is provided in accordance with all pertinent laws, regulations, and policies.

Research investigators must submit one copy of the complete research proposal to the Chairperson of the IRB. The Chairperson will then determine the appropriate level of review. Proposals may be designated **exempt** from review, referred for **expedited** review, or require **full** review (see p. 9).

PROJECT PROPOSAL

The project proposal should include the following items: Project Review Cover Sheet, the Project Description, the proposed Informed Consent Form(s), as well as copies of all research instruments and written authorization(s) from cooperating agencies or institutions, if applicable.

Project Description

The project description should be approximately 5 single-spaced pages in length, not including consent forms and instruments. It should include the following:

General Description. Briefly describe the overall goals of the proposed research and the general procedures to be used.

Significance of the Study. Provide a brief theoretical and empirical rationale for why you believe this study is important.

Subject Population. Describe the characteristics of the subject population. Include their anticipated number, age range, gender, racial and ethnic composition, and health status. Identify the criteria for inclusion in the study. If the study involves special classes of subjects, such as fetuses, pregnant women, children, minors, prisoners or other institutionalized individuals, or others who are likely to be vulnerable, please explain the rationale for their involvement. If the sample is limited to a specific racial or ethnic group or is gender specific, please explain your rationale for exclusion/inclusion. Briefly describe the site(s) from which you will draw your sample(s) and/or locate your research study.

Sources of Research Material. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Subject Recruitment. Describe plans for the recruitment of subjects and the consent procedures

to be followed, including the circumstances under which consent will be sought and obtained.

Risks. Describe any potential risks (to confidentiality, physical, psychological and social well-being, legal and financial risks, for example) and assess their likelihood and seriousness.

Protection Against Risks. Describe the procedures for protecting against or minimizing any potential risks identified above and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe provisions for secure storage of data.

Benefits. Discuss the specific benefits to subjects. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

NOTES: Though it is common to utilize the terminology "Human Subject" to connote an individual who participates as a subject in a research study, it is entirely appropriate to substitute the word "Participant". Application materials should not contain typographical and/or grammatical errors. Please be sure to define any technical terms in lay terminology, including description of special equipment and/or procedures.

Consent Form

If an Informed Consent Form is deemed necessary, research investigators must include copies of the proposed Informed Consent Form(s) with the proposal. You must also submit copies of any written or verbal explanation of the project to be given to subjects. The approved Consent Form is valid for a maximum of one year. In cases where a project is continuing beyond one year, permission to continue use of the Informed Consent Form must be applied for at least 45 days in advance of the one-year anniversary date. Such permission is granted in conjunction with the application for Continuing Review.

If your research study will include individuals with linguistic backgrounds other than English, the IRB will generally require that you translate the Informed Consent Form into the appropriate other language. It must be submitted with the other materials you are sending in your application. A "back translation" of the Form should be submitted, as well. In cases where an individual may be unable to read—whether it be English or another language—or has impaired vision, appropriate arrangements must be made to orally convey the contents of the Informed Consent Form. Arrangements must also be made for the individual to give or withhold their willingness to participate in the research project.

Please be sure that your consent form conveys all of the following information, at a minimum:

- a statement that the study involves research, a readily understood explanation of the purposes of the research and the expected duration of the subject's participation, a simple description of the procedures to be followed, including identification of any procedures

which are experimental;

- a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of any benefits to the subject or to others which may reasonably be expected from the research and/or findings (if no direct benefit, this should be stated);
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

Include a statement similar to the following: *If you have questions about the research, your rights as a research subject or if you experience any research related injury, you should contact [name and contact information of investigator] and/or the Human Protections Administrator in the Office of Sponsored Programs at 617-521-2414.*
NOTE: Students should also include name of and contact information for their research advisor.

- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- a statement concerning costs or compensation to the subject, if any.

When required by the IRB, the research investigator shall provide one or more of the following elements of information to each subject:

- ii. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable;
- iii. Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
- iv. Any additional costs to the subject that may result from participation in the research;
- v. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- vi. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and

- vii. The approximate number of subjects involved in the study.

Research investigators are responsible for insuring that written consent is documented by the use of a written Informed Consent Form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. In addition, research investigators must insure that each person signing the written Informed Consent Form is given a copy of that form. Research investigators are responsible for the safeguard of consent documents signed by human research subjects for at least three years following the termination of the project.

The IRB may waive the requirement for the investigator to obtain a signed Informed Consent Form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. For example, in the case of an anonymous survey, consent may be implied by return of the survey; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Reasons for request that a consent be waived should be explicitly stated in a cover memo accompanying the research proposal and protocol. When the documentation requirement is waived or altered, the IRB may still require the research investigator to provide subjects with a written statement regarding the research.

Research Instruments: Please submit copies of your research instrument(s).

Subject Recruitment

If you are recruiting subjects from another institution, you may need to get approval from that institution's IRB, as well as from the Simmons College IRB. If the institution does not require its own IRB review, you may be asked to provide written documentation of the institution's support for your project.

In most circumstances it is inappropriate for a researcher to use their own students as subjects because of the possibility of coercion. Nevertheless, the IRB recognizes that such use may at times be necessary. The researcher must substantiate the need to use their own students as subjects and propose an acceptable plan in accordance with IRB requirements and policies.

In cases where a research study poses at least minimal risk and involves vulnerable subjects, the proposal will receive Full Review. A listing of vulnerable subject categories is contained in *Project Review Cover Sheet* under Item 1b.

Procedures in the Event of Changes to the Protocol or Adverse Effects on Subjects

If a research procedure changes in any way after a research project has been approved, the research investigator must not proceed with the proposed changes without written approval of the IRB. Notification is also required if your project is discontinued.

In cases where a researcher is seeking approval for a project essentially identical to a project previously approved by the IRB, Renewed Approval should be obtained. This would apply to situations where a researcher submits a previously approved proposal to other funding agencies.

It is the researcher's responsibility to notify the IRB in writing of any adverse effects to research participants within one week of such event(s). If a researcher should encounter any unexpected and serious adverse effects on human subjects, research should be immediately discontinued and the IRB must be notified.

Procedures for Renewed Approval

Any project which exceeds a period of one year in duration must be reviewed and receive IRB approval *prior* to the beginning of the second and any successive years of the research project. Continuing Review must be sought at least 45 days *prior* to the anniversary date of approval for the research study.

The Consent Form is also valid for a maximum of one year after its approval. In cases where a project is continuing beyond one year, permission to continue use of the Informed Consent Form must be applied for at least 45 days in advance of the one-year anniversary date. Such permission is granted in conjunction with the application for Continuing Review.

Please complete the Continuing Review Form and submit an original plus one copy to the Office of Sponsored Programs.

Procedures for Project Completion

Upon completion of the research project, it is the researcher's responsibility to submit a Final Report form. The Final Report must include a description of the plan for destruction of the data or documentation that you have sought appropriate consent from participants to retain the data for future use. The prevailing IRB policy is that research data will be destroyed no later than three years after termination of the research project.

Final Note

It is the responsibility of the research investigator to comply with all IRB decisions, conditions, and requirements.

Proposal Attachments

Proposal attachments include the following:

Consent Form

Research Instruments, including but not limited to:

- Surveys
- Interview guides
- Observation tools
- Psychometric tests,
- Or any data collection tool

Proposal Checklist