INSTRUCTIONS FOR RESEARCHERS

Any person proposing to conduct research involving human subjects must prepare an IRB protocol for review by the IRB. The purpose of the protocol 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 participant is provided in accordance with all pertinent laws, regulations, and policies.

Research investigators must email their complete IRB protocol to the Human Protections Administrator via irbprotocols@simmons.edu. The Human Protections Administrator will then assign the protocol to an IRB reviewer. The reviewer will then determine the appropriate level of review. Proposals may be designated **exempt** from review, **expedited**, or require **full** review.

IRB Protocols

The IRB protocols should include the following items: Research Project Cover Sheet, the IRB Project Description Form, 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.

IRB Project Description Form

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.

Participant Population. Describe the characteristics of the participant 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 participants, 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.

Participant Recruitment. Describe plans for the recruitment of participants 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 participants. Also, where appropriate, describe provisions for secure storage of data.

Benefits. Discuss the specific benefits to participants. Discuss why the risks to participants are reasonable in relation to the anticipated benefits to participants 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 participants. 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.

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.

NOTE: A separate document with details about informed consent requirements can be found under “Forms and Templates.”

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

Participant Recruitment

If you are recruiting participants from another institution, you may need to get approval from that institution's IRB, as well as from the Simmons University 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 participants 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 participants 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 participants, the proposal will receive Full Review. A listing of vulnerable participant categories is contained in *Research Project Cover Sheet* under Item 1b.

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

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.

Continuing Review

For projects under the pre-2018 Common Rule, 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 electronic copy plus one original to the Office of Sponsored Programs.

NOTE: Continuing Review requirements have changed under the Revised Common Rule. For projects approved on or after January 21, 2019, the following applies:

Continuing Review of Expedited Research

Continuing review of the expedited research is no longer required. If a reviewer deems it necessary, the reason must be documented. In place of continuing review, the Human Protections administrator will send an email notification after one year asking the researcher to close the protocol if the research is completed. If the research is not completed, the researcher will be asked to submit modification requests if necessary and resubmit their consent form for an updated approval stamp.

Continuing Review of Full Committee Research

Continuing review is no longer necessary for research reviewed at a convened meeting, for which interventions and/or data collection have been completed and only involves analyzing data, including analyzing identifiable private information or biospecimens and/or accessing follow-up clinical data from clinical care procedures.

Procedures for Project Completion

Upon completion of the research project, it is the researcher's responsibility to inform the Human Protections Administrator that the project has been completed. The prevailing IRB policy is that research data will be destroyed no later than three years after termination of the research project.