

IRB 102 - Guidelines for the Preparation of Research Proposals for IRB Review

1. Certificate Program: Protecting Human Research Participants

Students in all programs who wish to pursue research that involves human participants must first receive approval from the Gratz IRB (Institutional Review Board) before undertaking their research.

The student must pay \$50 to receive training from Protecting Human Research Participants (PHRP). Here is the link to their web page for the training: <https://phrptraining.com/#/>. Just click on the "Buy Course" button at the top, select PHRP SBE, and pay for the course with a credit card. After you take the online training, you will receive a certificate of completion, which you must download and email to me. PLEASE NOTE THAT THE PHRP CERTIFICATE IS GOOD FOR 3 YEARS. If your dissertation or thesis is not completed within the 3-year period, you will have to obtain a new Certificate.

2. The Proposal Face Sheet (form IRB001)

Students applying to the IRB must first have a proposal formally approved by their thesis advisor. A copy of the Gratz College IRB Research Proposal Face Sheet must appear on the opening pages of the research proposal submitted for IRB approval. Provide all information requested on the form, including all signatures and dates. If additional space is needed for information on the face sheet, attach additional sheets.

After the Face Sheet, the Proposal should be attached and include but not limited to the following:

3. The IRB Proposal

3.1 Outline of Proposal

On a separate sheet, include a proposal that has the following subheadings:

- Purpose of the research project
- Type of research design employed in the project
- Subjects involved and maximum number of participants expected
- List of Questions for subjects or copy of any Questionnaires
- Procedures for data collection
- Anticipated type of data analysis to be employed
- Relevance of the research project
- Any potential risks – psychological, social, legal, physical, etc., to the subjects involved in the research and what you will do to minimize any risks. The following Risk statement appears on the Consent Forms for Adults 18 and older and Minors 15-17:

IRB RISK STATEMENT TEMPLATE – for Participants

There is minimal risk in participating in any research project and for most subjects, the risk of participating in this study is no greater than that ordinarily encountered during participation in general research studies. Although we do not expect that participating in the study will cause any distress, all research has potential risk associated with it. The participants should feel free to contact the IRB chair, Dr. Ruth Sandberg at rsandberg@gratz.edu, if there are any questions or concerns.

A shorter version appears on the Consent Form for Minors 7-14.

3.2 Informed Consent

Any research project that involves the use of human subjects requires implementation of procedures for obtaining the informed consent of the subjects. The research proposal must include a separate section on how informed consent will be obtained. The primary investigator must fill in all the blanks on all Consent Forms before having the participants sign them. After receiving approval by the IRB, ***the primary investigator must send the IRB Chair copies of all IRB signed Consent Forms from all participants before they begin or during their research.***

NOTE: ***If minors are involved in your research, you will need to request a Full Review.***

3.3 Confidentiality Statement and Protection of Subjects

The primary investigator's proposal must also include a section explaining how confidentiality of the participants will be protected.

Exception to confidentiality – Mandatory reporting: If a minor reveals that a probable crime has been committed against him or her (such as physical or sexual abuse), the research investigator is mandated by law to stop the research and immediately report the information to the appropriate legal authorities.

Primary investigators who involve minors in their research must indicate in the Proposal their awareness of this exception and the process to be employed in the event of a minor revealing a probable crime.

4. Proposal Submission

Email the completed Proposal to the IRB Chair, Dr. Ruth Sandberg at rsandberg@gratz.edu. The Research Proposal Face Sheet must be completed in its entirety, including all signatures, as well as inclusion of all required information in the Proposal, or the application will not be accepted for review. The Advisor must also submit IRB 103 Advisor Review Form.

It usually takes about two weeks for the IRB members to review a proposal.