INSTITUTIONAL REVIEW BOARD HANDBOOK

To ensure that all student research involving human subjects conforms to the federal requirements established through the U. S. Department of Health and Human Services (45 CFR 46)

Reviewed June 10, 2020
https://www.gratz.edu/institutional-review-board

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I. Application Process

DESCRIPTION OF PROCESS FOR PROPOSALS:

1. All necessary Forms for submission to the IRB are provided online. The IRB Chair can also provide students with the appropriate information and Forms.
2. IRB Chair keeps track of each student's application and the application process.
3. IRB Chair sends electronic copies of the logged applications to IRB Members.
4. IRB Members will review each application.
5. As part of the review process, IRB members will make a decision about approval in a timely manner.
6. Based upon the responses from the IRB members, the IRB Chair will make a determination as to the status of the application, which will be forward to the applicant and to all IRB members. All approvals are for a maximum of one year.

The possible determinations are:

- ***"Approve Expedited"***
- ***"Approve Full Review"***

TIMELINE for REVIEW PROCESS:

IF EXEMPT – the applicant should expect a response within 10 working days after date of submission.

IF EXPEDITED – the applicant should expect a response within 30 days after date of submission.

IF FULL Review – the applicant should expect a response after the meeting held by members of the Institutional Review Board

All FULL Reviews follow the schedule below but can be modified for students' needs:

Semester	IRB Full Review Meeting
FALL	October
SPRING	February

IRB Members for the academic year 2020-2021:

Dr. Ruth Sandberg, IRB Chair
Ms. Debbie Aron
Dr. Karen Galardi (external member)

Ms. Naomi Housman
Dr. Honour Moore
Dr. Philip Moore

DESCRIPTION OF ALL FORMS:

FORMS available on the Gratz web site:

You can find the IRB Handbook and IRB Forms on the Gratz web site at the following link: https://www.gratz.edu/institutional-review-board.

You will also find the following forms in this Handbook and on the IRB link above:

- Gratz IRB001 Face Sheet and Basic Guidelines
- Gratz IRB102 Guidelines for the Preparation of Research Proposals
- Gratz Proposal Advisor Review Form
- IRB010A Adult Consent
- IRB010B Consent Form Ages 7-14
- IRB010C Consent Form Ages 15-17
- IRB010D Parental Permission Form

II. POLICIES

Policies and Procedures Governing the Formation and Operation of the Gratz College Institutional Review Board

1. Introduction and Regulations

1.1 Gratz College is committed to fostering a number of core values which include compassion, social responsibility, and respect for the dignity of each person. In conducting research, it is paramount that investigators uphold these values in their interactions with human subjects, as well as comply with applicable federal regulations.

1.2 For information on the federal regulations, please refer to the United States Department of Health and Human Services Regulations, Protection of Human Subjects: Title 45, Code of Federal Regulations, part 46 (45 CFR 46), revised June 18, 1991, December 28, 2000, August 14, 2002, and 21 CFR parts 50 and 56 [Food and Drug Administration Regulation on Protection of Human Subjects]. Also see the Health Insurance Portability and Accountability Act (HIPAA) of 1996; the Privacy Rule (also known as Standards for Privacy of Individually Identifiable Health Information) is in Title 45 of the Code of Federal Regulations, Part 160 and Subparts A and E of Part 164.

1.3 The policies and procedures governing the formation and operation of the Gratz College Institutional Review Board (IRB) include the federal regulations outlined above in 1.2, the provisions of this document, and the Guidelines for the Preparation of Research Proposals for IRB Review.

2. Purpose

The purpose of the Gratz College Institutional Review Board is to review research proposals for compliance with federal regulations and ethical principles to insure that subjects are adequately protected from harm, and that they give voluntary, informed consent to their participation as documented in the forms below and maintained by the institution.

3. Authority

The Gratz College Institutional Review Board is established under authority delegated by the Board of Governors to the President of Gratz College and under the governing federal regulations outlined above in 1.2. The IRB has the authority to approve, require modifications, or disapprove proposals for research on human subjects conducted at Gratz College, or conducted by members of the Gratz College community (including faculty, students, staff, and administrators).

4. Jurisdiction

4.1 The Gratz College IRB has jurisdiction over any research project that involves or has the potential to involve human beings as the subjects of research and that is proposed to be carried out by a member of the Gratz College community (including faculty, students, staff, and administrators), or proposed to be carried out on Gratz College property, or that involves members of the Gratz College community as subjects of the research.

4.2 Under federal regulations, certain categories of research involving human subjects are exempt from IRB review [Federal Policy 45 CFR 46.101 (b)]. Examples include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data; research in normal educational settings, involving normal educational practices, such as research on the effectiveness of instructional techniques or curricula; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data. The Gratz College IRB will make the determination of which research proposals involving human subjects are exempt.

5. Statement of Principles

The following are the principles governing Gratz College in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research and are maintained by the IRB.

5.1 Research must be justifiable for its scientific or other meaningful purpose or value.

5.2 Even if an inquiry has scientific or other value, it must not be pursued if the benefit is outweighed by risk to the subject.

5.3 The research must be conducted by sufficiently competent and knowledgeable people.

5.4 The research must be conducted under a sound design, suited to the nature of the study.

5.5 Informed consent is a process ensuring ethical conduct of research. No person should serve as the subject of research unless he or she, or an authorized or legal representative, has given voluntary consent after being fully informed of the nature, risks, and benefits of the study and their rights as participants. Additional safeguards must be included in the study to protect the rights and welfare of subjects.

5.6 Participation as a subject in a research study should be voluntary, and care should be exercised to ensure that subtle pressures are not used to obtain participation.

5.7 Care must be taken throughout the duration of the research study (and sometimes beyond) to ensure against the risk of harm to subjects, either physical or emotional.

5.8 Research must be terminated if there arises a serious risk of harm to subjects, either

physical or emotional.

5.9 The subject should be entitled to withdraw from participation in a research study at any time.

6. Institutional Support

Gratz College will provide sufficient staff and resources to support the IRB's review and recordkeeping duties.

7. IRB Membership

7.1 The IRB shall have at least 5 members. The IRB members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as minors, prisoners, pregnant women, or physically or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

7.2 Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of persons of one gender, including the institution's consideration of qualified persons of both genders, so long as no selection is made to the IRB on the basis of gender.

7.3 The IRB may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB.

7.4 The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

7.5 The IRB Chair shall maintain a list of the current members of the IRB identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member of the IRB and Gratz College; for example: full-time employee, part-time employee,

member of governing panel or board, paid or unpaid consultant.

8. IRB Functions and Operations

8.1 The members of the IRB shall be appointed by the Dean/Vice President of Academic Affairs with terms of service determined by that person to ensure continuity of function of the IRB. No member shall be appointed to a term of less than one (1) year unless it is to serve out the unexpired term of a member who left the IRB before the end of his/her appointed term. There is no limit placed on the number of terms, or the number of consecutive terms, a person may serve on the IRB. The Dean/ Vice President of Academic Affairs has the right to remove a member from the IRB if they fail to meet the responsibilities of IRB membership.

8.2 The Dean/Vice President of Academic Affairs shall appoint the chairperson of the IRB and designate the length of term that he/she shall serve as the chairperson. The Dean/Vice president of Academic Affairs has the right to remove an IRB chairperson who is not meeting the responsibilities of the position.

8.3 Whenever an IRB document or form is created, revised or deleted, the inventory must be updated. The IRB administrator shall make copies of these documents available to members of the Gratz College community, or other interested parties, upon request.

8.4 Proposals being submitted for IRB review must be prepared in accordance with the Guidelines for the Preparation of Research Proposals for IRB Review. All proposals must be submitted to the IRB Chair. Proposals will be stamped with the date received and logged into the IRB records.

8.5 Except when a proposal is exempt or an expedited review procedure is used (see Sections 11 and 12 below), research proposals shall be reviewed by a majority of the members of the IRB.

8.6 The IRB will attempt to review any research proposal and respond with a decision within thirty (30) days of receipt of the proposal.

8.7 The IRB will maintain all shared forms on the Gratz web site. To the extent the IRB maintains hard copy documents, they shall reside in a locked file accessible only to the IRB chairperson and administrator.

9. Criteria for IRB Approval of Research

In order to approve research covered by this document, the IRB shall determine that all of the following requirements are satisfied:

9.1 Risks to subjects are minimized by using procedures which are consistent with sound

research design and which do not unnecessarily expose subjects to risk.

Minimal risk implies that the likelihood and degree of harm or discomfort expected as a result of the research are not greater than the risks encountered during the course of daily activity or during the course of routine physical or psychological examinations. Such risk considerations should not be limited to physical risk alone, but should also consider emotional and psychological risk, personal risk, and possible insurability risk.

9.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

9.3 Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as minors, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

9.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 20 (General Requirements for Informed Consent) of this document.

9.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by Section 21 (Documentation of Informed Consent) of this document.

9.6 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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 report the information to the appropriate legal authorities.

9.7 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as minors, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. A full description of safeguards to ensure the fair and equitable treatment of these subjects and protect their rights and welfare can be found in the Department of Health and Human Services Office for Human Research Protections Code of Federal Regulations.

10. Gratz College IRB Review of Research

10.1 The Gratz College IRB shall review and have authority to approve, require modifications in, or disapprove all research activities covered by this document. All proposals for human

subjects research must be submitted to the IRB for review and approval. No involvement of human subjects may take place prior to formal, written notification from the IRB.

10.2 All students, undergraduate and graduate, must submit research proposals to the Gratz College IRB for review before seeking external approval. All faculty and staff must submit research proposals to the Gratz College IRB for review.

10.3 The IRB shall require that information given to subjects as part of informed consent is in accordance with Sections 19 and 20 of this document. The IRB may require that information, in addition to that specifically mentioned in Sections 19 and 20, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of human subjects.

10.4 The IRB shall require documentation of informed consent.

10.5 The IRB shall notify investigators and the institution in writing of its decision to exempt, approve, approve with periodic review required, require re-submission with modifications, or disapprove the proposed research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in writing.

10.6 If the IRB requires re-submission of a research proposal, the principal investigator must prepare IRB form 008 including the required revisions or additional information, and submit these documents to the IRB.

10.7 If the IRB disapproves a proposal, a new research proposal must be prepared and submitted to the IRB if the investigators wish to pursue the same line of research.

11. Expedited Review

An expedited review may be granted if the only involvement of human subjects will be in one or more of the following five categories:

11.1 Research conducted in established or commonly accepted educational settings involving normal education practices such as regular and special education instructional strategies, or the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

11.2 Research involving use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior unless

a) Information obtained is recorded in such a manner that human subjects can

be identified directly or through identifiers linked to the subjects, and

b) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, reputation and general physical and mental health.

This exemption does not apply to research involving minors using surveys, interviews, or observations of public behavior when the investigator is a participant in the activities being observed.

11.3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if:

a) Human subjects are elected or appointed public officials or candidates for public office; or

b) Federal statutes require without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.

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 report the information to the appropriate legal authorities.

11.4 Research involving the collection or study of existing data, documents, records, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

11.5 The determination of eligibility for exemption is made by the IRB. Most projects that qualify for exemption can be reviewed and approved by the IRB within 10 working days provided that the application does not lack essential information or questions arise that cannot be promptly and fully answered by the investigator. If it is determined that a project is not exempt, the project will receive an expedited or full review. Modifications to an exempt project may cause it to become non-exempt necessitating re-approval.

12. Full Board Review

12.1 Full board review is required for studies that involve greater than minimal risk or vulnerable populations that require special protection by the IRB. These populations include, but are not limited to: pregnant women, prisoners, minors, mentally or physically disabled, and economically or educationally disadvantaged persons.

12.2 All research proposals are assigned for review at a convened meeting unless they meet the criteria for expedited review or exemption. The original copy the proposal must

be delivered to the IRB Chair, at which time the proposal will be dated and logged into the IRB records.

In order for the application to be approved, it must receive the approval of a majority of the majority of the IRB members.

12.3 The IRB will attempt to review any research proposal and respond with a decision within thirty (30) days of receipt of the proposal. Delays may occur if the IRB must request clarification from the investigators, or must consult persons not on the IRB who have expertise in the area of research in question and can provide input to the members of the IRB that will help them to better understand a proposal and its implications.

12.4 When a proposal is submitted, it is checked for completeness. If not complete, it is returned to the principal investigator. When completed, it will be circulated to the members of the IRB. The proposal will be evaluated for the extent to which it provides for the protection of human subjects, demonstrates merit and does not conflict with the Core Values of Gratz College. The IRB Chair will notify the principal investigator of the outcome of the full review.

13. Review by Institution

Research covered by this document that has been approved by the IRB is subject to further review and approval or disapproval by the President and/or Board of Governors.

14. Suspension or Termination of IRB Approval of Research

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will be determined by the committee as a whole, shall include a statement of the reasons for the IRB's action and shall be reported promptly to the principal investigator and appropriate institutional officials.

15. Protocol Changes

If the investigator(s) desires to change the research protocol after obtaining IRB approval, the principal investigator must prepare a Request for Review of Change in Research Protocol, and submit the form to the IRB along with an explanation and description of the desired changes. If the proposed changes necessitate a change in the consent form, then a revised consent form should also be submitted. IRB review and approval are required before investigators can modify research protocols, except when necessary to eliminate apparent immediate hazards to subjects.

16. Unanticipated or Unexpected Results

16.1 Investigator Responsibilities: In the event of an unanticipated or unexpected result, the principal investigator is required to submit a written report to the IRB. It should contain sufficient information for the IRB to judge whether or not the event raises new questions about either the risk/benefit ratio or the design of the research.

16.2 If the Principal Investigator wishes to proceed with the research, a Request for Review of Change in Research Protocol must be submitted to the IRB Chair.

17. IRB Documents and Records

17.1 The IRB Chair shall prepare and maintain adequate documentation of IRB activities, including the following:

a. Copies of all research proposals reviewed, approved consent documents, progress reports submitted by investigators, and reports of any injuries to subjects.

b. Actions taken by the IRB; the basis for requiring changes in or disapproving research.

c. Copies of all correspondence between the IRB and the investigators.

d. A copy of this document and all other IRB documents and forms.

e. A statement from the principal investigator describing the extent to which confidentiality of records identifying the subjects will be maintained.

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 report the information to the appropriate legal authorities.

17.2 All records shall be accessible for inspection and copying by authorized representatives of Gratz College at reasonable times and in a reasonable manner.

18. General Requirements for Informed Consent

No investigator may involve a human being as a subject in research covered by this document unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the

possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative and at an appropriate reading level. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

18.1 Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, and a description of the procedures to be followed

b. A description of any reasonably foreseeable risks or discomforts to the subject;

c. A description of any benefits to the subject or to others which may reasonably be expected from the research;

d. A statement describing the extent to which confidentiality of records identifying the subject will be maintained;

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 report the information to the appropriate legal authorities.

e. 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; and

f. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

18.2 The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

18.3 Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

19. Documentation of Informed Consent

19.1 Informed consent shall be documented by the use of the written consent forms approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

19.2 The consent form is a written consent document that embodies the elements of informed consent required in this section. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

20. Research Undertaken Without the Intention of Involving Human Subjects

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by the IRB.

21. Completion

The principal investigator must inform the IRB in writing when the research project has been completed.

III. GUIDELINES

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

I. Certificate Program: Protecting Human Research Participants

Students in all programs, as well as faculty, 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 or faculty member must first present evidence of having taken online training provide by Protecting Human Research Participants (PHRP) (https://phrptraining.com/#!/). Students and faculty who take the training receive a Certificate at the end of the course and must download the Certificate and email it to the IRB Chair. The cost for the PHRP training is $40.00.

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 accompany any research proposal submitted for IRB approval. This Face Sheet is available on the Gratz web site. Provide all information requested on the form, including all signatures. All information is to be typed, except for signatures. 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 the following (see Form IRB001 for a complete list of submission topics):

3. The Proposal

3.1 Abstract

On a separate sheet, include an abstract of the project of no approximately 500 words. The abstract should address the following:

- Purpose of the research project;
- Type of research design employed in the project;
- Subjects, if any, involved;
- 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.

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 address how informed consent will be obtained, and after receiving approval by the IRB, the primary investigator must provide copies of the actual IRB consent form(s) before they begin

their research. All consent forms can be found on the Gratz web site or can be obtained from the IRB Char. ***If minors are involved in your research, you will need to request a Full Review.***

3.3 Confidentiality Statement

The primary investigator must also include a statement explaining how confidentiality of the participants will be protected.

4. Proposal Submission

Email the completed Proposal to 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. In addition, the Advisor must also submit a Proposal Review Form.

Gratz College Consent Form Templates

IRB010A Adult Participant, IRB010B Assent to Participate in a Research Study, Minor Participant (7-14 years), IRB010C Assent to Participate in a Research Study, Minor Participant (15-17 years); IRB010D Parental Permission for a Minor to Participate in a Research Study Social Behavioral Form

The Consent Form templates should be used for all written consent form documents. These consent templates contain all of the basic elements described above. For clarity and to assure timely processing by the IRB, the consent form should follow the guidelines described below.

The consent form and study face sheet must be written at a level understandable to all potential participants, and it must contain all information that would reasonably influence the subject's willingness to participate. In order to facilitate this requirement, the IRB will provide templates which reflect appropriate language for various subject populations. The consent form should be written in the second person with "you" or "your child" consistently used to refer to the subject in all statements. The consent form must be written in clear, understandable English and typed. If the population to be sampled speaks another language, the investigators must attach to the English language version a certified translation of the consent form and have subjects sign both versions. A certified translation is one that has been approved by the IRB after consistency with the English language version has been certified by an IRB member or consultant to the IRB who is fluent in the language used in the non-English version of the consent form.

The consent form should be a succinct statement (no more than three pages) providing information about the research project including (but not limited to) its purpose, procedures, benefits, risks, duration, and (where applicable) alternative therapies that are available. The document should bear the title Consent Form and immediately beneath the title should bear the title of the research project, the name and address of the principal investigator, and the

names of any additional investigators. The consent form should identify the institution(s) represented by the investigator(s) and the institution(s) where the research project is to be carried out. The document should contain a footer identifying the date of the latest revision; only the form approved by the IRB may be used in the research project. The date on which the consent form was prepared should be indicated on the form so that revised forms can be easily distinguished from prior drafts.

The consent form must provide adequate information to enable a prospective subject to decide whether or not to participate in the research project and may not include language by which a subject is made to waive, or appear to waive, any of his/her legal rights or to release the investigator(s), or the sponsoring institution(s) or its (their) agents, from liability for negligence. Each adult subject and each legal guardian who signs consent for a subject who is a minor must receive a copy of the signed consent form. The principal investigator must retain in his/her confidential files copies of consent forms signed by each subject in the study for at least five years after completion of the research project or such longer period as may be specified by program requirements. In the case of subjects who are minors, the above rule on retaining copies of signed consent forms applies or the signed copies must be retained until the subject reaches his/her majority, whichever period is longer.

Subjects' Questions and Rights: Subjects must be provided with an opportunity to ask questions regarding the study and their participation in the study, or to request an elaboration of any of their rights as subjects of research. Subjects must be provided with the name and method of contacting a person who can answer their questions or requests for additional information. They also need to be provided with a way to contact the IRB if they have concerns about the treatment of human subjects.

Signatures: Lines for required signatures should be provided at the end of the consent form. All signature lines on the consent form should contain a printed or typed version of the signer's name and space for the date of signing. A person may not participate as a subject of the research unless they, or their legally authorized representative, have signed the affirmation. If the prospective subject is a minor, signature lines for both the subject and a relative or legal guardian must be provided. In the case of prospective subjects whose capacity or competence to give consent is limited for any reason, the signature of their legally authorized representative must be obtained. There must also be signature lines for the principal investigator and any required witnesses. If subjects are not fluent in English, they need to have the consent form explained by an interpreter along with the principal investigator. The interpreter needs to sign the consent form. Signature lines cannot appear alone on a separate page.

IV. FORMS

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IRB001 PROPOSAL FACE SHEET

Gratz College, Melrose Park, Pennsylvania
Research Proposal

Date submitted:

Request for *[Mark one choice]* **Expedited Review ____ Full Review ____**

Title of Research Proposal:

Principal Investigator	Project Advisor *(if Student Proposal)*
Name:	Name:
Mailing Address:	Title:
Phone:	School:
Email:	Email Address:
Additional Investigator(s)	Additional Investigator(s)
Name:	Name:
Institution:	Institution:
Email:	Email:

Location:

Other Institution(s) requiring review of this proposal:

Type of Study:

Population Involved:

Approximate no. of subjects:

Signatures:

	NAME	SIGNATURE	DATE
Principal Investigator			
Project Advisor			
Additional Investigator			

Written Consent Form: **IRB010A** Adult Consent

Gratz
College
Guidelines for Adult Consent Form
(IRB010A)
Adult Participants *[If using more than one adult form, identify adult group.*]

Title of Study:

Principle Investigator:
Principle Investigator's email address:
Co-Investigators *(if applicable):*
Co-Investigators' email addresses:
Project Advisor:
Project Advisor's email address:

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, at any time, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn about…

You are being asked to be in the study because…

Are there any reasons you should not be in this study?

You should not be in this study if…

How many people will take part in this study?
If you decide to be in this study, _____ number of people will be participating with you.

How long will your part in this study last?

What will happen if you take part in the study?

What are the possible risks or discomforts involved from being in this study?
There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will your privacy be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Gratz College will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the College, research sponsors, or government agencies for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. However, by signing this form, you do not give up any of your legal rights.

Will you receive anything for being in this study?

You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
No.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights

and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the IRB Chair at 215-635-7300, ex. 168.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

Written Consent Form: **IRB010B** Consent Age 7-14

Gratz College
Consent to Participate in a Research Study
Minor Participant (age 7-14 years)

Title of Study:

Principle Investigator:
Principle Investigator's Email address:
Co-Investigators *if applicable*:
Co-Investigators' email addresses: Project Advisor:
Project Advisor's email address:

These are some things we want you to know about research studies:
Your parent needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

Sometimes good things happen to people who take part in studies, and sometimes things we may not like happen. We will tell you more about these things below.

Why are they doing this research study?
The reason for doing this research is to

Why are you being asked to be in this research study?

How many people will take part in this study?
If you decide to be in this study, you will be one of approximately (*number*) people in this study.

What will happen during this study?
This study will take place at (*name study site)* and will last During this study

Who will be told the things we learn about you in this study?

Will you get any money or gifts for being in this research study?

People may have good things happen to them because they are in research studies. These are called "benefits." such as receiving candy or money. Aside from maybe having some fun, you will not receive any benefits from being in this research study.

What are the bad things that might happen?

Sometimes things happen to people in research studies that may make them feel bad. These are called "risks." These are the risks of this study

Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. You should report any problems to the researcher.

How will your privacy be protected?

You will not be identified in any report or publication about this study.

We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else. If you tell us that someone is or has been hurting you, we may have to tell that to people who are responsible for protecting children so they can make sure you and others are safe.

What if you or your parents don't want you to be in this study?

If you or your parents don't want you to be in this study, you can withdraw at any time.

Who should you ask if you have any questions?

If you have questions, or concerns, you should ask the people listed on the first page of this form. If you have other questions about your rights while you are in this research study you may contact the Institutional Review Board at 215-635-7300, ex. 168.

Participant's Agreement:

If you sign your name below, it means that you agree to take part in this research

_____ _____

study. Print your name here if you want to be in the study Date

_____ _____

Signature of Person Obtaining Assent Date

_____

Printed Name of Person Obtaining Assent

Written Consent Form: **IR010C** Consent Age 15-17

Gratz College
Assent to Participate in a Research Study
Minor Participant (age 15-17 years)

Title of Study:

Principle Investigator:
Principle Investigator's email address:
Co-Investigators *if applicable*:
Co-Investigators' email addresses:
Project Advisor:
Project Advisor's email address:

What are some general things you should know about research studies?

You are being asked to take part in a research study. Your parent, or guardian, needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, at any time, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn about

You are being asked to be in the study because

Are there any reasons you should not be in this study?
You should not be in this study if

How many people will take part in this study?
If you decide to be in this study, _____ number of other people will be participating with you.

How long will your part in this study last?

What will happen if you take part in the study?

What are the possible risks or discomforts involved from being in this study?
There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will your privacy be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Gratz College will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the College, research sponsors, or government agencies for purposes such as quality control or safety.

We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else. If you tell us that someone is or has been hurting you, we may have to tell that to people who are responsible for protecting children so they can make sure you and others are safe.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to your parents. However, by signing this form, you do not give up any of your legal rights.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
There will be no costs for being in the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the Institutional Review Board at 215-646-7300.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

Written Consent Form: **IRB010D** Parental Permission

Gratz College
Parental Permission for a Minor Child to Participate in a Research Study

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Title of Study:

Principle Investigator:
Principle Investigator's email address:
Co-Investigators *if applicable*:
Co-Investigators' email addresses
Project Advisor:
Project Advisor's email address:

What are some general things you should know about research studies?

You are being asked to allow your child to take part in a research study. To join the study is voluntary. You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason, at any time. Even if you give your permission, your child can decide not to be in the study or to leave the study early.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you and your child can make an informed choice about being in this research study.

You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn about

You are being asked to be in the study because

Are there any reasons you should not be in this study?
Your child should not be in this study if

How many people will take part in this study?
If you decide to be in this study, your child will be one of ____ other people in this research study.

How long will your child's part in this study last?

What will happen if your child takes part in the study?

What are the possible risks or discomforts involved from being in this study?
There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will your child's privacy be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Gratz College will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the College, research sponsors, or government agencies for purposes such as quality control or safety.

Exception to confidentiality – Mandatory reporting: If your minor child reveals that a probable crime has been committed against him or her (such as physical or sexual abuse), I am mandated by law to report that information to the appropriate legal authorities.

What will happen if your child is injured by this research?
All research involves a chance that something bad might happen. This may include the risk of personal injury. If such problems occur, the researchers will help your child get medical care, but any costs for the medical care will be billed to you and/or your insurance company. However, by signing this form, you do not give up any of your legal rights.

Will your child receive anything for being in this study?
Your child will not receive anything for taking part in this study.

Will it cost you anything for your child to be in this study?
There will be no costs for being in the study.

What if you or your child have questions about your rights as a research participant?
You and your child have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first

page of this form.

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Printed Name of Research Participant (Child)

_____ _____
Signature of Parent Date

_____
Printed Name of Parent

Dissertation Advisor IRB Proposal Review Form

INVESTIGATOR NAME / PROPOSAL TITLE/DATE

REVIEW ITEMS				
1. Eligibility	YES	NO	N/A	**COMMENTS**
a. The research project involves human subjects.				
b. The information on the proposal cover sheet is complete (including signatures).				
c. The principal investigator and the additional investigator(s) is (are) qualified to conduct this research project.				
2. Location and Duration	YES	NO	N/A	**COMMENTS**
a. The facility where the research is to be conducted is a reasonable choice for the proposed project.				
b. The proposed time frame is adequate for the research project.				
c. Other institutions involved in the research are clearly identified.				
d. Other institutions involved in the research have provided appropriate letters/documents indicating support of the research at the site.				
3. Purpose	YES	NO	N/A	**COMMENTS**
a. The purpose of the research project is clearly stated.				
b. The goals of the research project are realistic and potentially achievable.				
c. The research project is relevant and important to an identified discipline.				
4. Background	YES	NO	N/A	**COMMENTS**
a. There is sufficient need for the undertaking of this research project based on a lack of				

previous research or on significant potential for the application of the research to the intended discipline or for educational value.				
b. The background information supplied, including references, supports the proposed research project.				
5. Methods	YES	NO	N/A	**COMMENTS**
a. The proposed method is suited to the research question.				
b. The proposed instruments and measures are appropriate for addressing the research question.				
c. The procedures for analyzing the data are appropriate and clearly identified. **SEE 6				
6. Data and/or Stored Samples	YES	NO	N/A	**COMMENTS**
If Coded or Identified Source Data collected:				
a. A reasonable justification for need to retain identities or codes is provided.				
b. A description of how easy/difficult it would be to make a link to sources is provided.				
c. A description for plan for tracking, protecting and plans for the samples or data at the conclusion of the study is provided.				
d. PI indicates how will report the loss, destruction, or revealing of samples to the IRB				
If Unlinked or Unidentified Sources collected:				
a. Subjects cannot be identified directly or through identifiers linked to the subjects.				
7. Subject Recruitment and Selection	YES	NO	N/A	**COMMENTS**
a. The proposed population to be sampled is relevant to the research question.				
b. Criteria for inclusion and exclusion of potential subjects are documented and adequate.				
c. Inducements, if offered to subjects, are reasonable.				
d. The sampling design is achievable and relevant to the research project.				
8. Potential Risks	YES	NO	N/A	**COMMENTS**
a. Potential risks to subjects have been				

adequately identified.				
b. Potential risks to the investigators have been adequately identified.				
9. Protection	YES	NO	N/A	**COMMENTS**
a. Protection of all subjects from identified risks has been adequately addressed.				
b. Provision for the withdrawal of subjects from the study has been adequately addressed.				
c. Protection of the investigators from identified risks has been adequately addressed.				
10. Potential Benefits	YES	NO	N/A	**COMMENTS**
a. Potential benefits to subjects have been adequately identified.				
11. Risk/Benefit Ratio	YES	NO	N/A	**COMMENTS**
a. An adequate assessment of the risk/benefit ratio of the proposed research has been provided.				
12. Consent	YES	NO	N/A	**COMMENTS**
a. The consent procedures appear to be adequate.				
b. A copy of the proposed consent form has been submitted.				
c. The consent form is written in plain language, includes a description of the purpose of the research, the procedures to which the subject will be exposed, a statement regarding voluntary withdraw of the subject from participation in the project, and provides places for signatures of the subject, principal investigator(s), and a witness (if required).				
13. Budget	YES	NO	N/A	**COMMENTS**
a. The budget is reasonable for the type and duration of the research project, specifically as regards the safeguarding human subjects.				
b. The financial resources are appropriate and do not pose a conflict of interest, particularly as regards the safeguarding of human subjects.				
14. Resources	YES	NO	N/A	**COMMENTS**
a. The financial resources appear adequate for the proposed research project.				
b. The equipment resources appear adequate for the proposed research project.				
c. Equipment or supplies loaned, donated, or otherwise supplied at less than fair market				

value does not pose a conflict of interest.				
d. The use of prototype equipment in the research project does not bias the study design towards or against any equipment manufacturer.				

COMMENTS: