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 August 9 2017

https://www.gratz.edu/institutional-review-board
# Table of Contents

I. **APPLICATION PROCESS**  
II. **POLICIES & PROCEDURES** (IRB101)  
III. **GUIDELINES** (IRB102)  
IV. **FORMS INCLUDED:**
    
    - Proposal Face Sheet (IRB001 with imbedded IRB102 Guidelines)  
    - Proposal Outline  
    - Research Proposal Review Form (IRB002)  
    - External IRB Review Completion (IRB003)  
    - Exemption Request (IRB004A)  
    - Expedited Request (IRB004B)  
    - Consent Forms (IRB010A, B, C, D)  
    - Completion Form (IRB011)  
    - Re-Submission (IRB008)  
    - Request for IRB Re-Approval of Research and/or Review of Change in Research (IRB007)

V. **TRAINING & RESOURCES**

    **Online Training**  
    *Certificate Program: National Institutes of Health (NIH)*  
    [https://phrp.nihtraining.com/](https://phrp.nihtraining.com/)

    **Information:** U.S. Dept. of Health and Human Services “Protecting Human Subjects Training”  
    [https://www.hrsa.gov/publichealth/clinical/humansubjects/](https://www.hrsa.gov/publichealth/clinical/humansubjects/)

    **The Belmont Report**  

    **The Nuremberg Code**  

    U.S. Dept. of Health & Human Services “Protection of Human Subjects” (45 CFR 46)  
    [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#VTQeOo09F_s.mailto](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#VTQeOo09F_s.mailto)
I. Application Process

**DESCRIPTION OF PROCESS FOR PROPOSALS:**

1. Professors whose students are requesting IRB approval should provide a list of student names and email addresses to IRB Chair.
2. The IRB Chair will provide students on the list with the appropriate information and forms; professors will collect all student applications and ensure that the proposals contain all elements necessary for smooth review by IRB; professors will send files to IRB Chair for processing and log-in.
3. IRB Chair updates the Log sheet.
4. IRB Chair sends electronic copies of the logged and coded applications to IRB Members.
5. IRB Members will review each application.
6. As part of the review process, IRB members will fill out the appropriate form:
   - IRB002 Research Proposal Review Form
7. The IRB members will send completed and signed form IRB002 to the IRB Chair.
8. 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 Exempt”
- “Approve Expedited”
- “Approve Full Review”
- “Approve with periodic review required”
- “Require re-submission with modifications”
- “Disapprove the proposed research activity”

**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:

<table>
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<tr>
<th>Semester</th>
<th>IRB Full REVIEW Meeting</th>
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<tr>
<td>FALL</td>
<td>October</td>
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<tr>
<td>SPRING</td>
<td>February</td>
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**IRB Members for the academic year 2017-2018:**

Dr. Ruth Sandberg, IRB Chair  
Ms. Debbie Aron  
Dr. Joseph Davis  
Dr. Karen Galardi (external member)  
Dr. Honour Moore  
Dr. Shifra Vega  
Ms. Jessica Whittemore

**DESCRIPTION OF IRB AND IRB DOCUMENTS:**

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

**DESCRIPTION OF FORMS:**

**FORMS available on the Gratz web site:**

- IRB001 Proposal Face Sheet [that includes IRB-102 Guidelines for the Preparation of Research Proposals for IRB Review]  
- IRB002 Research Proposal Review Form  
- IRB003 Notification of External IRB Review Completion  
- IRB004A Request for Screening for Exemption, 004B Expedited Review Form  
- IRB010A Adult Consent; IRB010B Assent Age 7-14, IRB010C Consent Age 15-17; IRB010D Parental Permission  
- IRB011 Completion Form (for expedited and full only)

**FORMS provided to Re-Submit Applicants**

- IRB007 Request for re-approval—Change in Proposal  
- IRB008 IRB Resubmission

**FORM provided to Board Members Serving as Reviewers:**
• IRB002 Proposal Review Form
• Template for Response Letter
II. POLICIES


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.


1.3 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.

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.

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 meeting space and 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. No member shall be appointed for a term of more than two (2) years. 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 Meetings of the IRB shall be held at least once a semester at a time established by the chairperson. Additional meetings may be called by the chairperson in order to deal with exceptional workloads, emergencies, or external deadlines. When necessary and at the discretion of the chairperson, members of the IRB may be polled by telephone or e-mail in order to obtain decisions on urgent matters. In such instances, the chairperson shall document in writing the question(s) asked of IRB members contacted and their responses; these will then be reviewed at the next regularly scheduled meeting.

8.4 Minutes of the last regularly scheduled meeting and of all meetings held between regularly scheduled meetings shall be distributed to all IRB members prior to the next regularly scheduled meeting at which time a vote for approval of the minutes shall be taken.

8.5 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.

8.6 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, assigned a Proposal ID Number, and logged into the IRB records. The chairperson of the IRB will assign proposals to the agenda for the next meeting of the IRB on a first-come, first-served basis.

8.7 Except when a proposal is exempt or an expedited review procedure is used (see Sections 11 and 12 below), research proposals shall be reviewed at convened meetings of the IRB at which a majority of the members of the IRB are present. In order for a research proposal to be approved, it must receive the approval of a majority of those members present at the meeting.

8.8 The IRB will attempt to review any research proposal and respond with a decision within thirty (30) days of receipt of the proposal. However, the IRB is required to meet each semester and, although more frequent meetings may be scheduled when a large number of proposals has been submitted for review, only a limited number of proposals can be considered at each
meeting of the IRB. Delays may also occur if the IRB must request clarification, 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.

8.9 The IRB will maintain a shared drive or similar resource through which IRB members may access the most recent forms and other documents relevant to the functioning of the IRB. To the extent the IRB maintains hard copy documents, they shall reside in a locked file accessible only to the IRB chairperson.

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: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

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, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

9.7 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.

9.8 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. Approval by the Gratz College IRB is required before seeking external approvals. All faculty and staff must submit research proposals to the Gratz College IRB for review. However, this requirement is waived for faculty and staff if the research proposal must be reviewed by an external IRB for research conducted at an external site. A copy of all external IRB approval documents must be presented to the Gratz College IRB.

10.3 The IRB shall require that information given to subjects as part of informed consent is in accordance with Sections 20 and 21 of this document. The IRB may require that information, in addition to that specifically mentioned in Sections 20 and 21, 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 The IRB shall conduct continuing review of research covered by this document at intervals appropriate to the degree of risk, but not less than once a year, and shall have authority to observe or have a third party observe the consent process and the research. If the IRB requires periodic review of the research, the principal investigator must, at the appropriate intervals, prepare a report on the progress of the research activity to date, and submit this document to the IRB.

10.7 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.

10.8 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.

10.9 Cooperative Research. Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

11. Screening for Exemption

Research may be exempt from review by the convened IRB 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, or reputation.

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 In the case of a screening for exemption, the IRB Chair will report at the next regularly scheduled meeting of the IRB that a screening for exemption occurred and advise the IRB members of the nature of the research proposal and its disposition.

11.6 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. Expedited Review Procedures

12.1 The IRB may use the expedited review procedure to review research proposals in which either or both of the following conditions apply:

(1) The research proposal pertains to categories of research appropriate for expedited review and found by the reviewer(s) to involve no more than minimal risk. Such categories of research include research on or involving:
   a. research involving data, documents, or records that have been collected or will be collected.
   b. collection of data from voice, video, digital, or image recordings made for research purposes.
c. research on individual or group characteristics or behavior utilizing specified methodologies.

d. continuing review of research previously approved by the IRB where no new subjects are enrolled, all research-related interventions have been completed, and the research remains active only for the long-term follow-up of subjects or the remaining research activities are limited to data analysis.

e. continuing review of other research which meets specified guidelines and which the IRB determines and documents involves no greater than minimal risks, and no additional risks have been identified.

(2) The proposal involves minor changes to previously approved research during the period for which approval is authorized (generally one year or less). Minor change is defined as any change that does not materially affect the assessment of risks and benefits.

*Principal investigators should consult Decision Chart found at: http://www.hhs.gov/ohrp/policy/checklists/index.html to determine whether their proposal is eligible for expedited review. An expanded discussion of DHHS guidelines and regulations for expedited review is found at: http://www.hhs.gov/ohrp/policy/expedited98.html.

12.2 In the case of an expedited review, the IRB Chair will report at the next regularly scheduled meeting of the IRB that an expedited review occurred and advise the IRB members of the nature of the research proposal reviewed and its disposition.

13. Full Board Review

13.1 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.

Examples of greater than minimal risk are:
- a clinical interventional study that randomly assigns human subjects to alternative experimental or placebo groups
- studies involving sensitive information connected to personal identifiers

These studies require review by the full convened IRB at the next scheduled meeting.

13.2 All research proposals are assigned for review at a convened meeting unless they meet the criteria for expedited review or exemption. The original and 5 copies of the proposal must be delivered to the IRB Chair, at which time the proposal will be dated, assigned a proposal ID number and logged into the IRB records.
A majority of the members of the IRB must be present at the convened meeting. In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting.

13.3 The IRB will attempt to review any research proposal and respond with a decision within thirty (30) days of receipt of the proposal. The IRB is required to meet once a semester and, although more frequent meetings may be scheduled when a large number of proposals have been submitted for review, only a limited number of proposals can be considered at each meeting of the IRB. Delays may also 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.

13.4 When a proposal is submitted, it is checked for completeness. If not complete, it is returned to the principal investigator. If complete, it will be circulated to the members of the IRB for review at a convened meeting. At the meeting 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.

14. 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.

15. Length of Approval

The IRB will grant approval for one (1) year to conduct an approved research study. If the research will require more than one year to complete, an application for extension will need to be submitted (see Section 23 below).

16. 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.

17. 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.

18. Unanticipated or Unexpected Results

Definition: An “Unanticipated or Unexpected Result” refers to an adverse event or other problem arising during the research the specificity or severity of which is not consistent with information already provided to the Gratz College IRB. Adverse events are categorized as follows:

18.1 “Adverse Events”: Undesirable and unintended, though not necessarily unanticipated, injuries or physical or emotional consequences for the subject.
   “Serious Adverse Events (SAE)”- Adverse events which are fatal or life-threatening; that result in significant or persistent disability; that require hospitalization, or represent a significant hazard or potentially serious harm to research subjects or the researchers and their staff. “Unanticipated Problems (UP)”- Specific events experienced by subjects or developments that occur during implementation of research protocols that suggest the potential for increased risk to research subjects or the researchers and their staff.

18.2 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. Typically, the written report serves as IRB notification; however, in the instance of a serious adverse event (SAE), the PI should notify the IRB immediately then file the report within the time frame noted below. The time frame for the submission of the report is determined by the type of unanticipated or unexpected event that has occurred.

18.3 When an adverse event is serious and unanticipated, the principal investigator (PI) must notify the IRB in writing within 24 hours or by the end of the next working day.

18.4 When an adverse event is serious but not unanticipated, the PI must notify the IRB within five (5) working days.

18.5 When an adverse event occurs which is not serious but is unanticipated, the PI must notify the IRB within 10 working days.

18.6 When an unanticipated problem (UP) occurs which does not meet the definition of an adverse event, the PI must notify the IRB within 10 working days.

18.7 Guidelines For “Unanticipated Results” Written Report
   The written report must contain the following information:
• IRB study number
• Title of Protocol
• Name of Principal Investigator
• Subject Identifier
• Date and Site of Event
• Description of Event including nature of injury or other adverse occurrence, assessment of severity, and assessment of the relationship to the study
• Handling/ response of the researcher to the event
• Proposed changes in either research protocol or consent form in response to the event
• The names of others to whom the event has been reported
• Signature of the principal investigator

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

19. IRB Documents and Records

19.1 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. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

c. Records of continuing review activities.

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

e. A list of IRB members in the same detail as described on page 4 this document.

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

g. 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.

19.2 The records required by this document shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of Gratz College at reasonable times and in a reasonable manner.

19.3 Numbering shall include the year of submission and the numerical order in sequence, for example: 12017, 22018.

20. General Requirements for Informed Consent

Except as provided elsewhere in this document, 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.

20.1 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, a description of the procedures to be followed, and identification of any procedures which are experimental;

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.

20.2 Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

Any additional costs to the subject that may result from participation in the research;

The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

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

The approximate number of subjects involved in the study.

20.3 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.

20.4 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.

**21. Documentation of Informed Consent**

21.1 Informed consent shall be documented by the use of a written consent form 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.
21.2 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.

22. 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.

23. Periodic Review of the Approved Research

The principal investigator must inform the IRB in writing of the progress of the research one year after approval and, if necessary, apply for extension of the research.

24. Completion

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

Research studies can be deemed completed for a number of reasons, each requiring a different degree of IRB involvement. Most often, the investigator will close the study and the IRB’s role is passive, receiving study completion documents and archiving the records for the study. In some cases, the IRB must perform in a supervisory or disciplinary fashion and require that a study be ended.
III. GUIDELINES

IRB102 – Gratz College
Guidelines for the Preparation of Research Proposals for IRB Review

These guidelines govern the preparation of all research proposals submitted to the Gratz College Institutional Review Board (IRB). Proposals must contain the information specified herein. If a proposal has been prepared in a format required by an external agency, there is no need to rewrite the proposal; information required herein that does not appear in the proposal as written may be included in an attachment.

I. The Proposal Face Sheet (form IRB001)

A copy of the Gratz College IRB Research Proposal Face Sheet must accompany any research proposal submitted for IRB approval. The Proposal Face Sheet and all other required forms are available on the Gratz College Intranet. 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, mark the check box on the bottom of the face sheet, and indicate the number of additional sheets attached.

1.1 Principal Investigator/Additional Investigators

The principal investigator is the person who has ultimate administrative and fiscal authority in conducting and coordinating the research project. The principal investigator is the researcher when only one researcher is involved in a research project; any additional researchers involved in the project are considered co-investigators. This information should be included in all correspondence with the IRB.

1.2 Title of Research Project

The title should be brief but inclusive and descriptive.

1.3 Duration

The starting date is when the research proposal is finalized (including IRB approval) and sample selection and data collection may begin. The ending date is the anticipated date of completion of the research project.

1.4 Address

Provide the specific name and address of any and all facilities at which data collection will take place.
1.5 Other Institutions(s)

If the research proposal must be submitted to another institution or institutions for their internal review procedure, indicate the name of the institution and its address.

1.6 Type of Study

Provide a brief description of the type of research project.

1.7 Sampled Population

Provide a brief description of the population that you propose to sample and an estimate of the total number of human subjects that will be involved, including all experimental and control groups. If the proposed research is a qualitative study involving surveys or observation, estimate the numbers of persons you expect to survey or observe.

1.8 Resources

If the proposed research project is being submitted to an organization for consideration for financial and/or equipment support, indicate the name of the organization and the grant or funding program to which application for support will be submitted.

1.9 Signatures

A proposal for a research project is not approved until all the signatures indicated on the face sheet have been obtained, i.e., signatures of the following individuals must appear on the face sheet of the proposal:

- Principal investigator;
- Co-investigators (where applicable);
- Program Director

2. The Proposal

2.1 Abstract

On a separate sheet, include an abstract of the project of no more than 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;
• Procedures for data collection;
• Measurement instruments to be employed in the project;
• Anticipated type of data analysis to be employed;
• Relevance of the research project.

2.2 Narrative Description

A narrative description of the proposed research project should be brief (no more than ten (10) pages), but should provide sufficient information to permit the IRB reviewers to judge if the problem chosen is significant or important, if the research question and design are adequate to address the problem, and whether the investigators have the knowledge, funding, and access to any equipment and/or subject populations necessary to complete the proposed project.

The narrative description shall be prepared in accordance with the following outline (except as noted in the opening paragraph of this document):

2.2.1 Purpose

State the overall purpose of the research project and, if appropriate, hypotheses to be tested. Briefly explain what you feel is the potential significance of the research project.

2.2.2 Duration

Provide an estimate of the duration of the entire research project. The starting date is when the research proposal is finalized (including IRB approval) and sample selection and data collection may begin. The ending date is the anticipated date of completion of the research project. Note that IRB approval is required every 12 months (in some cases more often) while a research project involving human subjects continues.

2.2.3 Address

Provide the specific name and address of any and all facilities at which
data collection will take place.

2.2.4 Background

Briefly review the most significant previous work done in the topic area and the specific problem and describe the current status of work on this topic. Document this review with proper references using an appropriate professional style. Describe any preliminary work that the principal investigator, co-investigators, or others have done which led to this research project.

2.2.5 Methods

The methods section of the proposal should describe the:

- Type of study or research design that will be employed in conducting the project;
- Methods and instrumentation to be used for sample selection and for data collection;
- Data to be collected;
- Procedures used for data collection and analysis;
- Projected timetable of the study (all major steps in the study with approximate dates for initiation and completion).

2.2.6 Resources

- Describe the facilities, special equipment, consultative services, and other relevant resources available for the project. If any of these are to be secured through collaborative arrangements with institutions other than that which might be indicated in the address(es) of the investigator(s), attach letters from each such source confirming their willingness to provide these resources.

- Identify any supplies, equipment, or other resources that are required for completion of the project.

2.2.7 Subject Recruitment and Selection

- Summarize the process of obtaining subjects for the proposed research project. Specify the sample size needed for the level of significance desired in your proposed data analysis. If a larger sample is desired because attrition is expected, state the additional number of subjects desired. If your design uses experimental and control groups, specify the number of
subjects to be assigned to each experimental group and each control group. If your sample is to be generated by inviting \( m \) persons to participate, from which you shall select a sample of size \( n \) \( (n<m) \), specify the number \( m \).

- If potential subjects are to be excluded because of age, gender, economic status, or race, the reasons for the exclusion must be documented.

- Describe any inducements that will be offered to subjects, such as cash payments or other incentives.

- Include sample copies of all correspondence that will be presented or sent to subjects or prospective subjects, and any intermediaries involved.

- Indicate all special categories of subjects to be included in the research project, e.g., mentally or physically disabled, minors, pregnant women, prisoners, etc.

### 2.2.8 Potential Risks

Describe and assess any potential risks -- physical, psychological, social, economic, monetary, legal or other -- to the subjects involved in the research project and assess the likelihood and seriousness of such risks. If the research methods proposed create potential risks, describe other methods, if any, that were considered and provide the reasons why they were rejected.

### 2.2.9 Consent Procedures

Describe the procedures to be followed in obtaining informed consent from subjects, including how, when, where, and by whom informed consent shall be obtained.

### 2.2.10 Protection of Subjects

Describe the procedures including confidentiality safeguards that will be employed to protect against or minimize potential risks to subjects and provide an assessment of the likely effectiveness of these procedures.

**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.

The following issues must also be addressed:

- If there is a point at which the collection of data from subjects may be discontinued prior to the end of the data collection phase of the research project, state how monitoring of the data collection is to be performed and the criteria for determining the discontinuation point.

- Include a description of any measures that will be taken to handle side effects or problems identified during the research that are associated with or resulted from the procedures used.

- Include one (1) copy of any questionnaire(s) or rating scales that will be employed in the research project.

2.2.11 Potential Benefits

Assess any potential benefits that may be gained by individual subjects involved in the research project and any benefits that may accrue to society in general as a result of the proposed research.

2.2.12 The Risk/Benefit Ratio

Analyze the possible benefits that may be gained by the subjects involved in the proposed research in light of the risks involved. Minimal risk means that the risks of harm anticipated in the proposed research are not greater than, with respect to both probability and magnitude, the risks encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.3 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 must provide copies of the actual consent form(s) that will be employed by the investigators. If these form(s) are not submitted with the proposal, the proposal will be rejected. Consent forms must be prepared in accordance with Sections 20 and 21 of this document.
3. Informed Consent – A Process

Informed consent is a process rather than merely a document. Any subject invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide the potential subjects with readily understandable information in an amount and timing appropriate to the level of risk in participating.

The subject’s consent must follow and not precede receipt of this information unless the IRB approves a different procedure (as in some behavioral research that would be compromised by full disclosure in advance). Consent must be obtained from each subject who is legally, mentally, and physically able to provide it unless waived by the IRB. Consent should be in writing unless the IRB finds that written documentation of informed consent may be waived. Consent forms and informational letters should be written in simple language so as to be easily understood by persons with no technical background in the field.

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.

The standard consent process and documentation is that all subjects will sign a document containing all the elements of informed consent, as specified in the federal regulations. Unless waived by the IRB, participants must sign and date the consent form prior to participation in the study. The appropriate signed Consent Forms must be included in the application. The signed consent form should be retained in the investigator’s files and a copy of the signed consent form should be provided to the person giving consent.

3.1 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.

4. Proposal Submission

The Research Proposal Face Sheet must be completed in its entirety, including all signatures, or the proposal will not be accepted for review. For research projects involving personnel from more than one school within the college, approval must be obtained from each of the school deans.

4.1 Submissions for Full Review

The original and five (5) copies of the proposal must be delivered to the IRB Chair, at which time the proposal will be dated, assigned a Proposal ID Number, and logged into the IRB records. While every effort will be made to review research proposals in a timely manner, no guarantees can be made as to when a particular proposal will be scheduled for review by the IRB. Only a limited number of proposals can be placed on the agenda for a meeting of the IRB, and proposals are assigned to the agenda on a first-come, first-served basis. Investigators are urged to submit their proposals well ahead of any deadlines they are facing in order to ensure completion of IRB review prior to those deadlines.

4.2 Submissions for Expedited Review

In some instances a research proposal may qualify for expedited review. This
occurs if there is minimal risk to human subjects involved in the proposed
research, or if minor changes are being made in previously approved research.
Investigators should check the list of categories of research that qualify for
expedited review. If the investigators are requesting an expedited review for
the initial submission of a proposal, the original and five (5) copies of the
proposal must be delivered to the IRB Chair, at which time the proposal will be
dated, assigned a Proposal ID Number, logged into the IRB records and
forwarded for institutional approval.

4.3 Submissions for Exempt Research

In some instances, research conducted may be exempt from a full IRB review.
The investigator may file the Request for IRB Screening for Exemption (form IRB-
04A). This form and the original and 5 copies of the proposal must be delivered
to the IRB Chair, at which time the form will be dated and forwarded for
institutional approval.

5. The Review Process

5.1 Full Review

The IRB will attempt to review any research proposal and respond with a
decision within thirty (30) days of receipt of the proposal. The IRB is required to
meet once a semester and, although more frequent meetings may be scheduled
when a large number of proposals have been submitted for review, only a
limited number of proposals can be considered at each meeting of the IRB.
Delays may also 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.

When a proposal is submitted, it is checked for completeness. If not complete, it
is returned to the principal investigator. If complete, it will be circulated to the
members of the IRB for review at a convened meeting. At the meeting of the
IRB, the proposal will be evaluated for the extent to which it provides for the
protection of human subjects, demonstrates scientific merit and does not
conflict with the Core Values of Gratz College. If the research proposal is
approved by the IRB, the chairperson of the IRB shall forward the proposal for
institutional approval.

5.2 Expedited Review

The expedited review process is the same as the full review process except that
the research proposal will be considered by the chairperson of the IRB or by
one or more experienced reviewers designated by the chairperson from among the members of the IRB. If the decision of the reviewer(s) is not to approve the proposal, the proposal must then move onto the agenda of the IRB for a vote to disapprove. The reviewer may also require a full review by the IRB.

5.3 Exempt Research

The investigator will file the Request for IRB Screening for Exemption (form IRB-04A) and the form, with proposal, must be delivered to the IRB Chair, at which time the form will be dated and forwarded for institutional approval by the IRB Chair. The IRB Chair may require an expedited or full review if an exemption is not appropriate.

6. IRB Response

If the proposal is approved by the institution, the IRB Chair will notify the principal investigator of the approval. The consent form will be stamped with the official Gratz College stamp and dated. The consent form expires in one year, and the investigator is required to reapply for extension if the research is not completed within one year.

If the research proposal is not approved by the IRB, a response will be prepared by the IRB Chair and sent to the principal investigator. The response will include an explanation of the IRB’s action.

If the proposal is not approved by the institution, the IRB Chair will prepare a response and send it to the principal investigator. The response will include an explanation of the institutional action.
IV. FORMS
**IRB001** Proposal Face Sheet  
And **IRB102** Guidelines for Preparation of Research Proposals for IRB Review

Gratz College  
Melrose Park, Pennsylvania  
Research Proposal

**Date submitted:**

Request for [Highlight or mark one choice]:  
- Exemption  
- Expedited Review  
- Full Review

**Title of Research Proposal:**

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**Duration:**  

*from* to

**Location:**

**Other Institution(s) requiring review of this proposal:**

**Type of Study:** Sample

**Population:**

**Approximate no. of subjects:**

**Resources:**
Signatures

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<td>Additional Investigator</td>
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SECTION II
Proposal

I. Abstract Provide an abstract of the project

The abstract should be brief: no more than 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;
- Procedures for data collection;
- Measurement instruments to be employed in the project;
- Anticipated type of data analysis to be employed;
- Relevance of the research project.

II. Narrative Description Provide a narrative description that includes all of the information required in sections A-M below.

The narrative description of the proposed research project should be brief (no more than ten (10) pages), but should provide sufficient information to permit the IRB reviewers to judge if the problem chosen is significant or important, if the research question and design are adequate to address the problem, and whether the investigators have the knowledge, funding, and access to any equipment and/or subject populations necessary to complete the proposed project. The narrative description shall be prepared in accordance with the following outline (except as noted in the opening paragraph of this document):

A. Purpose
State the overall purpose of the research project and, if appropriate, hypotheses to be tested. Briefly explain what you feel is the potential significance of the research project.

B. Duration
Provide an estimate of the duration of the entire research project. The starting date is when the research proposal is finalized (including IRB approval) and sample selection and data collection may begin. The ending date is the anticipated date of completion of the research project. Note that IRB approval is required every 12 months (in some cases more often) while a research project involving human subjects continues.

C. Address
Provide the specific name and address of any and all facilities at which data collection will take place.

D. Background
Briefly review the most significant previous work done in the topic area and the specific problem and describe the current status of work on this topic. Document this review with proper references using an appropriate professional style. Describe any preliminary work that the principal investigator, co-investigators, or others have done which led to this research project.

E. Methods

The methods section of the proposal should describe the:

- Type of study or research design that will be employed in conducting the project;
- Methods and instrumentation to be used for sample selection and for data collection;
- Data to be collected;
- Procedures used for data collection and analysis;
- Projected timetable of the study (all major steps in the study with approximate dates for initiation and completion).

F. Resources

- Describe the facilities, special equipment, consultative services, and other relevant resources available for the project. If any of these are to be secured through collaborative arrangements with institutions other than that which might be indicated in the address(es) of the investigator(s), attach letters from each such source confirming their willingness to provide these resources.

- Identify any supplies, equipment, or other resources that are required for completion of the project.

G. Subject Recruitment and Selection

Summarize the process of obtaining subjects for the proposed research project. Specify the sample size needed for the level of significance desired in your proposed data analysis. If a larger sample is desired because attrition is expected, state the additional number of subjects desired. If your design uses experimental and control groups, specify the number of subjects to be assigned to each experimental
group and each control group. If your sample is to be generated by inviting \( m \) persons to participate, from which you shall select a sample of size \( n \) \((n<m)\), specify the number \( m \).

If potential subjects are to be excluded because of age, gender, economic status, or race, the reasons for the exclusion must be documented.

Include sample copies of all correspondence that will be presented or sent to subjects or prospective subjects, and any intermediaries involved.

Indicate all special categories of subjects to be included in the research project, e.g., mentally or physically disabled, minors, pregnant women, prisoners, etc.

H. Potential Risks

Describe and assess any potential risks -- physical, psychological, social, economic, monetary, legal or other -- to the subjects involved in the research project and assess the likelihood and seriousness of such risks. If the research methods proposed create potential risks, describe other methods, if any, that were considered and provide the reasons why they were rejected.

I. Consent Procedures

Describe the procedures to be followed in obtaining informed consent from subjects, including how, when, where, and by whom informed consent shall be obtained.

J. Protection of Subjects

Describe the procedures including confidentiality safeguards that will be employed to protect against or minimize potential risks to subjects and provide an assessment of the likely effectiveness of these procedures.

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.

The following issues must also be addressed:

- If there is a point at which the collection of data from subjects may be discontinued prior to the end of the data collection phase of the research project, state how monitoring of the data collection is to be performed and the criteria for determining the discontinuation point.

- Include a description of any measures that will be taken to handle problems identified during the research that are associated with or resulted from the procedures used.

- Include one (1) copy of any questionnaire(s) or rating scales that will be employed in the research project.
L. Potential Benefits
Assess any potential benefits that may be gained by individual subjects involved in the research project and any benefits that may accrue to society in general as a result of the proposed research.

M. The Risk/Benefit Ratio
Analyze the possible benefits that may be gained by the subjects involved in the proposed research in light of the risks involved. Minimal risk means that the risks of harm anticipated in the proposed research are not greater than, with respect to both probability and magnitude, the risks encountered in daily life or during the performance of routine physical or psychological examinations or tests.

SECTION III
Budget

III. Budget
If externally funded, the proposal must contain a budget summary page, which provides a breakdown of expenses in the following categories:

- Equipment purchase/rental;
- Supplies;
- Clinical site fees;
- Personnel/consultant fees;
- Participant support costs;
- Other.

The IRB is interested in budget information that has the potential to affect the safeguarding of human subjects involved in the research.

SECTION IV
Consent

IV. Informed Consent  Provide an explanation of the method of obtaining informed consent and attach all appropriate consent forms.
IRB002 RESEARCH PROPOSAL REVIEW FORM

Gratz College
Research Proposal Review Form

Date:

Date Submitted:

[Highlight or Check ONE]: □ Exempt  □ Expedited Review  □ Full Review

1. Title of Research Project:

2. Principal Investigator
   NAME:
   EMAIL ADDRESS:

   Program Director (In case of student research)
   NAME:
   EMAIL ADDRESS:

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<td>The principal investigator and the additional investigator(s) is (are) qualified to conduct this research project.</td>
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<td>Other institutions involved in the research are clearly identified.</td>
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provided appropriate letters/documents indicating support of the research at the site.

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<th>NO</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The abstract is complete, adequate, and within guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purpose</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The purpose of the research project is clearly stated.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The goals of the research project are realistic and potentially achievable.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The research project is relevant and important to an identified discipline.</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration and Location</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The facility where the research is to be conducted is a reasonable choice for the proposed project.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The proposed time frame is adequate for the research project.</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Background</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The background information supplied, including references, supports the proposed research project.</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The proposed method is suited to the research question.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The proposed instruments and measures are appropriate for addressing the research question.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The procedures for data collection are appropriate and clearly identified.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subject Recruitment and Selection</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The proposed population to be sampled is relevant to the research question.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criteria for inclusion and exclusion of potential subjects are documented and adequate.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Inducements, if applicable.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>The sampling design is achievable and relevant to the research project.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Potential Risks</strong></td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------------------</td>
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<td>----------</td>
</tr>
<tr>
<td>Potential risks to subjects have been adequately identified.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential risks to the investigators have been adequately identified.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Protection</strong></td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>Protection of all subjects from identified risks has been adequately addressed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provision for the withdrawal of subjects from the study has been adequately addressed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protection of the investigators from identified risks has been adequately addressed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Potential Benefits</strong></td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>Potential benefits to subjects have been adequately identified.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk/Benefit Ratio</strong></td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>An adequate assessment of the risk/benefit ratio of the proposed research has been provided.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Consent</strong></td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>The consent procedures are adequate.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Copies of the proposed consent forms have been submitted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Resources (if applicable)</strong></td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>The financial resources appear adequate for the proposed research project.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The equipment resources appear adequate for the proposed research project.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budget (if applicable)</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>Comments</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
<td>-----</td>
<td>----------</td>
</tr>
<tr>
<td>The budget is reasonable for the type and duration of the research project, specifically as regards the safeguarding human subjects.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The financial resources are appropriate and do not pose a conflict of interest, particularly as regards the safeguarding of human subjects.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

COMMENTS:
IRB004A Request for Screening for Exemption

Proposal ID No.: ______________________
(Assigned by IRB)

Gratz College
Request for IRB Screening for Exemption (IRB004A)

Date submitted:
Title of Research Proposal:

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Faculty Advisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
<td>School:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Email:</td>
<td>Email:</td>
</tr>
</tbody>
</table>

SECTION I: CATEGORY OF EXEMPTION

Directions: Research may be exempt from IRB review if the involvement of human subjects falls within one or more of the following six categories. Please highlight or check all that apply:

- Category 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 comparison among instructional techniques, curricula, or classroom management methods.

- Category 2: Research involving use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior provided that:
  a. information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects
b. there is no disclosure of the responses of human subjects outside of the research that might reasonably place them at risk for criminal or civil liability or be damaging to their financial standing, employability, or reputation.

c. the research does not involve children and the use of surveys, interviews, or observations of their public behavior in situations where the investigator is a participant in the activities being observed.

□Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, or observations of public behavior not exempt under Category 2 if:

a. human subjects are elected or appointed 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.

□Category 4: Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:

a. public benefit or service programs

b. procedures for obtaining benefits or services under these programs

c. possible changes in or alternatives to those programs or procedures

d. possible changes in methods or levels of payment for benefits or services under those programs

This exemption cannot be made if prior review is specifically required by statute or if the Secretary of HHS determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a subject. The standard requirement for informed consent may be waived if the research could not practically be carried out without the waiver and certain other HHS requirements are met and documented.

Decisions about exemption may not be made by the investigator. No involvement of human subjects may occur prior to notification of IRB approval.

**SIGNATURES REQUIRED:**

Signature of Principal Investigator:
Date:

Signature of Program Director (if student proposal):
Date:
<table>
<thead>
<tr>
<th>NAME</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Director</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- □ Attach copy of external review document.
- □ Additional sheets attached; this is sheet 1 of ____.
IRB004A Request for Screening for Exemption

Proposal ID No.: _______________________
(Assigned by IRB)

Gratz College
Request for IRB Screening for Exemption (IRB004A)

Date submitted:
Title of Research Proposal:

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Faculty Advisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
<td>School:</td>
</tr>
</tbody>
</table>

| Email:                  | Email:          |

SECTION I: CATEGORY OF EXEMPTION

Directions: Research may be exempt from IRB review if the involvement of human subjects falls within one or more of the following six categories. Please highlight or check all that apply:

- Category 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 comparison among instructional techniques, curricula, or classroom management methods.

- Category 2: Research involving use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior provided that:
  - a. information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects
b. there is no disclosure of the responses of human subjects outside of the research that might reasonably place them at risk for criminal or civil liability or be damaging to their financial standing, employability, or reputation.

c. the research does not involve children and the use of surveys, interviews, or observations of their public behavior in situations where the investigator is a participant in the activities being observed.

☐ Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, or observations of public behavior not exempt under Category 2 if:

a. human subjects are elected or appointed 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.

☐ Category 4: Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:

a. public benefit or service programs

b. procedures for obtaining benefits or services under these programs

c. possible changes in or alternatives to those programs or procedures

d. possible changes in methods or levels of payment for benefits or services under those programs

This exemption cannot be made if prior review is specifically required by statute or if the Secretary of HHS determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a subject. The standard requirement for informed consent may be waived if the research could not practically be carried out without the waiver and certain other HHS requirements are met and documented.

Decisions about exemption may not be made by the investigator. No involvement of human subjects may occur prior to notification of IRB approval.

SIGNATURES REQUIRED:

Signature of Principal Investigator:
Date:

Signature of Program Director (if student proposal):
Date:
IRB004B Expedited Review Form

Proposal ID No.: ____________
(Assigned by IRB)

Gratz College
Request for Expedited Review (IRB004B)

Date submitted:

Title of Research Proposal:

Principal Investigator:

Program Director (if student proposal):

Certain types of research may be reviewed and approved through an expedited process. The primary criterion for expedited review is that the research be of minimal risk to human subjects. In addition, the purpose of the research must fit within a set of categories stipulated by FDA and DHHS regulations. Expedited review refers to a review method rather than to an abbreviated or simplified protocol submission. The first step in requesting an expedited review is to complete the protocol application in full. In addition, the researcher must submit this form.

Directions: Details of the Research Design must indicate that the research fulfills both requirements A and B and one of the categories under C. Please review A, B, and C below and check off that the research meets the criteria:

- A. This research activity poses no greater than minimal risk to subjects; and
- B. The identification of subjects and/or their responses would not necessarily place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are not greater than minimal;
**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.

And

- C. The project falls under one or more of the expedited categories below. Please check all that apply.
  - Category 1. Research involving materials (data, documents, and/or records) that have been collected, or will be collected.
  - Category 2. Collection of data from voice, video, digital, or image recordings made for research purposes.
  - Category 3. Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
  - Category 4. Research involves continuing review of research previously approved by the IRB where no new subjects are enrolled, all research-related interventions have been completed, and the research remains active only for the long-term follow up of subjects or the remaining research activities are limited to data analysis.
  - Category 5. Research involves minor changes to previously approved research during the 12 month period for which approval is authorized. A Minor change is defined as a change that does not affect risk and benefits.

Please review the following statements and indicate that you have read them by signing below:

A. I understand that the research project may not be initiated until expedited review is completed and written permission is received from the IRB.
B. If this research proposal changes in such a way that it no longer conforms to the criteria for expedited review, a new request for a full review will be submitted.
C. If an expedited review is not approved, the proposal will be subject to a full review. The investigator will secure written approval from the IRB prior to initiating the research project.

Signature of Principal Investigator:
Date:
Signature of Faculty Advisor (if student proposal):
Date:
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:
Email address:
Co-Investigators if applicable:
Program Director:

Study Contact telephone number:
Study Contact Email:

---

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
(Optional)
You are being asked to be in the study because

Are there any reasons you should not be in this study? (If applicable)
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, how many 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.

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 are a Gratz College student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at Gratz College. You will not be offered or receive any special consideration if you take part in this research.

**What if you are a Gratz College employee?**
Taking part in this research is not a part of your College duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

**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

__________________________________________  ______________________________
Signature of Person Obtaining Consent          Date

__________________________________________
Printed Name of Person Obtaining Consent
Written Consent Form:  IRB010B Consent Age 7-14

Gratz College
Assent to Participate in a Research Study (IRB010B)
Minor Participant (age 7-14 years)

Title of Study:

Principal Investigator:  
Email address:  
Co-Investigators if applicable:  
Program Director:  

Study Contact telephone number:  
Study Contact Email:  

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 research 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?**

**What are the good things that might happen?**
People may have good things happen to them because they are in research studies. These are called “benefits”. The benefits to you of being in this study may be

People may have good things happen to them because they are in research studies. You will not benefit 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.

**Will you get any money or gifts for being in this research study?**
You will not receive anything for taking part in this study.

**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.

__________________________________________  __________________________
Sign your name here if you want to be in the study Date
Print your name here if you want to be in the study

__________________________________________  ____________
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 (IRB010C)
Minor Participant (age 15-17 years)

---

Title of Study:

Principle
Investigator: Email
address:
Co-Investigators:
Program
Director: Funding
Source:

Study Contact telephone
number: Study Contact Email:

---

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, how many 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

__________________________________________  __________________________
Signature of Person Obtaining Consent            Date

__________________________________________
Printed Name of Person Obtaining Consent
Written Consent Form: IRB010D Parental Permission

Gratz College
Parental Permission for a Minor Child to Participate in a Research Study (IRB010D)
Social Behavioral Form

Title of Study:

Principle Investigator:
Email address:
Co-Investigators:
Program Director:
Funding Source:

Study Contact telephone number:
Study Contact Email:

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
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

Only include the following section if consent obtained in-person.

__________________________________________________________
Signature of Person Obtaining Permission

Date

__________________________________________________________
Printed Name of Person Obtaining Permission
**IRB011 Completion Form (for expedited and full only)**

Date:_________________________  Proposal ID No.:_________________________

(Assigned by IRB)

Gratz College

Research Completion Report (IRB011)

Date of Original Submission:_________________________

1. Title of Research Proposal:_________________________________________________________

2. Principal Investigator:  Faculty Advisor (if student proposal):

   
   
   Name  
   
   Name  
   
   e-mail  
   
   e-mail  
   
   Additional Investigator(s):

   
   
   Name  
   
   Name  

3. Date of Project Completion:_________________________

4. List of Attached Summary Information:

5. Signatures:
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<tr>
<th>Principal Investigator</th>
<th>Date</th>
<th>Faculty Advisor (if student proposal)</th>
<th>Date</th>
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<td>Additional Investigators</td>
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IRB008 Re-Submission Form

Date:________________________  Proposal ID No.:________________________

Gratz College
Re-submission of Research Proposal  (IRB008)

Date of Original Submission:________________________

Request For: □ Expedited Review  □ Full Review

1. Title of Research Proposal:________________________________________________________

2. Principal Investigator:  Faculty Advisor (if student proposal):

   Name  Name

   e-mail  e-mail

   Additional Investigator(s):

   Name  Name

3. Reason for Re-Submission: □ Revision  □ Request for Additional Information by IRB

4. List Headings of Sections Containing Revisions:____________________________________

   __________________________________________________________

   __________________________________________________________

5. List Headings of Sections Containing Additional Information:________________________
6. **Signatures:**

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<td>Division Chair or Program Director (if required)</td>
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IRB007 Request for IRB Re-Approval of Research and/or Review of Change in Research Protocol Form

Date:_________________________  Proposal ID No.:_________________________ (Assigned by IRB)

Gratz College

Request for IRB Re-Approval of Research and/or Review of Change in Research Protocol

Date of Original Submission:____________________________________________________

1. Title of Research Proposal:__________________________________________________

2. Principal Investigator:  Faculty Advisor (if student proposal):

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3. Duration of Study: Start Date:_________________________  End Date:_________________________

4. Institution Sponsoring Study:____________________________________________________

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5. Other Institution(s) Requiring Re-Approval:

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6. Request for Re-Approval of Research: □  Please attach a copy of a progress report to this form.
7. Request for Review of Change in Research Protocol:
   □ Not requested    □ Requested previously by IRB    □ Requested by researchers
   Review of Change in: □ Study design    □ Procedures    □ Sampling    □ Other
   Please attach a description and explanation of the changes as well as a rationale for the request.

8. Signatures:

   ___________________________________________  ___________________________________________
   Principal Investigator                      Date

   ___________________________________________  ___________________________________________
   Additional Investigators                    Date

   ___________________________________________  ___________________________________________
   Program Director                            Date

   □ Additional Sheets Attached; This is sheet 1 of __________