USE OF HUMAN SUBJECTS:
ETHICAL CONSIDERATIONS AND APPROVAL PROCEDURES

National Research Act, Public Law 93-348, July 12, 1974

Sec. 474 (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurance satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an “Institutional Review Board”) to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the right of the human subjects of such research.

Although ethical questions surrounding the use of human subjects in research projects proceeded the Act quoted above, this is the legislation which served as a mandate for university and college “Institutional Review Boards” (or “Use of Human Subject Boards,” or “Research Review Boards”). The Act specifies a concern with “funded” (or “sponsored”) research. Universities and colleges have typically defined “sponsorship” to include use of university time, facilities, resources, etc. So, you do not have to be working on a Federally funded project—all you need to be doing is working on a project where you are employing the financial support of the college or university or operating under the auspices of the university or college (including simply using your title as a faculty member as your research credential).

Rationale for a College Policy

The IRB exists for several reasons. First, a college-wide policy will reflect Georgetown College’s commitment to basic ethical principles and will provide a consistent application of those principles across disciplines involved in research with human subjects. Second, this policy provides an environment in which students directly learn and apply ethical principles. Third, federal funding agencies require that all grant applications be reviewed and approved by an Institutional Review Board that ensures ethical compliance.

“The Belmont Report” (prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research) provides one of the commonly employed statements concerning ethical principles/guidelines in the use of human subjects. The remainder of this handout will summarize the primary raised in that report.

I. Three basic principles generally accepted as especially relevant to the ethics of research involving human subjects:

A. Respect for Persons

   1. Individuals should be treated as autonomous agents—they have the right to decide for themselves about involvement or non-involvement in research.

   2. Persons with diminished autonomy (children, prisoners, the infirmed, etc.) are entitled to protection—these groups should not be subjects simply out of convenience; if they are the group of interest, then special care must be taken in protecting their rights.

B. Beneficence
1. Every effort should be taken to protect the well-being of the persons involved in research.

2. “Beneficence” is understood to cover acts of kindness and charity that go beyond strict obligation.

3. Two general rules reflect the concept of beneficence:
   a. *Do not harm.*
   b. *Maximize possible benefits and minimize possible harms.*

C. Justice
   1. “An injustice occurs when some benefit to which a person is entitled is denied without good reason or when burden is imposed unduly.”
   2. It is just (fair to keep selecting a particular group of people as research subjects simply because of their availability or compromised position or manipulability rather than for reasons directly related to the problem being studied?

II. Applications of the three principles to the conduct of research.

A. Informed Consent
   1. Respect for persons requires that they be capable of making an informed decision about whether or not to be involved in a research project.
      a. *Information*—generally should inform potential participants about
         1. the research procedures
         2. the purpose
         3. the risks
         4. the benefits
         5. the participant’s rights to ask questions
         6. the participant’s right to withdraw at any time

   In general, you need to think about what a reasonable person would need to know in order to make an informed decision. Informed decisions require information about both the risks and the benefits. But what if the validity of your study would be undermined if you were to fully inform possible participants as to your purpose/method/etc.? Incomplete disclosure can be justified only if:
      1) incomplete disclosure is truly necessary to accomplish the goals of the research
      2) there are no undisclosed risks to subjects that are more than minimal
      3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them

   b. *Comprehension*—A person’s ability to understand their rights is a function of intelligence, rationality, maturity and language. It is
the researcher’s responsibility to be sure that information about the study is presented in a manner that can be understood.

c. **Voluntariness**—“An agreement to participate in research constitutes a valid consent only if voluntarily given.” This requires conditions which are:

1) free of coercion. Coercion exists when overt threat of harm is intentionally presented.
2) free of undue influence. Undue influence exists when there are offers of excessive, unwarranted, inappropriate or improper reward or other overtures in order to obtain compliance. Even inducements that would ordinarily be acceptable can be undue influences if the potential participant is especially vulnerable.

B. **Assessment of Risks and Benefits**—in making this judgment, members of the Institutional Review Board are supposed to determine:

1. the validity of the presuppositions of the research
2. the nature, probability and magnitude of risk—and the clarity with which the risk will be communicated to potential participants
3. the method by which the risks were ascertained (e.g., if a research claims there be “no” or “little” risk, how does he/she know that)
4. are the estimates of probable harm and benefits reasonable
5. when vulnerable populations are involved, the appropriateness of involving them must be demonstrated

C. **Selection of Subjects**

1. Individual justice—researchers should exhibit fairness. You should not offer beneficial research only to the “desirable” and risky research only the “undesirable”.
2. Social justice—distinguish between groups of individuals that ought, and ought not, participate in any particular kind of research. Do not burden those who are already overburdened.

**Composition of the Board**

In accordance with the federal Office for Protection from Research Risks (OPRR), which operates within the Department of Health and Human Services (DHHS), the board is composed of **five** members (NOTE: this is a minimum number) with varying backgrounds. It will include at minimum one male member, one female member, one member from scientific disciplines, one member from nonscientific disciplines and one member who is not otherwise affiliated with the institution.

**Function of the Board**

The IRB has the authority to approve, require modification in (to secure approval), or disapprove all research activities covered by this policy including:
1. Research funded externally by way of grant, contract, or similar agreement between the sponsor (public or private) and the College
2. Research funded internally by the College by way of grant, contract, or similar agreement
3. Research conducted upon assignment by the College
4. Research actively assisted by the use of College facilities, resources, supplies, equipment, or personnel.

Except when expedited review procedure is used, the IRB shall review proposed research at convened meetings at which a majority of members are present, including at least one member whose primary concerns are in nonscientific areas. In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting (OPRR 46.108).

Exceptions to the Review Process

The only exceptions to the review procedure are “minor” research studies conducted by students as part of class work. Student projects that fulfill a thesis or senior requirement do meet the criteria of “minor” research studies; these projects must go through the review process.

Review Process

All principal investigators must submit a completed review application to the Board chair and request either Exempt, Expedited, or Full Review. The Board will act on an application within fourteen (14) days of the submission date. The principal investigator will be informed, in writing, of the Board’s decision within seven (7) days of the date that the decision is made (OPRR 46.109).

Review Categories

1) **Exempt**: Research that involves no or minimal risk to participants under specified circumstances listed in the *Application for Review*. Upon agreement by the chair and one other member of the Board that the research meets the criteria for the Exempt category, the review application will be approved. The chair and member agreeing to the Exempt categorization must do so in writing and accompany any comments with their signatures.

2) **Expedited Review**: Research that involves minimal risk to participants under specified circumstances listed in the *Application for Review*, or involves minor changes in previously approved research during the time for which approval is authorized. Review decisions will be based on the approval of a majority of Board members. Comments and/or recommendations of individual Board members must be made in writing and signed by the member. It is the decision of the chair to convene the Board for an Expedited Review (OPRR 46.110).

3) **Full Review**: Research that involves more than minimal risk to participants, including research that utilizes deception, as listed in the *Application for Review*. Any member of the Board may request a Full Review of an application. The Board will convene and the decision will be based on the approval of the majority of members. Members’ comments and/or
recommendations must be submitted in writing and signed by the member. Research applications may be denied final approval only after a Full Review.

*The Application for Review includes more information about the review process and the procedures principal investigators need to follow to apply for approval to conduct research with human subjects.*
Institutional Review Board Guidelines for “Minor” Studies
Conducted by Students as a Part of Class Work

In some courses, students collect data individually or in groups as part of course requirements or to facilitate class discussion. The instructor in such a course has the responsibility to discuss ethics of research with the students who will be engaging in the research and must judge that the potential educational benefits from such research outweigh any risks to the participants. In such courses, the carrying out of the research process makes up a small portion of actual class work.

This category does not include senior research or thesis courses in which the focus of the course is on original research designed and carried out by individual students.

With these considerations in mind, research is considered minor if all of the following conditions are met:

1. There is not expectation that data from the study will be included in any publication or presentation outside class;
2. All participants are age 18 or older;
3. Participants are not recruited through any agency or school, publication (including the student newspaper), public posting, or departmental research participant pool;
4. Funding is not sought for research;
5. The research does not involve participants from clinically or otherwise sensitive populations (e.g., delinquents);
6. Participation in the research takes less than 30 minutes of the participants’ time;
7. The research does not involve deception;
8. No physically invasive procedures are used;
9. Privacy of participants is respected. No potentially self-incriminating, sensitive, or highly personal questions are asked, and participants’ identities are kept anonymous; and
10. Contact with participants is well scripted or standardized.
PRINCIPAL INVESTIGATOR’S PROJECT OUTLINE FORM FOR PROPOSALS
SUBMITTED TO THE INSTITUTIONAL REVIEW BOARD

IRB No. _____ (To be completed by the IRB chair)

Name of the project director ____________________________________________________________

Department __________________________ Phone __________________

Title of Research Proposal ______________________________________________________________

Starting Date _______________ Duration __________________

Source of Funding ____________________________________________________________

All requests must include the following elements: Complete and signed Principal Investigator’s Project Outline Form; complete Review Category Form; a description of the research including the methodological and analytical techniques; copies of consent forms (or a request for exemption form informed consent with full justification); copies of all surveys to be utilized in the study or, if incomplete at the time of submission, a description of the topics to be covered and sample questions; and any additional materials that will assist the Board in completing its review.

Estimated Number of Human Subjects Involved in the Project ______

I. Characteristics of the subjects (check as many boxes as appropriate).

_____ Minors  _____ Disabled  _____ University Students
_____ Adults  _____ Pregnant  _____ Secondary School Students
_____ Prisoners  _____ Legal Incompetence  _____ Elementary School Students
_____ Others (specify) __________________

IA. Review Requested (select one)  Exempt_______ Expedited_______ Full_______ (complete page 3 of this form)

Has this or similar research protocol been approved by Georgetown College IRB or any other?
Date _____________ Project __________________________________________________________

II. Consent

a. Consent obtained from individual ____.
   Legally authorized representative ____.

b. Method of presenting information on which to base informed consent:
   Written ____  Oral ____.
   (For an oral presentation, attach a summary, signed by the project director, or the information which will be presented orally to the prospective subjects.)

c. Briefly describe the methods used for selection of subjects. The response to this item and items III and IV should be typewritten on a separate page(s) and attached to this form.

III. Attach a description of the Project (See IRB Guidelines, Section III; Review of the Guidelines.)
IV. Agreements: By signing this form, the project director (and his/her faculty advisor/instructor) agrees to the following:

a. The project director will comply with Georgetown College policies on research and investigation involving human subjects.
b. The project director will provide documentation of selection and informed consent procedures upon request by the IRB.
c. The project director will inform the IRB of any planned changes in procedures which involve human subjects, giving the IRB sufficient time to review and approve such changes before they are implemented, and to supply IRB with such progress reports or annual assessments as it may require.
d. It is understood that any approval granted by the IRB applies to this project only and only under the conditions and procedures described in the application. Any change in the protocol or conditions set forth will require separate approval.
e. It is understood that the identification of human subjects in any publication is an invasion of privacy and requires the execution of a consent form. Informed consent must be obtained from each subject or the subject’s legally authorized representative. Documentation of the informed consent must be retained, in a secure environment, for a minimum of four years after termination of the project.

Date ____________ Signature ____________________________________________

If the project director is an undergraduate or graduate student, the student’s advisor for this research proposal must sign the form.

Date ____________ Signature ____________________________________________

*The Principal Investigator will receive written notification of the IRB’s decision within three (3) weeks of receipt of this application.

________________________________________________________  ___________________
Signatures of the IRB Chair        Date

Approved though full _____ or expedited _____ review.
Approved Exemption _____
REVIEW CATEGORY FORM

INDICATE THE REVIEW CATEGORY FOR WHICH YOU ARE APPLYING

_____ Application for exempt review. Check all categories that apply.
Submit one (1) copy of materials.

____ Research conducted in established or commonly accepted educational setting and involving normal educational practices.
____ Research involving the use of educational tests, if information from these sources cannot be linked to the participant.
____ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, where these sources are publicly available and data cannot be linked to the participant.
____ Research involving observation of public behavior where the participant’s behavior is not linked to their identity.
____ Research involving survey or questionnaire procedures where responses are not linked to the participant.

_____ Application for expedited review. Check all categories that apply.
Submit three (3) copies of materials.

____ Collection of voice video, digital, or image recording made for research purposes.
____ Research on group or individual behavior or characteristics or behavior (including, but not limited to research on perception, cognition, motivation, communication, cultural beliefs, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
____ Collection of hair and nail clippings in a non-disfiguring manner.
____ Collection of deciduous teeth at the time of exfoliation, or of deciduous or permanent teeth if routine patient care indicates a need for extraction.
____ Collection of excreta and external secretions (including sweat), saliva, skin cells, sputum, placenta removed at delivery, an amniotic fluid at time of rupture of the membrane prior to or during labor.
____ Recording of data from adult participants (18+ years of age) using noninvasive procedures (not involving general anesthesia or sedation) routinely used in clinical practice, excluding procedures involving x-rays or microwaves. Examples: physical sensors that are applied either to the surface of the body or at a distance; weighing or testing sensory acuity; moderate exercise, muscular strength testing.
____ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adult participants (18+years of age) who are in good health, not pregnant and weigh at least 110 pounds.
___ Collection of supra- and sub-gingival dental plaque and calculus in a routine manner.
___ Study of existing data, documents, records, pathological specimens, or diagnostic specimens that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
___ Continuing review of research previously approved by the convened IRB where no new participants will be recruited.
___ Research on drugs or medical devices that are not new investigations.

____ Application for full review. Check all categories that apply.
Submit five (5) copies of materials.

___ Research that utilizes deception of participants.
___ Research that involves the manipulation of participants’ behavior, with or without the participants’ knowledge.
___ Research that involves new and/or untested procedures.
SAMPLE INFORMED CONSENT FORM

Title of Research Project: __________________________________________________________

________________________________________________________________________________

Principle Investigator(s): _______________________________________________________

________________________________________________________________________________

I. Federal and College regulations require us to obtain signed consent for participation in research projects which involve human subjects. After reading the statement below, if you agree to participate in this research, please indicate your consent by signing this form.

II. Statement of Purpose
Describe the purpose of your research. You do not need to lay out all of your hypotheses; however, you should indicate the general focus or area of concern.

If someone agrees to participate, what will that involve? Describe the commitment that you are asking of them—the amount of time, the kind of activity etc.

Your participation in this research project is entirely voluntary. You may withdraw form the research project at any time.

Are there guarantees of anonymity that you need to give and can give, such as the participant never being personally identified on any transcripts or permanent records or in any reports concerning this research? Will you be destroying tapes? In some cases, identifiable material has to be kept; however, if the information on that material could be embarrassing or is personal in nature, then what are your security precautions?

Are there any particular risks that you need to spell out? What are the benefits that balance that (those risks)?

III. Contact Information
Any inquiries concerning the procedures of this study can be discussed with the Experimenter (insert name of principal investigator). This study has been reviewed and approved by Georgetown College’s Institutional Review Board. Questions, reservations, or appeals regarding the procedures can be referred to the Associate Dean, Dr. Glenn Rogers at 863-7086.
IV. Waiver
I agree that all risk to me have been explained to my satisfaction and I understand that no compensation is available from Georgetown College and its employees for any injury resulting from my participation in this research.

I certify that I have read and fully understand the Statement of Procedure and agree to participate in this research project. My participation is given voluntarily and without coercion or undue influence. I understand that I may discontinue participation at any time without penalty or loss of any benefits to which I might otherwise be entitled. I certify that I am at least eighteen years of age.

Signature ______________________________________   Date ___________________

Print Name ________________________________________________________________
SAMPLE DEBRIEFING (Study involving deception)

This experiment was designed to study the ways in which people evaluate themselves and others on the basis of their cognitive abilities. It is a study of social comparison theory, a theory that states everyone wants to evaluate him or herself on important personal qualities. This happens frequently in school, when students compare themselves according to the grades they receive. If we evaluate ourselves favorably compared to our classmates (for example, if we are at the top of the grading curve), then our self-esteem will be boosted. On the other hand, if we are at the bottom of the grading curve, then we will suffer from lowered self-esteem. In the experiment you just completed, we wanted to see how experiencing success or failure affected self-esteem and willingness to compare yourself to others.

It was necessary to withhold the true purpose of this experiment until after you had completed your participation so that you would not second-guess our goals and perhaps change your responses to our questions. Thus, the “Spatial-Verbal Manipulation Test” you took in which you unscrambled letters to make words (an anagram problem) did not measure any kind of cognitive ability. In fact, your score on that test was determined ahead of time. One half of you received a test in which 12 of the 15 word puzzles were solvable and 3 were impossible to solve (they did not form real words). The other half of you received a test which contained only 3 solvable and 12 unsolvable puzzles. It was impossible for you to score any better than you actually did, and everyone in your group scored exactly as you did. Therefore, your score is not related to any ability on your part.

We included this anagram task so that one-half of the participants would be successful and one-half would be unsuccessful on this task. We will analyze your answers to our questionnaires and then study the effect of the test feedback on your responses. We predict that people who feel they have performed poorly will attempt to boost their self-esteem by comparing themselves against a group of people who are worse off.

It is important that you understand that the “Spatial-Verbal Manipulation Test” was created specifically for this study and is not related to your grades or to any cognitive ability. Since most college students think learning is important, we linked our fake test to cognitive abilities so that you would become personally involved in the task and try to do your best. But please be aware that your score on the test was determined by random chance at the start of the study and in no way reflects on your intelligence or abilities.

We ask that you please not discuss this experiment with anyone on campus, since other students may participate during the remainder of the semester. Study results will be made available during (insert the Spring/Fall) semester; you may call (insert Project Director/faculty sponsor name) at (insert phone number) if you would like to know the outcome or would like to talk more about your participation in this study. Do you have any questions about the study that haven’t been answered?

[Note: This sample was obtained from the IRB proposal of Spring Hill College.]
Attachment 1: Additional Information Required for Full Review of Research Involving More than Minimal Risk to Participants

Please provide the requested information for all appropriate categories involved in your research.
NOTE: Based on APA guidelines

Risk
For research in which the possibility of injury is greater than minimal:
1. Identify and describe in detail the possible risks, including psychological, physiological, or social injury, to which participants may be exposed.

2. Explain why you believe the risks to the participant are so outweighed by the combined benefit to the participant or society at large and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept these risks. Discuss any alternative ways of conducting this research that would present fewer risks to the participant, and explain why the method you have chosen is superior.

3. Explain fully how the rights and welfare of participants at risk will be protected (e.g., equipment closely monitored, medical exam given prior to procedures, psychological screening of participants, etc.)

Equipment
For research in which the participants will be in contact with any mechanical, electronic, electrical, or other equipment, which might put him/her at risk of accidental harm or injury, should there be a mechanical failure in the equipment.
1. Identify and describe in detail the equipment to be utilized and the exact location. Use manufacturer’s name and serial numbers and submit copies of manufacturer’s literature on the equipment when available.

2. Identify and describe in detail how the participant will interact with the equipment.

3. Indicate the names and qualifications (with regard to the safe use of the equipment) for all individuals authorized to use the equipment.

4. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the equipment.

Psychological or Physiological Intervention
For research in which the participants will be exposed to any psychological interventions such as deception, contrived social situations, manipulation of participant’s attitudes, opinion or self-esteem, psychotherapeutic procedures, or other psychological influences, or in which the participant(s) will be exposed to any physiological treatments or interventions upon the body by mechanical, electronic, chemical, biological or any other means.
1. Identify and describe in detail the psychological intervention (or manipulation) and the means used to administer the intervention.

2. Identify and describe in detail the behavior expected of participant(s) and the behavior of the investigator during the administration of the intervention.

3. Describe how the data resulting from this procedure will be gathered or recorded.

4. Identify anticipated and possible psychological, physiological, or social consequences of this procedure for the participant(s).

5. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the means used to administer the intervention. For all equipment used, the questions regarding equipment above must be answered.

6. For research involving DECEPTION, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator.

7. For research involving psychological intervention, describe in detail the plan for debriefing participants.

Indicate the investigator’s competence and identify his/her qualifications, by training and experience, to conduct this procedure. Give name, title, academic affiliation and program, address, and telephone number of the individual(s) who will supervise this procedure.
PROCEDURES FOR OBTAINING INSTITUTIONAL REVIEW BOARD APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

All research investigation involving human subjects, conducted by faculty, staff, or students under the auspices or financial support of Georgetown College, must be reviewed and approved by the Institutional Review Board for Review of Research Involving Human Subject (IRB), or be declared exempt from the review by that board. The IRB operates under the policies and procedures of the colleges, established to insure compliance with the National Research Act (P. L. 93-348) and the regulations set forth in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46). The purpose of IRB review is to protect the rights and personal privacy of individuals and assure a favorable climate for conducting scientific inquiry.

APPLICATION AND REVIEW

A request for IRB approval of a research project should be prepared in accordance with the instructions in Appendix 1: Principal Investigator’s Project Outline Form. The requested number of copies (indicated below) and all supporting documentation must be submitted and must bear the original signature of the principal investigator. If the project director is an undergraduate or graduate student, the Appendix 1: Principal Investigator’s Project Outline Form must also be signed by the student’s faculty advisor for the research in question. The principal investigator also is encouraged to submit any additional materials with may help the Review Committee make a prompt, accurate evaluation of the project. A copy of the consent forms and/or introduction to the interview must be included with the application.

All research involving human subjects must be reviewed by the IRB. Research is reviewed by an expedited or full board process although some forms of research are exempt from review (see Section VI).

I. New Research

1. The Principal Investigator may seek review under one of the following categories, which are fully defined in Appendix 2.
   a. Exempt Review: research that involves no risk to the participants. Principal investigators should follow the procedures outlined below to apply for an exemption (see section VI). Submit one (1) copy of the requested materials.
   b. Expedited Review: research that involves no more than minimal risk to participants, or that involves minimal changes to previously approved research during the period of one year or less from the approval date. Submit three (3) copies of the requested materials.
   c. Full Board Review: research that involves more than minimal risk to participants, including research that uses deception of participants. Submit five (5) copies of the requested materials.

Exceptions: Exceptions to the review process are “minor” research studies conducted by students as part of class work. (See Appendix 3).
2. Applications are distributed to the Board members for individual review. Applications are considered to be confidential documents and are not to be openly discussed by Board members with others outside the Board.

3. The Board will complete its review within fourteen (14) days of the date the application was submitted. The chair of the Board will notify the principal investigator of the decision within seven (7) days of the decision.

II. On-going Research
Approval from the IRB will last for one calendar year from the date on the approval form. Research that is not completed in that year must undergo review before the approval expiration date. If there have been no changes to the original research protocol, the principal investigator should submit a new application form and request Expedited Review. However, if changes have been made in the research protocol, the principal investigator must treat the application as a new request.

III. Review of the Guidelines
The principal investigator should review the guidelines and respond to the sections outlined on the principal investigator’s form. A request should include:

A. Brief Project Description
   - A general description, including previous relevant research or activities of the principal investigator (and/or advisor).
   - The specific aims and objectives of the research component under review.
   - The research design, including the type of analysis and justification for the analytical approach, and the requirements for the facilities available to conduct the research.

B. Description of Risks and Benefits:
   - Describe the risks (physical, psychological, social) to the subjects
   - Describe the benefits (physical, psychological, social) to the subjects and/or the importance of the knowledge to be gained and significance of the research.

C. Description of Methodology and Personnel:
   - Detailed description of the methodology and procedures to be used, especially as they relate to human subjects; and
   - Identify the personnel, including the principal investigator, who will participate in the project and their qualifications for participation.

D. The Process for Informed Consent
   1. General Requirements
An investigator shall seek the consent of the prospective subject, or the subject’s legally authorized representative only under the 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 must be in language understandable to the subject or representative. 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.

2. **Documentation Requirements**

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 representative. A copy shall be given to the person signing the form. This consent form any be either of the following:

a. A written consent document that embodies the elements of informed consent enumerated below.

b. A “short-form” written consent document stating that the elements of informed consent enumerated below have been presented orally to the subject or the subject’s legally authorized representative. When this method is used there shall be a witness to the oral presentation. A written summary of what is to be said to the subject or the representative shall be provided to the IRB for review and approval. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short-form.

The short-form must be signed by the subject or the representative. The witness must sign both the short-form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary.

The requirements for the investigator to obtain a signed consent form for some or all subjects may be waived by the IRB if it finds either:

- **c.** That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with research, and the subjects wishes will govern; or

- **d.** That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived the IRB will require the investigator to provide subjects with a written statement regarding the research.
3. **Basic Elements of Informed Consent**  
   *(see Appendix 4 for sample consent form)*  
   In seeking informed consent the following information must be provided to each subject:

   a. A statement that the study involves research, an explanation of the purposes of the research, 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 disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

   e. A statement describing the extent, if any to which confidentiality of records identifying the subject will be maintained;

   f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

   Please Note: Unless additional arrangements have been made, all Consent Forms used at Georgetown College must include the following waiver:

   “I agree that all risk to me have been explained to my satisfaction and I understand that no compensation is available from Georgetown College and its employees for any injury resulting from my participation in this research.”

   g. 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

   h. A statement that participation is voluntary, refusal to participate involves 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.
i. A statement regarding the expectation that participants’ names will not be attached to their data.

4. Waiver of Requirements to Obtain Informed Consent
The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above if the research could not practically be carried out without the waiver or alteration; and provided the IRB finds and documents that:

a. The research involves no more than minimal risk to the subjects;

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. Whenever appropriate, the subject will be provided with additional pertinent information after participation.

IV. Post-Participation Debriefing/Feedback (Based on the American Psychological Association’s (APA) guidelines)
Investigators must provide a prompt opportunity for participants to obtain appropriate information about the purpose, results, and conclusions of the research study, and to attempt to correct any misconceptions that participants may have about their responses during the study. It is recommended that feedback be provided to participants immediately following their participation. In cases where the design of the study prevents immediate feedback, delayed feedback must be provided as soon as practical, and within six (6) months of completion of the study. If scientific or humane values justify delaying or withholding feedback, the researcher must take reasonable measures to reduce the risk of harm to participants. (See Appendix 5 for a sample debriefing).

V. The Use of Deception in Research (Based on APA guidelines)
Research involving deception may not be conducted unless the project director provides adequate rationale that the use of deceptive techniques is justified by the study’s prospective educational, scientific, or applied value and that equally effective alternative procedures that do not use deception are not feasible. The principal investigator must complete Attachment 1 and submit it with the Application for Review.

Researchers may not deceive participants about significant aspects that would affect their willingness to take part in the study, such as physical risks, discomfort, or unpleasant emotional experiences.

Any deception that is an integral feature of the research design or procedure must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research study.
VI. Exemption from Review

If the principal investigator believes that the research is exempt from the need for the IRB review and approval, a letter should be sent to the IRB requesting that determination. The letter should include a brief description (no more than two pages) of the project (including all the components required of the full review including a consent form and identification of the exemption category which is claimed. A signed copy of the Principal Investigator’s Project Outline Form must be included. A decision on the request will be confirmed in writing and will normally be made as soon as possible after receipt of the request.

It is the responsibility of the principal investigator to obtain approval or a determination of exempt status before the research activity is initiated. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be given in an exempt determination. There are three protected classes of subjects for which exemptions are not permitted or are permitted in limited categories (see below).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instruction strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

2. Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, 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.

4. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability, and (iii) the research deals with sensitive aspects of the subject’s own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subjects responses, if they become known outside the research, could reasonably place the subject at a risk of criminal or civil liability or be damaging to the subject’s financial standing or employability, and (iii) the research deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public office.

Protection for Special Classes of Subjects:
Research involving prisoners, pregnant women, fetuses and human in vitro fertilization must receive a full review by the IRB. Research involving minor children (under the age of eighteen) may be exempt only as it applies to categories 1, 2, and 3 above. Research involving minors which falls under category 4 above may be exempt if the investigator does not participate in the activities being observed. Research falling within category 5 may not be exempted for children under the age of 18.

VII. Continuing Review & Suspension of Approval
The IRB will conduct review of approved research at intervals appropriate to the degree of risk, but no less than once per year, and has the authority to observe or have a third party observe the consent process and the research. The IRB has the 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.