

Instructions for Submitting Applications to

**The Benedictine College
Institutional Review Board (IRB)**

September 2019

**Benedictine College
1020 North 2nd Street
Atchison, KS 66002**

Who Must Apply for IRB Approval (and Why)?

The National Research Act of 1974/1983 (PL 93-348) dictates that, in order for institutions to be eligible for behavioral or biomedical research grants from federal sources (e.g., The Department of Health and Human Services and its various research institutes), an Institutional Review Board (IRB) must be established and maintained to review research involving human subjects. The charge of this IRB is to protect the rights of those subjects participating in such research at this institution. The IRB must review application research involving human subjects if the research:

- (1) is in any way sponsored by the College (e.g., affiliated with the College in name), or
- (2) is conducted by, or under the direction of, any employee or agent of the College as part of their institutional responsibilities, or
- (3) is conducted by, or under the direction of, any employee or agent of the College using College facilities or property, or
- (4) involves the use of the institution's non-public information to contact or identify participants or prospective participants.

Investigators conducting research with human subjects that meets any of these conditions must submit an application to the IRB for approval. The IRB's review of the application is guided by the Code of Federal Regulations (Title 45, Part 46), which sets the minimum standards for protection of human subjects.

When to Submit

Applications for IRB approval can be submitted at any time. During the academic year, the IRB works monthly on the review of applications and meets on a regular basis.

Applicants will receive written notice of the IRB's review within one week of the meeting at which the application is reviewed.

The IRB recommends that lead-time for committee approval be figured into the schedule for the conduct of research, especially since committee action (i.e., discussion and vote on approval of the project) is not necessarily equivalent to or a guarantee of committee approval.

What to Submit

Applications are submitted using the IRB application form provided below.

Part I: The IRB application consists of four pages (a face page, a checklist page, a description page, and an abstract page).

Part II: Appendices should also be submitted with the application. Appendices contain supplementary information regarding the application, which usually include (but are not limited to) a copy of the Informed Consent form to be used in the conduct of the research, and copies of any additional supplementary materials (surveys, questionnaires, assessment materials, etc.) that will be used in the conduct of the research. However, the Principal Investigator (PI) should feel free to include any materials that (s)he believes will assist the committee in evaluating the application.

9/2019

BENEDICTINE COLLEGE
Institutional Review Board
Application for Research Approval

1. Name(s) of Investigator(s): _____

Email address of primary investigator: _____

Phone number of primary investigator (PI): _____

2. Name of faculty Sponsor/Staff Member (if faculty or staff member is not PI):

Email address of faculty/staff member: _____

Phone number of faculty/staff member: _____

Department: _____

3. Title of Research:

4. Individuals other than faculty, staff, or students at Benedictine College involved in the conduct of the research:

5. Is this research a Discovery project? ____ Yes ____ No

6. Certifications: By submitting this application, I am certifying that I have read, understand, and will comply with the policies and procedures of Benedictine College regarding human subjects in research. I subscribe to the standards and will adhere to the policies and procedures of the IRB, and I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of study.

Date: _____

Signature: _____

Faculty or Staff Member

7. Please check all that apply to the research activity proposed:

Does the research involve:

- a. drugs or other controlled substances?
- b. payment of subjects for participation?
- c. access to subjects through a cooperating institution?
- d. substances taken internally by or applied externally to the subjects?
- e. mechanical or electrical devices (e.g., electrodes) applied to the subjects?
- f. fluids (e.g., blood) or tissues removed from the subjects?
- g. subjects experiencing stress (physiological or psychological)?
- h. deception of subjects concerning any aspect of purposes or procedures (misleading or withheld information)?
- i. subjects who could be judged to have limited freedom of consent (e.g., minors, developmentally delayed persons, or those institutionalized)?
- j. any procedure or activities that might place the subjects at risk (psychological, physical, or social)?
- k. use of interviews, survey, questionnaires, audio or video recordings?
- l. data collection over a period greater than one year?
- m. the need to include an Informed Consent form? Note: The IRB makes the final approval of the Informed Consent form.
- n. receiving, accessing, collecting, compiling and/or maintaining information that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual?

8. Approximate number of subjects to be involved in the research: _____

12. Abstract of the proposed procedures in the research (must be complete on this page). (The abstract should be a succinct overview of the research without jargon, unexplained abbreviations, or technical terminology. Here is where you must provide details about checked items under questions 7.a. through 7.n. of the application: drugs, cooperating institutions, medical information requested, security measures and post-research plans for tapes, questionnaires, surveys, and other data, and detailed debriefing procedures for deception research.)

Submit one complete application inclusive of items 1–12 to the IRB, c/o Amy Posey by email to aposey@benedictine.edu.

Instructions for Completing the IRB Application Form

Part I: The IRB Application

Page 1.

1. Name(s) of Investigator(s). List the names of all persons conducting the research. For student research, list the names of all students involved in conducting the research. The first student listed should be the student research director. All research must also list a Benedictine College faculty or staff member who will ultimately be responsible for the proper conduct of the research with respect to the protection of human subjects.
2. Department Affiliation: Please indicate the campus department with which the faculty/staff member is affiliated.
3. Contact information for the faculty/staff member; correspondence from the IRB will be sent to this address.
4. Title of Research. Please give a brief title for the research.
5. List the names of other individuals or organizations outside of Benedictine College that will be participating in the conduct of this research, if applicable.
6. Is the research being conducted for a Discovery project?
7. Certification. The faculty/staff member must sign the bottom of the face page, thus affirming familiarity with the policies of the IRB and the professional codes of ethical conduct with respect to human subjects. This is an important step. The IRB cannot process applications that are not signed. Please note that by submitting the application you are certifying that you have read, understand, and will comply with the policies and procedures of Benedictine College regarding human subjects in research and that you subscribe to the standards and will adhere to the policies and procedures of the IRB.

Page 2.

8. Checklist. Please read each item carefully and check all those that may apply to your study. The checklist allows the IRB to rapidly screen applications for possible expedited or exempt conditions. Failure to do so accurately may result in delays in the processing or approval of your proposal. The section "Other Supporting Materials," (page 9) should be noted if item 7.c., about cooperating institutions, is checked. If item 7.k. is checked then copies of the survey instruments to be used in the research must be attached as an appendix. These materials will be retained in IRB files concerning this research.

Use of Audio and Video Recording

For research in which audio and/or video recording is intended, your abstract and consent form should explain who will have access to the tapes, security measures you will take to protect the privacy of subjects recorded, and what you will do with the tapes upon completion of your research (e.g. erase them, retain them for future research, etc.).

Payment to subjects

Please note that if the research involves payment to subjects (i.e., if item 7.b. is checked) payment is considered to be appropriate only if it is meant to compensate subjects for costs incurred as part of participation in the research (e.g. travel, time, etc.). Researchers should not use payment schemes that may be potentially coercive.

9. Approximate number of subjects to be involved in the research. Please indicate the number of subjects from whom you are planning to collect data.

Page 3. Information about the research purpose, proposed subjects, and selection procedures helps the committee discern the potential benefits to be derived from the research, whether the proposed population is especially vulnerable or at risk, and whether the processes for subject selection are equitable and sensitive to issues of confidentiality and privacy.

10. Research Purpose(s). Please describe briefly, and without jargon, the purpose of the research described in the application. Please use only the space provided.
11. Describe the Proposed Subjects. Please indicate any special criteria for including or excluding subjects involved in the proposed research. For example, if subjects are to be included in the research only if they are from a particular age group, racial group, or gender, please indicate this here. Additionally, if there is some medical attribute (e.g., Alzheimer's Disease, heart disease, etc.) or physical (e.g., marathon runners, bicyclists, weight lifters) that characterizes the subjects to be included in the study, please indicate this here as well.

Subject Selection Considerations

12. Describe how the subjects are to be selected. Please indicate how you will gain access to, and recruit these subjects for participation in the research. That is, will you recruit participants through word-of-mouth, fliers or poster, newspaper ads, public or private membership or employee lists, etc. (If subjects are to be recruited from a cooperating institution, such as a clinic or other service organization be aware that subjects' names and other private information may not be obtained without the subjects' written permission.) If subjects are to be recruited randomly (e.g. by email), or through a cooperating institution, please indicate the particulars here. If subjects are recruited by a flier or poster or newspaper ad, a copy of this should be included as an appendix.

Page 4. The abstract should be complete and provide an accurate description of the proposed research.

13. Abstract of the proposed procedures. The abstract should be a succinct overview of the research. Please describe the procedures to be employed in the research. The IRB committee is comprised of professionals from various academic and nonacademic fields. Therefore, it

is important that the procedures be described in terms that can be understood by such an audience. Describe the procedures in the space provided, without jargon, abbreviations, or technical terminology. If you must use technical terms, please define or explain them so that someone not knowledgeable about your field can understand them.

Part 2: Appendices

Supplementary materials should be attached to the application as appendices. These supporting materials often include the following items.

Copies of Research Instruments

If applicable (usually, if item 7.k. on the page 2 of the application has been checked), copies of instruments (assessments, scales, questionnaires, surveys, protocols, etc.) that are to be used in the proposed research are attached in appendices.

Informed Consent Form

If a written informed consent is being used, a copy of the consent form that will be used in the research should be attached. (A consent form template is provided on p. 15 of this document.) According to the federal code of regulations (45 CFR 46), the consent form must include the following items when appropriate and applicable:

- a. **Introduction:** A statement describing the purpose of the informed consent and the basic rights of research participants. This should include an assurance that participation is voluntary and may be discontinued at any time, and that refusal to participate in, or withdrawal of participation from, the research will result in no penalty or loss of benefits to which the subject is otherwise entitled.
- b. **Purpose of the Study:** A sentence or two stating the purpose of the research.
- c. **Procedures:** A brief description of the procedures to be followed (see template). This section should include an indication of the commitment in time required to participate in the study.
- d. **Risks and Benefits:** A description of any reasonably foreseeable discomforts or risks (psychological, sociological, or physical) to the participants, as well as a description of the benefits for the subjects, or for others, which may be reasonably expected from the research. For research involving experimental medical treatments, this is where you would also include disclosure of alternative procedures that would be advantageous to the subject.
- e. **Payment to Participants:** If applicable, a statement describing participant compensation (see template).
- f. **Confidentiality Statement:** If applicable, a statement describing the extent to which the confidentiality of records through which the subject can be identified will be protected.
- g. **Participant Certification:** This section includes assurances that researchers will answer any inquiries concerning the research, and information concerning whom to contact in case questions arise after the data collection session is completed. This is usually done by providing the name of the faculty/staff member, the departmental affiliation, email address, and telephone number on the consent form, following signatures.
- h. **Signatures:** The subject's signature, if appropriate (e.g., the subject is of legal age, the subject is competent to understand and provide informed consent). If individuals who are not of legal age (under 18 years) may be inadvertently recruited for participation in the research (e.g., when subjects are obtained from introductory courses), the following should

appear above the signature: "With my signature, I affirm that I am at least 18 years of age and that I have received a copy of this Informed Consent form." If the subject's signature is not appropriate, secure the signature of the parent or guardian, and the name of the subject.

Please note that, if the consent form is longer than a single page, then page numbers should be provided that indicate the entire length of the form on each of the pages (e.g., "Page 1 of 3," "Page 2 of 3," etc.). Copies of acceptable consent forms are provided for illustrative purposes with this packet.

If oral informed consent is being proposed for use, the PI should consult directions and regulations for documenting oral consent in the Federal Regulations (45 CFR 46.117.b.2). A copy of these regulations is available from the chair of the Benedictine College IRB Committee. This typically involves submission of a text or script of the consent procedures, the presence of a witness, and a summary description of the research provided for subjects.

Assent Procedures

In research with children or other participants for whom the ability to give informed consent is otherwise compromised, it is usually appropriate to obtain some form of agreement, or "assent" to participation in the data collection sessions. For example, even though children or individuals with developmental disabilities cannot provide informed consent for participation in research, a researcher should still describe the procedures in language that can be understood by the subjects, and obtain their verbal "agreement" to participate. If an assent procedure is to be used, a prototype of the "script" of this procedure should be included in the appendices of the application. In all cases an Informed Consent form must be completed by the parent or guardian of the research subject.

Surveys and Questionnaires

For mail or online surveys or questionnaires that are completely anonymous in nature, signed informed consent can often be waived. However, in the place of informed consent under such circumstances, an appropriate "letter of introduction" should accompany the survey. The letter of introduction should include the critical aspects of the informed consent form (e.g., risk-benefit statements, assurances of voluntary participation and confidentiality of responses, etc.). The letter should also include a statement that, by returning/completing the questionnaire, the respondent indicates his or her consent to participate in the study. A copy of the letter of introduction should be included in the appendices.

If investigators wish to use the Internet or electronic mail to conduct surveys some extra precautions are necessary. Because respondents' electronic addresses are typically provided when they return such surveys by e-mail, researchers should devise a plan for stripping such information to maintain the confidentiality and anonymity of respondents' names. Also, it is possible that, through intent or accident, someone other than the intended recipient may see the subject's response. The investigator should therefore inform subjects that, while effort will be made to protect subjects' privacy, security and confidentiality of participants' responses cannot be guaranteed.

Other Supporting Materials

Often, some of the concerns of the committee can be addressed by the inclusion of supporting letters from responsible individuals at institutions (schools, clinics, health care facilities, branches of law enforcement, etc.) that are involved or cooperating in the research. These letters might provide an indication of their willingness to cooperate in the conduct of the research, or their granting of permission to research personnel for access to subject populations located at such institutions. The letter may also indicate that such individuals have reviewed or (if applicable) have secured approval of the research protocol within that institution.

How Much to Submit

Investigators must submit: ONE copy of the entire completed IRB application (pages 1–4) plus Informed Consent form(s) and all appendix materials.

Where to Submit

An electronic pdf copy of the signed application, with appendices, should be sent to Amy Posey, IRB Chair, via email: aposey@benedictine.edu. If you have questions, Dr. Posey can be reached via email or at 913-360-7504.

On What Bases Are IRB Applications Evaluated?

General Issues of Subject Protection

Given the fundamental charge of the committee, there are particular aspects of the proposal to which IRB will be attending. By law, the IRB can grant approval only to research that satisfies certain requirements. The requirements for approval (as paraphrased from the Code of Federal Regulations), include the following:

Risks to subjects are minimized. This is the first and foremost concern in the review of application by the IRB. What potential risks, stresses, or discomforts (if any) will be incurred by participation in this research? Have the researchers taken steps in the design or procedures of the study to reduce the possibility of these risks or discomforts?

Risks to subjects are reasonable in relation to anticipated benefits. Do the benefits, if any, to be derived from this research outweigh the risks posed by this research to the subjects?

When applicable, **informed consent will be sought** from each subject (or the subject's legal representative) and documented. Are subjects fully informed of the risks and benefits of participation in the research? Are subjects informed of their basic rights in participating (e.g., withdrawal without penalty)? Are all of the appropriate aspects of informed consent included? If not, have the omissions been adequately justified? If the subjects themselves are unable to give informed consent, has consent been acquired from the appropriate responsible person(s), and has an assent procedure been provided? Is there adequate provision for the documentation of informed consent by the researchers?

Adequate provisions for monitoring data to ensure the safety of subjects. Is the research monitored so that previously unforeseen risks come to the attention of the PI and/or faculty/staff advisor? This section also includes the monitoring of data in the case that individual subjects are

identified as being at risk for medical or psychological problems. For example, in the course of research on exercise physiology, a researcher might discover the presence of a heart murmur; in the course of psychological research on depression, a researcher might discover a subject who is at some risk for suicide. What provisions, if any, are made for subjects who are identified as being at risk during the conduct of this research?

Adequate provisions to protect the privacy of subjects and maintain confidentiality. To what degree are subjects' responses protected with respect to confidentiality and anonymity? Will subjects' names be associated with their data? Who will have access to materials (e.g., data files, audio recordings or videotapes) through which subjects might be identified? Will data files be kept in a safe place? What are the plans for disposition of materials through which subjects might be identified when the study is finished?

Appropriate additional safeguards for subjects who are especially vulnerable. Have adequate additional provisions been made to protect the rights of those subjects who might be especially vulnerable to coercion or undue influence? Federal law specifically mentions children, those with physical illness or psychological disorders, or those who are economically or educationally disadvantaged, as being members of this class. Are there any circumstances in the proposed research under which subjects might feel coerced to participate?

IRB Policy on Experiments Involving Deception of Subjects

The IRB acknowledges that it is occasionally necessary to use deception in a research design in order to protect or strengthen the scientific integrity of an investigation. However, because participants are deliberately misinformed concerning the actual purposes or procedures of the research in such cases, the IRB considers such research to not meet the general requirement for informed consent as stated in the Code of Federal Regulations (45 CFR 46.116.a.1). This part of the law delineates the basic elements of informed consent, and states that in seeking informed consent, the following information shall be provided to each subject:

...an explanation of the purposes of the research and...a description of the procedures to be followed...

Please note that federal law does not necessarily restrict the concept of "informed consent" to the consent form that subjects sign at the start of a study.

The Code of Federal Regulations, however, does provide for instances in which informed consent can be altered or waived. Under this federal law (45 CFR 46.116.d.1-4), this can occur only if all of the following conditions are met:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration [of consent] will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration [of consent]; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Therefore, investigators proposing research to the IRB in which participants are misinformed concerning the study's procedures or purposes during the course of data collection must address

how their applications meet these conditions. This requirement may be met in a number of ways. However, in order to address these issues and facilitate review of such applications, the IRB recommends that applications for research involving deception include the following elements:

- a. **Justification for the Deception.** The justification should address condition 3 listed above. Investigators should provide specific and cogent reasons why fully informed consent is not appropriate for this study, and/or the manner in which fully informed consent threatens the integrity of the research.
- b. **Explicit Statement of No Risk/Minimal Risk.** This statement should address conditions 1 and 2 listed on the previous page. Investigators should provide a statement affirming that the proposed research presents no more than minimal risk to the participants.

Federal law (45 CFR 46.102.g) defines "minimal risk" as follows:

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- c. **Description of Debriefing.** Procedures for debriefing should address condition 4, listed above. Subjects should be informed that deception took place, and should be appropriately informed as to the actual purpose of the research, and the role of the deception in protecting the integrity of the research. Finally, subjects should also be reminded of their right to withdraw from the study at this time; this can be accomplished through a range of various procedures, extending from the inclusion of a simple statement to that effect in the debriefing, to having the participant sign a second informed consent form at the end of the study.

It is noted that the text of the Code of Federal Regulations allows for the possibility that circumstances may arise in which debriefing may not be judged to be "appropriate." The IRB allows for this possibility, but researchers should note that requests to omit such debriefing in research involving deception should be strongly justified.

Although applications involving deception must meet the conditions for alteration of informed consent, signed informed consent is still required to meet the requirements described in 45 CFR 46.116.a.2-8. Note that the informed consent form may not contain misinformation, may not be used as part of the deception, and may not be used as a means for manipulating subjects' behavior.

Initial Screening of Applications

The IRB chair first screens the applications to determine whether they fit the description of research that qualify for exemption or expedited review, or if they must receive full board review.

Exempt Status. When applicants request exempt status, the IRB chair will review the application to determine whether the research project qualifies for exemption. If it does, the chair will notify the faculty or staff member designated on the application, and research may commence. If the project does not meet requirements for exemption, the IRB chair will provide an explanation to the faculty or staff member, and the proposal will be considered for expedited review.

Expedited Review. Expedited approval may be granted for certain specific classes of research defined by the Code of Federal Regulations. Most often, PIs can receive expedited approvals for three classes of research:

- (1) research that has been previously approved by the IRB, in which minor protocol changes have been made, or
- (2) research that has been previously approved by the IRB, and whose approval date exceeds one year. In this latter case, the expedited approval takes the form of an "update."
- (3) some research not exempt but which involve no more than minimal risk, as described in 45 CFR 46.110 (f) (1–7). A copy of these regulations is available from the chair of the Benedictine College IRB Committee.

If a proposal fits one of these categories (which are strictly defined by the Federal Code of Regulations: 45 CFR 46), and the application meets criteria for approval, approval notification is sent out immediately to the faculty or staff member designated on the application. Upon receipt of this notification, the research may commence.

Committee Review

Applications that do not fit the expedited-review category are reviewed by the full committee. The committee members receive the full application plus appendices, and return their recommendations and comments concerning the proposal to the IRB chair. These recommendations and comments are compiled and integrated by the IRB chair, and then presented to the full committee at the next meeting. At that meeting, all research sent out for review are open for discussion and voted on. Results of that committee vote and the commentary from the reviewers are forwarded to the faculty or staff member designated on the application.

Forms of Committee Action

The outcome of the IRB review can take several forms. Each of these particular actions is discussed below.

Disapproval. Research is disapproved when the committee judges the risk to human subjects participating in such experiments to be unacceptable. The acceptability of the risk is determined by the judgment of the cost/benefit ratio of the research. Thus, higher levels of risk will be tolerated for research in which the potential benefit is judged to be higher; the opposite is true for research that presents no obvious benefit.

Failure on the part of the applicant to adequately describe the research in the abstract portion of the application is often the cause for disapproval, since it is here that the applicant must describe screening, safety precautions, and contingency plans to meet adverse reactions from subjects to research procedures, as well as to describe the procedures in layperson's terms without technical jargon.

No Decision. In some cases, not enough information is provided to allow the committee to determine the degree of risk to which subjects will be exposed. This occurs when critical information is omitted from the application. Thus, the application does not describe the research in detail adequate to allow a judgment of either approval, contingency, or disapproval. Occasionally, the cause for a failure to approve lies in the use of technical jargon which neither

reviewers nor prospective subjects may understand. In such a case, the applicant must submit the needed information so the proposal may be considered at the next IRB meeting.

Approval Upon Meeting Contingencies. The IRB may withhold approval of the application, contingent upon a request from the committee for clarification of some point concerning the research, or for changes to the consent form or materials involved in the research. The applicant then must respond to the request. Depending on the number of contingencies involved in the research, the determination of whether the response is adequate will be made by the chair or the opinion of other IRB members may be sought. If the response adequately meets the contingencies set by the committee, an approval is generated for the research.

Approval. The IRB may approve the application. Upon notification of approval, the applicant may begin the research.

Continuing Review of Approved Research

Please note that Federal Regulations limit the tenure of IRB approvals to one year. Therefore, even approved research is subject to what NIH calls "continuing review." Before the anniversary of each research approval, the PI will receive a notice from the IRB that the approval is about to expire, and is prompted for information concerning the proposal with respect to "updating" or extending IRB approval of the research for another year.

If the research is continuing, but the PI envisions that major changes will be made to the approved protocol, the research must be reviewed by the full committee. If the research is continuing as proposed, or is continuing with only minor changes to the protocol, then an expedited approval can usually be granted to update the approval for another year. PIs should note, however, that NIH has recently emphasized the need for thorough continuing review and monitoring of approved research. Thus, research that have been previously subject to full IRB review may be reviewed again by the full IRB prior to updating the approval.

At the very least, the IRB will require a copy of the Informed Consent form currently in use before issuing an expedited approval. Finally, if the PI reports that an approved research has been completed, that research will be designated Inactive and the IRB documentation of that research will be archived.

Acknowledgement: The IRB of Benedictine College is grateful for permission granted by the Human Subjects Committee—Lawrence Campus, University of Kansas to modify and use these application forms and instructions.

Template for Informed Consent Form

Introduction

The Department of _____ at Benedictine College supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. Refusal to participate or a decision to withdraw from the study will not result in a penalty of any kind for you.

Purpose of the Study

Provide a brief description of the purpose of the study.

Procedures

Provide a brief description of the procedures that will be followed, and the anticipated time commitment for the participants (i.e., tell prospective participants what they will be doing. For example, "In this study, participants will provide their reactions to a list of words presented to them on a computer screen and complete a brief demographics questionnaire. It is anticipated that this will take no more than 20 minutes of your time").

Risks and Benefits

Insert a description of any burdens, inconveniences, pain, discomforts, and risks associated with participation in the study. If no risks are anticipated, this should be stated explicitly. Insert a description of the potential benefits, if any, to the research participant. Specify if these are direct benefits to the participant, or indirect benefits (e.g., to society). If there are no anticipated benefits, this should be explicitly stated.

Payment to Participants

If participants will be paid, insert a statement regarding how much and on what schedule, and include the following statement: Because you are being paid, the researchers may ask for your social security number in order to comply with federal and state tax and accounting regulations.

Confidentiality Statement

For this study, the researchers will collect information about you. This information will be obtained from the study activities that are listed in the Procedures section of this Consent Form. In addition, information will be obtained from [*insert description, e.g., a health questionnaire that you complete; the Registrar's Office*]. Your name will not be associated in any way with the information collected about you or with the research findings from this study. The researcher(s) will use a study number, initials, or a pseudonym instead of your name.

The information collected about you will be used by [*list anyone who will have access to the data, including the student research director, co-researchers, faculty advisor. List any persons or groups external to the College with whom the researchers may disclose the information, and include a statement about the purpose of the disclosure*]. Again, your name will not be associated with the information disclosed to these individuals.

Participant Certification

I have read this Consent Form. I have had the opportunity to ask, and I have received answers to, any questions a had regarding the study and the use and disclosure of information about me for the study. I understand that if I have any additional questions about my participation in this study, I may contact the researchers listed at the end of this form.

I agree to take part in this study as a research participant. I further agree to the uses and disclosures of my information as described above. With my signature I affirm that I am at least 18 years old and that I have received a copy of this Informed Consent form to keep.

_____	_____
Print Participant's Name	Date

Participant's Signature	

Researcher Contact Information

John Doe
Student Research Director
Phone number
email address

Dr. Jane Doe
Principal Investigator
Department
Campus address
Phone number
email address