Belmont University Institutional Review Board

Application for IRB Review (Expedited or Full)

Level of Review Requested: Expedited ( ) Full ( )

Title of Project:

Date proposal submitted to the IRB:

Proposed start and end date of project:

*(Note: Start date should be at least a month from submission date)*

Type of Proposal or Activity:

1. ( ) New proposal ( ) Renewal ( ) Modification

 If renewal or modification, what was the date of last IRB approval? \_\_\_\_\_\_\_\_\_\_\_\_

Investigator information

1. Name of Principal Investigator:
2. Role: Please indicate either your credentials (e.g., Pharm D) or Program of Studies (e.g.,

 Master of Education Graduate Student)

 Faculty/Credentials:

 Student/Program of Study:

 Staff/Credentials:

1. Address:

 Phone Number: e-mail:

 Department, school, or program you represent:

1. List all Associate Investigators(please write or type full name of each investigator--no

 signatures required here):

 Associate Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Associate Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Associate Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Associate Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If more Associate Investigators are involved with this project, electronically insert their names or include them on an attached sheet.

1. Faculty Sponsor(s) – A faculty sponsor is required for all student research projects:

 Name:

 Phone Number: e-mail:

**FUNDING**

1. Expected cost of the research: *(Please itemize your research expenses. Please attach a separate list if needed.)*
2. Please identify all sources of funding

Governmental Agency or Agencies:

Foundation(s):

Corporation(s):

Organization(s):

Belmont University Departmental funds:

Individual(s):

Other:

1. Is this proposal part of a grant?

 Yes\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_

 If this proposal is part of a grant, please answer the following questions.

1. Name of grant:
2. Agency or institution providing the grant
3. Principal Investigator listed on the grant

# LOCATION OF RESEARCH

1. Where will the research physically be conducted?
2. Coordination for use of facilities or for medical supervision – Yes \_\_\_\_\_ NO \_\_\_\_\_\_

If coordination is required for a laboratory, clinical space, supervision, or medical assistance, a signed Letter of Agreement must accompany this application.

**COORDINATION** **WITH OTHER INSTITUTIONAL REVIEW BOARDS**

(Or other agencies involved with ethical review)

1. Subjects from other institutions:

Will subjects be from other institutions, such as other hospitals, high schools, or other universities?

Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_

Name of involved institution/school: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 2. Has this proposal been, or will it be submitted to other Human Subjects Review Boards (IRB Committees), departmental committees or community agencies for review and approval?

Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_

If yes, please list the agencies below and attach approval letters from these agencies.

**SUBJECTS**

 1. Number of Subjects and Controls:

1. Number of subjects you intend to solicit:
2. Approximate number of subjects you expect to participate:
3. Proposed number of controls (if appropriate; N/A if not relevant):
4. Types of Subjects and Controls:
5. Age range of subjects:
6. Population from which subjects were derived:
7. Inclusion criteria for subjects and controls:
8. Exclusion criteria for subjects and controls (include any age, sex, physical, mental and health restrictions):

1. Describe the specific steps to be used to identify and/or contact prospective participants. If applicable, describe how you have access to lists of potential participants. Recruitment telephone and/or e-mail scripts and advertisements should be submitted with this form as well.
2. Subject Screening Procedures: Describe the screening procedures you will use to determine if subjects are able to participate in your study. Specifically explain how the results of your screening procedures will be used to identify subjects who are eligible to participate in your study and identify persons who are ineligible to participate in your study. Attach any questionnaires or screening forms you will use with this application.
3. Will your subjects receive compensation in any form for participating in this study?

 Yes\_\_\_\_\_\_ No\_\_\_\_\_\_\_

 If yes, please explain how and when subjects will be compensated.

**STUDY DURATION**

Probable duration of the entire study (end date):

Total average time commitment of each subject involved with this project:

If this application is approved, the approval period will be noted in your approval letter. A report requesting an extension is required for all research that exceeds the length of approval provided (i.e., if approval period of one year is granted, a report requesting an extension is required prior to the one-year approval period date). Additionally, the Principal Investigator is responsible for providing the IRB with findings and/or notification of the status of the research at the completion of the project.

**DESCRIPTION OF THE RESEARCH PLAN**

 Please be sure to address all of the following questions using lay language. Please write in complete sentences.

1. Provide a brief (no more than one paragraph) review of the pertinent literature (with citations) and identify the need for the study.
2. Clearly state the purpose(s) of your project.
3. Describe your study design. If applicable also identify your variables and hypotheses.
4. Explain your instrumentation and methods. Please describe your proposed methodology step by step and attach a copy of surveys, educational tests, or interview scripts.
5. Describe your plan for data analysis and statistics (if applicable).

**ASSESSMENT OF RISKS AND BENEFITS:**

1. List and describe any possible risks: Be sure to include potential physical, psychological, and social risks. For each risk listed also describe risk frequency, severity, and reversibility.

1. Describe procedures and precautions to be taken to avoid or minimize each risk listed above to the extent possible.
2. List and describe any benefits to the subjects:
3. If appropriate, describe any withholding of normal treatment and alternative treatments.
4. Based on the information you provided above, identify the risk: benefit ratio for the subjects.
5. Explain the conditions under which an individual subject’s participation in the study would be discontinued.
6. Explain the conditions under which the entire study would be discontinued if hazards materialize.
7. Does this study involve deception?

 Yes\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_

If yes, how and when will you provide debriefing? Also please attach a copy of your debriefing script and note in the Informed Consent section that you are requesting a waiver of consent for the deception portion of this project.

# REPORTING OF SERIOUS AND UNEXPECTED ADVERSE EVENTS

# Explain the emergency procedures for your study and how you will handle adverse events.

1. In addition to the emergency procedures described above, in the case of an adverse event you must also do the following:
2. Immediately report the event by telephone to the Chair of the IRB or to University Counsel.
3. Submit a written report of the event to the chair of the IRB and University Counsel within three working days.
4. In some circumstances you may be required to report any adverse events to the sponsoring agency and the appropriate state and federal agencies.
5. The IRB requires that any research project must be terminated if there has been unexpected serious harm to subjects.

# PRIVACY, CONFIDENTIALITY AND DATA MANAGEMENT

1. Subject Privacy: When gathering data, what measures will you take to protect your subjects’ privacy? Examples include interviewing subjects one at a time in a closed room, interviewing subjects over the phone, or e-mailing a questionnaire in such a way that subjects cannot see identifying information of other subjects.
2. Subject Confidentiality: Will any identifying information (name, date of birth, company working for, etc.) or protected health information be collected from subjects or their records?

Identifying information collected: Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_

Protected health information collected: Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_

If you intend to protect the confidentiality (identity) of your subjects, describe your methods of doing so prior to, during, and after data collection. If applicable, describe your de-identification and coding system to ensure that your subjects’ identity and data remains confidential.

Remember: If you intend to keep a subject’s identity confidential, when the results of your study are presented in publications (including theses and dissertations) and presentations, no information may be provided that would reveal the identity of that subject.

1. Data Confidentiality and Management:
Will you be audio or video recording subjects? *If yes, include Recording Permission with protocol submission.*

 Yes\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_

1. If yes, please explain why this is necessary.
2. Please explain how you will protect the identities of subjects who have had audio or video recordings. The usual procedure is to transcribe recordings and then destroy the original audio or video recordings.

 Data Storage:

1. How long do you plan to store your data? (*Note you must store data a minimum of three years per federal regulations.)*
2. How will you dispose of your data at the end of your data storage time?
3. Where will you store your data (be specific)? If you are de-identifying your data, where will you store your identification key? *(The identification key must be stored separately from your data.)*
4. Please explain who will have access to the data and under what circumstances.
5. How will you protect the data from unauthorized access?

\*\*Compliance with HIPAA Privacy Regulations\*\*

It is expected that all studies approved by the Belmont University IRB comply with other federal regulations including HIPAA. In accordance with the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), investigators shall respect the confidential nature of all information that they may have access to, including but not limited to the subjects’ personal health information provided to them orally or contained in medical records in written or electronic form.

# INFORMED CONSENT

Please attach a copy of your Informed Consent form and/or Letter of Invitation

1. Who will obtain voluntary and informed consent from study participants?
2. How will consent be obtained?
3. When will consent be obtained?
4. How often will consent be obtained (applies to longitudinal studies)?
5. How will you verify that the subject fully understands the consent?
6. Will you be requesting a Waiver (or Alteration) of Informed Consent?

 No\_\_\_\_\_\_\_\_\_ Yes\_\_\_\_\_\_

 If yes, please confirm ALL the following criteria are true:

* The research involves minimal risk to subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practicably be carried out without the requested waiver or alteration;
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; AND
* Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study (i.e., in deception scenarios, a debrief is required).

All the above criteria are true regarding my waiver or alteration of informed consent for this project. No\_\_\_\_\_ Yes\_\_\_\_\_\_\_\_

1. Will you be requesting a Waiver of Documentation of Informed Consent (i.e., waiver of signatures only)?

 No\_\_\_\_\_\_\_\_\_ Yes\_\_\_\_\_\_\_\_

If yes, please select below which of the following regulatory options your research activities fall within.

Option 1: No\_\_\_\_\_ Yes\_\_\_\_\_\_\_

The only record linking the participant AND the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs). (Please note: FDA will not accept this option for waiving signature/documentation of consent.)

Option 2: No\_\_\_\_\_\_ Yes\_\_\_\_\_\_

The research presents no more than minimal risk to subjects AND involves no procedures for which written consent is normally required outside of the research context (i.e., a cover letter on a survey, or a phone script). (Please note: FDA will accept this option for waiving signature/documentation of consent.)

Option 3: No\_\_\_\_\_\_ Yes\_\_\_\_\_\_

The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, AND the research presents no more than minimal risk to the subject, AND there is an appropriate alternative mechanism for documenting that informed consent was obtained.

**If you answer YES to #6 or #7 above and plan to use PHI, also please address the following.**

If you plan to use or share protected health information (PHI) when conducting your research, you must conduct your study in accordance with the Privacy Rule of the [Health Insurance Portability and Accountability Act](https://irb.northwestern.edu/node/120) (HIPAA). This means that when applying for a waiver of documentation of informed consent or a waiver/alteration of informed consent, you will also have to request a waiver or alteration of HIPAA Authorization. The IRB, in collaboration with the HIPAA Covered Entity’s Privacy Office/Board, can grant the waiver of alteration if it deems the following criteria are met. A letter of permission is also required from the Covered Entity unless owned by Belmont University. Please address each part of the criteria below:

1) You need an adequate plan to destroy identifiers at the earliest opportunity unless there is a health or research justification or legal requirement to retain them, and

1. An adequate plan to protect health information identifiers from improper use or disclosure
2. An adequate plan to destroy identifiers at the earliest opportunity unless there is a health or research justification or legal requirement to retain them, and
3. Adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule;

2) Research could not practicably be conducted without the waiver or alteration; and

3) Research could not practicably be conducted without access to and use of PHI.

**CERTIFICATION**:

My signature below indicates that I will operate in accordance with all federal and Belmont University regulations governing research involving human subjects as stated in the IRB guidelines for the protection of human subjects.

I certify I will follow the study protocol and the method of obtaining informed consent as approved by the IRB during the period of the research project. I will submit any changes of protocol, investigator, consent or recruiting of participants to the IRB and receive IRB approval before implementing any changes. I will prepare an Annual Progress Report if my study was approved under Full Board and as needed for Expedited and a Final Report at the conclusion of this study. I will report any adverse reactions or subject complaints will be reported within 48 hours to the Office of University Counsel and to the Chair of the IRB. I will maintain all records of this research as required by the Belmont University IRB.

The Principal Investigator, Principal Faculty Advisor (for student projects), and their immediate supervisor (Department Chair, Associate Dean, or Dean) must sign below:

Principal Investigator Date

Department Chair / Dean Date

Principal Faculty Advisor’s Statement (for student projects only)

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, am the faculty advisor for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My signature below indicates that I have read the attached protocol and have checked the contents with IRB guidelines.

Faculty Advisor Date

Additional signatures may be required by your department. Add lines below as needed:

Faculty Advisor Date

Associate Investigator Date