**Instructions for Application for Initial Protocol Approval**

**Benedictine College Institutional Review Board**

 Details concerning the purpose of the Institutional Review Board (IRB), basic ethical principles for conducting research with human participants, and review process are available on the [Benedictine College IRB website](https://www.benedictine.edu/academics/research/irb/index). All researchers are expected to familiarize themselves with that information before applying for IRB approval. Applicants are reminded of these critical points:

* No data collection, including pilot testing, may begin until final approval has been granted by the IRB and a project number has been assigned.
* The Principal Investigator (PI) on all projects must be a faculty or staff member at Benedictine College. The PI is expected to give a thorough review of the application before signing and submitting.
* Once approval has been granted, any changes to the research protocol or research team must be submitted for approval before data collection can begin/resume.
* Any adverse events concerning the research must be reported immediately to the Chair of the IRB.
* IRB approval expires after one year, and all researchers are required to provide a progress report and request for renewal (if applicable) at that time.

**What and Where to Submit**

Applicants must complete the IRB application form provided below. **In addition to the application, researchers must append all research materials in their finalized form.** Appendices typically include a copy of the Informed Consent form and any additional materials (surveys, questionnaires, assessment materials, etc.) that will be used in the conduct of the research. Once approval has been granted, no edits to research materials may be made without approval from the IRB.

Completed applications, signed by the principal investigator, should be submitted via email attachment to the Chair of the IRB:

Dr. Amy Posey: aposey@benedictine.edu

**Benedictine College Institutional Review Board**

**Application for Initial Protocol Approval**

 **Principal Investigator (may not be a student)**

Name:

 Position and Department at Benedictine College:

Benedictine College email address:

**Provide names, email addresses, and status of all others affiliated with Benedictine College who are involved in the conduct of the research (add additional entries as needed)**

Name

Email

Status (check one): \_\_\_\_\_ Student \_\_\_\_\_ Faculty \_\_\_\_\_ Staff

Name

Email

Status (check one): \_\_\_\_\_ Student \_\_\_\_\_ Faculty \_\_\_\_\_ Staff

Name

Email

Status (check one): \_\_\_\_\_ Student \_\_\_\_\_ Faculty \_\_\_\_\_ Staff

**Provide names, email addresses, and status of any researchers not affiliated with Benedictine College who are involved in the conduct of the research (add additional entries as needed)**

Name

Email

Institution/organization

Status (check one): \_\_\_\_\_ Student \_\_\_\_\_ Faculty \_\_\_\_\_ Staff \_\_\_\_\_ Other

**Title of Research:**

Is this research a Discovery project? \_\_\_\_ Yes \_\_\_\_ No

**Check all that apply to the proposed research activity:**

 \_\_\_\_\_ a. drugs or other controlled substances

 \_\_\_\_\_ b. payment of participants for participation

 \_\_\_\_\_ c. access to participants through a cooperating institution

 \_\_\_\_\_ d. substances taken internally by or applied externally to the participants

 \_\_\_\_\_ e. mechanical or electrical devices (e.g., electrodes) applied to the participants

\_\_\_\_\_ f. fluids (e.g., blood, saliva) or tissues removed from the participants

 \_\_\_\_\_ g. participants experiencing stress (physiological or psychological)

 \_\_\_\_\_ h. deception of participants concerning any aspect of purposes or procedures (misleading

or withheld information)

 \_\_\_\_\_ i. participants 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 participants at risk (psychological,

 physical, legal, or social)

 \_\_\_\_\_ k. use of interviews, surveys, questionnaires, audio or video recordings

 \_\_\_\_\_ l. data collection over a period greater than one year (note that application for renewal

must be submitted prior to expiration of initial IRB approval)

\_\_\_\_\_ m. waiver of inclusion of Informed Consent form (note that the IRB makes the final

decision as to consent waivers)

 \_\_\_\_\_ 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

\_\_\_\_\_ o. research methods in which participant identity could be connected to participants’

responses (i.e. anonymity cannot be ensured)

**Approximate number of participants to be involved in the research:**

 **Purpose of the research:**

 **Describe the proposed research participants (age, sex, race, or other special characteristics).** If there is a physical or mental health condition that characterizes the participants to be included in the study, please indicate this here as well.

 **Describe how the participants are to be selected.** Please indicate how you will gain access to and recruit your research participants. That is, will you recruit participants through word-of-mouth, professor invitations, fliers or posters, social media, public or private membership or employee lists, etc.

**Note:** Reasonable levels of extra credit may be offered for participating in research. If extra credit is offered for participation, students must be provided with and informed of non-research alternatives involving comparable time and effort to obtain the extra credit in order for the possibility of undue influence to be minimized. Moreover, students must not be penalized for refusing to participate in research ([45 CFR 46.116(a)(8)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)). **If researchers are requesting that professors share information about the research with their students, the researchers must also communicate these extra-credit-alternative requirements to those professors, and a description of that communication must be included in the recruitment protocol described below.**

 **Description of the proposed procedures in the research.** The description should be a succinct overview of the research without jargon, unexplained abbreviations, or technical terminology. The research description must include details about checked items a. through o. from the checklist above (drugs, payment of participants, etc.) and should make reference to numbered appendices, including the consent form and all research materials, that will be included with the application. Researchers should use the appropriate consent form template provided on the IRB website [here](https://www.benedictine.edu/academics/research/irb/irb-forms). The description should also include details about how participant data will be protected, anonymity will be achieved, and confidentiality will be maintained.

**Certifications from the Principal Investigator:**

By submitting this application, I am certifying that this application has been completed in a way that is consistent with the application instructions. I further certify that I understand and will comply with the policies and procedures of Benedictine College regarding human participants 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 human research participants.

 Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Principal Investigator

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_