Westminster College IRB requires that each human research proposal for expedited or full board review be submitted for review in a specific form. The proposal will not be accepted for review if it exceeds the required page limitations. Please submit one copy of your research proposal in the IRB format below. The review process (see section D, pp. 2-3) usually requires five working days for expedited review and ten working days for full review. The research activity may be initiated only after final approval by the IRB in writing (see Form F).

I. Cover page

Date:

To: The Westminster College Institutional Review Board

From: Principal Investigator
Co-Investigators

Title of research activities

Academic program/dean approval
(Proposals are required to be reviewed, approved and signed by the academic program chair (if applicable) and the dean of the respective school prior to submission to the IRB)

Links to DocuSign form…

Honors
Education
Arts & Sciences
Gore School of Business
Nursing/Public Health

II. Research protocol

A. Specific aims (not to exceed one page)

Briefly state the purpose and measurable research objectives.

B. Significance (not to exceed two pages)

Describe the contributions that the study will make to the health of human beings and/or to a scientific data base, using documentation from the literature where appropriate.

C. Progress report/preliminary studies (not to exceed one page)

Summarize preliminary studies by the investigator, if any have been performed. State “none” if applicable.
D. Research Methodology (not to exceed two pages)

1. Subjects

Describe the subjects, including the projected sample size, plans for selection and source of subjects, and inclusion and exclusion criteria. Please identify source from which you will obtain your study population (e.g. specific school community, aging institution). Submit promotional advertisements (including posted notices) to be used for recruiting subjects.

2. Consent Form: The Consent Form is to be a separate document. Use form B or C for all adult studies and forms D & E (if possible) for all studies involving children. It is imperative that these forms follow the IRB format.

Describe at what point in the process the consent form will be obtained. The consent statement should be signed by (1) the adult subject and the Investigator, or by (2) his/her legal representative (if the subject is blind, illiterate, certified incompetent, or a minor), the Investigator, and one witness.

The subject or the person signing for the subject must be given a copy of the Informed Consent Form, and the Investigator is required to retain a copy for his/her files.

A copy of the summary given orally must be submitted as part of the research proposal, if appropriate.

3. Research protocol for data collection and analysis

a. Detailed data collection protocol:

Describe the procedures in detail. Clearly identify any experimental element of the study. Include a thorough description of any procedures, monitoring techniques, or measuring instruments. Describe briefly where the study will be conducted (e.g. a specific school).

b. Data analysis:

Describe plans for analysis of data when appropriate.

c. Data Storage:

Describe the process used to maintain confidentiality.

E. Human subjects (not to exceed one page)

1. Discuss the physical and psychological risks and benefits. Include both immediate and long term considerations. Describe any potential risks or discomforts in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g. confidentiality, etc.), and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to mankind. Describe how, when and to whom the results will be disseminated.

2. Payment

Describe any financial remuneration for subject participation.
F. Estimated period of time to complete the study

G. Funding

Please describe in full the sources of funds that will support the proposal, if any.

H. Physician notification statement if applicable (verbatim)

“In the event a hospitalized patient is to be asked to participate as a subject of my study, I will inform the patient’s attending physician. Prior to approaching the patient, I will obtain the attending physician’s approval to request the patient’s participation.”

I. Vita of all investigators

J. Literature cited (not included in page limitation)