Westminster College
Institutional Review Board (IRB) for the Protection of Human Subjects

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Form A
Research Proposal Format
Instructions for Investigator

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)

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)
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Form B
Consent Form for Adults

Before agreeing to participate in this study, it is important that the following explanation of the proposed procedures be read and understood. It describes the purpose, procedures, benefits and risks of the study. It also describes alternative procedures available and the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results. See below.

You have been invited to participate in a research study, the purpose of which is ______.

The study procedure(s) have been identified as ______.

The duration of the study is expected to be ______. You will be notified of any significant variance from the stated duration of the study.

Benefits that may occur from participation in this study have been identified as ______.

INVESTIGATORS: Include one of the following two statements as applicable:

Projects for which there are no or minimal foreseeable risks:
There are no foreseeable side effects/risks associated with this project, other than the possibility of ________________. However, some side effects/risks may be unforeseeable.

Projects for which possible side effects/risks have been identified, including psychological side effects:
The potential side effects/risks associated with the study have been identified as ______. In the event that you are affected by these side effects/risks, the following remedies are available to you: _____. Some side effects/risks may be unforeseeable.

Your participation in this study is entirely voluntary, and you may withdraw from the study any time you wish without any penalty to you.

If you have any questions about this study or wish to withdraw, please contact:

__________________________
Principal Investigator
Phone:

If you have any questions regarding your rights as a research participant, please contact:

__________________________
Chair of IRB
Phone:

All personally identifiable study data will be kept confidential. However, the results of this study may be made available to you upon request or used in form publications or presentations.

If you feel that you have received a satisfactory explanation as to the risks and benefits of this study as well as your rights as a research participant and you would like to participate, please sign and date below. You will be given a copy of this form for your records.

__________________________
Signature of Subject
Date

__________________________
Signature of Investigator
Date
You have been invited to participate in the research investigation entitled: ______, conducted by or under the supervision of ______.

The nature and general purpose of the research procedure, as well as known risks and benefits, have been explained to you by: ______.

You do not have to participate if you don’t want to, and you can stop participating at any time. Your identity will be kept confidential. If you feel that you understand the risks and benefits of this study, as well as your rights as a participant, and you would like to participate, please sign and date below.

________________________________________   _______________________
Signature of Participant                      Date

________________________________________   _______________________
Signature of Witness                          Date

________________________________________   _______________________
Signature of Investigator                     Date
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Form D  
Parent/Guardian Permission Form  
Research Involving Minors (under age 18)

Before agreeing to participate in this study, it is important that the following explanation of the proposed procedures be read and understood. It describes the purpose, procedures, benefits and risks of the study. It also describes alternative procedures available and the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results. It is also understood that refusal to participate in this study will not result in negative consequences for you or your child.

Your child is being asked to participate in a research study, the purpose of which is _____.

The study procedure(s) have been identified as _____.

The duration of the study is expected to be _____. You will be notified of any significant variance from the stated duration of the study.

Possible benefits that your child might realize from participation in this study have been identified as _____.

INVESTIGATOR: Include one of the following two statements as applicable:

Projects for which there are no or minimal foreseeable risks:  
There are no foreseeable side effects/risks associated with this project, other than the possibility of _____. However, some side effects/risks may be unforeseeable.

Projects for which possible side effects/risks have been identified, including psychological side effects: The potential side effects/risks associated with the study have been identified as _____. In the event that your child is affected by these side effects/risks, the following remedies are available: _____. Some side effects/risks may be unforeseeable.

Your child's participation in this study is entirely voluntary, and he/she may withdraw from the study any time he/she wishes.

The contact person, should your child wish to withdraw from the study or should you or your child have questions about the study, is:

Principal Investigator’s name: __________________________ Phone: __________________________

If you have any questions regarding your child’s rights as a research participant, please contact:

Chair of IRB: __________________________ Phone: __________________________

All personally identifiable study data will be kept confidential. However, the results of this study may be made available to you upon request or used in formal publications or presentations.
If the risks and benefits associated with this study have been explained to your satisfaction, as well as your child’s rights as a research participant, and you wish to allow your child to participate, please sign and date this form where indicated. You will be provided a copy of this form for your records.

__________________________________________  
Signature of Parent/Guardian  
__________________________________________  
Date

__________________________________________  
Signature of Witness  
__________________________________________  
Date

__________________________________________  
Signature of Primary Investigator  
__________________________________________  
Date
You have been asked to participate in a research study called: 
___________________________________________________________________.

The study has been explained to you by:
___________________________________.

You don’t have to participate if you don’t want to, and you can quit at any time. All of your information will be kept private.

If you want to participate, please sign your name below and write the date next to your name.

Signature of Participant                      Date

Signature of Witness                        Date

Signature of Investigator                  Date
Form F
IRB Approval Notification Form

(applicant fills out the top portion)

Principal Investigator: _____________________________________________

Co-Investigators: ________________________________________________

Title: __________________________________________________________

________________________________________________________________

□ Approved

□ Approved with conditions

________________________________________________________________

□ Disapproved

Comments:

1. You are required to immediately report any adverse reactions or complications of the project to the Institutional Review Board.

2. There may be no change or addition to the project, or changes of the investigators involved, without prior approval of the Institutional Review Board.

3. If applicable, the attached consent statement has been approved by the IRB. Please copy this document and use for all subjects entered into this study.

Chairperson, Institutional Review Board             Date
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**Form G**  
**Notification to IRB of Exempt Research Activities**  
**Please answer each question below, sign, and submit to the IRB prior to instigating research activities**

1. I am the faculty member serving as the principal investigator on a project entitled:

   ____________________________________________

2. Said project involves ONLY the following activity as defined in section C1 (check one):

   _____ Research conducted in an established educational setting involving standard educational practices.

   _____ Research involving the use of educational tests, surveys, interviews, or observations of public behavior in which the researcher does not interact with the participants and information is recorded in such a way that participants cannot be identified.

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

   _____ Research involving study, evaluation, or examination of public service or benefit program; and such research has been approved by the agency or program head.

   _____ Research involving only a taste and food quality evaluation.

   **If none of the above are applicable, this project is not exempt.**

3. Does the project involve the use of vulnerable populations as defined in section D1a.

   If “yes”, this project is not exempt.

   ____________________________________________

I certify that the above information is true and accurate. I also agree to suspend research activities and notify the IRB immediately should said project change in such a way that it no longer qualifies as exempt.

_____________________________________
Name of principal investigator

_____________________________________
Date

_____________________________________
Signature
EXAMPLES OF RISK

Physical Risk
Physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.

Psychological Risk
May be experienced during the research situation and/or later, as a result of participating. Includes anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, altered behavior.

Social/Economic Risk
Alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject's opportunities and status in relation to others. Economic risks include payment by subjects for procedures, loss of wages or income, and damage to employability.

Legal Risk
Risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally or civilly liable.

Loss of Confidentiality
Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks include invasion of privacy, as well as the social, economic and legal risks outlined above.

MINIMAL RISK

Federal regulations define "minimal risk" as follows: "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." In broad terms, a project involves minimal risk if:

1. The participant experiences no pain or physical danger;
2. The participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life;
3. The project neither induces nor attempts to induce long-term significant change in the participant's behaviors (including attitudes toward self and others);
4. The data would not embarrass or socially disadvantage the participant, were confidentiality to be violated; and
5. If the investigator conceals information about the specific purpose of the project, there is no reason to believe the subject would choose not to participate if s/he had known that information initially.
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge? [45 CFR 46.102(d)]

- **NO**
  - Activity is not research, so 45 CFR part 46 does not apply.

- **YES**
  - Activity is research. Does the research involve **obtaining information about living individuals**? [45 CFR 46.102(f)]
    
    - **NO**
      - The research is not research involving human subjects, and 45 CFR part 46 does not apply.
    
    - **YES**
      - Does the research involve **intervention or interaction** with the individuals? [45 CFR 46.102(f)(1), (2)]
        
        - **NO**
          - **BUT**
            - Is the information **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]
              
              - **NO**
                - **BUT**
                  - Is the information **private**? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)(2)]
                      
                      - **NO**
                        - Go to Chart 2
                      
                      - **YES**
                        - Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.

        - **YES**
          - Activity is research involving human subjects. Is it **conducted or supported by HHS**? [45 CFR 46.101(a)(1)]
            
            - **NO**
              - **BUT**
                - Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?
                  
                  - **NO**
                    - Go to Chart 2
                  
                  - **YES**
                    - Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS **prohibited** exemption of the human subjects research? (All research involving prisoners, some research involving children.)

[Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

NO

Will the **only** involvement of human subjects be in one or more of the following categories?

Research conducted in **established or commonly accepted** educational settings, involving **normal education practices**?

YES -> Exemption 45 CFR 46.101(b)(1) may apply. Go to Chart 3

AND/ OR

Research involving the use of **educational tests, survey procedures, interview procedures, or observation of public behavior**?

YES -> Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply. Go to Chart 4

YES

Research involving collection or study of **existing** data, documents, records, or pathological or diagnostic specimens?

AND/ OR

Research studying, evaluating, or examining **public benefit or service programs**?

YES -> Exemption 45 CFR 46.101(b)(5) may apply. Go to Chart 6

AND/ OR

Research involving **taste and food quality evaluation or consumer acceptance studies**?

YES -> Exemption 45 CFR 46.101(b)(6) may apply. Go to Chart 7

NO

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations. Go to Chart 8

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.