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

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

Westminster College has established an Institutional Review Board (IRB) to review research projects that involve human subjects. The IRB for the protection of human subjects applies to all human subject research conducted by anyone on the premises of Westminster College and to research conducted elsewhere by faculty, students, staff or other representatives of the College. The IRB is not responsible for animal research. For access to the guidelines for animal research, please go to the following link: Animal Welfare Information Center.

IRB approval is required by the College for any independent research involving human subjects but is mandated by federal regulations for research done under a federal grant. The purpose of this document is to assist college investigators in the preparation and submission of research proposals for review by the IRB and provide guidance during the conduct of human subject research.

The US Department of Health and Human Services defines research as “any systematic investigation involving human subjects including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (Title 45, Section 46.102)”. Student classroom, clinical, or lab assignments are not considered research if conducted solely for the purpose of teaching research skills, provided such research involves activities listed below under “Exempt” or “Expedited” categories and involves only students, faculty, and staff of Westminster College as subjects. However, classroom projects involving subjects not meeting the above requirements, as well as senior theses, summer research projects, etc. are defined as research and are subject to the regulations contained herein. See Chart 1 for help in determining whether your project is defined as “human subjects research”. The US Department of Health and Human Services provides guidelines for human subjects research. These complete guidelines can be accessed on the following web site: Office for Human Research Protections.

Membership

IRB members will represent a cross-section of the faculty, will serve for two-year terms, will include at least four faculty elected by the faculty with at least one representative from Nursing, Education, Arts and Sciences, Business, and a person to be appointed from outside the college community. The IRB will be chaired by one of the deans. If a member of the IRB is involved as an investigator in a research proposal, she or he will be excused from the deliberations and decisions of the IRB. If the chair is involved as an investigator in a research proposal, she or he will be excused and appoint another member of the IRB to serve as chair for that review.

Purpose and Function of IRB

The basic function of the IRB is to protect the rights of research subjects. This is accomplished by reviewing proposed research to ascertain that the subjects are not exposed to undue risks by the research, that the subjects understand the experimental nature of the study, and that the subjects’ participation is voluntary as evidenced by the subjects’ consent.

A. Activities and Research Requiring IRB Review and Approval

Any systematic investigation involving human subjects which is designed to develop or contribute to generalizable knowledge must receive IRB approval prior to initiation. This includes investigations conducted by faculty, students, staff or others on the premises of Westminster College as well as investigations conducted elsewhere by any representative of the college. While certain categories of research are considered exempt from review, investigators are still required to report such activities to the IRB. Exemptions are detailed in section C1, below.
B. Submission of Research Proposals Requiring Expedited or Full Review

Five typed originals of the proposal must be submitted to the chair of the IRB in the required format (see Form A) by the principal investigator. It will be the investigator’s responsibility to insure that the program chair’s (if applicable) and the school dean’s approval signatures are present and that the protocol is in the proper format with all required elements included. Upon receiving the proposal, the chair of the IRB will decide if the research should receive expedited review or full-board review (see C 2, 3). The IRB has established deadline dates of September 5, November 15, January 15, March 15, and May 15. Full board review will occur within ten working days of the deadline dates. Please submit your applications as Word or PDF files in an email to the IRB chair. Emergency reviews which must occur outside the deadline dates and require full review, may be conducted by the Council of Deans with the Chair of the IRB presiding.

C. IRB Review Categories

1) Exempt Review

The following categories of research exempted from review and approval by the IRB as specified in OHRP regulation 45CFR 46.101(b)(1)-(6). NOTE: To determine whether a project is exempt under federal regulations, refer to Decision Charts 1 & 2. Investigators conducting exempt research MUST complete Form G and submit it to the head of the IRB prior to initiation of the project.

a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

2. Expedited Review
Research activities meeting federal guidelines for expedited review as outlined below will be reviewed by the Chair who may elect to send it for further review to one or more of the IRB representatives. The investigator will be notified within ten working days of receipt of the proposal (see Form F). See Decision Charts 1 & 2 to determine whether a project may be eligible for expedited review. However, the Chair of the IRB may, at his or her discretion, elect to require full review of a project even though it may fit the federal guidelines for expedited review. The following regulations and guidelines apply:

a. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories may be eligible for expedited review. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

b. The categories in this list apply regardless of the age of subjects, except as noted.

c. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

d. The following categories, one (1) through seven (7), pertain to both initial and continuing IRB review.

e. The following categories may be eligible for expedited review. More information about the following categories can be accessed at the following link: Categories Eligible for Expedited Review

   (1) Category 1 applies to clinical studies of drugs and medical devices. If you are involved in such research, please access the above link for further details.

   (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. If you are involved in such research, please access the above link for further details.

   (3) Prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings, or the collection of saliva or skin cells. If you are involved in such research, please access the above link for further details.

   (4) Collection of data through noninvasive procedures such as EKG, EEG, or MRI; or involving moderate exercise by participants. If you are involved in such research, please access the above link for further details.

   (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects as detailed in section C1. This listing refers only to research that is not exempt.)

   (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects as detailed in Section C!). This listing refers only to research that is not exempt.) Such research does not involve manipulation of subjects’ behavior or environment for experimental purposes and does not involve more than minimal risk to subjects.

(8) Continuing review of research previously approved by the convened IRB as follows:
   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Full Board Review

   All other research not eligible for exempt status or expedited review needs to be submitted to the IRB for full review. Full board review research activities involve greater than minimal risk and/or involve manipulation of subjects’ behavior or environment for experimental purposes.

D. The IRB Review Process and Criteria

   In order to approve a research project involving human subjects, the IRB must be assured that:

   1. The prospective subject population is appropriate and the number of subjects is no larger than necessary with respect to the nature and goals of the research
      a. The utilization of any vulnerable class of subjects must be clearly justified. Vulnerable subjects are defined as: children, mentally or emotionally disabled, physically disabled, terminally ill, institutionalized people, and pregnant women.
      b. IRB review of the prospective subject population also includes methods of subject recruitment. Any form of advertisements used to recruit subjects is considered an extension of the research protocol process and, therefore, must be reviewed by the IRB.
      c. Study of subjects in a secondary organization, such as an educational or health care setting, must follow the human subject guidelines of that agency. It is the responsibility of the investigator to determine those guidelines, to obtain institutional IRB approval prior to submission to Westminster College IRB, and to provide evidence to the Westminster IRB that they have been met.
2. The research design of the study is sound with respect to risk to subjects, and any risks associated with the research project are minimized to the greatest extent possible.
   
a. A risk is a potential harm or injury associated with the research (physical, psychological, social, financial, or otherwise). Minimal risk is defined in the federal regulations as when “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. See “Examples of Risk” for additional clarification.

3. The potential benefits are maximized to the greatest extent possible.
   
a. A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified generally as those that accrue to subjects directly (e.g., improvement of subjects’ health status, acquisition by subjects of knowledge about themselves, such as results of a fitness test or cholesterol screening, and education) and those that accrue to society (e.g., additions to the knowledge base). The investigator should identify anticipated/expected benefits to the subject or to others.

4. The risks to the subject are outweighed or balanced by the potential benefits and by using procedures consistent with sound research.

5. The methods used to obtain informed consent are ethically and legally acceptable.
   
a. In order for consent to be ethically and legally valid it must meet the requirements stated in Principle I of the Nuremberg Code and the Informed Consent Section of the Federal Regulation which is based, in part, upon the Nuremberg Code. Principle I of Nuremberg Code states, “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an enlightened decision.” The IRB will review the proposed procedure for obtaining informed consent to ensure compliance with the aforementioned Principle I. Attached are approved consent forms.

   Federal guidelines stipulate that specific elements be included in consent forms. Westminster’s consent forms have been formatted to include all required elements. Therefore, deletion of any element of a consent form may violate federal regulations. In addition, the IRB may require additional information to be included in the consent form on a case by case basis.

b. Under certain circumstances, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

   (1) The research involves no more than minimal risk to the subjects;
   (2) The waiver or alteration 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; and
   (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
These circumstances often apply to social science research in which full disclosure of the purpose of the study to participants could possibly change the behavior of the subject in such a way as to render the data meaningless. For guidelines regarding the use of deception in research, see APA Ethics - Guidelines for Use of Deception.

c. Federal guidelines require that informed consent be documented in one of the following ways:

(1) A written consent document (Form B) that embodies the elements of informed consent required by OHRP. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document (Form C) stating that the elements of informed consent required by OHRP have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

d. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

6. The principal investigator and any collaborative researchers have the appropriate qualifications to conduct the research. For undergraduate research, the faculty advisor serves as primary investigator.

E. The Use of Children in Research

1) The federal government has established additional guidelines governing the use of children as research subjects. With regard to these guidelines, the following definitions apply:

(a) Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.
(d) *Parent* means a child's biological or adoptive parent.
(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

2) The IRB may approve research involving children provided that the following conditions are met:
   
a. Research not involving more than minimal risk:
      
      Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, and such assent and permission is documented accordingly.
   
b. Research involving more than minimal risk:
      
      Refer to the provisions listed at [OHRP Guidelines for Research Involving Children](#) for further details.

3) Provision 46.408 requires investigators to solicit the assent of minor participants as well as permission of participants’ parent or guardian.
   
a) Whenever possible, assent should be obtained in written form (see Form E). However, assent may be obtained verbally if the IRB determines that the age and/or mental capacity of the participant would prevent understanding of the written document. See [Assent for Children](#) for further clarification.
   
b) Investigators are also required to obtain permission from participants’ parent/s or guardian. For research involving no more than minimal risk, the permission of one parent is adequate. In all other circumstances, both parents must provide permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. See Form D.
   
c) For regulations regarding children who are wards of the state or any other institution, see [Wards](#).

F. Additional regulations apply when using prisoners or pregnant women and/or fetuses.
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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 formal 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
Westminster College  
Institutional Review Board (IRB)  
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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 _______. I will be notified of any significant variance from the stated duration of the study.

Possible benefits that my 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:

I understand that 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

Signature of Witness

Signature of Primary Investigator

Date

Date

Date
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Form E
Assent Form for Minors
(Attach statement of what is said to subjects about the research, including signature lines for the witness and investigator)

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
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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

IRB Policies and Procedures (5-24-06)
Westminster College
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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?

September 24, 2004

Start here.

Is the activity a _systematic_ investigation _designed_ to develop or contribute to _generalizable_ knowledge? [45 CFR 46.102(a)]

**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**

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**

**NO**

**BUT**

**YES**

Activity is research involving human subjects. Is it _conducted or supported by HHS_? [45 CFR 46.101(a)(1)]

**YES**

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)]

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.

Go to Chart 2

**AND**

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)?

From Chart 1

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)]

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

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?

AND/OR

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

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?

AND/OR

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

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.

YES

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

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

Exemption 45 CFR 46.101(b)(4) may apply. Go to Chart 5

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

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

Go to Chart 8