CUA

THE CATHOLIC UNIVERSITY OF AMERICA
Committee for the Protection of Human Subjects (CPHS)

GUIDELINES
FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

Subject Name: _____ **Date:** _____

Title of Study: _____

Principal Investigator: _____ **FWA00004459**_____

1.0 Introduction

Federal regulations and CUA policy require the research projects involving human subjects be reviewed and approved in advance by the CUA Committee for the Protection of Human Subjects (CPHS) for research with human subjects. According to the Office of Human Research Protection (OHRP) "awardees and their collaborating institutions are 'engaged' in human subject research whenever their employees or agents intervene or interact with living individuals for research purposes; or obtain, release, or access individually identifiable private information for research purposes." This stipulation applies to all research projects regardless of which Agency is providing the funds or to which Agency the report is to be submitted for financing to be provided. This includes research projects that are supported by CUA funds and also those not supported by CUA funds. Researchers and investigators are responsible for compliance with relevant federal and state laws and institutional policies.

All CUA researchers and administrators are required to complete training in the protection of human subjects. A way to do this is to visit the NIH Training Link at: http://phrp.nihtraining.com/users/login.php. A certificate will be issued upon completion of the computer-based training.

The CPHS has the authority to approve, require modifications in or not to approve research involving human subjects if the researcher is deemed not to conform to federal regulations or institutional policy.

These guidelines are intended to provide guidance to researchers and investigators in compliance with regulations involving human subjects.

1.1 Student research and faculty responsibilities

Students conducting research investigations such as for a thesis and for class projects also need to seek approval from CPHS prior to conducting investigations. The faculty supervising such research or investigation is required to insure that approval has been sought from CPHS.

Research that may not require CPHS review includes that which is conducted primarily for instructional purposes in a formal classroom context and not designed to contribute to generalizable knowledge as long as the instructor is prepared to accept professional and ethical responsibility for all such research. In such circumstances, it is the responsibility of the instructor to ensure that professional and ethical priority are adhered to and maintained by applying criteria stipulated in this document. The instructor is advised to seek CPHS review when doubt about the ethical propriety as it affects their research proposal.

2.0 The review process

In keeping with federal regulations and guidelines, the CPHS may process protocol in 3 ways:

- by full review
- by expedited review
- by exemption certification

2.1 Procedures for Expedited (or Full) Review

Investigation must complete and submit to the Office of Sponsored Programs copies of the CPHS Human Subjects Protocol Application form along with copies of the statement before they start investigations or research involving human subjects. The forms may be obtained from the Office of Sponsored Programs or at their web site (sponsoredprograms.cua.edu) or from Room 213, McMahon Hall in the Office of Sponsored Programs.

The protocol form must have information spelling out the following:

a) Name and department(s) of the investigator(s)
b) Title
c) Signature of responsible faculty members
d) Whether or not external funding is proposed
e) Purpose of the study
f) Description of the subjects
g) Description of the methodology
h) Potential scientific benefits of the research
i) Qualifications of the investigator(s)
j) Description of any deception
k) Procedures for protecting the anonymity of the subjects
l) Methods for ensuring informed consent, including a copy of the proposed informed consent statement.

2.2 Protocols Eligible for Expedite Review:

An expedited review is permitted under Federal regulation (45 CFR 46.11D and 21 CFR 56.110). Under and expedited review procedure for protocols that meet certain eligibility requirements, the review may be carried out by the chair of the CPHS of by one or more experienced reviewers from among the members of the committee. The reviewers may exercise all the authority vested in the committee in the reviewing the research, but may not disapprove the research. However, the research may be disapproved in accordance with the non-expedited procedures. Upon submission of the Human Subjects Protocol Form to the committee, a researcher may request an expedited review if the following criteria are met:

2.2.1 Applicability

Where there is no minimal risk to human subjects and where certain procedures are involved, the CPHS may conduct a review through the expedited review procedures as stipulated in 45 CFR 46.11D and 21 CFR 56.110. The activities listed should not be considered to be of minimal risk by virtue of their being included on this list. Inclusion on the list may simply signify that the research activities proposed may be eligible in accordance with expedited review procedures when specific circumstances of the research involve no more than minimal risk to human subjects. The categories in this list shall apply regardless of age of subjects except as noted.

The expedited review procedure **may not** be applied in the following cases:

a) where the subjects are identifiable

b) where the subjects responses would reasonably place then at criminal, civil or other liability or risk financial standing, employment, insurability, reputation or cause them to be stigmatized unless reasonable and appropriate protection is undertaken or implemented so that the risks are removed or minimized. The human subject's right to confidentiality and privacy must be upheld,
c) Where classified research involving human subjects is undertaken.
d) The standard requirements for informed consent (or it's waiver, alteration, or exception) apply regardless of the type of review.

Categories 1-7 below pertain to both initial and periodic review by the CPHS.

2.2.2 Research categories

a) Clinical studies of drugs and medical devices only when (i) or (ii) is met.
   i) Research on drugs for which an investigational new drug application (21 CFR part 312) is not required. NOTE: Research on marked drugs that significantly increase the risk or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
   ii) Research on medical devices for which
      a. An investigational device exemption application (21 CFR part 812) is not required; or
      b. The medical device is clearly/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b) Collection of blood samples by finger stick, ear sick, or venipuncture as follows:
   i) From healthy non-pregnant adults who weight at least 110 lb. For these subjects amount drawn may not exceed 550 mL during a period of 8 weeks and the collection may not occur more than twice weekly; or
   ii) From other adults and children, considering the age, weight and health of subjects, the collection procedure, the amount of blood to be collected, and frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 mL or 3 mL per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

c) Prospective collection of biological specimens for research purposes by noninvasive means.[1]

d) Collection of data through non-invasive procedures (not having general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. If medical devices are employed in the investigations/research, approval or clearance to market them should be sought. (Studies aimed at assessing the effectiveness of medical devices are not normally eligible for expedited review, including those that have already been cleared for new indications.)[2]

e) Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects. 45 CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)

f) Collection of data from voice, video, digital, or image recordings made for research purposes.

g) 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 HHS regulations for the protection of human subjects. 45 CFR 46. 101 (b)(2) and (b)(3). (This listing refers only to research that is not exempt.)

h) Continuing review of research previously approved by the convened CPHS as follows:
   i) Where:
      a. The research is permanently closed to the enrollment of new subjects.

b. All subjects have completed all research-related interventions and;
c. The research remains active only for long-term follow up of subjects or;

ii) Where no subjects have been enrolled and no additional risks have been identified; or
iii) Where the remaining research activates are limited to data analysis.

i) Continuing review of research, not conducted under an investigational new drug application or investigational exemption where categories two (2) through eight (8) do not apply but the CPHS has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Investigators who believe that their research meets the above criteria may request expedited review when they submit to the Human Subjects Research Protocol Form to the committee. Protocols should be submitted to the Office of Sponsored Programs.

2.3 Research categories exempt from review:

In cases where an investigator believes that the proposed research projects are exempt from review, it is required that she or he submit an exemption certification form to the CPHS through the CUA Office of Sponsored Programs. It is the responsibility of the researchers and investigators to carefully review the federal exemption criteria or categories and to have a clear understanding of the CPHS's interpretations of the exemptions. The office shall notify the researcher/investigator in writing whether the proposed research is exempt or not and where such research is not exempt it shall be required that the researcher submit a Human Subjects Protocol form to the CPHS for expedited or full review. The CPHS has the authority to determine within the provisions of the law and federal guidelines those categories of research protocols which may be subject to limited review or which may be exempt from review by the committee.

Researchers are asked to note that the exemption categories **do not apply** when research activities include

a) Prisoners, fetuses, pregnant women or human in-vitro fertilization
b) Surveys or interview techniques involving minors as subjects
c) The review of medical records which have information that may clearly identify the subject in those records
d) Research techniques that may cause the human subjects to feel harassment of discomfort beyond levels that may be encountered in normal daily life
e) The deception of human subjects

The federal categories of research activities eligible for exemption certification are as follows:

a) Research involving usage of educational tests (cognitive, aptitude, diagnostic, achievement) survey procedures or observations of public behavior unless the human subject can be directly or indirectly identified from information obtained.
b) Research where the human subjects involved may be placed at higher risk of criminal or civil liability or be damaging to financial standing or employability or reputation.
c) 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 or investigations into the effectiveness of or comparisons among instructional techniques, curriculum or classroom management methods.
    iii. Research involving the use of educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, observation of public behavior that is not under exempt under (1) of this section are if:
        a. The human subjects are elected or appointed public officials or candidates for public office federal statue(s) require(s) without exemption that the confidentiality of the personally identifiable information will be maintained during the research and subsequent to the research

iv. Research involving the study or collection of existing data, records, documents, pathological or diagnostic specimens, where these sources are available to the public or if the investigator has recorded relevant information in such a fashion that the human subjects involved in the research cannot be directly or indirectly identified
v. Research and demonstration projects which are designed to study, evaluate or otherwise investigate the following:
    1. Public benefits or service programs
    2. Procedures or systems for obtaining benefits or services under those programs
    3. Likely changes in the way payments, benefits or services under those programs
    4. Likely changes in the way payments, benefits or services are made
vi. Taste or food quality evaluation and consumer acceptance studies:
    1. If wholesome foods without additives are ingested or
    2. If food is ingested that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemicals or environmental contaminants at or below the level found to be safe, by the food and drug administration or approved by the EPA of the food safety and inspection services of the US Department of Agriculture

If the project is determined not to be exempt, it is required that the investigator or researcher submit the Human Subjects Protocol Form to the CPHS through the Office of Sponsored Programs for a full or expedited review.

3.0 Criteria for Approval of Research:

The CPHS reviews protocols for research in accordance with federal regulations governing research with human subjects. In its deliberations, the committee may also apply such codes of professional ethics as the committee may deem appropriate. It is the policy of CUA that in order for any research protocol to be approved, the committee must determine that all of the following requirements are met:

- Risks to subjects are minimized and are reasonable in relation to anticipated benefits of the research;
- Selection of subjects is equitable given the purposes and setting of the research;
- Appropriate informed consent will be sought from each subject of the subject's legally authorized representative, and such consent will be appropriately documented;
- The research plan makes appropriate provision for monitoring the data collected to insure the safety of subjects;
- Appropriate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data; and
- Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included to protect the rights and welfare of these subjects.

3.1 Investigator's Right of Appeal:

It is CUA policy that the final decision regarding approval or disapproval of all protocols rest with the CPHS. In accordance with federal regulations, no research involving human subjects may be conducted under CUA's auspices without prior and continuing approval of the Committee. Any investigator who disagrees with a decision of the Committee, may request a hearing of special appeal at any duly convened meeting of the Committee, during which he/she may present relevant arguments and/or witnesses. The investigator may also request that the Provost be informed of the appeal. However, the final decision rests with the Committee.

3.2 Periodic Review of Research

After a research protocol has been reviewed by CPHS, it is the investigator's responsibility to report to the Committee any proposed changes in the research as well as any previously unanticipated problems which may arise involving risk to subjects. Upon receipt of such information, the Chair of the Committee may determine that reconsideration of the protocol by the full Committee is justified. If such a determination is made, the procedures governing initial review of protocols will apply.

In addition, federal regulations require that the Committee conduct continuing review of approved research at least once per year. At the time of the review, the investigator will be required to complete the Periodic Review Form (download a Word 97 file) which (a) determines whether or not the research is continuing, and (b) details any changes from the original protocol by the full committee. The Committee will review the project annually until it has been completed, unless otherwise determined by the CPHS.

4.0 Instructions for the Proposal to External Funding Agencies:

The relevant letters of approved from the CPHS are required by researchers ONLY if projects are funded. It is the investigator's responsibility to obtain the letters after notification of approval of funding and submit them to the Research Committee. Standard review procedures will be followed.

The CPHS is not directly involved in the grant/contract process involving external funding agencies. Therefore, it is critical that an investigator who plans to submit a proposal to and external funding agency be familiar with the agency's and the University's policies regarding CPHS certification and the approval procedure.

4.1 Overview of Funding Agencies' Requirements:

Each agency has its own certification requirements. For example, some agencies have a special form or "item" on the application which must be completed by the applicant and signed by the University's Authorized Institutional Official. Other agencies accept the University's CPHS approval letter which is signed by the Chair of the Committee.

Agencies also differ with respect to their flexibility in accepting certification notices after the proposal has been received. For example, when submitting an application to the National Institutes of Health (NIH), it is critical that certification of approval be transmitted to the agency as soon as possible after the submission of the grant proposal. Other agencies may not require that certification be sent until the final decision with respect to funding status has been made. On the other hand, some agencies will not accept and application unless CPHS certification is included. Questions regarding agency CPHS certification policies should be directed either to the individual agencies or to the Office of Sponsored Programs staff.

4.2 University Certification Procedures:

a) Whenever possible, the research proposal should be submitted to the CPHS prior to submission of the grant/contract application to the agency. The investigator is responsible for submitting the protocol for CPHS review in a timely fashion.
b) If, due to time constraints on the investigator's part, the research proposal has not been submitted to or reviewed by the CPHS by the time of submission of the grant/contract application to the agency, then the investigator is responsible for submitting the protocol to the CPHS as soon as possible thereafter. NOTE: The Office of Sponsored Programs does not submit protocols to the CPHS; it is the investigator's responsibility to do so.
c) After the final CPHS approval has been obtained, the investigator should request the Office of Sponsored Programs to prepare the certification document. The Office of Sponsored Programs will prepare the form, obtain the authorizing official's signature and transmit the form to the relevant agency.

4.3 Resubmission of Grant Application

a) In the event that an investigator proposes to resubmit a research protocol previously approved by the CPHS to an external funding agency, it is his/her responsibility to contact the Office of Sponsored Programs to determine the current CPHS status of the protocol before submitting the grant/contract application to the agency.
b) If an existing CPHS approval was obtained prior to the 12-month period preceding the agency's submission deadline, it will be necessary for the investigator to submit a new protocol to the CPHS as necessary. A new certification document cannot be issued until the Committee has reviewed the study in accordance with the regular review procedures.
c) If CPHS approval has been obtained in the 12 months preceding the agency's submission deadline, a new Human Subjects Protocol need not be submitted to the Committee, provided no changes have been made in the research activities which affect the human research subjects. The investigator is responsible for submitting either (a) a letter to the CPHS indicating that the revised application does not include modifications regarding the human subjects' participation; or (b) a revised Human Subjects Protocol Form, if appropriate. The investigators must request that the Chair of the Committee prepare the certification document, as specified by the funding agency.
d) If a revised grant application includes changes which affect the human subjects, it will not be necessary for the investigator to submit a new Human Subjects Protocol Form to the CPHS, provided the previously reviewed study had received CPHS approval in the 12 months preceding the agency deadline. The investigator is required, however, to submit to the CPHS the following: (a) a description of the proposed changes; (b) revised consent and/or assent form; and (c) a revised copy of the grant application. Instructions for submitting the request for approval of modification may be obtained from the Office of Sponsored Programs. After the proposed modifications have been approved by the CPHS, the certification document will be prepared and The Office of Sponsored Programs will transmit the form to the agency.

4.4 Related Grant Proposals: No Plans for Resubmission or Implementation of Research

If the grant proposal is rejected and if the investigator does not intend to implement the research project, the investigator should notify the CUA Office of Sponsored Programs, in writing, so that the file may be deemed closed.

4.5 Externally Funded Projects: Annual Recertification Procedures

Most funding agencies require that funded research projects involving human subjects receive a continuing review by the CPHS at least once every 12 months. The agencies also require that an updated certification document be submitted at specified intervals. The Committee cannot provide an updated certification document unless the project has been reviewed and approved in accordance with the University's Periodic Review of Research procedures. Once Committee approval has been obtained, the investigator is responsible for transmitting the certification to the agency.

5.0 Special Populations:

5.1 Including Women and Minorities as Subjects in Clinical Research

In 1994 the National Institutes of Health issued new guidelines on the inclusion of women and minorities as subjects in clinical research. It is the responsibility of the CPHS, to ensure that NIH protocols follow those guidelines for clinical trials. Investigators conducting clinical trials should contact the Office of Sponsored Programs for more details.

5.2 Including Children as Subjects in Clinical Research

In 1988 the National Institutes of Health (NIH) set forth policy and guidelines on the in clusion of children in research involving human subjects. It is the responsibility of the Human Subjects Committee, as the

Institutional Review Board, to ensure the NIH protocols follow these guidelines for clinical trials. Investigators conducting clinical trails should contact the Office of Sponsored Programs for more details.

5.3 Requesting Data from the Student Information System

Departments within the University requesting data from the student information system for the purpose of conducting research must submit to the Registrar's Office a notice of review approval from CPHS. Departments within the University requesting student data for research that is exclusively and directly linked to the University and not intended to contribute to generalizable knowledge may be given such data without prior review by the Committee. However, if the research involves collections of "sensitive" information, the request must be accompanied by a notice of review and approval by the Committee. ("Sensitive" information includes, but is not limited to, information regarding sexual behavior, use od controlled substances, illegal activities, voter registration, religious preference and practice, and similar information.)

6.0 Research Involving a Student Thesis or Dissertation

Graduate students who plan to conduct a thesis or dissertation must file a completed form titled "Petition for Topic Approval" with the Graduate School. This form is available from the Graduate School. If the thesis/dissertation involves the use of human subjects, then the student must attach a copy of the CPHS approval form to their petition.

7.0 Deadline Dates and Meeting Dates

The CPHS establishes regular monthly meeting dates throughout the school year. All material for review by CPHS is to be submitted to the Office of Sponsored Programs by 5 p.m. on the specified deadline date. Protocols submitted after 5p.m. on the deadline date will be scheduled for the next meeting. Investigators may be asked to attend a CPHS meeting in order to answer questions and clarify research projects. Contact the Office of Sponsored Programs at x5218 for scheduled meeting times.

8.0 CPHS Membership

The CPHS is appointed by the Associate Provost for Research in accordance with the federal regulations governing the composition of Institutional Review Boards for research utilizing human subjects. The committee consists of at least six members, with varying backgrounds to promote complete and adequate review or research activities commonly conducted at CUA. It is made up of persons of both sexes and includes at least one persons whose primary concerns are nonscientific areas, as well as at least one member who is not otherwise affiliated CUA (nor part of the immediate family of Persons affiliated with CUA).

Members of the Committee are appointed for terms of three years, and are replaced at staggered intervals. No member of the Committee may participate in the Committee's review of any project in which the member has a conflicting interest, except to provide information requested by the Committee.

9.0 Human Subjects Committee Forms (Word 97 downloads)

"Requirements for Informed Consent"
Investigators may request paper copies from the Office of Sponsored Programs.

[1]Examples:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliations or routine patient indicates a need for extraction;
- Permanent teeth if routine patient indicates a need for extraction

- Excreta and external secretions (including sweat)
- Uncannulated saliva collected either in unstimulated fashion or stimulated by chewing gumbase or wax or by applying dilute citric solution to the tongue
- Placenta removed at delivery
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
- Supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic techniques
- Mucosal and skin cells collected by buccal scrapping or swab, skin swab, or mouth washings
- Sputum collected after saline mist nebulization

[2]Examples:

- Physical sensors either applied to the surface of the body or at a distance which do not involve input of significant amounts of energy into the subject and will not be an invasion of the subject's privacy.
- Weighing or testing sensory acuity
- Magnetic resonance imaging
- Electrocardiography, electro-encephalography, thermography, detection of naturally occurring radio activity, electro retinography, ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography
- Moderate exercise, muscular strength testing, body composition assessment, flexibility testing where appropriate give age, weight and health of the individual.

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RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: _____

Principal Investigator: _____ FWA00004459 _____

INVITATION TO PARTICIPATE

PURPOSE

DESCRIPTION OF THE PROCEDURES

DISCOMFORTS AND RISKS

RISKS DURING PREGNANCY

EXPECTED BENEFITS

WITHDRAWAL FROM THE STUDY

COSTS AND PAYMENTS

CONTACTS

RESEARCH SUBJECT RIGHTS: I have read or have had read to me all of the above.

_____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of benefits to which I am entitled.

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RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: _____

Principal Investigator: _____ FWA00004459 _____

I understand that any information obtained as a result of my participation in this research study will be kept as confidential as legally possible.

The results of this study may be published, but my records will not be revealed unless required by law.

NOTE:
If I have any questions about the conduct of this study or my rights as a subject in this study, I have been told I can call The Catholic University of America Office of Sponsored Programs at (202) 319-5218.

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

_____ _____
Subject's Signature Date

_____ _____ _____
Signature of Subject's Representative* Date Subject's Representative (Print)

_____ _____ _____
Signature of Witness Date Witness (Print)

_____ _____
Signature of person obtaining consent** Date

_____ _____
Signature of Principal Investigator Date

***Only required if subject not competent.**
****Only required if not investigator.**

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THE CATHOLIC UNIVERSITY OF AMERICA
Committee For The Protection of Human Subjects (CPHS)

GENERAL NOTE ON HUMAN SUBJECTS PROTECTION

1) According to the Office of Human Research Protection (OHRP) "under Federal Policy (Common Rule) at Section 102 (f) awardees and their collaborating institutions are 'engaged' in human subject research whenever their employees or agents intervene or interact with living individuals for research purposes; or obtain, release, or access individually identifiable private information for research purposes."

2) All CUA researchers and administrators are required to complete training in the protection of human subjects. A way to do this is to visit the NIH Training Link at:
http://phrp.nihtraining.com/users/login.php
A certificate will be issued upon completion of the computer-based training.

3) Investigators who believe their research projects involving human subjects are exempt must complete and submit an ***"Exemption Certificate"*** and a ***"Justification for Exemption Form"*** to the IRB, through the **Office of Sponsored Programs**. The ***"Justification for Exemption Form"*** includes an area for researchers to provide a description of the protocol of their study and how the regulation applies.

4) If the research project is not exempt, the investigator must submit the Human Subjects Protocol application to the IRB, through the **Office of Sponsored Programs**, for expedited or full review. Evidence that participants were informed must be maintained in the investigator's files.

5) In summary, CUA researchers are required to inform all participants in written or verbal form of the primary purpose of the research project and of any procedures which they will undergo. Additionally, participants must be informed of their rights regarding the study (voluntary participation, protecting anonymity and privacy) and risks or benefits associated with the project.

Note that the exemption categories **DO NOT APPLY** when the research activities include:

- Prisoners, fetuses or pregnant women;
- The review of medical records if the information is recorded in such a way that subjects can be identified, directly or through identifiers linked to the subjects;
- Survey or interview techniques which include minors as subjects;
- Techniques which expose the subjects to discomfort or harassment beyond levels encountered in daily life;
- The deception of the subjects.

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APPLICATION FOR HUMAN SUBJECTS PROTECTION REVIEW

Researcher's Name: _____ **Date:** _____

School: _____ **Department:** _____

Please Check One: **Faculty**_____ **Staff** _____

Title of Study: _____

Principal Investigator: _____ FWA00004459 _____

I. CATEGORY OF RESEARCH (please check one):

A. _____ **Classroom Project** **Name of class** _____

B. _____ **Dissertation Project** **Degree Program** _____

C. _____ **Faculty/Staff Research Project** **Field of Research** _____

II. TYPE OF REVIEW: I am requesting (please select one):

_____ **An Expedited Review**

_____ **A Full Review**

III. ATTACHMENT:

- **Please include your "Protection of Human Subjects" Training Certificate with this application.**

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JUSTIFICATION FOR EXEMPTION FORM

Researcher's Name: _____ **Date:** _____

Title of Study: _____

Principal Investigator: _____ FWA00004459 _____

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1. **Description of Research Procedures:**

2. **This project is exempt under 45 CFR 46.101** _____

   because:

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EXEMPTION CERTIFICATE

Principal Investigator(s): _____ **Date:** _____

Department(s) _____ FWA00004459

Title of Study: _____

The project is exempt under the following category of 45 CFR 46.101:

1. (b) (1) _____ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as a) research on regular and special education instructional strategies, or b) research on the effectiveness of or the comparison among instruction techniques, curricula, or classroom management methods.

2. (b) (2) _____ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and b) 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.

3. (b) (3) _____ Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under (2), it: a) the human subjects are elected or appointed public officials or candidates for public office; or b) federal statues(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. (b) (4) _____ 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.

5. (b) (5) _____ Research and demonstration projects which are conducted by or subject to the approval of the department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) Public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in methods or levels of payment for benefits or services under those programs.

6. (b) (6) _____ Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed or b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Certification as Exempt:

_____ _____

Secretary of the Institutional Review Board (IRB) for Research with Human Subjects **Date**
