GUIDELINES FOR RESEARCH PROPOSAL SUBMISSION

1. INSTITUTIONAL RESEARCH RISK COMMITTEE'S HUMAN SUBJECTS SUBCOMMITTEE (HSS) FUNCTION:

The HSS reviews all projects involving human subjects conducted by individuals affiliated with West Chester University to confirm that subject's rights, privacy, welfare, and civil liberties are protected. The HSS is responsible to the Federal Government (45 CFR 46, revised as of March 8, 1983) for determining whether research protocols qualify for exemption this document. The HSS does not evaluate the study's design or evaluate its potential contribution.

2. RESEARCH ACTIVITIES REQUIRING HSS REVIEW:

The following research activities require review by the HSS.

   A. Projects involving human subjects which are to be funded by the Department of Health and Human Services (DHHS).

   B. Projects involving human subjects which are to be funded by sources other than DHHS that require review by the HSS.

   C. All projects, including classroom research, involving human subjects which the HSS determines not exempt from review.

3. CRITERIA FOR DETERMINATION OF COMMITTEE REVIEW:

The DHHS requires that all research projects involving human subjects must be screened by the HSS to determine if the research is exempt from or requires review. The researcher should note these general categories and make a recommendation to the HSS as to whether the project in the researcher's opinion should be exempt from review, treated through expedited review, or requires full committee review. If students in classes conduct projects within the exempted criteria, professors need NOT submit their proposals for review. Professors will be required to submit the enclosed FACULTY AGREEMENT TO PARTICIPATE IN THE GROUP EXEMPTION PROCESS form each semester.

A. EXEMPT

* Revised 04 April 2000
In accordance with Federal Regulations (45 CFR 46.101 Revised as of March 8, 1983), the following research activities are exempt from review by the HSS.

(1) 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 classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, after all the research has been completed.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subject can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5). Research involving the collection or study of existing data, documents, records, pathological specimen, or diagnostic specimen, 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.

B. EXPEDITED REVIEW

It is now possible for the HSS to review through expedited procedures certain categories of research which recur with some regularity (source: 46 CFR. 8392, 1/26/81). They include:

(1) Collection of: hair and nail clippings, in a non disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for the extraction.

* Revised 04 April 2000
(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using non invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. This includes such procedures as weighing, testing sensory acuity, electrocardiography, thermography, and electroetinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and sub gingival dental plaque, and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise of healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subject's behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

(11) Any other category specifically added to this list by DHHS and published in the Federal Register.

The results of this expedited review are announced at the first subsequent meeting of the full HSS and the decision confirmed by the full membership and recorded in the minutes. Any member of the HSS, however, may ask that an expedited proposal be given the consideration of the full Subcommittee.

The Chairperson of the Subcommittee will determine whether the proposal will be considered under expedited or full-subcommittee review.
C. FULL SUBCOMMITTEE REVIEW

All other projects not described as exempt or expedited will require Full Subcommittee review.

4. PROCEDURES FOR PROPOSAL SUBMISSION: (For ALL PROPOSALS)

A. Complete SECTION I of the Protection of Human Subjects Approval Form.

B. Complete the Principal Investigator's Project Outline form, including:

(1) A copy of the INFORMED CONSENT FORM to be used.

(2) Statements describing potential RISKS and BENEFITS of the study.

(3) A copy of the proposal, including a brief ABSTRACT of the proposal describing the Methodology/Procedures of the study.

C. Submit one (1) copy of completed materials to your department Human Subjects Review Committee (HSRC) Chair. If your department has no HSRC, submit materials directly to the HSS Chair:

Chair, Human Subjects Subcommittee
Office of Sponsored Research
302 McKelvie Hall
West Chester University
West Chester, PA 19380

The HSS reserves the right to ask the researcher to provide additional copies of all materials provided for review of project activities.

D. Obtain a signed copy of Protection of Human Subjects Approval form from the office to which it was submitted. Please allow two (2) weeks for processing. No research involving human subjects may be conducted prior to receipt of HSS approval. If the research has been completed the HSS cannot consider the proposal, and the materials will be returned. Faculty members are expected to inform graduate students concerning the HSS's functions. The HSS meets quarterly. Meeting dates may be obtained from the Office of Sponsored Research, (610)436-3310.

5. GENERAL PRINCIPLES

* Revised 04 April 2000
There are general principles that will be used as part of the review process. These are presented for the information of the researcher to aid in the preparation of the research protocol.

A. All data should be recorded anonymously or identifying information deleted at the end of the study. The coding system to protect subjects' identity should not use subject initials, I.D. numbers, addresses, etc., in place of name. Such information could readily be used to identify specific individuals. Instead, assignment of unique or random numbers to subjects is recommended. In cases where follow-up is important, a master key could be maintained with the subject's name and number. However, only the number is placed on test materials. When the final analyses are completed and no follow-up is planned, this key is then destroyed.

B. When required, subject/parental permission must always be written permission that is returned to the researcher.

C. If a control group is used as part of the treatment-type study, the advantages derived from the research should be made available to the control group or the control group told of the advantages.

D. Subjects should be given the address of the researcher in order to request details of the study.

E. Results generally should be given to the subjects in aggregate or group form; generally individual results should not be reported back to the subjects.

F. Services are not to be terminated or negatively affected if the subject refuses to participate or withdraws from the study.

G. THE FOLLOWING SHOULD BE INCLUDED IN THE COVER LETTER OR INSTRUCTIONS TO THE SUBJECTS:

(1) The researcher's affiliation with West Chester University.

(2) A brief description of the project (what exactly the subjects will be asked to do) in terms lay persons can readily understand. This statement should avoid the use of jargon, technical terms, or medical terms or phrases.

(3) A statement of the voluntary nature of the project.

(4) A statement of anonymity/confidentiality of the subject's data.

H. All participants should be volunteers or the researcher must demonstrate why participation is necessary.
I. The HSS must review all cover letters, scripts, instructions to subjects, introductory remarks, etc.

J. The Informed Consent Form must include the following elements stated in terms that the subject can readily understand.

(1) An explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subjects.

(3) A description of any benefits to the subjects or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

(6) An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

K. THE FOLLOWING STATEMENT MUST BE INCLUDED IN THE INFORMED CONSENT FORM FOR PROJECTS WHICH POSE A RISK TO SUBJECTS.

"The Department of Health and Human Services requires that you be advised as to the availability of medical treatment if a physical injury should result from research procedures. No special medical arrangements have been made regarding your participation in this project. If you subscribe to the University Health Plan, you may receive medical treatment at the University Health Service. If you are not a registered student at the University, immediate medical treatment is available at the usual and customary fees at the Chester County Medical Center. In the event you believe that you have suffered any injury as a result of participation in the research program, please contact the Chairperson of the Human
Subjects Subcommittee, (610)436-3310, who will review the matter with you, and identify any other resources that may be available to you.

6. SPECIAL POPULATIONS RESEARCH

A. RESEARCH INVOLVING POPULATIONS FROM CLINICAL, COUNSELING, AND REHABILITATION CENTERS (AND SIMILAR INSTITUTIONS):

(1) Prospective subjects may be asked to indicate on initial contact with the organization whether they or their children can be contacted for possible research involvement in the future. The subject retains the right at all times to decline participation in the study without the threat of loss or reduction of service.

(2) Access to confidential files should be obtained in a legal and ethical manner. The researcher is obligated to maintain confidentiality of information obtained.

(3) In situations in which the experimenter has professional contact with the prospective subject, as in a therapist-client relationship, the solicitation of the client for participation in that research project should be conducted through a third party.

B. RESEARCH INVOLVING CHILDREN

(1) All projects with infants (under 3 years) or those not conducted in a school setting require the permission of at least one parent.

(2) All projects involving children which do not meet the expedited review process criteria require the permission of both parents. In a setting where the child does not live with both parents, the permission of the legal guardian or the custodial parent is required, unless otherwise determined by the HSS.

(3) In all research projects involving children, participation must be terminated at any time at the request of the parent or child.

7. RESEARCH UTILIZING ELECTRICAL EQUIPMENT

All electrical equipment connected to the subject (such as EEG, polygraph equipment) or that the subjects come in contact with should be checked by a qualified technician within one month period prior to subject testing and on a regular basis during subject testing (i.e., normally one month intervals). Assurances of this should be included on the review sheet.

BASIC CHECKLIST FOR HUMAN SUBJECTS SUBCOMMITTEE PROPOSALS

(PLEASE TYPE ALL MATERIALS)
In order to strengthen your proposal for compliance with Federal Regulation (45CFR46) requirements for research involving human subjects and an expedient review, please pay special attention to the following items. Please also remember that the "Exempted" category refers to the possible exemption from Full Committee Review, **NOT** exemption from application submission procedures to the Human Subjects Subcommittee of the IRRB.

___ Cover Letter to subjects - It is suggested that the cover letter to subjects contain information relative to **risk**, **benefits**, and a **short description** of the **methods** used in the study. The letter can then be referenced on the form, i.e., see Cover Letter, for items III, IV, and V. Items listed under V-C. must be submitted with copies of the proposal.

___ Informed Consent statement - All basic elements of Informed Consent listed below must be stated on the Informed Consent agreement to be **signed by the subject or his/her legal guardian. Tacit or passive agreement or consent is usually NOT acceptable.** If all Informed Consent elements are contained in the Cover Letter for research using only written survey instruments, a statement indicating that "completion of the survey by legally responsible subjects constitutes consent to participate in the study" **MAY** be approved in lieu of a separate "Informed Consent form". Institutional consent alone is usually not acceptable.

**NECESSARY INFORMED CONSENT ELEMENTS**

1. Statement that the study involves research; Explanation of purposes of the research and expected duration of subject's participation; description of procedures to be followed and identification of any procedures which are experimental.
2. A statement of the risks or discomforts to the subject.
3. A description of the benefits to subjects or others.
4. Disclosure of alternative procedures, if appropriate.
5. Description of the extent to which confidentiality and anonymity will be maintained.
6. For research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs.
7. Explanation of whom to contact if questions arise about the research, the subjects' rights or whom to contact if research-related injury occurs.
8. Statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue at anytime

___ PLEASE MAKE SURE ALL FORMS ARE SIGNED AND A COPY OF THE PROPOSAL IS ATTACHED AND ALLOW AMPLE TIME FOR REVIEW.

* Revised 04 April 2000
SECTION I. (Completed by Applicant)

Name of Principal Investigator: _________________________________________________

Major Professor, University Division, Address, and Telephone:
__________________________________________________________________________

Title of Proposed Project: ______________________________________________________
____________________________________________________________________________

Recommended Review Category:

_____ Exempted _____ Expedited Review _____ Full Review

SECTION II. (Completed by HSS)

In compliance with Federal Requirements for Protection of Human Subjects (45 CFR 46, Revised as of March 8, 1983) the above research study has been classified as:

_____ EXEMPTED UNDER FEDERAL REGULATION (45 CFR 46.110).

_____ APPROVED BY "EXPEDITED REVIEW" -- NOT GREATER THAN MINIMAL RISK1.

_____ APPROVED BY "FULL REVIEW" OF THE INSTITUTIONAL RESEARCH RISK COMMITTEE.

_____ DISAPPROVED -- REASON: _______________________________________________

SUGGESTED CORRECTION: __________________________________________________

*** INFORMED CONSENT FORM usage _____ NOT WAIVED _____ WAIVED ***

Signature: Chair, HSS, or Designated Official ___________________________ Date ______________

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1 "Minimal risk" means that 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 (45CFR46.102g).
Name of Principal Investigator: ___________________________________________________

Major Professor, University Division, Address, and Telephone:
______________________________________________________________________________

Title of Proposed Project: ________________________________________________________
______________________________________________________________________________

Proposed Starting Date: _________________________  Duration: _______________________

Estimated Number of Human Subjects Involved in the Project: __________________________

I. Characteristics of Subjects (check as many boxes as appropriate).

_____ Children  _____ Mentally Retarded  _____ University Students

_____ Adults  _____ Pregnant Women  _____ Secondary School Pupils

_____ Prisoners    _____ Legally Incompetent _____ Elementary School Pupils

_____ Others (Specify): ____________________________________________________

II. Consent and Withdrawal Procedures.

A. Consent obtained from: Individual _____, Institution _____,
Parent or Legal Guardian _____, Other (Specify) _____.

B. Type of Consent: Written (attach copy of consent statement) _____, Oral _____
(explain reason for not using written form and attach a verbatim statement of the oral request to the subject).

C. Subjects are informed of withdrawal privileges (attach copy of statement).

2 "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 (usually 18 years).
III. Risks: Briefly describe the risks (physical, psychological, social, etc.) to the subjects, and indicate the degree of risk involved in each case.

Use additional sheets, as necessary, to respond to the remaining portions of this form.

IV. Benefits: Briefly describe the benefits (physical, psychological, social, etc.) to the subjects and/or humankind in general.

V. Methodology/Procedures

A. Briefly describe the methods used for the selection of subjects/participants.

B. Briefly describe all other procedures to be followed in carrying out the project.

C. Attach a copy of the proposal you will submit and a copy of subject orientation and instruction information. Include questionnaires, interview questions, tests, and other similar materials.

VI. Agreements: By signing this form, the principal investigator agrees to the following:

A. To conform to the policies, principles, procedures and guidelines established by the HSS.

B. To supply the HSS with documentation of selection procedures and informed consent procedures.

C. To inform the HSS of any changes in procedures which involve human subjects, giving sufficient time to review such changes before they are implemented.

D. To provide the HSS with any progress reports it may request.

_________________________________________________ ________________________
Signature: Principal Investigator       Date

* Revised 04 April 2000
This project has been reviewed and approved by the West Chester Institutional Research Review Committee's Human Subjects Subcommittee (HSS). The HSS believes that the research procedures adequately safeguard the subject's privacy, welfare, civil liberties, and rights. The HSS Chairperson may be reached through the Director of Sponsored Research, West Chester University, West Chester, PA 19380 or, by telephone, (610)436-3310.

Project Title: ________________________________________________________________

Principal Investigator, address, phone: _____________________________________________

I understand that the purpose of this study/project is:

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

** I confirm that my participation is entirely voluntary. No coercion of any kind has been used to obtain my cooperation.
** I understand that I may withdraw my consent and terminate my participation at any time during the project.
** I have been informed of the procedures that will be used in the project and understand what will be required of me as a subject.
** I understand that all of my responses, written/oral/task, will remain completely anonymous.
** I understand that a summary of the results of the project will be made available to me at the completion of the study if I so request.

I wish to give my voluntary cooperation as a participant.

_________________________________________________ ________________________
Subject Signature                                        Date

_________________________________________________ ________________________
Address _____________________________________________

_________________________________________________ ________________________
Parent or Guardian (If subject is under 18 yrs)            Date

_________________________________________________ ________________________
Witness                                               Date

WEST CHESTER UNIVERSITY
* FACULTY AGREEMENT TO PARTICIPATE IN THE GROUP EXEMPTION PROCESS *
* TO BE USED FOR ROUTINE UNIVERSITY CLASS PROJECTS *

Recognizing the importance of protecting human subjects during class projects/research, I agree to review plans for such activity to be conducted by students enrolled in the following course(s).

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If, in my opinion, the project/research planned by a student(s) does not qualify for Exempt Review status (see attachment), I will recommend that the student(s) either revise procedures to conform to the criteria for Exempt status or have them submit the proposal to the HSS for consideration. For those activities qualifying for Exempt Review status, I will obtain written informed consent from all human subjects (from parent/guardian if a minor) on which information is collected and I will keep the informed consent forms on file.

_________________________________________________ ________________________
Faculty Signature                              Date