



West Chester University of Pennsylvania

GUIDELINES

for

Submitting Protocols to the Human Subjects Committee

and

Application Package

Rev. 11/18/2010

The following Guidelines are provided to assist Principal Investigators (PIs) with their applications for Human Subjects Committee (HSC) of the Institutional Review Board (IRB) approval of research projects using Human Subjects. These Guidelines are intended to be helpful in explaining the concepts of protecting Human Subjects but may not be all inclusive. The official Policy and Procedures for the Protection of Human Subjects in Research and Research Related Activities is located on the Office of Sponsored Research (OSR) website <http://www.wcupa.edu/facstaff/facdev/SponsoredResearch/Guidelines.asp>. After a careful review of the Policy and Procedures and these Guidelines, any questions concerning these documents or any questions related to the application package should be addressed to the Associate Vice President (AVP) of Sponsored Research at (610) 436-3592.

Permission to adapt the Policy and Procedures for the Protection of Human Subjects in Research & Related Activities was obtained from Ms. Donna Stremke, Office of Research and Sponsored Programs, Florida Gulf Coast University on February 2, 2008. Approved April 26, 2009

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I. INTRODUCTION

This guide has been prepared for faculty, staff and students at WCU who are or will be involved with research projects that involve human subjects. It is designed to be a user-friendly adjunct to the Institutional Review Board's Policy concerning the Protection of Human Subjects. The Human Subjects Committee (HSC) is the division of the Institutional Review Board (IRB) that deals with the protection of human subjects. This guide provides the step-by-step procedures for preparing and submitting applications to the IRB/HSC. The *Faculty Guidelines*, including the Application Form, is located on the WCU Office of Sponsored Research (OSR) website (<http://www.wcupa.edu/facstaff/facdev/SponsoredResearch/Guidelines.asp>).

For the regulations and ethical principles regarding research involving human subjects at WCU, please refer to the Policy, also located on the WCU OSR website.

The intent of the Human Subject Policy and related review procedures is to safeguard the rights and welfare of human subjects (by the elimination or minimization of research-related risks and the requirement for informed and voluntary participation by subjects), and to ensure WCU is in compliance with the Federal rules (45CFR46).

The goal of the WCU Human Subjects Committee (HSC) is to work with faculty to promote research which protects all participants, including the university and its investigators. When you conduct research that has been approved by the HSC, your personal liability is limited in the same way that it is when you are teaching in the classroom (or conducting other activities associated with the terms of your employment.)

The OSR has the publication by the Office of Human Research Protection/Federal Department of Health and Human Services' instructional videotapes/CDs series on "Protecting Human Subjects". The instructional resource is strongly recommended to anyone who intends to submit an application to the Institutional Review Board. Please contact the OSR check out a tape or CD.

II. BACKGROUND INFORMATION YOU NEED TO KNOW

A. DEFINITIONS

Human Subjects Research is a systematic investigation designed to develop or contribute to general knowledge, which involves the collection of data from or about living human beings. Activities which meet this definition constitute "research," whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities. Human Subjects Research does not include research utilizing published or publicly available documents or research on elected or appointed public officials or candidates for public office. The HSC will make that determination.

Human Subject means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

IRB/HSC - Institutional Review Board/Human Subjects Committee. The IRB is appointed to review research involving human subjects, animal subjects, and hazardous materials for compliance with applicable federal, state, and local regulations; the HSC reviews research involving human subjects. The IRB and HSC membership includes WCU faculty and staff from relevant disciplines, as well as member(s) of the local community.

At Risk - to be placed in a position with greater potential for physical, mental, social, or financial harm than would be expected for that individual in his or her normal occupation or daily activities.

Minimal Risk means that 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.

Reasonable Risks means the relationship of anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

B. IRB/HSC SCOPE

All research involving human subjects, including research training, must be reviewed and approved by the University's Human Subjects Committee (HSC) of the Institutional Review Board (IRB) before any human subject research can begin. The HSC has full authority to approve, require modifications, or disapprove all research activities that fall within its jurisdiction.

There are three types of review classifications--Exempt from Further Review, Expedited Review, and Full Board Review. Criteria for qualifying for a particular review category are specified by the Department of Health and Human Services. The Exempt classification does **not** mean that the research project is exempt from review by the HSC; rather, it is a classification assigned by the HSC after its review of the protocol to indicate that the project is exempt from further HSC review as long as there are no modifications in the procedures. **Submission of an application is required even if the PI thinks the project should qualify as Exempt.**

A detailed discussion of the criteria for the classifications is found in Appendix C. This information is included for your general knowledge and to help you determine a general time frame for the review process.

C. EXPLANATION OF APPLICATION ELEMENTS

The HSC review process focuses on the consideration of the following elements:

- **Risk.** Are the procedures and subject's participation adequately described? Do the study's procedures place the subject at risk in any form? Are risks fully described? Is the risk

minimal or reasonable, as defined by the Policy? Are the procedures adequate to minimize any risk?

- **Benefit.** If there are potential risks, should the knowledge from the research be pursued? Do the benefits outweigh the risks? Have the benefits to the subject and/or society been described?
- **Informed Consent.** Are the subjects provided with sufficient detail in the consent form to assure voluntary and informed consent? Are participants notified that they can withdraw at any time? Are the participants informed about their recourse in the event of injury? Are the participants provided with a name and phone number of a person to call with any questions or problems? Is there any indication of coercion or undue influence?
- **Confidentiality/anonymity.** Is the selection of participants/subjects fully explained? If the subjects are anonymous, how is anonymity ensured? Are the procedures sufficient to allow for confidentiality of information about individual subjects, in both gathering and disseminating information? Are security measures adequately described?
- **Special or vulnerable populations.** Are vulnerable populations involved? If so, have particular and appropriate steps been taken to assure they or their legal guardians understand what is going to happen, their participation is voluntary, legal consent has been obtained, etc.? Is selection of subjects equitable? A detailed description of especially vulnerable subjects and appropriate safeguards is found in Section IX.G of the *Policy and Procedures*.

A pivotal issue in the review process is deciding whether or not the proposed research might place subjects at more than minimal risk. There is no simple, objective criterion that can be applied in all such judgments. The University's policy document on human subjects' research states that "minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering possibility and magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests or examinations." This definition acknowledges that most peoples' daily lives include challenges and stresses. In practice, the kinds of experiences that "most people" have on a "typical" day are considered minimal risk; exposing subjects to the kinds of physical or psychological stressors that make some of our days rather painful or disturbing would be judged to involve more than minimal risk, despite the fact that such experiences may not always cause lasting harm.

Two other issues central to the evaluation of virtually all proposals are the issues of **confidentiality** and **informed consent**. Your application must provide a thorough description of the steps that will be taken to maintain the confidentiality of data. For instance, if the participants will be completing written questionnaires, will they be asked to include or omit their names from these forms? Even when names are omitted, individuals can sometimes be identified from demographic or other background information that they provide. When identifying information is needed, what other steps will you take to ensure that the data will remain confidential? What steps will you take to ensure the confidentiality of photographs and video or audio recordings? **A statement to the effect that "confidentiality will be maintained" is not sufficient.**

You must obtain the legally effective informed consent of your participants or of their legally authorized representatives. This will mean obtaining a signed consent in essentially all cases.

Informed consent must be written or explained in language that is understood easily by the subject or representative, usually language appropriate for the 7th or 8th grade. You must seek such consent under circumstances that provide the prospective subject with sufficient opportunity to consider whether or not to participate. These circumstances must also minimize the possibility of coercion or undue influence. Subjects must be informed of any foreseeable risks or discomforts. They must also be given an explicit statement explaining that their participation is voluntary, that refusal to participate will involve no penalty, and that they may discontinue participation at any time without penalty.

In the case of an anonymous questionnaire where a signed informed consent form would provide the only means of identifying the subject, an explanatory letter (see the sample in Appendix B) attached to the questionnaire may substitute for a signed informed consent form.

More detailed information concerning the Informed Consent Process is found in the *Policy and Procedures*, Section IX.

III. THE APPLICATION

The application (electronic version is located on the WCU OSR website) is to be completed by the principal investigator. If the principal investigator is a student, the application must be approved by the student's faculty sponsor. The responsibility for complying with the Policy and Procedures is shared by the faculty sponsor and the student.

The PI then submits a complete application package of this document **with original signatures** to the chair of the HSC via the WCU OSR. **E-mail submissions are recommended; however the signature page must have the actual signatures. Processing will not begin until the application is complete, including the signatures.**

Any questions about the completion of the application should be directed to the chair of the HSC or the WCU OSR.

Please bear in mind that you may not initiate any research involving human subjects until you have received written notification of HSC approval.

If you have submitted this project to an external agency for funding, attach one copy of the external proposal to the application. If you intend to submit this project to an external agency for funding, forward a copy of the external support proposal to the OSR as soon as feasible.

The application package should be submitted, ALL entries TYPED, except signatures, in the following order:

1. Checklist completed and signed by the PI
2. Section I Project Information – All appropriate boxes checked and categories/explanations given.
3. Section II Detailed Protocol – Concise, complete responses following each individually lettered requested for information. Include all information requested.

4. Section III Signatures
5. Appropriate Informed Consent Form(s).
6. Any research instrument used (questionnaire, survey, psychological test, etc.).
7. Letters of approval from participating institutions, if any.
8. External support proposal, if any (one only, attached to the application with original signatures). Do not include the budget.
9. Computer-Based Training at <http://phrp.nihtraining.com/users/login.php> Use the link which is open to the public.
10. Please submit all materials as ONE (1) INCLUSIVE WORD E-MAIL ATTACHMENT FILE to the humansubjectcommittee@wcupa.edu address for review. ONLY COMPLETE APPLICATIONS OR REVISIONS WILL BE ACCEPTED. Multiple files, additional documents, piece-meal applications or .pdf documents will not be accepted. The Human Subjects Committee cannot edit or add to your application once submitted. It is suggested you keep a complete editable copy, preferably electronic, in case revisions are necessary. Scanners, if needed, are located in various departments on campus, the Office of Sponsored Research, and Anderson Hall, Rm. 7.

The checklist, application form and sample Informed Consent Forms are located in Appendix A and B.

IV. THE REVIEW PROCESS

The Office of Sponsored Research (OSR) will log in the application, assign reviewer(s) for a Technical Review, notify you in writing when your application is approved, and file the ID # assigned.

On a weekly schedule, the HSC chair or assigned reviewers, will conduct a Technical Review to determine completeness of the application package and determine the type of review (exempt, expedited, or full board review) appropriate to the project application.

The chair or his/her designee will notify you of the results of the Technical Review and the type of review required for your application. He/she will coach you through the approval process to completion. If your package is missing any required components, your application will be returned to you with instructions on how to complete it. You may correct any deficiencies and return the complete revised package to your reviewers(s) for re-review. If your application is deemed eligible and ready for an Expedited Review, you may be invited (but not required) to attend the Review. (You may be informed of, and invited to attend, all meetings where your application will be reviewed.) If the chair determines the application needs a full board review, you may be asked to provide additional copies.

The Technical Reviewer(s) may request clarifications or changes. A detailed, written explanation of the Committee's concerns and requests will be forwarded to you by the reviewer(s) within two weeks of the review.

If your application does need modifications, a **complete revised application** is to be submitted to the reviewer, with the modifications clearly identified and explained in a cover letter (or e-

mail) so that the reviewer(s) can quickly locate them. The **complete revised application** must be submitted to the HSC in one (1) WORD or PDF file. An approval letter, including the assigned file ID#, and results of the Technical Review will be forwarded to you upon final approval.

Written notification of the Committee's approval of your application (or a request for further clarifications, if needed) will be forwarded to you within two weeks of the Committee's review of your modified application.

If your application is to appear before the HSC for full review, you will be invited to attend the review. A HSC may request modifications or clarifications; these will be forwarded to you in writing within two weeks of the Committee review. When those modifications have been included within your revision of the document and it has been re-reviewed, you will receive written notice of approval or of further revisions needed for your application.

APPENDIX A: APPLICATION PACKAGE

The electronic version of this Application Package is found on the
WCU OSR website.

From the Main Page, click on:
Faculty & Staff, then Institutional Review Board, then
HSC Application (WORD) Downloadable Version

HUMAN SUBJECT COMMITTEE APPLICATION PACKAGE

The application package should be submitted, ALL entries TYPED, except signatures, in the following order:

The application package should be submitted, ALL entries TYPED, except signatures, in the following order:

1. Checklist completed and signed by the PI
2. Section I Project Information – All appropriate boxes checked and categories/explanations given.
3. Section II Detailed Protocol – Concise, complete responses following each individually lettered requested for information. Include all information requested.
4. Section III Signatures
5. Appropriate Informed Consent Form(s).
6. Any research instrument used (questionnaire, survey, psychological test, etc.).
7. Letters of approval from participating institutions, if any.
8. External support proposal, if any (one only, attached to the application with original signatures). Do not include the budget.
9. Computer-Based Training at <http://phrp.nihtraining.com/users/login.php> Use the link which is open to the public.
10. Please submit all materials as ONE (1) INCLUSIVE WORD OR PDF E-MAIL ATTACHMENT FILE to the humansubjectcommittee@wcupa.edu address for review. ONLY COMPLETE APPLICATIONS OR REVISIONS WILL BE ACCEPTED. Multiple files, additional documents, or piece-meal applications will not be accepted. The Human Subjects Committee cannot edit or add to your application once submitted. It is suggested you keep a complete editable copy, preferably electronic, in case revisions are necessary. Scanners, if needed, are located in various departments on campus, the Office of Sponsored Research, and Anderson Hall, Rm. 7.

REV. 7-20-2010

CHECKLIST

(Please complete checklist after completing application)

- I. Project Information**
1. All appropriate boxes are marked.
 2. If this research is being undertaken with another institution, a letter of approval from that institution is attached.
 3. Copies of questionnaires, surveys, etc. are attached.
 4. Is this protocol associated with an application for external funding? yes no
- II.A. Summary**
1. Major hypotheses or research questions are provided (if applicable).
 2. Research design has been reviewed by directing professor if submitted by a student.
- II.B. Selection of Subjects Identified**
1. Source of subjects is identified.
 2. Selection criteria are explained.
 3. Contact method is explained.
- II.C. Informed Consent Form**
1. All relevant Informed Consent Forms are attached.
 2. Consent forms were based upon WCU sample.
 3. Appropriate language is used (usually 7th/8th grade language)
 4. Items 1-8 of sample are included and explained.
 5. Withdrawal Notice is included.
 6. Any special circumstances dictated by the research design are included.
- II.D. Procedure Outlined**
1. Step by step description of each procedure is provided.
 2. Frequency, duration and location of each procedure are provided.
- II.E. Confidentiality**
1. Location of signed Consent Form originals is identified.
 2. Method of storage is identified.
 3. Names of people with access are listed.
 4. The means for maintaining confidentiality are fully explained.
- II.F. Risks**
1. Known or anticipated risks are explained.
 2. Possible side effects, use of placebos, risks of normal treatment, etc. are fully explained.
- II.G. Benefits**
1. Anticipated benefits to the subject are described.
 2. Importance of resulting knowledge is described.
- III. Signatures**
- All required signatures are present...

Effective November 1, 2009, everyone submitting a protocol to the HSC, including a faculty sponsor, is required to provide evidence of HSC training. We recommend the following web site for training: <http://phrp.nihtraining.com/users/login.php>

Check the box that applies:

- All investigators and any faculty sponsor have already submitted evidence of completion of HSC training.
- Evidence of completion of HSC training is attached for each investigator and faculty sponsor.
- HSC training is in progress and documentation will be provided by _____.

All the above checked items are included in this application and are complete and accurate to the best of my knowledge.

Signature of Principal Investigator

Typed or Printed Name

For OSR use only:	Grant Title: Sponsor Name: OSR PI Name & File #:
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I. PROJECT INFORMATION (PLEASE TYPE)		
I.A. <hr/> <i>Principal Investigator's Name/Phone Number</i> <hr/> <hr/> <i>Co-Investigator's Name</i>	I.B. College or Academic Unit: <input type="checkbox"/> Arts & Sciences <input type="checkbox"/> Health Sciences <input type="checkbox"/> Business <input type="checkbox"/> Professional Studies <input type="checkbox"/> Education <input type="checkbox"/> Other _____ I.C. Project Period: From: _____ To: _____	
I.D.		
<hr/> <i>Title of Project</i> <hr/>		
I.E. If the Principal Investigator is a student, provide the following:		
<i>Faculty Sponsor</i>	<i>Department</i>	<i>Phone Number</i>
Check if project is a: <input type="checkbox"/> Class Project <input type="checkbox"/> Thesis <input type="checkbox"/> Dissertation <input type="checkbox"/> Neither	Student's mailing address: _____ _____ _____ e-mail address: _____	
I.F. Has this project previously been considered by the HSC? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, approximate date of review: _____	I.G. Check if submission is a <input type="checkbox"/> renewal <input type="checkbox"/> revision/resubmission ID# of original submission: _____	
I.H. Are you applying for an exempt category? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, indicate the category number (see Guidelines) (# I.1-I.6 on pages C-2 & C-3 of the <i>Faculty Guidelines</i>). Are you applying for an expedited review? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, indicate the category number (# II.1-II.9 on pages C-3 & C-4 of the <i>Faculty Guidelines</i>).	<u>Category Number</u> _____ _____	
I.I. If your project may involve any of the following as subjects, please check: <input type="checkbox"/> pregnant women <input type="checkbox"/> children <input type="checkbox"/> prisoners <input type="checkbox"/> fetuses <input type="checkbox"/> elderly persons <input type="checkbox"/> non-English speaking persons <input type="checkbox"/> persons with acute and/or severe mental or physical illness		
I.J. Is this research being undertaken with another institution? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, name of cooperating institution: _____ <i>If yes, attach a letter of approval from the cooperating institution.</i>		
I.K. Has a proposal for external support been submitted? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, please provide the title of the proposal. _____ If yes, is notification of Human Subject Approval required? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, provide sponsor's name: _____		

II. PLEASE PROVIDE COMPLETE ANSWERS TO THE FOLLOWING QUESTIONS.

- A. Provide a brief summary of the proposed research in lay terms. Include major hypotheses (if appropriate), research questions and research design.
- B. Describe the source(s) of subjects and the selection criteria. Specifically, how will you obtain potential subjects, and how will you contact them? Will any compensation or incentives be given for participation? If so, what?
- C. Informed consent: Describe the consent process. Attach a copy of all consent documents after Section III, Signatures Page.
- D. Procedures: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.
- E. How will confidentiality of the data be maintained? Include the exact location of the signed originals of the Informed Consent Forms, the method of storage, and the names or titles of individuals (other than University and federal officials) having access to the consent documents. Specify the date for destruction of data (surveys, disks, etc)?
- F. Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.
- G. Describe the anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result.

Additions or changes in procedures involving human subjects, as well as any problems connected with the use of human subjects once the project has begun, must be brought to the attention of the HSC. All adverse effects to the subjects are to be brought to the attention of the HSC immediately and in writing.

III. SIGNATURES

A. I certify that I have read the West Chester University Human Subjects Research Policy and to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

Principal Investigator

Date

Co-Investigator

Date

B. **Approval by faculty sponsor (required for all students):** I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the HSC.

Faculty Sponsor Signature followed by Typed Name

Date

APPENDIX B: SAMPLE INFORMED CONSENT FORMS

SAMPLE INFORMED CONSENT FORMS
(Note: This format is suggested by the HSC)

Project Title: _____

Investigator: _____

(include name, department and phone of contact person)

You are being asked to participate in a research project conducted through West Chester University of PA [and, if applicable—any other cooperating institution]. The University requires that you give your signed agreement to participate in this project.

The investigator will explain to you in detail the purpose of the project, the procedures to be used, the expected duration or frequency of your participation, and the potential benefits and possible risks of participation. You may ask him/her any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the researcher any questions you may have.

If you decide to participate in the project, please sign on the last page of this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

Refusal to participate in this study will have no effect on any future services you may be entitled to from the University. Anyone who agrees to participate in this study is free to withdraw from the study at any time with no penalty.

[To the Primary Investigator: Please use the second person “you” when completing the following explanations and use appropriate language no higher than the 7th grade level. Include the bold-face headings; these are intended for organizational purposes. All elements of the headings are to be included in this document.]

- 1. Nature and Purpose of the Project**
- 2. Explanation of Procedures**
- 3. Identification Of Any Experimental Medical Treatments Or Procedures**
- 4. Discomfort and Risks**
- 5. Benefits**
- 6. Confidentiality**
- 7. Explanation of compensation, if any. (If extra credit is being offered for participation in the research project, the amount of extra credit should be specified; an alternative project should be identified, requiring a comparable amount of student effort and offering a comparable amount of extra credit as the research project.)**
- 8. Name of person to contact in case of research-related injury**

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Committee through the OSR, 610-436-3310.

I have read this form and I understand it. I understand that if at any time I become uncomfortable with this project I am free to stop my participation. I understand also that it is not possible to identify all potential risks in an experimental procedure, and I believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks.

Signature

Date

Signature

Date

OBTAINING ASSENT FROM CHILDREN OR MINORS --

Parents, legal guardians, or a legally authorized official must sign consent forms permitting minors to participate in research projects. The Informed Consent Document for children or minors must be prepared with the same thoroughness as the Informed Consent Document for adults. An Informed Consent Document for children or minors must be completed by the child or minor’s parent/guardian.

Both children and minors are required to sign an “Assent” Form. The following are two samples of Assent Forms. Language must be simplified as appropriate for the age group used as subjects, such as:

SAMPLE ASSENT DOCUMENT FOR RESEARCH INVOLVING MINORS

(Note: This format is suggested by the HSC)

CHILD/MINOR ASSENT FORM

I, _____, understand that mom and dad have said it’s okay for me to take part in a project about _____ under the direction of _____ . I am taking part because I want to. I have been told that I can stop at any time I want to and nothing will happen to me if I want to stop.	
_____	_____
Signature	Witness by Parent/Guardian

***** OR *****

I, _____, understand that my parents have given permission for me to participate in a study concerning _____ under the direction of _____. My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time. If I choose not to participate, it will not affect my grade (treatment/care, etc., as appropriate) in any way.	
_____	_____
Signature	Witness by Parent/Guardian

For children unable to read and sign written assent forms, a verbal script for assent should be submitted in lieu of the above.

**LETTER OF CONSENT
(REQUEST FOR WAIVER OF STANDARD INFORMED CONSENT FORM)**

Dear _____,

I am a professor/graduate student under the direction of Professor Insert PI's name here, in the insert College/Department name here at West Chester University. I am conducting a research study entitled Insert the Project Title Here. The purpose of the research is to Insert a variation of the hypothesis statement or research question here.

You are being asked to participate in this study. Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, it will not affect your [or your child's] grade (treatment/care, etc.). The results of the research study may be published, but your [or your child's] name will not be used. Your participation will involve Insert a summary of the subject's role, including the expected duration of the subject's participation.

Although there may be no direct benefit to you (or your child), the possible benefit of your participation is Insert an explanation of the anticipated benefits of the study.

Insert an explanation of any anticipated discomfort or risks involved. Describe the procedures designed to minimize any risks.

If you have any questions concerning the research study [or your child's participation in this study], please call me [or Dr. Co-PI] at Insert phone number. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Committee through the OSR, 610-436-3310.

If this is to be attached to an anonymous questionnaire, include: Return of the questionnaire will be considered your consent to participate.

Sincerely,

Insert Your Name, Title
Department

* * * * * Alternate closing for Parental/Guardian Consent * * * * *

I give consent for my child/ward Insert child's name to participate in the above study.

Signature

Date

APPENDIX C: REVIEW AND APPROVAL CATEGORIES

It is the policy of WCU that the HSC will utilize Federal Department of Health and Human Services criteria for all projects involving human subjects in research when evaluating proposed research protocols. The chairperson or one or more HSC members designated by the chairperson may determine one of three actions: *Exemption From Further Review*, *Expedited Review*, or *Full Board Review*. The following section elaborates upon the types of HSC reviews.

I. Research Considered Under the “Exempt From Further Review” Category

In order to establish an individual research project as Exempt From Further Review, the principal investigator must complete the “Application for Approval of Investigations Involving the Use of Human Subjects” (located in Appendix A) and any appropriate informed consent documents (samples are located in Appendix B). Final determination as to whether a research project is Exempt From Further Review rests with the Chair of the HSC or his/her designee. If the project is certified Exempt From Further Review by the HSC, the principal investigator need not resubmit the project for continuing HSC review as long as there are no modifications in the exempted procedures. **Submission of an application is required even if the PI thinks the project should qualify as Exempt.**

A. The following categories are considered Exempt From Further Review:

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, or classroom management methods.
2. 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.
3. 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.
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. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under

those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

II. Research Considered Under the “Expedited Review” Category

The principal investigator shall submit the “Application for Approval of Investigations Involving Use of Human Subjects” (Appendix A). Research activities involving no more than “minimal risk” to subjects and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed by the HSC Expedited Review Subcommittee:

1. Collection (in a non-disfiguring manner) of hair, nail clippings, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
2. Collection for analysis 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. It also include such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays and microwaves).
4. Collection of blood samples by fingerstick or 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 who are in good health and not pregnant.
5. Voice recordings made for research purposes such as investigations of speech defects.
6. Moderate exercise by healthy volunteers.
7. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

8. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigation does not manipulate subject's behavior and the research will not involve stress to subjects.
9. Collection of both supra- and subgingival 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.

III. Research Considered Under the “Full Board Review” Category

Any research or training project involving the use of human subjects which does not fall into the “Exempt from Review” or the “Expedited Review” categories must be submitted to the HSC for a full board evaluation. The principal investigator must complete and submit the “Application for Approval of Investigations Involving the Use of Human Subjects” (Appendix A).

IV. Conditions Under Which HSC Approval is Not Required for Survey Research

Students wanting to collect data from human subjects as part of the requirements **for a specific class** may conduct **opinion research** that is not specific to the behaviors and/or experiences of the interviewees, as long as informants are not identifiable by name or description.

For example, HSC approval is **not required** for a student to survey people's opinions about topics such as the following:

- a. opinions of political candidates or issues
- b. opinions regarding American made vs. foreign-made products
- c. opinions concerning environmental issues or policies
- d. opinions regarding the subject's favorite television show, preferred vacation spot, musical preference, etc.

The key factor shared by these examples is that they do not require subjects to reveal anything about their personal experiences, behaviors, and/or identity. Therefore, the subjects are not considered to be placed **at risk** by their participation. Thus, in these cases, HSC approval is not required.

Class or course projects that will not be disseminated *beyond the university* do not need HSC approval.

APPENDIX D: FREQUENTLY ASKED QUESTIONS

1. What types of projects must faculty/student/staff submit to the HSC?

The human subjects review process applies to all research involving the use of human subjects. This applies to research that is funded or unfunded; research that is undertaken by faculty, staff or students at WCU; research done on the property of or using the facilities of WCU; and/or research using university personnel or students as subjects.

2. What types of course activities do not require HSC approval, and can I make that decision?

Course activities which use human subjects (including individuals outside the classroom setting) are exempt from review as long as the purpose is purely pedagogical and the results are intended solely for use within the university community. If the results have the potential for public dissemination, HSC approval must be obtained. Anonymous classroom assessment techniques of students for the purpose of improving classroom instruction would be considered exempt from HSC review. If the activities clearly fall within these criteria then the instructor/investigator could make this determination. If the instructor/investigator is not clear on the status of the project or would prefer that the HSC decide such status of the project, the instructor/investigator can submit the proposal to the HSC for review.

3. Do students undertaking a project as part of a class assignment require HSC approval?

Certain types of survey research, conducted as a portion of a specific course, do not require HSC approval. This includes research where the responses of participants are not identifiable by name or description, and where the survey is seeking opinions about various topics. In cases where the participant is not asked to reveal personal experiences or behaviors, HSC approval is not necessary.

When survey research is conducted as a portion of a class where a participant is asked to disclose identifying information, HSC approval is required. Further, survey research that seeks to identify participants only within a specialized population or investigates a variety of sensitive areas (available in the WCU Human Subjects Research Policy) requires approval.

For all student research conducted as a part of a course, the protocol must be reviewed and approved by the course instructor.

All other research conducted with human subjects as part of a course will require normal HSC approval.

4. My project involves a community partner. Do I need WCU HSC approval?

Partnering with a community member in no way alters the WCU employee's or affiliate's responsibility to participate in the HSC review process. All policies regarding the review and safeguards for research participants must be maintained in accordance with standard policy.

In some cases, a community partner may have their own institutional review board. In these cases, the community partner may require adherence to policies that are more protective of a participant's rights than WCU policy, and WCU employees would be expected to comply with those policies. If an outside review board sets policy that is less stringent than WCU policy, all employees will be required to adhere to the policy of WCU.

5. Who determines that a project is exempt?

Final determination as to whether a research project is exempt from HSC review is determined during the Technical Review process following initial submission.

6. What happens if my HSC application is not approved?

You are not authorized to start your project, but you may reapply with recommended changes.

7. What happens if I do not agree with the committee?

You may reapply with recommended changes.

8. I have a sponsored project for an outside organization that must be done within a tight time constraint. Do I need approval and if so, how long will it take? Will review force me to reject the funding?

Sponsored projects are treated as any other research projects. How long it takes depends on which level of review is required. Technical Reviews are conducted weekly. The normal review process on a complete application may take three to six weeks; modifications to the application will extend this process.

Yes, unless approved, funding may have to be rejected.

9. I submitted a protocol for review because it was part of an externally sponsored project. The external sponsor did not fund my project. What do I do?

Many agencies provide investigators with feedback about grant applications that are not funded. If you incorporate any of the suggested modifications into your research protocol, it will be necessary to obtain HSC approval on the new research protocol. Obviously, re-approval would be necessary with any change in the subject informed consent form.

If you decide not to conduct the research, you should inform the HSC in writing and the HSC file will be closed.

10. I intend to use some standardized intelligence test, (attitudinal or aptitude tests) in class for research purposes; do I need approval?

A protocol would need to be submitted to the HSC for Technical Review.

11. My potential subjects do not speak English in the home; how do I ensure they understand informed consent?

To obtain Informed Consent for a non-English speaker to participate in research, the subject should be asked in his or her own language for consent/assent to participate. The Informed Consent form should be written in the subject's home language. OR Consent of a guardian who speaks the subject's language and understands the subject's linguistic culture is needed for any non-English speaker because the subject is not capable of giving fully informed consent. Assent of a non-English speaker who is a minor may be obtained verbally however, if assent of the subject is to be obtained verbally, the submission should include a description of how the investigator will ask for assent from the minor subject.

Additional FAQ can be obtained from the following website of the Office for Human Research Protections (OHRP) in the United States Department of Health & Human Services (HHS):

<http://www.hhs.gov/ohrp/faq.html>

APPENDIX E: GUIDELINES FOR PARENTAL CONSENT

Research concerned with sensitive issues and involving the participation of minors is becoming more common. In Pennsylvania, individuals under the age of 18 are generally considered minors. Such research often presents difficult questions related to the protection of human subjects. The purpose of these guidelines is to help researchers plan procedures and prepare proposals that can be approved by the HSC.

RISKS

Research on health and social issues often involves requesting sensitive information from subjects, some of whom may be minors. The procedures for collecting and handling such data often do pose risks to the subjects. These risks may include some or all of the following:

1. **Violation of Privacy:** Collection of data concerning at-risk or socially questionable behavior (for example, questions about substance use or sexual activity) is viewed by many individuals as violations of privacy.
2. **Legal Risks:** Data concerning illegal behaviors may place individuals at risk of legal action, if (a) names can be linked to particular responses or observations and (b) the research has not received specific legal protection (e.g., by Certificate of Confidentiality).
3. **Psychosocial Stress and Related Risks:** Procedures that raise sensitive issues may generate stress for participants. For example, questions about at-risk behaviors may cause students to feel stress related to their self-image or contribute to perceived peer pressure.
4. **Social Relations:** Because relevant questions often request information about the behavior, or relations with, family members, peers, or authorities, some procedures may pose a risk to those relations if confidentiality is not adequately safeguarded.

In addition to these risks, which may be applicable to either minor or adult subjects, research involving minor subjects may also pose risks to parents or other family members. In particular, research soliciting information about at-risk behaviors of family members may place those individuals at legal risk. Furthermore, some parents may feel that their right to determine the activities of their children is violated if signed parental consent is not obtained.

PROTECTION

In general, protection from these risks may be achieved by (a) ensuring the confidentiality of information obtained about subjects, (b) providing access to or information about resources for coping with psychosocial stress caused by the research procedures, and (c) ensuring that the procedures meet the principles of voluntary participation and informed consent. Guidelines for achieving this protection include:

1. **Confidentiality and Anonymity:** Information is considered **confidential** when only the investigator has access to the identity of the individual about whom information is obtained. Information obtained from individual subjects must be kept confidential from public scrutiny, from parents and peers, and from legal and school authorities. This is most easily accomplished by collecting data in a manner that insures **anonymity**. Information is considered **anonymous** when names or other identifying information about individual subjects can at no point be associated with observations or with responses to a survey or other data collection instruments. However, anonymity is not always compatible with research goals (for example, when data collected from the same individual at different times must be linked for analysis). In these cases, procedures for protecting confidentiality must be fully spelled out. When information that might put subjects at legal risk is to be collected, it is the investigator's responsibility to obtain and document specific legal protection (e.g., by Certificate of Confidentiality obtained from a governmental agency).

2. **Psychosocial Stress:** The procedures needed to help subjects cope with psychosocial stress that may arise from participating in research will vary depending on the exact nature of the research. If such procedures are required, it will typically be sufficient to provide subjects with information about resources (e.g., counselors) available to them. In cases in which more severe stress seems likely, it may be necessary to ensure that someone qualified to handle such stress be present during data collection.

3. **Voluntary Participation and Informed Consent:** These are basic ethical principles for conducting research with human subjects. Subjects **must** be informed that participation is voluntary, that answers to specific questions may be withheld without penalty, and that they may withdraw from the research at any time. Because research of this type is often conducted in an institutional setting where subjects' presence is mandatory (e.g., the school classroom), it is especially important that procedures for meeting this requirement be made explicit in the proposal.

The procedure for obtaining informed consent must be documented; often this requirement can be met by informing subjects that responding to survey items constitutes permission to use the collected data, without identifying individual subjects, in published reports of the research.

PARENTAL CONSENT

A particular concern with research of this nature is the role of parental consent for the participation of minor subjects. The general requirement is that explicit parental consent be obtained in writing for each subject. However, there are situations in which such a consent procedure is not appropriate. The HSC **may** approve the research as meeting Federal requirements for exemption when **all** of the following conditions are met:

1. Data collection is **anonymous**; that is, at no point are subjects' names associated with information about them.

2. Data are collected as part of a required or elective education program in which subjects are already participating; for example, a school curriculum, school band, school sports, etc.
3. Participating in the research does not involve risks greater than those incurred by participating in the relevant educational program.

These conditions are not met, and parental consent **is** required, when:

1. A data base linking identifying information with responses is maintained, or subjects' identities can be otherwise linked to information about them; or
2. The research instruments elicit information about the behavior of specific individuals, rather than about conceptual knowledge covered by the educational program.

There may be additional exceptions to this requirement in other special circumstances. Such circumstances must meet criteria established by 45 CFR 46 at sections 116.d. and 408.c. Usually such exceptions are based on demonstrating one or more of the following:

1. That seeking parental consent increases the risk to subjects;
2. That no meaningful parental consent can be obtained; or
3. That the research cannot practically be conducted if parental consent is required (please note that "practically" here refers to insurmountable obstacles rather than the researcher's convenience).

Researchers are reminded that the reading level of informed consent documents should be appropriate to the typical educational background of the research population, and that documents designed for college students may not be suitable for seeking parental consent. Researchers should write these documents using short sentences and everyday language. For example, "voluntary participation" may be paraphrased by "you do not have to do this if you don't want to."

APPENDIX F: OBTAINING AND DOCUMENTING ASSENT FROM MINORS

Parental consent is usually a prerequisite to the recruitment of human research subjects who are minors. However, parental consent constitutes only half of the consent process. Assent, the agreement of a minor to participate in research, is the second component of the informed consent procedure for minors.

The means of obtaining assent from minors must be appropriate for the age ranges and levels of mental development found within the proposed subject pool. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research expects that assent be requested from children who are 7 years of age or older. However, for children between the ages of 7 and 18, the appropriate method for obtaining assent will vary.

Age 6-7 A simple oral description of the child's involvement is given to the subject and oral assent is requested. The procedure may be documented on the informed consent form by the presence of the signature of a witness.

Age 8-13 A more complete oral description of the research (in lay terminology) is given to the subject. Verbal assent is requested. The procedure may be documented on the informed consent form by the signature of a witness.

Above age 13 Written assent should be requested from both parent and child, using age-appropriate and background-appropriate documents.

Although age is used as the primary criteria in determining an appropriate means of obtaining assent, factors such as literacy and mental development must also be considered. The need for flexibility in the methods for obtaining assent from minors is universally recognized. Because a single method of obtaining assent may not be appropriate for all potential subjects, investigators may need to be prepared to use different approaches with different subjects. As in any consent process, the primary concern is that the subject is able to understand the explanation that is presented. The need for a witness to document verbal assent procedures is dependent upon the complexity of the research and the risks to the subject. Minor status may be defined differently by federal government agencies.

APPENDIX G: GUIDELINES FOR INTERNATIONAL RESEARCH INVOLVING HUMAN PARTICIPANTS

These guidelines are prepared as a brief overview of considerations when conducting research in international settings. The Human Subjects Committee (HSC) believes that culturally appropriate procedures are an important aspect of protecting participants in research. Because there are specific rules to be followed when conducting research involving human participants in countries other than in the United States, there are often local customs that are not usually considered in the HSC deliberations. These differences must be brought to the attention of the researcher. The guidelines contained in this document are intended to apprise researchers of the various issues that arise when conducting research with human participants in international settings.

1. When documents are translated into a language other than English, the researcher should provide a copy of the document in English, a copy in the language to be used in the document, and a letter from an individual (e.g., a WCU faculty member) indicating that the translated version of the document is complete and does not contain information that is not presented within the context of the English version of the document.
2. When human participants under the age of 18 are to be used in research, written, parental permission is required. If local customs and regulations are such that active parental permission would be culturally inappropriate, the researcher must supply the HSC with proof that such permission is not culturally appropriate. Examples of such proof would be: specific regulations (in English and certified to be accurate) that indicate that such permission is not required; an official letter from a ranking official in the country of interest indicating that such permission is not culturally appropriate; or being accompanied to the HSC meeting by another WCU employee (preferably a faculty member) who can attest to the cultural inappropriateness of the requirement for active parental permission. In those cases where seeking active parental permission for minors to participate in research is culturally inappropriate, a waiver of such permission may be granted at the discretion of the HSC, as long as the research does not place the participant(s) at untoward risk. Regardless, the participant(s) in the research retain(s) the right to discontinue participation, without penalty, at any time during the gathering of data.
3. If a waiver of active parental permission is granted, a letter informing the parents of the research, written at a literacy level that would be understood by the parents, must be prepared and sent to the parents by the most expeditious method possible.

Letter(s) of agreement from the appropriate official(s) (e.g., government officials, school officials, community officials, Chief Executive Officers, etc.) indicating that the research protocol and any and all instruments to be used (including any biomedical equipment) have been reviewed and are acceptable to those officials are to be submitted. The certification letter must be on letterhead stationary and carry an original signature.

5. When appearing before the HSC to answer questions about the research, it is helpful if an individual who is familiar with the culture (unless the researcher is recognized as an "expert") can accompany the researcher.
6. If data will be collected by someone other than the researcher, that individual or individuals must be identified and letters of agreement presented to the HSC. If the data collector(s) will have access to the data, such access must be specified.
7. Specific processes for assuring anonymity and/or confidentiality of all data must be specified, particularly if the analysis will occur away from WCU.
8. Processes for transporting data from the international location to WCU, with particular reference to #6 above, must be specified.