

# HUMAN SUBJECT COMMITTEE APPLICATION PACKAGE

The application package should be submitted in the following order:

1. Checklist completed and signed by the PI
2. Section I Project Information
3. Section II Detailed Protocol
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.

SUBMIT THE COMPLETED APPLICATION MATERIALS TO  
THE OFFICE OF SPONSORED RESEARCH (PAPER COPY)

OR BY E-MAIL WORD ATTACHMENT TO:

HUMAN SUBJECT COMMITTEE

[WCU-HumanSubjectCommittee@wcupa.edu](mailto:WCU-HumanSubjectCommittee@wcupa.edu)

(See Global Address Book)

<b>For OSR use only:</b>	<b>Grant Title:</b>
	<b>Sponsor Name:</b>
	<b>OSR PI Name &amp; File #:</b>

## CHECKLIST

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

Effective October 1, 2008, 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://www.nihtraining.com/ohsr/site/cbt/cbt.html> or <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protect> or <http://ohsr.od.nih.gov>

**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 \_\_\_\_\_.

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

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<i>Signature of Principal Investigator</i>	<i>Typed or Printed Name</i>
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<b>I. PROJECT INFORMATION (PLEASE TYPE)</b>		
<b>I.A.</b> <hr/> <i>Principal Investigator's Name/Phone Number</i> <hr/> <hr/> <i>Co-Investigator's Name</i> <hr/>	<b>I.B. College or Academic Unit:</b> <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 _____ <b>I.C. Project Period:</b> From: _____  To: _____	
<b>I.D.</b>		
<hr/> <i>Title of Project</i> <hr/>		
<b>I.E. If the Principal Investigator is a student, provide the following:</b>		
<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: _____	
<b>I.F.</b> Has this project previously been considered by the HSC? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, approximate date of review: _____		<b>I.G. Check if submission is a</b> <input type="checkbox"/> renewal <input type="checkbox"/> revision/resubmission <b>ID# of original submission:</b> _____
<b>I.H.</b> Are you applying for an exempt category? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, indicate the category number (# 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> _____ _____
<b>II.</b> 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		
<b>I.J.</b> 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>		
<b>I.K.</b> Has a proposal for external support been submitted? <input type="checkbox"/> yes <input type="checkbox"/> no <b>If yes, please provide the title of the proposal.</b> _____ 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*

C. **Approval by Departmental Chair or Equivalent, if applicable:** I am familiar with the requirements for Human Subjects Research as explained in the West Chester University Human Subjects Research Policy and confirm the accuracy of the information stated in this application. I have reviewed and approve the procedures involved in this protocol.

\_\_\_\_\_  
*Department Chair Signature followed by Typed Name*

\_\_\_\_\_  
*Date*

D. **Approval by Departmental Dean, if applicable:** I am familiar with the requirements for Human Subjects Research as explained in the West Chester University Human Subjects Research Policy and confirm the accuracy of the information stated in this application. I have reviewed and approve the procedures involved in this protocol.

\_\_\_\_\_  
*Department Dean Signature followed by Typed Name*

\_\_\_\_\_  
*Date*

E. **Advising Physician:** Physician signature is needed only if the project involves medical procedures and the investigator is not a licensed physician...

\_\_\_\_\_  
*Physician's Signature followed by Typed Name*

\_\_\_\_\_  
*Date*