

Office of Research and Sponsored Programs West Chester University | Wayne Hall

West Chester, PA 19383 | 610-436-3557 www.wcupa.edu

# **INSTITUTIONAL REVIEW BOARD APPLICATION PACKAGE**

The application package should be **one** Microsoft Word document assembled in the following order:

1. Section I: Project Information – Fill in all appropriate information and check all appropriate boxes under review categories.
2. Section II: Detailed Protocol – Concise, complete responses following each individually lettered request for information. Include all information requested.
3. Completed Checklist
4. Section III: Signatures (accepted forms of signature include: scans of original signatures, electronic signatures, and typed 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. CITI human subject training completion certificate. Please visit <http://www.wcupa.edu/research/irb.aspx> for more information.

Submission Instructions: Visit <http://wcupa.edu/research/irb.aspx> for more information.

1. Please e-mail complete application and all attachments as **one** Microsoft Word document to irb@wcupa.edu. A submission containing multiple files will not be accepted. The IRB 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.
2. Once your application passes initial vetting (2-4 business days), you will receive an e-mail stating that your application has been forwarded to a committee member for review. You will then be provided contact information for your reviewer and an estimated time for approval.
3. Any questions or concerns regarding your review can be sent directly to your reviewer.

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| \* All PI’s, co-PI’s, and faculty sponsors submitting a protocol to the IRB are required to provide evidence of CITI human subject training. Please Visit: <http://www.wcupa.edu/research/irb.aspx> for more information. Training must have been completed no more than 3 years from date of this application.  |

Please note:

* If you have any additions or changes in procedures involving human subjects, it is required to revise your IRB application with the amendments and submit to the IRB as a revision (i.e., under I.G. check off that the submission is a *revision*). Please note that your revised application will go through IRB office’s routine application processing. You cannot employ the revisions until you receive IRB approval of your revised application submission.
* Any and all adverse effects to the human subjects are required to be brought to the attention of the IRB immediately and in writing.
* All IRB protocols approved as Expedited or Full Board Review will be required to undergo a continuing review process at an interval that is no more than one year from the protocol approval date.

Any questions regarding this form can be directed to the Office of Research and Sponsored Programs at irb@wcupa.edu or 610-436-3557

WCU Institutional Review Board Application Form

**Section I: Project Information**

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| **Application Date:** |  |
| **Research Project Period:** From |  | To  |  |
| (Research cannot begin until IRB approval and analysis should be complete before closing the protocol) |

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| **I.A Principal Investigator Name:** |  | Email: |  |
| College: |  | Department: |  | Phone: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |
| Mailing Address (If PI is a student): |  |

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| **Co- Principal Investigator Name:** |  | Email: |  |
| College: |  | Department: |  | Phone: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |

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| **Co- Principal Investigator Name:** |  | Email: |  |
| College: |  | Department: |  | Phone: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |

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| **Research Team** |  |  |  |  |  |
| **Student Investigator Name:** |  | Role: |  | Email: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |
|  |
| **Student Investigator Name:** |  | Role: |  | Email: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |
|  |
| **Student Investigator Name:** |  | Role: |  | Email: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |
|  |
| **Student Investigator Name:** |  | Role: |  | Email: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |
|  |
| **Student Investigator Name:** |  | Role: |  | Email: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |
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| **I.D Title of Project:** |  |

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| **I.E If the Principal Investigator is a student, provide the following:** |  |
| **Faculty Sponsor:** |  | Email: |  |
| College: |  | Department: |  | Phone: |  |
| Date of IRB (CITI) Training: |  | (Must attach CITI completion report) |

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| **I.F Has this project previously been considered by the IRB?** | Yes: |  | No: |  |
| If yes, approximate date of review: |  |

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| **I.G For previously approved protocols only: Check if submission is a**  | renewal |  | revision |  |
| Protocol ID# of original submission: |  |

**I.H Review Category:**

Please check (or place an “X”) in **either Exempt, Expedited, or Full Board Review** based on the categories below the review designations. Mark any items that may apply under the selected review designation:

 \_\_\_ **Exempt Review** (based on the following categories):

 \_\_\_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.

 \_\_\_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.

\_\_\_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.

\_\_\_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.

\_\_\_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.

\_\_\_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.

**\_\_\_Expedited Review** **\*Skip this section if the Exempt category above applies.**

Does the Research Present **no more than minimal risk** to human subjects and involve only the procedures described in one or more of the categories below: (please choose)

\_\_\_Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b)from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

\_\_\_Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

\_\_\_Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

\_\_\_Collection of data from voice, video, digital, or image recordings made for research purposes.

\_\_\_Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

 \_\_\_**Full Board Review** (check if none of the above applies)

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| **I.I** If your project involves any of the following as subjects, please check: |
|  |  | pregnant women |
|  | prisoners or other persons under the supervision of the criminal justice system |
|  | children |
|  | fetuses |
|  | elderly persons |
|  | non-English speaking persons |
|  | persons with acute and/or severe mental or physical illness |

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| **I.J** Is this research being undertaken with any non-WCU organization? |  | Yes |  | No |
| If yes, name of cooperating institution:  |  |
| **If yes, attach letter of approval from the cooperating institution** |

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| **I.K** Has a proposal for external support been submitted?  |  | Yes |  | No |
| If yes, please provide the title of the proposal: |
| If yes, is notification of IRB approval required? |  | Yes |  | No |
| If yes, provide sponsors name: |

**Section II: Detailed Protocol: PLEASE PROVIDE COMPLETE ANSWERS TO THE FOLLOWING QUESTIONS:**

**(**NOTE: Please keep headings, and type or cut and paste your text below each heading.)

1. Provide a brief summary of the proposed research in lay terms**.** Include major hypotheses (if appropriate), research questions and research design.
2. 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?
3. Informed consent: Describe the consent process, or if you are applying for a waiver of consent, provide detailed justification for the requested waiver. Attach a copy of all consent documents after Section III, Signatures Page.

([see 45 CFR 46.116(c) and/or 45 CFR 46.116(d)](http://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013-title45-vol1-sec46-116.xml) for waiver guidelines.

1. Procedures: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.
2. 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.)?
3. Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.
4. Describe the anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result.

**CHECKLIST**

(Please complete checklist **after** completing application)

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| **I. Project Information** |
|  | All appropriate fields are filled in. |
|  | If this research is being undertaken with any non-WCU organization, a letter of approval from that organization is attached. |
|  | Copies of questionnaires, surveys, etc. are attached. |
| Is this protocol associated with an application for external funding? |  | Yes |  | No |
| **II.A. Summary** |
|  | Major hypotheses or research questions are provided (if applicable).  |
|  | Research design has been reviewed by faculty advisor if submitted by a student. |
| **II.B. Selection of Subjects Identified** |
|  | Source of subjects is identified. |
|  | Selection criteria are explained. |
|  | Contact method is explained. |
| **II.C Informed Consent Form** |
|  | All relevant Informed Consent Forms are attached. |
|  | Contact information for Office of Research and Sponsored Programs (610-436-3557) is included.  |
|  | Appropriate language is used (usually 7th/8th grade language) |
| **The following bold headings must be included and explained in each informed consent form:** |
|  |  | Nature and Purpose of the Project. |
|  | Explanation of Procedures. |
|  | Identification of Any Experimental Medical Treatments or Procedures. |
|  | Discomfort and Risks. |
|  | Benefits |
|  | Confidentiality |
|  | Explanation of compensation, if any. |
|  | Name of person to contact in case of research-related injury. |
|  | Withdrawal Notice is included. |
|  | Any special circumstances dictated by the research design are included.  |
| **II.D Procedure Outlined** |
|  | Step by step description of each procedure is provided. |
|  | Frequency, duration and location of each procedure are provided.  |
| **II.E Confidentiality** |
|  | Location of signed Consent Form originals is identified. |
|  | Method of storage is identified. |
|  | Names of people with access are listed. |
|  | The means for maintaining confidentiality are fully explained. |
| **II.F Risks** |
|  | Known or anticipated risks are explained. Possible side effects, use of placebos, risks of normal treatment, etc. are fully explained. |
| **II.G Benefits** |
|  | Anticipated benefits to the subject are described. |
|  | Importance of resulting knowledge is described.  |
| **Attachments:** |
| Identify attachments that have been included and those that are not applicable (n/a). |
|  | Attached |  | N/A | Copy of fliers, ads, posters, emails, web pages, letters for recruitment |
|  | Attached |  | N/A | Scripts of intended conversations to participants to introduce the research |
|  | Attached |  | N/A | Copies of IRB approvals or letters of permission from other sites |
|  | Attached |  | N/A | Copies of all instruments, surveys, focus group or interview questions, tests, etc. |
|  | Attached |  | N/A | NIH (or other vendor, i.e. CITI) Human Subject Training Certificate(s) – **REQUIRED** |

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| **III. Signatures** |
|  | Faculty sponsor has reviewed the application in its entirety |
|  | All required signatures are present |
| **Section III: Signatures** |
| **A.** | 1. 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.
 |
| PI Signature: |  | Date: |  |
| Co-PI Signature: |  | Date: |  |
| Co-PI Signature: |  | Date: |  |
| **B.** | **Approval by faculty sponsor (required when PI is a student):** |
|  | I have read this application in its entirety and affirm the accuracy of this application. 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 IRB. |
| *Signature* |  | *Date* |  |

**Insert Attachments here**