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**

**REVISED COMMON RULE**

*Effective 1/21/2019*

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. (must be on institution letter head with signature)
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 as Full Board Review and some expedited 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**

|  |  |
| --- | --- |
| **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: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 AMENDED categories):

 \_\_\_(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

 \_\_\_(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

\_\_\_(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

\_\_\_(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

\_\_\_ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a ***limited IRB review*** to make the determination required by §\_\_.111(a)(7)

\_\_\_(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

\_\_\_(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

\_\_\_(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

\_\_\_(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a ***limited IRB review*** to make the determination required by §\_\_.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

\_\_\_(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

\_\_\_(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

\_\_\_ (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.

**\_\_\_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: |
|  |  | prisoners or other persons under the supervision of the criminal justice system |
|  | children |
|  | fetuses |
|  | elderly persons |
|  | non-English speaking persons |
|  | individuals with impaired decision-making capacity |

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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 (signed on letterhead)** |

|  |  |  |  |  |
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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, please provide the funding source: |
| If yes, is notification of IRB approval required? |  | Yes |  | No |

**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. **OVERVIEW/PURPOSE:** Provide a brief summary of the proposed research in lay terms**.** Include brief background (with citations), major hypotheses (if appropriate), research questions, and research design.
2. **PARTICIPANTS:** Describe the source(s) of participants and the selection criteria. Include inclusion/exclusion criteria for selection and why this population is appropriate for the study. Include approximate number of participants. Also specifically, how will you obtain potential participants, and how will you contact them? As an Appendix - include a copy of all emails, flyers, advertisements, etc. that you will use to invite people to participate. Will any compensation or incentives be given for participation? If so, what?
3. **INFORMED CONSENT PROCESS**: Describe the consent process step by step, include who will be doing the consenting process, where, etc.

(or if you are applying for a waiver of consent, provide detailed justification for the requested waiver. ([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.)

Attach a copy of all consent documents as an Appendix after Section III, Signatures Page – do not include it in this section.

1. **PROCEDURES**: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure. Include specific information about the participants’ time and effort commitment. Also include all data collection instruments (e.g., surveys, questionnaires, scripts, data collection sheets, interview questions, audio/video recording methods). Explain how the data will be analyzed.
2. **CONFIDENTIALITY:** How will confidentiality of the data be maintained? Include the exact location (e.g., building and office number) of the signed originals of the Informed Consent Forms, the method of storage, and the names and titles of individuals having access to the consent documents and data. Specify the date for destruction of data (surveys, disks, etc.; must be a minimum of 3 years)? *(The faculty advisor should have full access and be able to produce the data in the case of an audit.)*

1. **RISKS & DISCOMFORTS:** Describe all known and anticipated risks to the participant that they may encounter in this research. (e.g. side effects, risks of placebo, deception, confidentiality breach) Include how you are mitigating them and how you will handle them in the event that they occur.
2. **BENEFITS:** Describe the anticipated benefits to participants by participating in this study. If there are none, please state that there is no direct benefit to the participant. Also, please state the importance of the knowledge that may reasonably be expected to result from this research study.

**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** |
|  | Background with supporting evidence |
|  | 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. |
|  | Include approximately how many. |
|  | Selection criteria are explained. |
|  | Contact method is explained. |
| **II.C Informed Consent Form** |
|  | Consent process described step by step. |
|  | Including location and who/how conducting consent process |
| **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.  |
| **APPENDIX Informed Consent Form** |
|  | All relevant Informed Consent Forms are attached. (in English and translated if necessary if participant population is non- English speaking population) |
|  | 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:** |
|  |  | Summary (must begin with a concise focused paragraph of key information) |
|  | 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.  |
|  |  |
| **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 |  |  | 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.
2. I certify that all information provided in this application is complete and correct.
3. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the West Chester University IRB.
4. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with West Chester University policies regarding the collection and analysis of the research data.
5. I agree to comply with all West Chester policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
	1. Conducting the project by qualified personnel according to the approved protocol
	2. Implementing no changes in the approved protocol or consent form without prior approval from the IRB
	3. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
	4. Promptly reporting significant adverse events and/or effects to the IRB in writing within 5 working days of the occurrence.
6. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise the IRB, by letter, in advance of such arrangements.
7. I agree to conduct this study only during the period approved by West Chester University IRB.
8. I will prepare and submit a renewal request and supply all supporting documents to the IRB before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the West Chester University IRB.
9. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above. |
| PI Signature: |  | Date: |  |
| Co-PI Signature: |  | Date: |  |
| Co-PI Signature: |  | Date: |  |
| **B.** | **Approval by faculty sponsor (required when PI is a student):** |
|  | 1. *By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.*
2. *I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.*
3. *I agree to meet with the investigator on a regular basis to monitor study progress.*
4. *Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.*
5. *I assure that the investigator will promptly report significant adverse events and/or effects to the IRB in writing within 5 working days of the occurrence.*
6. *If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the IRB by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.*
7. *I have read the application in its entirety and affirm the content accuracy, clarity, and methodology.*
8. *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.*
9. *I understand that I should have full access to the data and be able to produce the data in the case of an audit.*

 |
| *Signature* |  | *Date* |  |

**Insert Attachments here**