|  |
| --- |
| **DIRECTIONS:** This form must be submitted via email to irb@wcupa.edu and electronically signed. Complete all required sections and attach any supporting documentation to avoid delays in review. |
| Form Submission Date: |  | Original Approval Date: |  |
| 1. PROJECT TITLE | **PROTOCOL ID** |
|  |  |

|  |
| --- |
| 2. PRINCIPAL INVESTIGATOR (If PI or Faculty Advisor has changed, complete Appendix A) |
| Name (Last, First) |  | E-mail: |  |
| **Faculty Advisor (If Principal Investigator is student)**  | Name(Last, First) |  |
| E-mail: |  |

|  |
| --- |
| **3. Has the CO-INVESTIGATOR(S)/RESEARCH TEAM associated with this study changed?** ☐ Yes ☐ No 🡪 If YES, complete Appendix A |

|  |
| --- |
| **4. Have the EXTERNAL CO-INVESTIGATOR(S) & KEY PERSONNEL associated with this study changed? :** ☐ Yes ☐ No 🡪 If YES, complete Appendix A (non-WCU personnel only) |

|  |
| --- |
| **5. IF PROJECT IS CONTINUING: REQUIRED CITI TRAINING CERTIFICATIONS for all investigators are current** [ ]  Yes [ ] No **(CITI training must be within 3 years) Please insert your CITI Certifications at the end of this document** |

|  |
| --- |
| **6. FUNDING/OTHER SUPPORT** [ ] None [ ] Funded-same sponsor [ ] Funded New Sponsor (**If new sponsor, complete Appendix C**) |
| If there is a new, revised, or renewal grant application since the last IRB review, include a copy of grant application |

|  |
| --- |
| **7. LOCATION OF THE RESEARCH : Has the location of research changed,** ☐ No ☐Yes 🡪 **If YES complete Appendix D** |

|  |
| --- |
| **8. Is your current protocol approved as EXPEDITED or FULL?** [ ]  Expedited **🡪** Complete **Appendix B** [ ]  FULL |
| **Are you intending to continue to recruit/enroll new participants** [ ]  Yes (IF YES - see below) [ ]  No |
| **IF YES, please provide a revised informed consent form to comply with the updated 45 CFR 46 Common Rule that went in to effect January 21, 2019.** *This requires that there is a small paragraph of Key information presented at the beginning of the informed consent form. See page 7 of this document:* [*https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Comprehensive-Guide-to-Informed-Consent-Changes.pdf*](https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Comprehensive-Guide-to-Informed-Consent-Changes.pdf) |

|  |
| --- |
| **9. PROTOCOL STATUS** [ ]  Research is ongoing (including Identifiable Data Analysis) OR [ ]  Closed (**If CLOSED, must meet all requirements in Appendix E and be completed)** |

|  |
| --- |
| **10. Summary of Research Study (design, enrollment status, phase of study)** |
|  |

|  |
| --- |
| **11. Describe any adverse events (AE) and/or unanticipated problems involving risks to subjects on the study including the number of subjects involved. Include date AE/problem was reported to the IRB.** |
|  |

|  |
| --- |
| **12. Has there been any additional or new information made available on this study or related studies which may affect a subject’s willingness to continue participation in the study?** [ ]  No [ ]  Yes, and **explain below**  |
|  |

|  |
| --- |
| **13. Please provide a brief summary of the study results at this point in the space below.**  |
|  |

|  |
| --- |
| **14. Participant Enrollment & Drop Outs**  |
| Participants Entered (Must Equal GRAND TOTAL below) |  |
| 1. **Participant Status**
 |  |
| Active |  |
| Complete and in follow-up only |  |
| Complete- no further follow-up |  |
| (\*) Completed due to death during follow-up |  |
| (\*) Lost to follow-up |  |
| **TOTAL** |  |
| 1. **Participant dropped from study with explanation**
 |  |
| Voluntarily |  |
| By Investigator |  |
| Due to Adverse Events |  |
| (\*) Due to death during active phase of study |  |
| **Total Subjects Dropped** |  |
| 1. **Grand Total (sum of a + b)**
 |  |
| **Please explain any starred items here:** |

|  |
| --- |
| **15. If still recruiting participants, provide NEW CONSENT FORM as an Appendix** (Please submit copy of new consent form with highlighted Key Information Paragraph)  |

|  |  |
| --- | --- |
| **16. Investigator Signature:**  |  |

|  |
| --- |
| 17. APPLICATION CONTENTS  |
| Indicate the documents submitted for this continuing review. Check all appropriate boxes. |
| **[x]**  | **Continuing Review of Human Subjects Research Application** |
| [ ]  | Appendix A: Change in Study Personnel  |
| [ ]  | Appendix B: Expedited Review – Continuing Review  |
| [ ]  | Appendix C: Change in Funding  |
| [ ]  | Appendix D: Change in Location of Research |
| [ ]  | Appendix E: Close your research protocol |
| [ ]  | Complete Grant Application or Funding Proposal, if applicable - ***(new, revised, or renewals only)***  |
| **PI Comments:** |  |
| **IRB Approval Signature:** |  | **Type of Review:** |  |

**APPENDIX A**

**Change in Study Personnel**

|  |
| --- |
| **Complete this form to add or delete study personnel.**  |

|  |
| --- |
| **A: Add or Remove West Chester University PRINCIPAL INVESTIGATOR(S)**  |
| [ ] Add [ ] Remove Personnel Name (Last, First, MI): |  | E-mail: |  |
| Department: |  | College:  |  |
|  |  |  |  |
| [ ] Add [ ] Remove Personnel Name (Last, First, MI): |  | E-mail: |  |
| Department: |  | College:  |  |
|  |  |  |  |
| 1. Provide reason for change in PI and credentials:
 |
| 1. Has the sponsor or funding source of the study been notified of the change in PI?
 | [ ] Yes [ ] No [ ] N/A |
| **If No**, explain: |
| 1. Will the former PI continue to have a role in the research?
 | [ ] Yes [ ] No |
| **If Yes**, explain role (e.g., co-investigator, consultant, etc.): |

|  |
| --- |
| **B: Add or Remove West Chester University CO-INVESTIGATOR(S)**  |
| [ ] Add [ ] Remove Personnel Name (Last, First, MI): |  | E-mail: |  |
| Department: |  | College:  |  |
|  |  |  |  |
| [ ] Add [ ] Remove Personnel Name (Last, First, MI): |  | E-mail: |  |
| Department: |  | College:  |  |

|  |
| --- |
| **C: Add or Remove EXTERNAL CO-INVESTIGATOR(S)**  |
| [ ] Add [ ] Remove Personnel Name (Last, First, MI): |  |
| Organization: |  | Degree: |  |
| E-mail: |  | Phone: |  |
| Mailing Address: |  |
| [ ] Add [ ] Remove Personnel Name (Last, First, MI): |  |
| Organization: |  | Degree: |  |
| E-mail: |  | Phone: |  |
| Mailing Address: |  |

**APPENDIX B**

**Expedited Review Request**

|  |
| --- |
| **Complete this form to request expedited review for the continuing review of the research. If the research qualifies for expedited review, protocol review will be carried out by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB outside the convened IRB meeting.** **See** [**45 CFR 46**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) **and** [**21 CFR 56**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56) **for more information.** |

**Conditions required for expedited IRB review:**

1. The Federal Regulations establish two main criteria for an expedited review:
	1. The research may not involve more than "minimal risk." (This does not apply to category 8b.) "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” ([45 CFR 46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)(i) and [21 CFR Part 56.102](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)(i)).
	2. The entire research project must be consistent with one or more of the federally defined categories.
2. The categories in this list apply regardless of the age of the participants, except as noted.
3. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (This does not apply to category 8b.)
4. The expedited review procedure may not be used for classified research involving human subjects.
5. Investigators and IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review (i.e., expedited or convened) utilized by the IRB.

|  |
| --- |
| Indicate all categories that describe the research project. |

|  |  |
| --- | --- |
| [ ]  | 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. Research on drugs for which an investigational new drug application ([21 CFR Part 312](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312)) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
3. Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 |
|[ ]  1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
2. from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, 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.
3. from other adults and children (defined as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” [45 CFR 46.402(a)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402)), considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.
 |
|[ ]  1. Prospective collection of biological specimens for research purposes by non-invasive means.

Examples: (a) hair and nail clippings in a nondisfiguring 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. |
|[ ]  1. 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 participant or an invasion of the participant'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. |
|[ ]  1. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch 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)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101). This listing refers only to research that is not exempt.)
 |
|[ ]  1. Collection of data from voice, video, digital or image recordings made for research purposes.
 |
|[ ]  1. Research made 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](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
 |
|[ ]  1. Continuing review of research **previously approved by the convened IRB** as follows:
 |
|  |  |[ ]  1. Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; **or**
 |
|  |  |[ ]  1. Where no participants have been enrolled and no additional risks have been identified; **or**
 |
|  |  |[ ]  1. Where the remaining research activities are limited to data analysis.
 |
|[ ]  1. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the **IRB has determined and documented at a convened meeting** that the research involves no greater than minimal risk and no additional risks have been identified.
 |

**APPENDIX C**

**Changes in Funding**

|  |
| --- |
| **Complete this form to add or delete funding sources.**  |

|  |
| --- |
| **A: Add or Remove funding sources** |
| [ ] Add [ ] Remove funding source Sponsor: |  |  |  |

|  |
| --- |
| **B: Support other than monetary (e.g., drugs, equipment, etc.)** |
| [ ] Add [ ] Remove other source Sponsor: |  |  |  |
| Type of support: |  |  |  |

**APPENDIX D**

**Change in Location of Research**

|  |
| --- |
| **Complete this form to add or change in location of research.**  |

|  |
| --- |
| **C. List specific site(s) at which WCU research was or is being conducted**  |
| **Location Name (or description)** | **Address (street, city and state, or country)** |
|  |  |
|  |  |
|  |  |
|  |  |

**APPENDIX E**

**Protocol Closure Form**

|  |
| --- |
| **DIRECTIONS: Include as part of Continuing Review form and any closure correspondence.**  |

|  |  |  |  |
| --- | --- | --- | --- |
| Submission Date: |  | Original Approval Date: |  |
| PROJECT TITLE | **PROTOCOL ID** |
|  |  |

|  |
| --- |
|  PRINCIPAL INVESTIGATOR  |
| Name (Last, First) |  |
| **Faculty Advisor (If Principal Investigator is student)**  | Name(Last, First) |  |

|  |
| --- |
| In order to close this study, it MUST meet ALL of the following requirements: |
| [ ]  All subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing)  |
| [ ]  All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained)  |
| [ ]  No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary)  |
| [ ]  Analysis of subject identifiable data, records, specimens are complete (i.e., use or access to subject identifiable data is no longer necessary. Note: this includes review of source documents by study sponsors. |

|  |
| --- |
| Study is Closed / Terminated (No further enrollment; study is completed) |
| Effective Date: |  |
| Reason:  |  |
| Additional comments:  |  |

|  |  |
| --- | --- |
| **Investigator Signature:**  |  |

|  |  |
| --- | --- |
| **IRB USE ONLY:**  |  |

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