WCU Institutional Review Board (IRB)

Technical Review Form-2019

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol # *(IRB office only)*:** |  | **Review Date:** |  |
|  |  |  |  |
| **Primary Reviewer Name:** |  | **Secondary Reviewer Name:** |  |
|  |  |  |  |
| **IRB Application Title:**  |  |
|  |  |  |  |
| **Principal Investigator (PI):** |  | **Faculty Sponsor (if student PI):** |  |

**NOTE: Applicant will have 2 weeks to make changes to the IRB Application, per the comments below. Applicant will email the Reviewer and copy IRB@wcupa.edu with completed revisions OR email reviewer and IRB that applicant needs more time to respond, giving a specific completion date. At one month, without an email response from the applicant, the application will be considered withdrawn.**

|  | **Included/****Complete** | **N/A** | **Missing/****Incomplete** | **Comments:** |
| --- | --- | --- | --- | --- |
| **I. Project Information** |  |  |  |  |
| Date of application |  |  |  |  |
| Project period (no more than 1 year) |  |  |  |  |
| Review category |  |  |  |  |
| Letter of approval from cooperating institution, if applicable |  |  |  |  |
| Letter of acknowledgement from internal department/affiliation |  |  |  |  |
| Copy of external support proposal |  |  |  |  |
| Other  |  |  |  |  |
| **II.A. Summary** |  |  |  |  |
| Background with supporting evidence |  |  |  |  |
| Objectives/hypotheses  |  |  |  |  |
| Research design  |  |  |  |  |
| Other  |  |  |  |  |
| **II.B. Selection of Participants Identified** |  |  |  |  |
| Source of participants  |  |  |  |  |
| Selection criteria (inclusion/exclusion) |  |  |  |  |
| Contact method  |  |  |  |  |
| Approximately how many |  |  |  |  |
| Other  |  |  |  |  |
| **II.C Consent Process** |  |  |  |  |
| Consent process description |  |  |  |  |
| Waiver of consent/justification |  |  |  |  |
| Other |  |  |  |  |
| **II.D Procedure Outlined** |  |  |  |  |
| Frequency, duration and location of each procedure |  |  |  |  |
| Other  |  |  |  |  |
| **II.E Confidentiality** |  |  |  |  |
| Location of signed consent forms |  |  |  |  |
| Location of deidentified data |  |  |  |  |
| Method of storage (locked &/or password protected) |  |  |  |  |
| Names of people with access (specific names spelled out) |  |  |  |  |
| Data destruction date (minimum of 3 years) |  |  |  |  |
| Other |  |  |  |  |
| **II.F Risks** |  |  |  |  |
| Description of known or anticipated risks & how minimizing |  |  |  |  |
| Description of side effects, placebos, normal treatment, etc. & how handling |  |  |  |  |
| Other  |  |  |  |  |
| **II.G Benefits** |  |  |  |  |
| Anticipated benefits  |  |  |  |  |
| Importance of resulting knowledge  |  |  |  |  |
| Other |  |  |  |  |
| **III. Signatures** |  |  |  |  |
| Signatures included from PI and co-PIs |  |  |  |  |
| **IV. Consent Form** |  |  |  |  |
| Based upon WCU sample? |  |  |  |  |
| Readability (7th/8th grade language) |  |  |  |  |
| Summary of study: |  |  |  | New requirement for 2019 is that there is a small paragraph of Key information presented at the beginning of the informed consent form.  |
| Consent is being sought for participation & is voluntary |  |  |  |  |
| Purpose, expected duration, & basic procedures |  |  |  |  |
| Risks/discomforts |  |  |  |  |
| Benefits |  |  |  |  |
| Any alternative procedures if applicable  |  |  |  |  |
|  |  |  |  |  |
| Included the 9 bolded headings? |  |  |  |  |
| Required Items in Consent Form: |  |  |  |  |
| 1. Nature and Purpose of the Project

(A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental) |  |  |  |  |
| 1. Explanation of Procedures

(Description of procedures and a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |  |  |  |  |
| 1. Identification Of Any Experimental Medical Treatments Or Procedures (Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject)
 |  |  |  |  |
| 1. Discomfort and Risks

(A description of any reasonably foreseeable risks or discomforts to the subject) |  |  |  |  |
| 1. Benefits

(A description of any benefits to the subject or to others which may reasonably be expected from the research) |  |  |  |  |
| 1. Confidentiality

(A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained) |  |  |  |  |
| 1. Explanation of compensation, if any.

(For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained) |  |  |  |  |
| 1. Name of person to contact in case of research-related injury

(An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject) |  |  |  |  |
| 1. Statement about future use
 |  |  |  |  |
| Withdrawal Notice  |  |  |  |  |
| Other  |  |  |  |  |
| **OTHER APPENDICES:** |  |  |  |  |
| Questionnaires, surveys, etc. |  |  |  |  |
| Recruitment materials (scripts, flyers, etc.) |  |  |  |  |
| Current certification of *CITI Human Subject Research* online training for PI, co-PI(s), and any research assistant/individual participating in the project (NOTE: training must have been completed no more than three years prior to the application date)  |  |  |  |  |

Is the protocol to be returned to the PI for resubmission? **\_\_ \_** Yes **\_\_\_** No

This protocol qualifies for which of the following review categories?

**\_\_\_** Exempt

**\_\_ \_** Expedited

**\_\_\_** Full Board Review

 *\_\_\_\_Limited*