**William Carey University (WCU) Institutional Review Board (IRB)**

**Primary Application**

|  |
| --- |
| **For IRC Committee Only** (Applicants should not type or write in this section.) Approval Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approval Date: \_\_\_\_\_\_\_\_\_\_\_  Full Review Expedited Review Exempt from Review List the IRB Members involved in an expedited review, if applicable (Omit list for full reviews and exempted research):  **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_ (IRB Chair or Vice-Chair) |

**Table of Contents**

**Part A: Questionnaire**

**Part B: Agreements**

**Part C: Checklist**

**Part D: Attachments**

**Part A**

1. **Title of Research Project**

Response:

1. **Investigators –** The following contact information must be provided for the Principal Investigator (PI) and if applicable, the Faculty Research Advisor (FRA) and any Co-Investigators (CI) assisting with the Research Project [Co-Investigators are individuals assisting the PI with any aspect of the Research Project’s design, procedures, analysis, recruitment of subjects, reporting and/or summation, as well as the secure collection, storage, and maintenance of data.]. If a CI is not affiliated with William Carey University, then utilize the space provided to indicate their professional affiliation. If the PI is a student, then contact information for the Faculty Research Advisor (FRA) is also required.
	1. **Principal Investigator (PI):**

Name:

E-mail:

Phone:

WCU School/Department:

* 1. **Faculty Research Advisor (FRA):**

Name:

E-mail:

Phone:

WCU School/Department:

* 1. **Co-Investigator (CI):**

Name:

E-mail:

Phone:

WCU School/Department:

Professional Affiliation:

* 1. **Co-Investigator (CI):**

Name:

E-mail:

Phone:

WCU School/Department:

Professional Affiliation:

* 1. **Co-Investigator (CI):**

Name:

E-mail:

Phone:

WCU School/Department:

Professional Affiliation:

1. **Conflicts of Interest – Do any of the aforementioned Investigators (PI, FRA, and/or CI) have a Conflict of Interest in relation to this Research Project? If so, describe any potential Conflict of Interest. [Conflict of Interest can be summarized as (1) any personal, professional, authoritative, and/or financial relationship with potential human subjects and/or funding sources involved with the Research Project and (2) any personal, professional, and/or financial stake in the outcome of the Research Project.]**

Response:

1. **Funding – Describe any and all sources of funding associated with the Research Project. Please provide information such as the name of the funding source(s), the grant amount, the grant number, the grant’s duration, etc.**

Response:

1. **Purpose, Hypothesis/Research Question, & Justification**
	1. **Briefly describe the purpose of the Research Project?**

Response:

* 1. **What are the hypothesis/research question(s) of the Research Project?**

Response:

* 1. **Briefly describe the justification for conducting this Research Project?**

Response:

1. **The Use of Human Subjects in the Research Project –** Answer the following questions within Section VI if the Research Project will utilize the active participation of human subjects. The “WCU IRB Medical Treatment Supplemental Application” must also be submitted along with this application if the Research Project will involve any of the following: (1) obtaining human biological samples, (2) recording height, weight, blood pressure, temperature, or any other externally derived measure, (3) having subjects engage in physical activity, (4) obtaining medical information or history, and/or (5) administering biological, pharmaceutical, herbal, and/or dietary supplemental products to subjects.
	1. **Vulnerable Populations – Will the Research Project involve vulnerable populations as subjects? If so, describe these potential subjects. [Vulnerable populations include – but are not limited to - minors, fetuses, neonates, prisoners, pregnant women, the physically disabled, the intellectually impaired/diminished, and/or those who are educationally or economically disadvantaged.]**

Response:

* 1. **Consent – Describe the proposed instrument(s) to be utilized in obtaining *Informed Consent* from human subjects participating in the Research Project. Please address (1) Why was this instrument(s) chosen? (2) Are you also seeking *Broad Consent* related to the maintenance and future use of personally identifying information or bio-specimens? (3) How will you document the consent of participant subjects, e.g. signatures or verbal assent? (4) Why is this instrument(s) and its documentation appropriate? (5) What procedures will be in place for a participant subject to revoke consent? [All instruments of consent must be attached to this application.]**

Response:

* 1. **Sampling – Describe the rationale for the sample selection of human subjects utilized in this Research Project, e.g. age, race, gender, education, income, etc. Please address (1) What criteria must be met in order for one to be a potential subject? (2) What criteria would disqualify one from being a subject? (3) What is the sample size to be utilized, and why is this sample size appropriate?**

Response:

* 1. **Recruitment – Describe the methods that will be utilized to recruit human subjects. Please address such aspects as whether you will utilize paid media advertisements, free signage such as flyers/handouts, social media blasts, professional referrals, face-to-face invitations, etc.**

Response:

* 1. **Compensation – Describe any compensation used to recruit human subjects for the Research Project. Please address (1) What will be used as compensation? (2) Who will distribute compensation? (3) When and how often will compensation be distributed within the lifespan of the Research Project? (4) What happens regarding compensation if and when a subject opts out of the Research Project, i.e. will you seek reimbursement in-full, pro-rata, or not at all? (5) What controls will be instituted regarding an accounting of the disposition, possession, and distribution of the compensation used?**

Response:

* 1. **Disclosure – Will any information pertinent to the Research Project (procedures and instruments, the project’s overall results, the specific and personal results/effects of an individual’s participation) be intentionally withheld from subjects? Will subjects be intentionally misled in any way regarding any aspect of the Research Project? If so, describe the plans and rationale for withholding and misleading information.**

Response:

* 1. **Risks – Will subjects be exposed to any potential risk(s), e.g. compromised personal information, temporary or permanent psychological distress, and/or physical pain, discomfort, injury, illness, disability, and/or death? If so, please address (1) The potential risk exposure to subjects, (2) Methods for minimizing risk exposure, and (3) The specific responses to be taken by the researchers if any risk exposure occurs, e.g. What persons should be notified? What organizations should be notified? How should notifications be sent?.**

Response:

* 1. **Benefits – Might participating subjects be expected to realize any benefits as a result of participating in the Research Project? If so, please describe and explain these potential benefits.**

Response:

* 1. **Confidentiality – If you will be collecting personally identifying information and/or bio-specimens, describe how the privacy of participant subjects will be protected from breach in terms of data collection, analysis, maintenance, and reporting.**

Response:

* 1. **Anonymity – If you are not collecting personally identifying information and/or bio-specimens, please describe how the anonymity of participant subjects will be ensured in terms of data collection, analysis, maintenance, and reporting.**

Response:

1. **The Use of Archival/Retrospective Data in the Research Project** – Answer the questions within Section VII if the Research Project will utilize data obtained from outside sources
	1. **Confidentiality – If you will be collecting personally identifying information and/or bio-specimens, describe how individual privacy will be protected from breach in terms of data collection, analysis, maintenance, and reporting.**

Response:

* 1. **Anonymity – If you are not collecting personally identifying information and/or bio-specimens, please describe how personal anonymity will be ensured in terms of data collection, analysis, maintenance, and reporting.**

Response:

1. **The Organization of the Research Project –** In this section please explain the Research Project’s design, the procedures to be followed, the instruments/measurements to be utilized, and the manner in which data will be analyzed. In each subsection, be sure to explain why these methods and tools have been chosen and what makes them appropriate for this Research Project.
	1. **Design**

Response:

* 1. **Procedures**

Response:

* 1. **Instruments/Measurements**

Response:

* 1. **Analysis**

Response:

**Part B**

**AGREEMENTS: By signing this form the PI, and FRA if applicable, agree(s) to the following:**

1. All information provided as part of the WCU IRB Primary Application – as well as the WCU IRB Medical Treatment Supplemental Application, if applicable – represents a true, complete, and accurate description of this Research Project.
2. The PI/FRA will comply with WCU policies on research and investigation involving human subjects.
3. The PI/FRA will provide documentation of selection and informed consent procedures.
4. The PI/FRA will inform the IRB of any proposed changes in procedures that involve human subjects, giving the IRB sufficient time to review and approve such changes before they are implemented, and to supply IRB with such progress reports or annual assessments as it may require.
5. It is understood that any approval granted by the IRB applies to this project only and only under the conditions and procedures described in the application Parts A-D. Any change in the protocol or conditions set forth will require separate approval.
6. It is understood that the identification of human subjects in any publication is an invasion of privacy and requires the execution of a consent form. Informed consent must be obtained from each subject or the subject’s legally authorized representative. Documentation of the informed consent must be retained, in a secure environment, for a minimum of four years after the termination of the project.

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (Principal Investigator)

**If the PI is an undergraduate or graduate student, the student’s FRA for this research proposal must also sign the form.**

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (Faculty Research Advisor)

**Part C**

**Checklist: Some of all of the following may be needed in order to process your application in a timely manner. *Include a Part D for attachments following this checklist*. Please be diligent in adhering to the list in order to ensure you receive a timely reply.**

\_\_\_ The completed WCU IRB Primary Application, including Part D for all necessary attachments.

\_\_\_ CITI certificate(s) for all WCU students and faculty, and/or other evidence of research ethics training

\_\_\_ Research proposal approval (for students working on master’s thesis, specialist research project, or doctoral dissertation)

\_\_\_ All recruitment documents (as applicable: e.g., flyers, email content information)

\_\_\_ All cover-letter(s) or cover-letter information

\_\_\_ All instrument(s) and/or measurement instruments (e.g., surveys, interview questions, intake forms)

\_\_\_ All instruments of consent utilized by this Research Project

\_\_\_ The completed WCU IRB Medical Treatment Supplemental Application, if applicable

\_\_\_ HIPPA form, if applicable

\_\_\_ Any other supporting documents

It is expected that narrative sections be professionally and clearly written. To this end, please proofread all form entries and attached documents for grammar, spelling, punctuation, and completeness. Attention to these details will facilitate the review of your protocol by the IRB.

Please email the application and all supporting documents to irb@wmcarey.edu

Complete the application, scan as **one file** and email.  In the subject line of the email, type “IRB application – ‘Your Name.’”  IRB will respond within 15 working days.

**The PI/FRA will receive a response from the IRB within 15 business days of receipt of the application. This response will request more information or include electronic notification of the IRB’s decision.**