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

Social-Behavioral-Educational Application

For IRB 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)

Advisory

This application is only for projects that can be described as Social, Behavioral, and/or Educational. The "WCU IRB Clinical & Biomedical Application" should instead be submitted if at any point 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) actively collecting medical information or history, and/or

(5) administering biological, pharmaceutical, herbal, and/or dietary supplemental products to subjects.

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Part A: Questionnaire

I. Title of Research Project

Response:

II. 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. Student PIs must have an FRA.

[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.]

a. Principal Investigator (PI):

Name:

E-mail:

Phone:

WCU School/Department:

b. Faculty Research Advisor (FRA):

Name:

E-mail:

Phone:

WCU School/Department:

c. Co-Investigator (CI):

Name:

E-mail:

Phone:

WCU School/Department:

Professional Affiliation:

d. Co-Investigator (CI):

Name:

E-mail:

Phone:

WCU School/Department:

Professional Affiliation:

III. Conflicts of Interest – Do any of the Investigators (PI, FRA, and/or CI) have a Conflict of Interest related to this Research Project? If yes, explain why the conflict should not disqualify your protocol.

a. **Are any investigators *employed at any locations or by any organizations* at which the Research Project will take place?**
Response:

b. **Do any investigators have personal, professional, authoritative, and/or financial relationships with potential *human subjects*?**
Response:

c. **Do any investigators have personal, professional, authoritative, and/or financial relationships with potential *funding sources*?**
Response:

d. **Do any investigators have a personal, professional, authoritative, and/or financial *stake in the outcome* of the Research Project?**
Response:

IV. 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:

V. Purpose, Hypothesis/Research Question, & Justification

a. **Briefly describe the purpose of the Research Project.**

Response:

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

c. **Briefly describe the justification for conducting this Research Project.**
Response:

VI. The Use of Human Subjects in the Research Project

Section VI is only for protocols involving active collection by the investigators and active participation of human subjects in real time.

If your project is limited only to archival/retrospective data collected by others in the past, skip to Section VII and continue.

Complete *both* Sections VI and VII if your project involves active *and* archival/retrospective data collection.

a. **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:

b. **Consent –** All Research Projects involving human subjects must obtain *Informed Consent* from those subjects, and if applicable, their parent/legal guardian. If a Research Project will result in the maintenance and future use of personally identifying information or bio-specimens, then *Broad Consent* for such collection, maintenance, and use must also be secured. Describe the proposed instrument(s) to be utilized in obtaining consent from human subjects participating in the Research Project. Please address, for example:

- Why was this consent method(s) chosen?

- How will you document the consent of participant subjects (e.g. signatures or verbal assent)?
- Why is this consent method(s) and its documentation appropriate?
- What procedures will be in place for a participant subject to revoke consent?

All instruments of consent must be attached to this application.

Response:

c. 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, for example:

- What criteria must be met in order for one to be a potential subject?
- What criteria would disqualify one from being a subject?
- What is the sample population to be utilized, and why is it appropriate?

Response:

d. 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:

e. Compensation – Describe any compensation used to recruit human subjects for the Research Project. Please address, for example:

- What will be used as compensation?
- Who will distribute compensation?
- When and how often will compensation be distributed within the lifespan of the Research Project?
- What happens regarding compensation if and when a subject opts out of the Research Project? Will you seek reimbursement in-full, pro-rata, or not at all?
- What controls will be instituted regarding an accounting of the disposition, possession, and distribution of the compensation used?

Response:

f. Disclosure – Will any information pertinent to the Research Project (e.g., 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:

g. Risks – All Research Projects involve some level of risk to human subjects, including in the very least that experienced in daily life and data breaches.
1) Describe the risks your human subjects will face (e.g. compromised personal information, violation of privacy rights, concerns for job security, temporary or permanent psychological distress, and/or physical pain, discomfort, injury, illness, disability, and/or death).
Response:

2) What are your methods for minimizing these risk exposures?
Response:

3) What actions will you take if any risk exposure occurs?
Response:

h. Benefits – Might subjects expect to realize any benefits resulting from participation in the Research Project (unrelated to Compensation described earlier)? If so, please describe and explain these potential benefits.
Response:

i. Confidentiality – If you will be collecting personally identifying information, describe how the confidentiality of participant subjects will be protected from disclosure in terms of data collection, analysis, maintenance, and reporting.

Response:

j. Anonymity – If you are not collecting personally identifying information, please describe how the anonymity of participant subjects will be accomplished in terms of data collection, analysis, maintenance, and reporting.

[Achieving *Anonymity* is not limited to avoiding financial information and social security numbers. If you personally know the subject; if you interview the subject in-person or online; if you have the subject's name, address, or phone number; if you have the subject's Email; if you have the subject's financial data; if you have the subject's social security number; if you have the subject's medical information; or anything like these examples; it is not an anonymous protocol.]

Response:

VII. The Use of Archival/Retrospective Data in the Research Project – Answer the questions within Section VII only if the Research Project will utilize archival/retrospective human subject data collected by others in the past (i.e., the investigators are receiving access to other's data from the past).

a. Vulnerable Populations – Will the Research Project involve data that was collected from vulnerable populations in the past? If so, describe the 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:

b. Permission, Access, & Consent – Please address, for example:

- Why will you have the right to use this data? Who is granting you permission?
- How will you request access to this data?
- How will the data be made available to you?
- Will the data be de-identified before you receive it? If not, why not?
- Is it necessary to seek consent from the source-subjects of the data? If not, why not?

All permission and access request scripts must be attached to this application.

Response:

c. Sampling – Describe the rationale for the sample selection of human subject data you seek for this Research Project (e.g. age, race, gender, education, income, etc.). Please address, for example:

- What criteria make the source-subjects appropriate for this project?
- What is the sample population to be utilized, and why is it appropriate?

Response:

d. Risks – All Research Projects involve some level of risk to human subjects, including in the very least that experienced in daily life and data breaches.

1) Describe the risks your project poses to the source-subjects of your data (e.g. compromised personal information, violation of privacy rights, concerns for job security, temporary or permanent psychological distress, etc.).

Response:

2) What are your methods for minimizing these risk exposures?

Response:

3) What actions will you take if any risk exposure occurs?

Response:

e. Benefits – Might the source-subject population of this data realize any benefits resulting from your Research Project, even if unbeknownst to them (unrelated to Compensation described earlier)? If so, describe and explain these potential benefits.

Response:

f. Confidentiality – If you are receiving archival/retrospective data containing personally identifying information, describe how the confidentiality of the source-subjects will be protected from disclosure in terms of your collection, analysis, maintenance, and publishing.

Response:

g. **Anonymity –** If you are <u>not</u> receiving personally identifying information, please describe how the anonymity of source-subjects will be accomplished in terms of data collection, analysis, maintenance, and publishing.

[Achieving *Anonymity* is not limited to avoiding financial information and social security numbers. If you personally know the subject; if you interview the subject in-person or online; if you have the subject's name, address, or phone number; if you have the subject's Email; if you have the subject's financial data; if you have the subject's social security number; if you have the subject's medical information; or anything like these examples; it is <u>not</u> an anonymous protocol.]

Response:

VIII. 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.

a. **What is your Research Design?**

Response:

b. **What are your Research Procedures? This requires <u>details</u> about how your study will be carried out.**

Response:

c. **What Instruments & Measurements will you utilize?**

Response:

d. **What Data Analysis will you utilize?**

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 Social-Behavioral-Educational Application 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 Social-Behavioral-Educational Application, including Part D for all necessary attachments.

___ Up-to-date CITI certificate(s) for all WCU students and faculty, and/or other evidence of research ethics training (One is encouraged to take all courses applicable to their field and research; however, the PI must at least complete two courses: (1) the Responsible Conduct of Research course and (2) the Social-Behavioral-Educational human subjects research course.).

___ Research proposal approval (for students working on master's thesis, specialist research project, or doctoral dissertation)

___ All applicable recruitment documents

___ 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

___ HIPAA form, if applicable

___ Any other supporting documents the PI believes to be important

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.'"

The IRB will strive to respond to the PI within 20 business days. This response will either request more information or include electronic notification of the IRB's decision.