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

# Clinical & Biomedical 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 Clinical & Biomedical, meaning at any point the Research Project will involve one or more 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.

Projects that do not entail what is described above should instead use the "WCU IRB Social-Behavioral-Educational Application".

## Table of Contents

## 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*:

## Part B: Research Project Design

I. **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*:

II. **The Organization of the Research Project –** In this section please explain the Research Project's design and procedures. 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*:

III. **The Use of Human Subjects in the Research Project**

Section III is only for protocols involving <u>active</u> collection by the investigators and <u>active</u> participation of human subjects in real time.

If your project is limited only to archival/retrospective data or biological samples collected by <u>others in the past</u>, skip to Section IV and continue.

Complete *both* Sections III and IV if your project involves active *and* archival/retrospective data or biological sample 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 (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. 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*:

**h. Confidentiality –** If you will be collecting personally identifying information and/or bio-specimens, describe how the confidentiality of participant subjects will

be protected from disclosure in terms of data collection, analysis, maintenance, and reporting.

*Response*:

i. **Anonymity –** If you are not collecting personally identifying information and/or bio-specimens, 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*:

j. **Patient Safety -** All Research Projects involve some level of risk to human subjects, including in the very least that experienced in normal daily life and data breaches**.**

**1) Describe the risks your human subjects will face (e.g. compromised personal information; violation of privacy; job security concerns; temporary or permanent psychological distress; physical pain, discomfort, injury, illness, and disability; and/or death).**

*Response*:

**2) What are your plans for minimizing the risks to your human subjects (e.g., data security, patient training, safety equipment, investigator training, etc.)?**

*Response*:

**3) How and at what intervals will the safety of your human subjects be monitored? (e.g., vital signs, physical examinations, laboratory data, observation, interviews, etc.)**

*Response*:

**4) Describe all plans for responding to risk exposures and medical emergencies that might develop during the Research Project.**

*Response*:

**IV. The Use of Archival/Retrospective Data and/or Biological Samples in the Research Project** – Answer the questions within this Section IV only if the Research Project will also utilize archival/retrospective data and/or biological samples collected by others in the past (i.e., the investigators are not actively collecting new data themselves in real time but are instead receiving access to other's data or samples 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 rights to use this data/sample? Who is granting you permission?
- How will you request access to this data/sample?
- How will the data/sample be made available to you?
- Will the data/sample be de-identified before you receive it? If not, why not?
- Will you seek consent from the source-subjects of the data/sample? 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/bio-sample 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 <u>in the very least</u> that experienced in daily life and data breaches.

**1)** Describe the risks your project poses to the source-subjects of your data and/or biological samples (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 and/or biological samples with 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 not an anonymous protocol.]

*Response*:

## V. Screening, Monitoring, and Measurements

**a. Medical History Review –** Include all information (e.g., DOB, surgical history, comorbidities, etc.) that will be extracted from the subject's medical chart (paper or electronic) or via interview.

*Response*:

**b. Physical Examination –** Describe baseline evaluations to be conducted, including physical examination, demographic characteristics, etc.

*Response*:

**c. Vital Signs –** Describe measures that will be taken and how they will be made. (e.g., Will blood pressure be measured using an automated device or with an aneroid sphygmomanometer? Which arm will be used? Will the subject be sitting or lying down? Will more than one blood pressure measurement be made & averaged?)

*Response*:

**d. Blood Testing –** Provide detail and description if any blood sampling will be performed for laboratory evaluations (e.g., pregnancy testing, hemoglobin, hematocrit, RBC count, WBC with differential, etc.).

*Response*:

e. **Other Evaluations & Measures:** Describe <u>all</u> other rating scales, tests, psychological tools, laboratory evaluations, etc. not already covered previously on this application that you will utilize in this Research Project.

*Response*:

**VI. Efficacy Evaluations –** If applicable, describe the measures that will be used to assess the efficacy of the Research Project's intervention. In an observational study, assignment to the intervention is not made by the investigator. Note that the discussion of these evaluations is usually quite detailed. Please address, for example:

- What diagnostic tests, scales, measures, etc. will be utilized to evaluate efficacy?
- What will be the methods and schedules utilized to implement these diagnostic tests, scales, measures, etc.?

*Response*:

**VII. Pharmacokinetic Evaluation –** If applicable, describe all pharmacokinetic evaluations to be utilized by the Research Project. Please address such issues as the following, along with any other relevant details:

- What sampling method will be utilized?
- What will be your parameters?
- Will you utilize model-dependent or model-independent methods?

*Response*:

## <u>Part C: Safety Management Disclosure</u>

**Part C is an explanation of safety management, including important definitions and processes.**

**Please read carefully, keep *a copy* for your records, and refer to them if necessary in order to follow proper protocol should that become necessary.**

**This copy of Part C is to be initialed by the Principal Investigator (PI) beside all six numerals – indicating that the PI has read and understood its contents – then submitted with the entire application.**

***Initials***

**_____ I. Clinical Adverse Events (AE)**

Clinical AEs are to be monitored by the PI throughout a study.

**_____ II. Adverse Event Reporting**

The PI is responsible for recording and reporting unanticipated problems related to research that occur during and after study treatment. Serious adverse effects (SAE) will be reported. It is noted that "All on-site SAEs or related sites will be reported to the IRB in accordance with IRB policies. AEs that are not serious will be summarized in narrative or other format and submitted to the IRB at the time of continuing review".

When study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of a study (including SAEs), these will be reported to the IRB in accordance with IRB guidelines.

Unanticipated Problems Involving Risks to Subjects. AEs that are not serious, but that are notable and could involve risks to subjects will be summarized in narrative or other clear format and submitted to the IRB at the time of continuing review.

**_____ III. Definition of an Adverse Event (AE), what to report, and where to report**

An adverse event (AE) is any untoward medical occurrence in a subject who has received an intervention (drug, biologic, or other intervention). The occurrence does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable or unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

All AEs will be reported to the institution's IRB (see subsection V) and noted in the study records and any other required documents. Include

- the nature on the onset,
- date and time of onset,
- determination of non-serious versus serious adverse effects,
- intensity (mild, moderate, severe) of adverse effects,
- duration,
- causality, and
- outcome of the event.

**_____ IV. Definition of a Serious Adverse Effect (SAE), what to report, and where to report.**

An SAE is any adverse drug experience occurring at any dose that results in any of the following outcomes:

- Death,
- A life-threatening event (at risk of death at the time of the event),
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant disability/incapacity, or
- A congenital anomaly/birth defect in the offspring of a subject.

Important medical events that may not result in death, but be life-threatening, or require hospitalization may be considered a serious adverse drug event when based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

A distinction should be made between a serious adverse effect (SAE) and a *severe* adverse effect. A serious adverse effect (SAE) is a major event as described above. A *severe* adverse effect does not necessarily need to be considered serious, i.e. Nausea which persists for several hours may be considered *severe* nausea but not a SAE; however, a stroke that results in only a limited degree of disability may be considered a mild stroke but is quite obviously a SAE.

All SAEs will be reported to the institution's IRB (see subsection V), and noted in the study records, and on the case report form.

- **Relationship of SAE to study drug or other intervention**
  The relationship of each SAE to the study intervention should be characterized using one of the following terms in accordance with IRB Guidelines: *definitely, probably, possibly, unlikely* or *unrelated*.

## _____ V. IRB Notification of SAEs, AEs, and Other Unanticipated Problems

The PI will notify the WCU IRB Chair (irb@wmcarey.edu) of all SAEs, AEs, and Other Unanticipated Problems related to the research activity in accordance with the manner and timeline found within the chart below:

| Type of Unanticipated Problem | Initial Notification (Phone, Email, or Fax) | Written Report |
|---|---|---|
| All SAEs | 24 hours | Within 2 calendar days |
| All AEs | 7 days | Within 7 business days |
| Other Unanticipated Problems | N/A | Summary of important Other Unanticipated Problems may be reported at time of continuing review |

- **Follow-Up Report**
  If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator's assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history)

should be submitted to WCU's IRB. The WCU IRB investigator is responsible for ensuring that all SAEs are monitored until the situation is either resolved or stable.

**_____ VI. Investigator Report of a SAE to Sponsor**

Reporting must be consistent with regulatory or sponsor requirements.

## Part D

**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 Clinical & Biomedical 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-F. 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 E

**Checklist: Some of all of the following may be needed in order to process your application in a timely manner. *Include a Part F 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 Clinical & Biomedical Application, including Part F 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 Clinical & Biomedical 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.**