WEST COAST UNIVERSITY
Founded 1909

Institutional Review Board Application

(for research and investigation involving human subjects)

Please review the policy and procedures for the protection of human subjects prior to completing questions in this application. WCU Policy and Procedures for research involving human subjects may be found on the University central repository known as FRED.

This form is designed to describe proposed programs in which the investigator identifies if there will be justifiable risk or not to human participants. If any member of the Institutional Review Board (IRB) should require additional information, the investigator will be so notified.

Please submit the following: an Application, a specimen Statement of Informed Consent, and other documentation such as a Written or Oral Description Form, Survey, Questionnaire, Measurement Tool, etc. These documents should be submitted to the Chair of the IRB at least eight (8) weeks before the planned investigation starting date.

1. Title of the Research Study/Project

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2. Research Study Time Line

a) Projected Start Date:

b) Projected Completion Date:

Please note that the IRB approval is applicable for a maximum of one year from the final Board approval date. Research extending beyond one year requires re-submission and approval of an updated IRB Application including a completed Request for IRB Time Extension'form.

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3. Investigator: (Principal Investigator - AKA: Advisor, Faculty, Staff)

If this is a student project, the student is considered the "Student Investigator" and the advisor is considered the "Principal Investigator." The Principal Investigator has ultimate responsibility for the research being conducted.

Every researcher must submit a copy of a Human Research Protections training completion certificate with this application. WCU accepts Human Research Protections training certificates from either CITI, PHRP, or in-house. A completion certificate is valid for 3 years.

Principal Investigator:

School/Program:

Position (check one):

☐ Full-time Faculty

☐ Other:

E-mail:

Phone:

Address:

Required human subjects training:

☐ CITI ☐ PHRP ☐ In-house

Date of training:

Student Investigator/Co-Investigator:

School/Program:

Role in Study (specific activities, including recruitment and obtaining consent):

E-mail:

Phone:

Address:

Required human subjects training:

☐ CITI ☐ PHRP ☐ In-house

Date of training:

☐ **Co-Investigator OR** ☐ **Study Personnel**

School/Program:

Role in Study (specific activities, including recruitment and obtaining consent):

E-mail:

Phone:

Address:

Position (check one):

☐ Full-time Faculty

☐ Other:

Required human subjects training:

☐ CITI ☐ PHRP ☐ In-house

Date of training:

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4. Conflict of Interest

Do you or any of the investigators have a potential conflict of interest associated with this study?

☐ No

☐ Yes, please attach a disclosure statement as an addendum (Disclosure of Financial Interests of other conflict of interest)

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5. Funding

a) Is this a funded project?

☐ No, skip this section

☐ Yes, attach a copy of the grant without the budgetary information.

b) Does the study have a contract?

☐ No

☐ Yes, If yes, who or what official office is responsible for signing off on the contract?

Name, Address, and Phone Number of official office:

Note: The IRB cannot review this project if you answered yes, and you do not provide the name of the parties responsible for signing off on the contract

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6. Classification of the Study

a) Will primary data collection from human subjects be done in this study?

☐ Yes, original data only is collected from human subjects and no archival data will be used.

☐ Yes, both the original data from human subjects and archival data will be collected and used.

☐ No, only archival data will be used.

b) Are the research study results applicable and/or relevant to a larger population or only relevant to one organization or entity?

☐ Results are applicable to a larger population.

☐ Results are relevant only to one organization or entity.

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7. Data Usage and Ownership

If your research involves access to, and/or use of, a pre-existing private or restricted database (one that is not open access/publicly available), please briefly describe the type of data in the database, the organization or individual owner or controller of the data, how the data will be accessed and how data confidentiality will be ensured. Please note that permission to access and use of private or archival data for this study must be documented as an addendum to this application.

a) During data collection or subject recruitment, will access be needed to any health information created, received or achieved by health care providers, clearinghouses, or health care plans that pertains to the past, present or future health conditions or provision of health care to an individual living or deceased?

☐ Yes ☐ No

b) Will school or student related data be collected in this study?

☐ Yes, individual student data ☐ Yes, aggregate student data ☐ No

If so, please explain:

8. Project Description

Briefly explain and address the following questions as indicated:

a) Purpose and Anticipated Study Goal(s) and Benefits:

i) The purpose of the study:

ii) The anticipated study goal(s):

iii) The benefits of the study to the subjects, to the organization, and to society:

b) Will a pilot study be conducted before the primary data collection occurs?

☐ No ☐ Yes

c) What is the research methodology? Check one:

☐ quantitative analysis ☐ phenomenological study ☐ case study

☐ qualitative analysis ☐ mixed methods

☐ other (specify): _____

d) How will data be collected? Check any that apply:

☐ face to face interview ☐ focus group ☐ online survey

☐ mail survey ☐ telephone survey ☐ on-site survey

☐ e-mail survey ☐ Delphi method ☐ Skype or related technology

☐ instrumentation ☐ lab-based

☐ other (please specify): _____

e) Where will data collection occur? Check any that apply and specify the location below.

☐ WCU ☐ online ☐ private premises ☐ public facility

☐ open access site ☐ other ☐ not applicable

If the research is not taking place at West Coast University, please attach a permission letter signed by a person of authority at the site to this application.

f) What is the degree or magnitude of risk/stress (physical, psychological, emotional, legal, financial) to the human subjects because of their participation in this study?

☐ Minimal risk/stress, not greater than encountered in ordinary daily life/activities or routine tests

☐ Greater than minimal risk/stress with potential for direct benefit to the individual subjects

☐ Greater than minimal risk/stress with little/no potential direct benefit to individual subjects

g) If greater than minimal risk/stress to human subject is possible, please explain the severity and frequency of the risk, as well as how the risk/stress will be mitigated or lessened:

h) Are any third parties assisting with this study that will have access to the data?

☐ No

☐ Yes (specify):

i) Will any aspect of the study take place outside of the United States?

☐ No

☐ Yes (specify where):

Please note that IRB approval may be needed in the country where research is taking place.

PLEASE PROVIDE HERE (OR AS AN ADDENDUM TO THIS APPLICATION) ANY ADDITIONAL INFORMATION OR EXPLANATION THAT YOU THINK WILL BE HELPFUL TO THE IRB REGARDING YOUR RESEARCH STUDY DESIGN OR IMPLEMENTATION.

(continued from last page)

9. Subjects

a) Who are the subjects (inclusion and exclusion criteria) of this study and where are they located? (for example, PharmD students at WCU-LA)

b) What are the subjects expected to do as participants in this study and what is the time commitment involved? Include any possible risks. **Must be completed**. Do not attach an addendum. Speak directly about participants. You may use bulleted items to itemize the procedures specific to the participants.

(continued from last page)

c) If the research participants are WCU students:

i) Can students choose not to participate?

☐ Yes ☐ No

ii) Explain how you plan on avoiding student's feelings of undue influence for participation:

iii) Testing. Describe how often and why:

iv) Review and collection of student grades and standardized test scores. Describe what scores or grades will be collected.

v) Will you be observing and recording data on a faculty member or a student?

☐ on teacher ☐ on student

vi) Review of student coursework. Describe what course work will be reviewed and how student identity will be protected:

vii) Will the research activities occur during class time?

☐ No

☐ Yes (If yes, explain the role of the teacher):

viii) If class time will be used to conduct this study, will that time be a normal part of the course's educational activities as described on the syllabus? If not, how will the actual class tie be made up?

d) Will the subjects recruited to participate in this study include any that are in protected groups identified below as specified within the federal human subject guidelines? (The guidelines are defined at www.citiprogram.org).

If any category from this list is checked 'yes,' please explain in the 'Comments' area below how the subjects will be protected from harm, risk, or stress as a study participant and how stress/risk will be mitigated or lessened.

Children/minors under age 18?

☐ Yes ☐ No

Prisoners?

☐ Yes ☐ No

Pregnant women?

☐ Yes ☐ No

Cognitively impaired or mentally disabled?

☐ Yes ☐ No

Educationally or economically disadvantaged?

☐ Yes ☐ No

Will the subjects be traumatized, comatose, or terminally ill patients?

☐ Yes ☐ No

Will the subjects be elderly or aged persons?

☐ Yes ☐ No

Will information be withheld from subjects prior to, or during, participation?

☐ Yes ☐ No

Will the subjects be deceived, misled, or coerced in any way?

☐ Yes ☐ No

Will information be requested that is, or may be, personal or sensitive?

☐ Yes ☐ No

If the subjects are active duty military, will their supervisors have influence on their participation in this research or will participation be affected at all by the reporting relationship(s)?

☐ Yes ☐ No

Will any aspect of this study involve subjects from countries outside of the U.S.?

☐ Yes ☐ No

If yes to any of the above items, please explain how these risks will be mitigated:

10. Subject Recruitment and Selection: Briefly explain and address the following:

a) Which of the following will be used to find and recruit subjects? (Check all that apply and include copies with this application). **Please note that permission to recruit subjects from organizations must be documented and included as an addendum to this application (For WCU students, faculty, and staff recruitment, please contact Provost's office).**

- ☐ Flyers
- ☐ Events, meetings, conferences
- ☐ Phone solicitation
- ☐ Newspaper/radio/television
- ☐ Institutional "gatekeepers"
- ☐ Face to face interaction
- ☐ Bulletin board post
- ☐ Poster
- ☐ E-mail announcement
- ☐ Area canvassing
- ☐ Registry
- ☐ Referrals from others
- ☐ Direct mail
- ☐ Internet/websites
- ☐ Social media (ex. LinkedIn, Facebook, etc.)
- ☐ Other (please specify): _____

b) What is the anticipated sample size?

☐ 10 or less ☐ 11-20 ☐ 21-50 ☐ 51-99 ☐ 100-199

☐ 200 or more

Please justify sample size:

c) Will any external parties provide assistance for recruitment purposes?

☐ No

☐ Yes (please identify and explain how they will assist): _____

If yes, a completed Non-Disclosure Agreement should be appended to the application.

d) Are any of the research subjects, students, employees, or patients of the researcher?

☐ Yes ☐ No

f) Identify all persons who will be presenting the study to the participants. (This would include teachers, etc.)

PLEASE PROVIDE HERE (OR AS AN ADDENDUM TO THIS APPLICATION) ANY ADDITIONAL INFORMATION OR EXPLANATION CONCERNING THE ABOVE QUESTIONS THAT YOU THINK MAY BE HELPFUL TO THE IRB REGARDING THE RECRUITMENT OF SUBJECTS FOR YOUR RESEARCH STUDY.

(continued from last page)

11. Informed Consent: Briefly explain and address the following questions.

In addition, please include (as an addendum to this application) a proposed Informed Consent form. Please ensure that the reading level of the Informed Consent language is at the 7th to 8th grade level. Unless the study is done over the phone, all consent and/or withdrawal should be documented in writing. If either is given over the phone, please keep a detailed Phone Consent Form in order to document said consents and/or withdrawals.

a) How will subjects be informed of the study's purpose, procedures, intent, duration of the study, and any potential risks or discomforts to them? Check all that apply:

- ☐ Informed consent form
- ☐ E-mail
- ☐ Letter
- ☐ Meeting
- ☐ Phone Call
- ☐ Other

If ŏther,'please specify:

b) How will subjects be informed of withdrawal procedures? Check all that apply:

- ☐ Informed consent form
- ☐ E-mail
- ☐ Letter
- ☐ Meeting
- ☐ Phone Call
- ☐ Other

If ŏther,'please specify:

c) How will the researcher contact information be provided to the subjects? Check all that apply:

- ☐ Informed consent form
- ☐ E-mail
- ☐ Letter
- ☐ Meeting
- ☐ Phone Call
- ☐ Other

If ŏther,'please specify:

d) How will subjects withdraw from the study as participants after data collection is completed?

☐ E-mail the researcher ☐ Phone call to researcher ☐ Submit withdrawal form

☐ Other

If ŏther,'ƥlease specify:

e) Please explain what subjects must do to withdraw from the study after data is collected and how subject data will be retrieved and handled to ensure security and confidentiality.

f) If any subjects are under the age of 18 years, parental consent is required. What provisions are made to answer any questions the parents have about this study or to address any individual concerns? (For example, will there be an informational meeting with the parents, etc.?) If this scenario does not apply to this study, please indicate "not applicable" here.

g) Describe who will conduct the verbal consent process if needed?

i) Explain what will be said to the participant during the verbal consent process. If your study is a telephone survey or interview, you must include a telephone script.

ii) From the following table please check all that apply. Prepare and attach forms/scripts for review:

- ☐ PARENTAL CONSENT - If the research is on a minor, parental consent is required. If minors are over 12 they can sign parental consent if consent is written at a low literacy level.
- ☐ INFORMED CONSENT - Adults
- ☐ ASSENT WRITTEN - If child is ages 12-17, a written assent is required
- ☐ ASSENT-WITHIN PARENTAL CONSENT
- ☐ ASSENT - VERBAL - If child is ages 7-11, a written assent or verbal assent is required. Script is needed for verbal.

PLEASE PROVIDE HERE (OR AS AN ADDENDUM TO THIS APPLICATION) ANY ADDITIONAL INFORMATION OR EXPLANATION THAT YOU THINK MAY BE HELPFUL TO THE IRB REGARDING ANY OF THE ABOVE QUESTIONS OR ABOUT THE INFORMED CONSENT FOR YOUR RESEARCH STUDY.

PLEASE READ AND CONFIRM THROUGH CHECK MARKING THE BOXES BELOW:

☐ I attest that no primary data collection from human subjects will occur without a prior signed Informed Consent form completed for each subject and that Informed Consent documentation will be retained separately from study data.

☐ I attest that a process for subject withdrawal will be implemented whereby subjects may withdraw without penalty before, during and after data collection has been completed and submitted and that the information they provided will be identified, secured, withdrawn and kept confidential.

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12. Confidentiality and Privacy: Briefly explain and address how the identity and privacy of the individual subjects will be protected. Check any of the following that apply:

a) How will subject identity and data will be protected?

☐ Subject names will not be used or identified

☐ Pseudonyms or numbers will be used instead of subject names

☐ Data will be coded alphanumerically

☐ Other (please specify): _____

b) Will any audio and/or video tape or other recording of data be done in this study?

☐ Yes ☐ No

c) Describe how the confidentiality of the study records will be maintained and protected.

d) How long will study data be kept after study completion?

☐ Three years (please note this is the minimum required retention time)

☐ More than three years

e) Where will the data be stored:

- [ ] In an office or other location at the researcher's residence
- [ ] At an office at the researcher's place of employment
- [ ] At a third party facility
- [ ] Other

If ät a third party facility'or öther,'please specify:

f) How will data be destroyed at the appropriate time?

- [ ] Shredding
- [ ] Burning or incineration
- [ ] Smashing
- [ ] File deletion
- [ ] Other

If öther,'please specify:

g) Will there be a link to identify subjects?

- [ ] Yes
- [ ] No

Please explain:

h) How will the results of this study be disseminated?

- [ ] Publication
- [ ] Presentation
- [ ] Other (please specify):

PLEASE PROVIDE HERE (OR AS AN ADDENDUM TO THIS APPLICATION) ANY ADDITIONAL INFORMATION OR EXPLANATION CONCERNING THE ABOVE THAT YOU THINK MAY BE HELPFUL TO THE IRB REGARDING CONFIDENTIALITY AND PRIVACY CONCERNS ASSOCIATED WITH YOUR RESEARCH STUDY.

PLEASE READ AND CONFIRM THROUGH CHECK MARKING THE BOX BELOW:

☐ I attest that the data from this research will be kept in a secured location for at least three years following study completion, and then will be permanently destroyed.

13. Compensation/Extra Credits

Will the participants receive any compensation or extra credit?

☐ Yes ☐ No

Will the participants receive monetary compensation?

☐ Yes ☐ No

If yes, in what amount and how will it be distributed?

Will the participants receive gift card/certificate compensation?

☐ Yes ☐ No

If yes, in what amount and how will it be distributed?

Will the participants receive extra credit?

☐ Yes ☐ No

If yes, in what amount and how will it be distributed?

Will the participants receive compensation or extra credit in another way?

☐ Yes ☐ No

If yes, please specify, provide the amount and how will it be distributed.

14. Risks

i) Are there any of the following risks associated with the research? Check all that apply:

- ☐ A. Use of identifiable audio or video for data collection
- ☐ B. Use private records including: educational records or medical charts
- ☐ C. Economic risk
- ☐ D. Physical risk
- ☐ E. Psychological risk
- ☐ F. Legal risk
- ☐ G. Social risk
- ☐ H. Collection of information that would be reportable to authorities or collection of information that might render the subject prosecutable under the law (e.g., child abuse, alcohol abuse by a pregnant woman, danger to self or others)

If you checked any boxes above, describe the nature of the risk of harm for each using the corresponding letter. (These risks must be presented in the consent statement or cover letter):

ii) What direct and societal benefits do you expect the subjects you enroll to get from this study? If there is no direct benefit to the subjects, simply state that there will be no benefit to the subjects enrolled.

iii) Have you notified all areas (personnel and facilities) that need to be prepared to assist you in your research? For example: school counselor, school secretary, principal, etc.

- ☐ N/A
- ☐ Yes, please list area and contact person's title:

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15. Submission Checklist:

Use the checklist below to assist you in determining what items you may need to include in your IRB submission.

- ☐ Consent Form
- ☐ Assent Form
- ☐ Implied Consent
- ☐ HIPPA Waiver
- ☐ Disclosure of Financial Interest
- ☐ Recruitment Materials
- ☐ Grant Application
- ☐ Information/Cover Letter
- ☐ Advertisement(s)
- ☐ Waiver of signed Consent
- ☐ Contract
- ☐ Letter of Collaboration
- ☐ Survey Questionnaire(s)
- ☐ Certificate of completion, IRB required training (e.g., CITI, PHRP, In-House)
- ☐ Permission Letter - Waiver of Consent
- ☐ Permission Letter - Additional IRB Review
- ☐ Other Documentation
- ☐ Subject Demographic Data Collection Form/Sheet

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16. Responsibilities and Assurances:

Please fill out below (Title of study and name of investigator(s)

Title of Study:

Investigator(s) Name:

By signing below, I attest that the information provided in this form is correct. I agree to seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedure, co- investigators, consent statements, survey/interview questions, etc. I will immediately report any unexpected or unanticipated problems or incidents that occur during the study. I will report in writing any significant findings which develop during the course of the study which may affect the risks and benefits to the participants. I will not begin my research until I have received approval from the IRB. I will abide by the IRB requests for report on the status of the study. I will maintain the records and documents of this research for a minimum of three years from the completion of the study. If there is a grant associated with this research, it completely reflects what is contained in this application. If the above conditions are not met, I understand that approval of this research could be suspended or terminated.

Principal Investigator Signature:

Signature: Date:

Student Investigator Signature:

Signature: Date:

Co-Investigator Signature:

Signature: Date:

Advisor and Department Chair Assurances:

By signing below, I attest that I reviewed the above application and find the research is scientifically and scholarly sound and that competencies and resources are adequate.

Advisor (for Student Investigator) Signature:

Signature: Date:

By signing below, I attest that I reviewed the above application and find the research is scientifically and scholarly sound and that competencies and resources are adequate.

Department Chair Signature:

Signature: Date:

FOR COMPLETION BY WCU IRB

This application has been reviewed by the West Coast University IRB with the following decision:

- ☐ Full Board Review
- ☐ Expedited Review
- ☐ Exempt
- ☐ Non-Exempt
- ☐ Deferred
- ☐ Initial Approval with Conditions*
- ☐ Not Approved

**Changes or modifications/conditions for initial approval, or reasons for non-approval:*

NOTE: This application is effective for one year from the date of finalized IRB approval.

Reviewer #1's Name:

Reviewer #1's Signature:

Date:

Reviewer #2's Name:

Reviewer #2's Signature:

Date:
