Appendix A



Instructions for Submission of Documents to IRB

1. Complete the Application Form (Attachment 1).
2. Complete the Consent Form (Attachment 2).
3. Complete the Request for Exemption from Review Form (Attachment 3).
4. Complete Research Design and Methodology Document (Attachment 4).
5. Complete Research Questions Document, if applicable (Attachment 5).
6. Submit 5 attachments to Program Director/Dean of Doctoral Studies or IRB@wciu.edu

Attachment 1

IRB Application Form

Request for Consideration of Human Studies

(All items must be completed by Principal Investigator. If Not Applicable, explain why)

Principal Investigator’s (PI) Name:

PI WCIU Email Address:

PI Mailing Address (please provide complete address, including zip code):

PI’s Phone Number:

Course Instructor or University Supervisor:

Other Investigator(s) – please list (if applicable):

Non-WCIU persons involved:

Research Title:

Level of Review (please highlight and underline 1): Full Expedited Exempt

Duration of Study:

Request Start Date (must follow IRB approval):

Request End Date (must follow IRB approval):

Location of Research (if **international** – kindly refer to and comply with guidelines via <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>, an e-copy of this document is also available from WCIU’s IRB):

External sponsor or funder (if applicable):

Purposes/Objectives of Research:

Is this study a part of a doctoral dissertation? Yes No

If yes, please attach your proposal.

Overview of Research Design and Methodology (additional details to be filled out in Attachment 4):

Potential Risks for Human Participants:

* For additional details on principles of professional responsibility and ethics, please refer to American Anthropological Association’s (AAA) Statement on Ethics: <https://www.americananthro.org/LearnAndTeach/Content.aspx?ItemNumber=22869>

How Risks will be minimized:

Anticipated benefits of study:

Plan to obtain Informed Consent:

Confidentiality of Data:

To be completed by IRB Reviewer:

Research:

Date Submitted:

IRB Checklist Completed:

Notification sent to PI:

IRB Reviewer:

Date:

Attachment 2

**Consent Form for Participation in Research and**

**The Subsequent Use of Data in a Research Project**

I consent to participating in the research project/study being conducted by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ focusing on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. In case of additional information or questions, I may contact the researcher(s) at: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ .

I understand the purpose of this study is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ .

I understand that I will participate in an interview and the interview will be audio recorded. I understand that my participation is voluntary and that I can withdraw at any time without penalty, and that I will be exposed to no risk. I further understand that my participation will last only \_\_ minutes and that I may refuse to answer some questions.

I understand that my identity will be kept confidential by the researcher. I further understand that the raw data will be shredded and deleted \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and the aggregate data will appear in the final copy of the study.

I understand that the results of this study may be presented at a professional conference, or otherwise reported to academic bodies, but that my identity will in no way be revealed in such a report.

For further information about the research project, the researcher, or my rights as a participant, I may contact Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_ at E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ or Telephone Number: \_\_\_\_\_\_\_\_\_\_\_\_

Or I may contact the Institutional Review Board of William Carey International University at IRB@wciu.edu

NAME OF PARTICIPANT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attachment 3

Request for Exemption from Review

Please check the reason you believe this study is exempt from review.

#### \_\_\_\_\_\_\_\_\_ Category 1 – Education research

Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students’ opportunity to learn or assessment of educators

**Examples:**

* Evaluating the use of accepted or revised standardized tests
* Testing or comparing a curriculum or lesson

#### \_\_\_\_\_\_\_\_\_ ****Category 2 – Surveys, interviews, educational tests,********public observations****

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior and:

* Recorded information cannot readily identify the subject (directly or indirectly/linked) **OR**
* Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)

##### ****Examples:****

* Surveying teachers, nurses, or doctors about a technique or an outcome
* Interviewing managers about a management style or best practice
* Conducting a focus group about an experience or an opinion of a community program

#### ****\_\_\_\_\_\_\_\_\_\_** **Category 3 – Benign Behavioral Interventions****

Research involving Benign Behavioral Interventions through verbal, written responses, (including data entry or audiovisual recording**)**from **adult** subjects who prospectively agrees and ONE of following met:

* Recorded information cannot readily identify the subject (directly or indirectly/linked) **OR**
* Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)

#### ****Example:****

* Solving puzzles under various noise conditions
* Playing an economic game
* Being exposed to stimuli such as color, light or sound (at safe levels)
* Performing cognitive tasks

#### ****\_\_\_\_\_\_\_\_\_\_** **Category 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens****

Secondary research with identifiable Information/specimens collected for some other initial activity, if**ONE of following**:

* Biospecimens or information is publically available
* Information recorded so subject cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects
* Collection and analysis involving Investigators Use of identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”
* Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities

#### ****Example:****

* Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers

#### ****\_\_\_\_\_\_\_\_\_\_ Category 5 –**** Federal research or demonstration projects

Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.

* Federal agencies must publish a list of projects covered by this exemption prior to research commencing

#### ****\_\_\_\_\_\_\_\_\_\_ Category 6 – Taste and food quality evaluation studies****

Taste and food quality evaluation and consumer acceptance studies,

* if wholesome foods without additives are consumed **OR**
* if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
1. \_\_\_\_\_\_\_\_\_\_ Category 7 Use of anonymous experiments or/and behavioral tasks that are already published in the literature.

### **Research that doesn’t fit an Exempt Category**

What if a research activity does **not** fall into on of the exempt categories?
The research is probably not exempt and must be submitted for **Expedited** / **Full Board** review.
Research is not exempt if it:

* is greater than minimal risk \*
\* minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. or;
* involves administration or use of drugs or devices.

Attachment 4

Research Design and Methodology

1. **Research Title:**
2. **Investigator(s):**
3. **Research Description -** In this study I will address the following Research Question(s):
4. **Statement of Research Goals and Intended Outcomes**

**5.   A timeline indicating key points in the Research**

1. **Research Design and Methodology (PLEASE provide full details and if interviews are needed, please complete Attachment 5):**

Attachment 5

Research Interview Questions (if applicable)

Research Title:

Research Question(s):

Interview Questions: