Standard Operating Procedures
Institutional Review Board
William Carey University

Revised May 2019

I. Purpose and Scope of the Institutional Review Board:

The Institutional Review Board (IRB) of William Carey University (WCU) has been formally designated to approve, require modifications to secure approval, or disapprove all human subjects research activities overseen and conducted in accordance with Title 45 of the Code of Federal Regulations, Part 46 and the Belmont Report of 1979 (see Section VIII) as well as the standards set forth in the Mission of the University.

The IRB reviews and monitors any investigation involving human subjects conducted by faculty, staff, and/or students, or which utilizes facilities and resources of the University. This includes, but is not limited to, human subjects utilized in association with:

1. Research methodology classes;
2. Research for course credit;
3. Research investigations by students required for degree completion;
4. Research conducted in association with another institution;
5. Research conducted in another country.

IRB approval must be obtained before commencing any research involving human subjects. WCU risks losing federal funding if investigators perform research on human subjects without the appropriate IRB approval. Even more importantly, it is consistent with the Mission of the University that the rights and welfare of all subjects involved in research by WCU faculty, staff, and students are protected and ensured.

II. Composition and Governance of the Institutional Review Board:

The IRB of William Carey University is composed of at least five faculty members from various schools of the University, with at least two members being graduate faculty members. Members are chosen with attention to the balance between members with and without scientific backgrounds. By regulation the IRB includes at least one member who is not otherwise affiliated with WCU and is not part of the immediate family of a person who is affiliated with WCU and one member who serves as a non-scientist. The Chair and members of the committee are appointed by the Committee on Committees of the University, with the Provost's input. The IRB reports to the Provost.
Following the appointment of any new members, the Chair of the IRB will conduct an orientation session to include topics such as: research compliance, evaluation and processing of protocols, meeting procedures, and expectations of an IRB member. Additionally, new members will receive a binder of reference materials to include a copy of these guidelines and other important documentation.

Within 30 days of the orientation session, all new members must complete the appropriate CITI modules for IRB member training, found at **www.citiprogram.org.** The Chair of the IRB will maintain a permanent record of each member's documentation of training.

From time to time, additional individuals may be invited by the IRB Chair to attend meetings in order to provide the IRB with specialized expertise concerning particular research proposals. These invited individuals may not vote or otherwise engage in the procedural work of the IRB.

No IRB member may participate in the review of a project in which he or she has a conflict of interest, except to provide the IRB with essential information.

III. Indications for IRB Review:

Research studies that have the characteristics of human subjects research may or may not require IRB review. There are three broad categories of studies:

1. studies that are human subjects research;
2. studies that may be considered human subjects research (gray area);
3. studies that do not qualify as human subjects research.

Whenever a Principal Investigator (PI) or Project Director (PD) is uncertain as to whether the study falls under IRB jurisdiction, an informal letter (or e-mail) describing the proposed activities can be sent to the IRB. The IRB will then send a response to the investigator advising whether or not the research activity constitutes human subjects research. Research that will involve human subjects should not be initiated until the IRB review process has been completed and approval has been provided. The investigator should always err on the side of caution and communicate openly with the IRB.

A. Examples of Studies That Are Human Subjects Research

1. Studies that involve human subjects for testing new devices, products, drugs, or materials.

2. Studies that collect data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.

3. Studies using private information that can be readily linked to individuals, even if the information was not collected specifically for the study in question.

4. Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the coding systems.

5. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.

6. Studies that use human beings to evaluate environmental alterations. For example, making changes to a living or working space (e.g. changing the temperature).

B. Examples of Studies That May or May Not Be Considered Human Subjects Research

1. Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

2. Studies based on data that are individually identifiable but are also publicly available may not constitute human subjects research. However, the term "publicly available" is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

C. Examples of Studies That Do Not Qualify as Human Subject Research

1. Data collection for internal departmental, school, or other University administrative purposes. (Examples: teaching evaluations, customer service surveys.)

2. Service surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.*

3. Information-gathering interviews (through interviews, surveys, etc.) where questions focus on things, products, or policies rather than people or their thoughts. Example: asking company officers to provide data about company facts (such as number of employees) or to provide copies of company policies. *Note: If the study involves collecting the officers' opinions of company policies (e.g. in your opinion, is the policy effective?), then the study will need IRB review.*

4. Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques.

5. Biography or oral history involving a living individual that is not generalizable beyond that individual.

6. Activities involving cadavers, autopsy material or bio-specimens from now deceased individuals. *Note: Some research activities in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review.*

7. Innovative therapies except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) *Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.*

8. Quality improvement projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

9. Case histories which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge. *Note: Generally, projects which involve more than two subjects of this kind should be submitted to the IRB for review.*

10. Publicly available data do **not** require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available".*

11. Coded private information or biological specimens that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not allowed to make this determination. These projects require verification from the IRB.*

12. Some examples of **Non-Engagement in Research** include: when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information; perform commercial services for the

investigators (e.g. noncollaborative services meriting neither professional recognition nor publication privileges); or simply inform prospective subjects about the availability of research, but at no time obtain consent or act as authoritative representative of the investigator(s). *Note: The examples above are not an all inclusive listing.*

IV. Levels of IRB Review:

1. A **FULL REVIEW** by the IRB is required if the proposed research involves or includes:

a. the likelihood of greater than minimal risk, or substantial stress or discomfort, to subjects;
b. procedures that may potentially threaten or embarrass subjects;
c. personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher;
d. sensitive aspects of a subject's behavior that could reasonably place a subject at risk of criminal or civil liability or be damaging to a subject's financial standing or employability;
e. sensitive aspects of a subject's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol and/or drugs;
f. health care procedures that are not conducted for the primary benefit of the subject;
g. diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice;
h. exposure to surgery, drugs, or chemical agents;
h. exposure to electromagnetic radiation (X-rays, microwaves), lasers, and/or high frequency sound waves;
i. deception or procedures that are not known to the subject (e.g., the subject will not be fully informed);
j. subjects under the age of 18 years if more than minimal risk and does not meet expedited review criteria;
k. special populations (e.g., children, prisoners, pregnant women, fetuses, or individuals who are mentally or psychologically ill or incompetent);
l. collection of blood samples or other body fluids in any amount.

2. An **EXPEDITED REVIEW** by the IRB may be appropriate if the proposed research involves:

a. minimal risk;
b. recording data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical or educational practice;
c. analysis of voice or video recordings made for research purposes;
d. moderate exercise by healthy volunteers;
e. research on individual or group behavior, or characteristics of individuals, without manipulation of a subject's behavior and in a manner that does not cause stress to subjects.

3. An **EXEMPT REVIEW** by the IRB may be considered if the proposed research involves no or minimal risk to the participants. An example of this is use of an anonymous survey to collect data. *The determination of Exempt status is made by the IRB Chair, not by the investigator.* A brief description of the various exempt categories is available at the website of the HHS Office for Human Research Protections at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2 .

V. Process for Submitting an Application for IRB Review:

All Principal Investigators (PIs) must submit the completed WCU IRB Primary Application and any supplementary materials required by that protocol application form to the IRB Chair at irb@wmcarey.edu . Application forms are available on the IRB page of the WCU website. Completed applications will be reviewed according to the following guidelines:

Full Review (research that involves more than minimal risk to participants, including research that utilizes deception, as listed above): Any member of the IRB may request a Full Review of an application. The IRB will convene under the guidelines in Section VII below, and the decision will be based on the approval of the majority of members. Members' comments and/or recommendations must be submitted in writing and signed by the member. Research applications may be denied final approval only after a Full Review.

Expedited Review (research that involves minimal risk to participants under the specified circumstances listed above or involves minor changes in previously approved research during the time for which approval is authorized): The Chair of the IRB, or one or more IRB members designated by the Chair, will review the proposal. In cases where more than one IRB member takes part in the review, decisions will be based on the approval of a majority of participants. Comments and/or recommendations of individual IRB members must be made in writing and signed by the member. The Chair will inform the entire membership of the IRB of the details concerning proposals approved by Expedited Review.

Exempt Review (research that involves no or minimal risk to participants under the specified circumstances listed above): Upon agreement by the Chair of the IRB that the research meets the criteria for the Exempt category, the review application will be approved. The Chair must agree to the Exempt categorization in writing and accompany any comments with his/her signature.

VI. IRB Review, Reporting Requirements, and Actions:

According to DHHS Regulations, the IRB must review proposed research requiring review by the full board at convened meetings at which a majority of the members of the IRB are present. This may include members joining the meeting by teleconferencing. The minutes must indicate that such members 1) have received all pertinent material prior

to the meeting, and 2) can actively and equally participate in the discussion of all research proposals.

Applications for full review by the IRB are due by noon on the deadline date (two weeks prior to the published meeting date). The Chair of the IRB will distribute all materials to each member at that time to ensure adequate time for review.

Applications for expedited or exempt review will be accepted and reviewed on a rolling basis and have no deadlines.

PIs are strongly encouraged to attend meetings in which their proposals are being discussed, in order to facilitate discussion and questioning. They will be excused from the meeting prior to the final discussion and vote of the IRB.

The IRB will act on expedited and exempt review applications within 15 working days of the submission date. For full reviews, the PI will be informed in writing of the IRB's decision within seven days of the decision date.

Approval from the IRB will last for one calendar year from the date on the approval form. Research requiring full-board review that is not in data analysis that is not completed in that year must undergo review before the approval expiration date. Other studies will require an update from the PI on an annual basis to confirm the study remains active and ongoing. This review will require a progress report from the PI describing the number of subjects studied, any unanticipated or serious adverse events, and other information as requested by the Chair of the IRB. If changes have been made in the research protocol, the PI must treat the application as a new request.

If the IRB feels that a continuing research proposal presents significant physical, social, or psychological risks to subjects, it may decide to review the research more frequently than once a calendar year.

Any PI dissatisfied with the IRB's decisions or requirements is entitled to a rehearing at a subsequent IRB meeting, at which time the PI must be present for purposes of questioning and further discussion.

Possible actions of the IRB include, but are not limited to, the following:

Full Approval: Instructions concerning any further reporting requirements will be provided in the letter. Continuing progress reports as well as immediate reports of unanticipated or serious adverse events will be required.

Deferral: Proposals may be deferred when the IRB requests substantive clarifications or changes to the research protocol, including any informed consent documents required by the research. Deferred proposals will require significant revision and resubmission for full IRB review. The normal IRB deadlines will be followed in the resubmission.

Tabled: Tabled proposals cannot be reviewed due to the omission of required documentation necessary for the IRB to make a decision concerning the research. The PI must resubmit a complete proposal for full IRB review by the normal deadlines.

Disapproval: Disapproval is necessary when the research risks outweigh the benefits to study participants, or other significant problems exist, specific to the protocol. The decision to disapprove can only take place by the full IRB at a convened meeting.

Suspension or termination: The IRB has the authority to suspend or terminate human subjects research that is not being conducted in accordance with the IRB's decisions, conditions, or requirements. Suspension or termination can also be used for research that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the IRB's action, and shall be reported promptly to the PI, the appropriate WCU administrators, and any necessary governmental agencies.

In all of the actions named above, the PI of the proposed research will be notified promptly in writing.

Unanticipated problems/Serious adverse events: It is the responsibility of the PI to report promptly to the IRB any unanticipated problems which may involve risks to human subjects, or any serious adverse events which are the result of participation in the research. The IRB should be notified in writing, according to the chart below and following the steps detailed in the protocol application.

Type of Unanticipated Problem	**Initial Notification** (Phone, Email, or Fax)	**Written Report**
All SAEs related to research	24 hours	Within 2 calendar days
All AEs related to research	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