Carlos Albizu University
PROCEDURES FOR THE PROTECTION OF HUMAN SUBJECTS
Institutional Review Board (IRB)

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May 30, 2019

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CARLOS ALBIZU UNIVERSITY

PROCEDURES FOR THE PROTECTION OF HUMAN SUBJECTS

INSTITUTIONAL REVIEW BOARD (IRB)

I. INTRODUCTION

The Carlos Albizu University (CAU) has formally assured the United States Department of Health and Human Services (DHHS) that it will follow procedures that will assure the protection of any human being exposed to risk in sponsored projects, dissertations or any research projects conducted by the faculty, students, researchers, or others under CAU. The Human Subject Protection Regulations (45 CFR part 46) of the DHHS require that institutions performing DHHS conducted or supported non-exempt research involving human subjects have the research reviewed and approved by an Institutional Review Board (IRB). The IRB's main goal is to ensure that the rights and welfare of human subjects are protected. The regulations for protecting human subjects are based on the ethical principles described in the Belmont Report (respect for persons, beneficence, and justice) and regulated by the Code of Federal Regulations (CFR)-Title 45-Public Welfare of the United States Department of Health and Human Services (DHHS), Part 46-Protection of Human Subjects.

"An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8))."
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1109

The Institutional Review Board (IRB) of the Carlos Albizu University will make a decision based on common sense and intellectual and professional judgment as to whether or not a proposed research places an individual "at risk." An individual is considered to be at risk if he/she may be exposed to the possibility of harm (physical, psychological, sociological, or other) as a consequence of any activity that goes beyond the application of those established and accepted methods necessary to meet his/her needs. The obvious example includes subjection to injury or pain, deceit, public embarrassment and humiliation. There is, however, a wide range of projects in which, although there may be no immediate physical risk, procedures are introduced that may involve discomfort, anxiety, harassment, invasion of privacy, or constitute a threat to the subject's dignity through the imposition of demeaning or dehumanizing procedures. Finally, the risk element will be examined for those studies dependent upon stored data or information (paper or electronic), which might have been obtained for different purposes. First, CAU's IRB Administrator evaluates the risk of human subjects in the submitted proposal, and classifies it according to 45 CFR 46. Then the IRB Chair or a designee evaluates in detail the proposal classified as "Expedited" and the IRB Full Committee the

ones classified as "Full Review." These classifications are discussed in detail later in this document.

Appropriate provisions will be made for safeguarding information that could be traced to, or identified with subjects. The IRB requires that the project or principal investigator (s) (PI) take steps to insure the confidentiality and security of the data (paper or electronic).

If it is judged that a project will expose an individual to risk, then the IRB must assure itself that:

1). The risks to the subject are so outweighed by the sum of the benefits to the subject and the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

2). The rights and welfare of any such subject will be adequately protected.

3). Legally Effective Informed Consent will be obtained by adequate and appropriate methods in accordance with the provision of the regulations, and

4). An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f), according to 45 CFR 46.

Subjects should be informed that the Carlos Albizu University has filed an Institutional Assurance with United States Department of Health, Education, and Welfare (DHEW) to assure the protection of human subjects, and that a copy of this assurance will be made available upon request to the IRB Administrator at the respective CAU's local campus IRB office.

A. DEFINITIONS

The following main concepts as defined by the DHHS apply to this document:

a). *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

b). *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

c). *Intervention* includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

d). *Interaction* includes communication or interpersonal contact between investigator and subject.

e). *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.*, a medical record).

f). *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

g). *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

h). *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

i). *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative*means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

j). *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

k). *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

For example, some demonstration and service programs may include research activities.

l). *Written,* or *in writing,* for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

Additional relevant definitions can be found at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102

B. INFORMED CONSENT

1). General Requirements

a). Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

b). An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

c). The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

d). The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

e). Except for broad consent obtained

(i). Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii). Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated

facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

f). No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2). Basic Elements of Informed Consent

The following information shall be provided to each subject or the legally authorized representative:

a). A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

b). A description of any reasonably foreseeable risks or discomforts to the subject;

c). A description of any benefits to the subject or to others that may reasonably be expected from the research;

d). A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e). A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

f). For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g). An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

h). A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

i). One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i). A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii). A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

3). Additional Elements of Informed Consent

One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

a). A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

b). Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

c). Any additional costs to the subject that may result from participation in the research;

d). The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e). A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

f). The approximate number of subjects involved in the study;

g). A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

h). A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

i). For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Carlos Albizu University's IRB also requires the following additional statements:

1). A statement indicating the approximate time that participation in the study requires (Ex. expected time in treatment, duration of sessions or interviews, etc.).

2). A brief statement describing the instruments (if any) to be used and the time required to complete them without any pressure.

3). A statement describing the possible future use of collected data (Ex. professional publications, presentations, academic purposes). (DATA MUST BE USED OR PRESENTED WITHOUT IDENTIFIERS).

4). Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements. More information about broad consent can be found at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116

C. WAVING OF INFORMED CONSENT DOCUMENTATION

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

a). That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

b). That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

c). If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

1). Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements established in 45 CFR 46 an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

a). The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

i). Public benefit or service programs;

ii). Procedures for obtaining benefits or services under those programs;

iii). Possible changes in or alternatives to those programs or procedures; or

iv). Possible changes in methods or levels of payment for benefits or services under those programs; and

b). The research could not practicably be carried out without the waiver or alteration.

2). General waiver or alteration of consent

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements established in 45 CFR 46 an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

a). The research involves no more than minimal risk to the subjects;

b). The research could not practicably be carried out without the requested waiver or alteration;

c). If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

d). The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

e). Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

3). Screening, recruiting, or determining eligibility

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

a). The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

b). The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

CAU's IRB will only waive the requirement to obtain a signed consent form if the research complies with the above requirements. In all cases, the principal investigator must describe how the anonymity or confidentiality of the information collected from the

research subject and his/her voluntary participation in the research will be assured and maintained. In all cases, the researcher is responsible for the filing of all proof of compliance required by the IRB and is responsible to keep them for a period of five years.

Modification or waiver of consent procedures must be approved by the IRB and recorded in the minutes signed by the IRB Chair. Granting of permission to modify or waive consent procedures imposes additional responsibility upon the IRB and the Institution to establish that the risk to subjects is minimized, that normal procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and that any reasonable alternative means for attaining these objectives would be less advantageous to the subject.

The IRB's reasons for permitting modification or waiver of any of the eight basic elements of informed consent, or for altering the requirement to obtain a subject's signature or signature of an auditory witness, or for substitution (i.e., debriefing), or other modification of full, complete, written prior consent, must be individually and specifically documented in the IRB minutes and in reports of IRB actions kept in the institutional files. Approval of any such modification or waiver should be regularly re-assessed as a function of a process of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation of the modification as appropriate.

The following are types of alternate and/or simplified Consent Forms that may be used.

1). Oral instructions read to a group. In the case of minimal risk research where instructions are read to a group of subjects (e.g., survey at an organization regarding work schedule preferences), a short form to document the oral instructions presented to the participants/subjects may be handed to the subjects, in case they want further information. A witness (must be one who hears the oral instructions read to the group) **must** co-sign the short consent form along with the principal investigator (and supervisor if necessary). A written copy of the oral instructions that are to be read to the group must be submitted to the IRB with the research proposal.

2). Anonymous surveys or questionnaires. In the case of minimal risk research involving the use of surveys or questionnaires which are distributed individually and returned anonymously, a cover letter explaining the purposes and procedures of the research project may be considered a substitute for the consent form. Such a cover letter must be submitted to the IRB with the research proposal. It should de clearly stated in the cover letter that the returned survey or questionnaire serves as a form of implied consent.

3). Simplified oral interviews. Investigators conducting simple oral interviews on non-sensitive issues, behaviors, or life events (the content of which qualifies as expedite for review), may submit to the IRB an alternate form of written

documentation in place of an informed consent form. Such documentation should describe how the interviewer will explain his/her research to the subjects/interviewee and how the investigator will insure the interviewee's confidentiality and his/her right to refuse participation in the interview.

In all cases, the principal investigator must demonstrate how the anonymity and confidentiality of the subject and his/her voluntary participation in the research will be assured and maintained. In all cases, the researcher is responsible for the filing of all proof of compliance required by the IRB and is responsible to keep them for a period of five years.

II. REQUIREMENTS

A. IRB PROCEDURES FOR REVIEW OF RESEARCH

1. Method of Review

a. IRB Meeting

CAU's IRB shall meet monthly on previously scheduled dates. CAU's IRB shall have at least five members, with varying backgrounds, member diversity, and sufficiently qualified experience and expertise. CAU's IRB may not consist entirely of members of one profession. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB (45 CFR 46).

Except when an expedited review procedure is used, an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. All members are cited and then the quorom is established when the majority attends. Should the quorum fail during a meeting, the IRB may not take further actions or votes unless the quorum is restored.

The IRB is responsible for insuring that members who review research have no conflicting interest. Therefore, no IRB member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB, must be part of the Committee or is allowed to

vote. IRB members with conflict of interest on any project must excuse and abstain of any vote or discussion of that specific project.

Research proposals evaluated at the convened meetings are those classified as "Full Review" by the IRB Administrator and that represent more than a minimum risk to human subjects participants. Some examples of these proposals could be, but no neccesarily:

- Research studies with identifiers
- Substance abuse research studies
- Sexual behavior research studies
- Criminal activities research studies
- Studies with diagnosed populations
- Studies with special populations (e.g., people without home, illiterates, HIV patients, sexual workers, etc.)
- Studies with prisoners (45 CFR 46-Subpart C- Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) (Prisoner representative is required)
- Studies with children and adolescents (45 CFR 46-Subpart D- Additional Protections for Children Involved as Subjects in Research)
- Studies with pregnant women (45 CFR 46-Subpart B- Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research)
- Studies that involve the use of any medication, treatment or medical examination

IRB members present at meetings will decide by majority vote the IRB action for every proposal evaluated. These actions could be:

- *Approved*- The PI has authorization to begin his/her research
- *Not approved with minimal modifications*- The PI does not have authorization to begin his/her research. He/she must submit the required minimal modifications for IRB approval.

- *Not-approved*-The PI does not have authorization to begin his/her research. He/she must re-submit his/her complete proposal addressing the general issues raised by the panel.

- *Denied*- The proposal is not approved as it is.

If, after review, no agreement has been reached, the IRB Administrator and/or the IRB Chair shall have the right to request additional expert advice, which will be presented to the IRB for another review. The IRB shall meet to render a final decision.

In addition to the initial review, at least one meeting will be held annually to continue the review of ongoing research projects within the IRB's jurisdiction. The IRB will keep minutes of meetings and will notify the PI and his/her mentor (if necessary) of proposal determination by a standard written letter signed by the IRB Administrator.

In those cases where a negative decision has been made on any project, the PI is entitled to a new review after making the changes that are requested by the IRB, and to make any consultation with the IRB Administrator that he/she considers necessary. All communications with the PI will be filed and kept locked in a cabinet and will be available for external audits by the DHHS at any time.

b. Expedited Review

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.

An IRB may use the expedited review procedure to review the following:

1). Some or all of the research appearing on the list established by the Secretary of HHS and published as a Notice in the Federal Register

2). Minor changes in previously approved research during the period for which approval is authorized; or

3). Research for which limited IRB review is a condition of exemption

The IRB will notify the PI of its determination by a standard written letter signed by the IRB Administrator. All letters to the PI's are filed. All the IRB's records are filed in a separate office and are available for audit by the DHHS at any time. Actions are communicated to all IRB members at the next convened meeting.

c. Exempt Review

The IRB Administrator certifies the proposals classified as "Exempt." It is optional to the IRB Administrator to evaluate the proposal or assign it to the IRB Chair or designee for evaluation. These proposals need to meet the following criteria:

1). Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a). The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

b). Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c). The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

3). a. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i). The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii). Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal

or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii). The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

b). For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

c). If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4). Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a). The identifiable private information or identifiable biospecimens are publicly available;

b). Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

c). The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

d). The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5). Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

6). Taste and food quality evaluation and consumer acceptance studies:

a). If wholesome foods without additives are consumed, or

b). 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.

7). Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review

8). Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

a). Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with what is established in respective subparts in the 45 CFR 46.

b). Documentation of informed consent or waiver of documentation of consent was obtained

c). An IRB conducts a limited IRB review and makes the determination required in accordance with what is established in respective parts in the 45 CFR 46 and makes the determination that the research to be conducted is within the scope of the broad consent referenced in in accordance with what is established in respective parts in the 45 CFR 46 and, the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

The IRB Administrator will tnotify the Principal Investigators (PIs) by a written letter that the proposal is excempt.

2). Reviewer System

a. Initial Review

Principal Investigators (PIs), researchers, or students wishing to conduct a research project must submit a proposal to the CAU's IRB following these steps:

- Fill and submitt Form IRB-1 in Appendix A
- Submit the CITI Online Training (https://www.citiprogram.org/)
- Submit a Literature Review
- Submit a detailed Method
- Submit a copy of Proposed Informed Consents and/or Children Assents Forms
- Submit questionnaires, instruments, scales, any form of evaluation, assessment forms, or tests.
- Submit appendixes (Permissions, letter of authorizations by different agencies to collect samples, author permission for the use of questionnaires or instruments, trainings, or other pertinent document related to the research project).

- PI must fill the Renewal/Changes Form (Appendix B) (Form IRB-2) at any time changes are necessary or when the approved proposal time has expired and the PI needs to continue his/her research.

- Submit the Individual Investigator Agreement (Form IRB-3)(Appendix C)

The IRB Administrator classifies the proposals following the Human Subject Protection Regulations (45 CFR 46) and assigns reviewers for every proposal. To evaluate the risk of the submitted proposals the IRB uses the following classifications:

- *Full Review*- (More than minimal risk)

- *Expedited*- (Previously approved research by the IRB, minimal risks)

- *Exempt*- (Non-risk, education type research, instrument construction)

The secretary sends all these forms and documentation to the IRB members two weeks in advance to the convened meeting. On expedited review, all forms are sent to the IRB Chair or the designee approximately two days after receiving documentation.

Reviewers have the responsibility of carefully reading every assigned research proposal, make comments and request modifications based on participants' risk, be present at the IRB meeting and emit a vote. The IRB is responsible for ensuring that members who review research have no conflicting interest. Therefore, no IRB member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB, must be part of the Committee or is allowed to vote. IRB members with conflict of interest on any project must excuse and abstain from any vote or discussion of that specific project.

The following actions could be taken for evaluated proposals classified as full review:

- *Approved*- The PI has authorization to begin his/her research

- *Not approved with minimal modifications*- The PI does not have authorization to begin his/her research. He/she must submit the required minimal modifications for IRB approval.

- *Not-approved*-The PI does not have authorization to begin his/her research. He/she must re-submit his/her complete proposal addressing the general issues raised by the panel.

- *Denied*- The proposal is not approved as it is.

If, after review, no agreement is reached, the IRB Administrator and/or the IRB Chair shall have the right to request additional expert advice, which will be presented to the IRB for another review. The IRB shall meet to render a final decision.

In expedite procedure, the reviewer may exercise all of the authorities of the IRB except that the reviewers may not denied the proposal and instead either should submit specific recommendations or bring it to the full committee.

No project involving potential of risks to human subjects will be approved by the IRB unless evidence is presented that appropriate Legally Effective Informed Consent to participate in the study has been given. Parents should sign an Informed Consent authorizing their children to be participant of any research project. NO CHILDREN CAN BE INTERVIEWED, INTERVENED OR BE PARTICIPANT OF ANY PART OF A RESEARCH PROJECT WITHOUT HIS/HER PARENT/LEGALLY GUARDIAN CONSENT. Children must also sign an assent form when needed.

The IRB will determine, by majority vote, whether information given to subjects is a fair explanation of the procedures, and/or risks, and whether the consent of subjects must be secured in writing or orally.

The written "consent forms" must be filed and stamped with the IRB seal and signed by the IRB Chair or designee and available at all times. Only stamped and signed consent forms with the dates of approval and expiration of the research protocol may be used in any IRB approved research study. The PI must provide a copy of this document of assurance to any voluntary subject, and is required to immediately report any adverse effect as result of their research to the IRB and to document it (Appendix D-Reporting Form-IRB-4).

After initial review, a letter is sent to the PI reporting the IRB's determination with a limited period. The IRB will keep minutes of meetings and will notify the PI and his/her mentor (if necessary) of proposal determination by a standard written letter signed by the IRB Administrator. In those cases where a negative decision has been made on any project, the PI is entitled to a new review, after making the pertinent changes, and to consult the IRB Administrator. All the IRB's records are filed on a separate office and are to be available for audit by the DHSS at any time.

After approval, if the PI (s) does not complete his/her proposal in a year or in the approved period and wishes to continue the investigation or to change any aspect of the approved methodology, the investigator should then submit the Renewal/Changes Form (Appendix B) (Form IRB-2) for the IRB's approval. The IRB will evaluate the petition for continuation and will inform the PI (s) of the decision.

The IRB could evaluate a proposal before the year of completion or more than once a year if necessary. PI are required to submit a termination protocol when finishing their research (Appendix E).

b. Continuing Review

PIs are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out continuing review prior to the expiration date of the

current IRB approval (usually three weeks prior to the expiration date). An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year.

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

1). Research eligible for expedited review in accordance to the established at 45 CFR 46

2). Research reviewed by the IRB in accordance with the limited IRB review

3). Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

a). Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

b). Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

All research activities involving human subjects must stop after the IRB's approval has expired. **Enrollment of new subjects cannot occur after the expiration of the IRB's approval**.

The PI must fill and submit the Renewal/Changes Form (Appendix B) (Form IRB-2) when the proposal has expired and the PI needs to continue his/her research. Twice a year the IRB Administrator conducts an internal audit to close protocols that have expired or need continuing review and report the findings to the IRB Institutional Officer.

For all research, requesting extensions after **one year** or for protocols that have expired and need an extension period, the PI must comply with the following requirements:

- Submit Form IRB-2 (Renewal/Changes form) to the IRB at the CAU's local campus' IRB office
- Renovate the CITI online training for the protection of human subjects if necessary (https://www.citiprogram.org/)
- Submit a written report to the CAU's local campus' IRB office providing the following details:
    - Summary of project (including possible amendments to the project since initial review)

- Number of subjects accrued and subjects withdrawn
- Why did the research protocol was not finished on the required time
- Research stage/phase of the project
- An approximate timetable needed to finish the research project
- Explain in detail how many participants are still needed in order to conclude the research protocol
- Any new relevant information
- Any unanticipated problems and subject complaints, if any
- Certify that the research method approved by the IRB remains the same and has not changed since initial review
- For continuing review of multicenter research, the local investigator must include in the progress report a summary of all of the above for subjects who participated at that institution. The IRB could require other documentation regarding the whole project.

The IRB secretary receives and sends all these forms and documentation to the IRB members two weeks in advance to the convened meeting. On expedited review process, all forms are sent to the IRB Chair or designee approximately two days after receiving documentation.

Reviewers at the convened meeting have the responsibility of carefully reading every assigned research proposal, make comments and request modifications based on participants' risk, be present at the IRB meeting and emit a vote. The IRB is responsible for ensuring that members who review research have no conflicting interest. Therefore, no IRB member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB, must be part of the Committee or is allowed to emit a vote. IRB members with conflicts of interest on any project must excuse themselves and abstain from any vote or discussion of that specific project.

Continuation of previously approved protocols are reviewed and evaluated at a convened meeting following the previously described requirements for a convened meeting (Section II.A.1.a of this document). When continuing review of research is conducted under an expedited review procedure, the review must be conducted by the IRB chairperson or one or more experienced reviewers designated by the IRB Administrator or chairperson from among the IRB members. Disapproval of a research project at the time of continuing review can only occur after review by the IRB at a convened meeting, not by the expedited review process.

When conducting continuing review and evaluating whether research continues to satisfy the criteria for IRB approval of research, IRB should pay particular attention to the following four aspects of the research:

- *Risk assessment and monitoring.* One of the most important considerations for the IRB at the time of continuing review is whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's previous conclusion.
- *Adequacy of the process for obtaining informed consent.* At the time of continuing review, the IRB should review a copy of the sample informed consent document submitted by the investigator to verify that the investigator is using the most recently approved version and that the document contains the most accurate, up-to-date information about the research.
- *Investigator and institutional issues.* When appropriate, CAU's IRB should consider issues regarding the investigator and the institution(s) where the research is being conducted during its continuing review, such as the following:
    - Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, change in medical license status, or increase in number of research studies conducted by the investigator);
    - Evaluation, investigation, and resolution of any complaints related to the investigator's conduct of the research;
    - Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and applicable regulations, State and local law, or standards of professional conduct or practice; and
    - Reports from any third party observations of the research carried out.

- *Research progress.* The IRB will take into consideration three criteria for evaluating research progress. These are:

    1). Confirmation that continuing review information is consistent with the IRB-approved Protocol- The information provided by the investigator at the time of continuing review is consistent with the research protocol previously approved by the IRB. If this information suggests that the investigator is not conducting the research in accordance with the IRB approved either protocol or the requirements or determinations of the IRB, the IRB should either defer re-approving the research or re-approve the research for a limited period of time (e.g., one month) and seek an explanation from the investigator regarding the apparent discrepancies.

    2). Total subject enrollment- Usually the IRB will have approved a protocol that includes the expected total number of subjects to be enrolled at the research study. Evaluating information about the number of

subjects enrolled in the research at the time of continuing review may allow ascertaining whether enrollment is consistent with the planned sample described in the IRB-approved protocol. A significant difference between the actual and expected rates of enrollment may indicate a problem that requires further evaluation.

3). Subject withdrawals- Subjects may discontinue their participation in research at any point for diverse reasons (e.g., serious adverse events, conflicts with the investigators, transportation problems, etc.). The IRB in continuing review procedures should review the number of subjects who discontinued their participation; and a summary of the reasons for the withdrawals, if known.

PI (s) should be aware that a research study previously approved under an expedited review procedure in some circumstances would need to undergo continuing review by the IRB at a convened meeting if changes are made and more than minimal risk to subjects is determined.

If using a different IRB than was used for the initial review, members must have the appropriate experience, expertise, and access to all prior relevant IRB records. An IRB that is conducting continuing review of research should be familiar with, and have access to, all IRB records related to the research, including those associated with the initial review and approval and any other previous reviews.

The IRB is responsible for ensuring that members who review research have no conflicting interest. Therefore, no IRB member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB, must be part of the Committee or is allowed to emit a vote.

The following actions could be taken for continuing review at a convened meeting:

- *Approved*- The PI has authorization to begin his/her research
- *Not approved with minimal modifications*- The PI does not have authorization to begin his/her research. He/she must submit the required minimal modifications for IRB approval.
- *Not-approved*-The PI does not have authorization to begin his/her research. He/she must re-submit his/her complete proposal addressing the general issues raised by the panel.
- *Denied*- The proposal is not approved as it is.

If, after review, no agreement has been reached, the IRB Administrator and/or the IRB Chair shall have the right to request additional expert advice, which will be presented to the IRB for another review. The IRB shall meet to render a final decision.

After review, a letter is sent to the PI reporting the IRB's determination with a limited extended period. The IRB will keep minutes of meetings and will notify the PI and his/her mentor of the proposal's determination by a standard written letter signed by the IRB Administrator. In those cases where a negative decision has been made on any project, the PI is entitled to a new review, after making the pertinent changes, and to consult the IRB Administrator. All letter to the PI's are filed. All the IRB's records are filed on a separate office and are to be available for audit by the DHSS at any time.

The written "consent forms" with the new expiration date must be filed and stamped with the IRB seal and signed by the IRB Chair, and available at all times. Only stamped and signed consent forms with the dates of approval and expiration of the research protocol may be used in any IRB approved research study. The PI (s) must provide a copy of this document of assurance to any voluntary subject. PI is required to immediately report to the IRB any adverse effect as result of their research and to document it (Appendix D-Reporting Form IRB-4).

c). Review of Protocol Changes

The PI must complete and submit the Renewal/Changes Form (Appendix B) (Form IRB-2) at any time changes are necessary. For any changes during the approved period, the PI must comply with the following requirements:

- Submit Form IRB-2 (Renewal/Changes form) to the IRB Administrator
- Submit a written report to the CAU's local campus' IRB office for re-approval with all proposed changes
- Submit a new proposal to the CAU's local campus' IRB office (if applicable)
- The new proposal must include all changes/modifications, including consent forms, in **bold letters.**
- Submit the CITI Online Training Certificate (https://www.citiprogram.org/)

The IRB secretary receives and sends these forms and documentation to the IRB Chair who evaluates the proposed changes to be presented and finally approved at the convened meeting. **No changes in protocols shall be made or implemented without the IRB approval.**

After review and approval, a letter is sent to the PI reporting IRB's determination. If changes are not approved, corrected changes must be submitted to the IRB and if new consent/assent forms are required, these must again be stamped and signed by the IRB

Chair prior to continuing with the study. In those cases where a negative decision has been made on any project, the PI is entitled to a new review, after making the pertinent changes, and to consult the IRB Administrator. All communications with the PI's are filed. All the IRB's records are filed on a separate office and are available for audit by the DHSS at any time.

3). Documents Received and Distributed for Review

Principal Investigators (PIs), researchers, or students wishing to conduct a research project must submit a proposal to the CAU's local campus' IRB office completing all required documents as described in Section II Part A.2.a of this document. A model of the "Informed Consent," all required forms, instructions, and links for the mandatory online training are available in CAU's Blackboard System.

Research proposals are received on scheduled datelines established by the IRB Administrator. These dates are established in advance and announced to the academic community. Once the proposals are received, the IRB secretary assigns an IRB control number and opens a file for every submitted proposal. These are documented on a "Control Sheet" and then forwarded to the IRB Administrator. The IRB Administrator evaluates the submitted protocol to determine the type of review the proposal is to be submitted to: Full, Expedited or Exempt Review. This review is determined after the evaluation of risk to human subjects following DHHS regulations as described in 45 CFR 46.

The IRB Chair or designee reviews those proposals evaluated as "Expedite" and submit recommendations and modifications. Those proposals classified as Full Review must be submitted to the IRB Full Committee to be evaluated in their monthly-convened meetings.

The IRB's secretary distributes a copy of the following documents two weeks prior to the convened IRB meeting to the designated reviewers.

- IRB forms (See appendixes)
- CITI Online training certificate for the protection of human subjects (https://www.citiprogram.org/)
- Chapter I (Literature Review),
- Chapter II (Method)
- Copy of proposed Informed Consents
- Copy of any form or instrumentation to be used
- Appendixes (Permissions, letter of authorizations by different agencies to collect samples, author permission for the use of questionnaires or

instruments, trainings, or other pertinent document related to the research project).

IRB members should read, make comments and request modifications to the proposals to be discussed at the convened meeting. To present a proposal, the IRB Chair or designee makes an oral summary and opens the discussion. Then each member makes comments and recommendations and they emit a vote. Action is determined by majority vote.

The IRB secretary keeps minutes of meetings and notifies the PI of IRB's determination by a written letter signed by the IRB Administrator. All communications with the PI's are filed. All the IRB's records are filed in a separate office and are available for audit by the DHSS at any time.

4). IRB Review, Findings, and Determinations

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1). Risks to subjects are minimized:

a). By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

b). Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2). Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3). Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

4). Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5). Informed consent will be appropriately documented or appropriately waived.

6). When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7). When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8). For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section decribed at the 45 CFR 46 (See 45 CFR 46).

Based on the above criteria the IRB uses the following classifications to evaluate the risk of the submitted proposals to the IRB: *Full Review; Expedited; Exempt*

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head

5). IRB Possible Actions

After evaluation by the IRB, proposals would be evaluated as the following:

- *Approved*- The PI has authorization to begin his/her research
- *Not approved with minimal modifications*- The PI does not have authorization to begin his/her research. He/she must submit the required minimal modifications for IRB approval.
- *Not-approved*-The PI does not have authorization to begin his/her research. He/she must re-submit his/her complete proposal addressing the general issues raised by the panel.
- *Denied*- The proposal is not approved as it is.

In those cases where a negative decision has been made on any project, the PI is entitled to a new review, after making the pertinent changes, and to consult the IRB Administrator. If, after review, no agreement has been reached, the IRB Administrator and/or the IRB Chair shall have the right to request additional expert advice, which will be presented to the IRB for another review. The IRB shall meet to render a final decision. Determined actions are marked and signed by the voting members. Minutes are taken and all documents are filed at the CAU's local campus' IRB office.

Protocol approval can be revoked if there is proof of Research Misconduct. Procedures for research misconduct must follow the CAU's Manual for Procedures for Responding to Allegations of Research Misconduct. An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

6). Institutional Further Review

If the PI (s) does not complete his/her proposal in a year or in the approved period and wishes to continue the investigation or to change any aspect of the approved method section, the investigator should then submit Form IRB-2 (Renewal/Changes form) to the IRB Administrator. IRB will evaluate the petition for continuation after expiration date and will inform PI of the decision. The IRB could evaluate a research protocol before the year of completion or more than once a year if necessary. PI are required to submit a termination protocol when finishing their research (Appendix E).

Any complaints of Research Misconduct must follow CAU's Manual for Procedures for Responding to Allegations of Research Misconduct for CAU.

B. REPORTING IRB'S FINDINGS AND ACTIONS

1). To Principal Investigators

After review, an IRB determination letter is sent to the PI (s). If the determination is that he/she has authorization to begin his/her research the letter specifies that the PI (s) should submit the approved consent forms to the CAU's local campus' IRB office before the established dateline (approximately a week after approval). It also specifies that consent forms will be officially stamped and signed by the IRB Chair with the expiration date. If required by IRB determination PI must submit the required changes to CAU's local campus' IRB office as soon as possible.

In those cases where a negative decision has been made on any project, the PI is entitled to a new review by the full IRB and to consult the IRB Administrator. If, after review, no agreement has been reached, the IRB Administrator and/or the IRB Chair shall have the right to request additional expert advice, which will be presented to the IRB for another review. The IRB shall meet to render a final decision.

Proposals that have expired should follow the previously required steps included in this document about continuing review. Any suspension or termination of approval must be in a written report to the PI and should include a statement of the reasons for the IRB's action.

2). To the Institution

Statistical reports of the number of proposals approved and how they are classified are report to the Institutional Officer and to any other Administartion Official upon request. An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head

C. IRB REVIEW FREQUENCY

The IRB Full Committee must meet monthly for proposal review and evaluation. Under special circumstances (e.g., natural disaster, excessive volume of proposals to be evaluated, funded grants with rush datelines) an extraordinary meeting could be convoked.

The IRB decides the frequency of continuing review for each research project necessary to ensure the continued protection of the rights and welfare of research subjects. Almost all protocols have a year timeframe for implementation. After a year of approved period the PI (s) that wish (es) to continue must follow the previously required steps discussed on Section II. A.2.b of this document.

The IRB considers the following factors when deciding on an appropriate interval for continuing review:

- The nature of any risks posed by the research project
- The degree of uncertainty regarding the risks involved
- The vulnerability of the subject population
- The experience of the investigators in conducting research
- The IRB's previous experience with the investigators (e.g., compliance history, previous problems with the investigator obtaining informed consent, or prior complaints from subjects about the investigator)
- The projected rate of enrollment; and
- Whether the research project involves novel interventions.

Projects that present complex research designs (e.g., Big samples > 500, multiple sites) or with a history of concern (investigator compliance) will be evaluated twice a year for quality control. If necessary, the IRB could audit participant's protocols, files, and require the submission of special reports to the PI (s) at any time.

D. VERYFING NO CHANGES SINCE FIRST IRB REVIEW

The IRB could determine that a project needs verification from other sources other than the PI (s) that no material changes have occurred since first IRB review.

Projects that present a complex methodology (Ex. Big samples > 500), multiple sites, with a history of concern (investigator compliance) or with concern about possible material change occurring without IRB approval will be evaluated twice a year for quality control. The IRB could audit participants' protocols, files, and require the submission of special reports to the PI (s). If necessary, the IRB could verify and/or can require information about the project to agencies facilitating samples, authors, co-investigators, etc., at any time.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head

E. ENSURING PROTOCOL CHANGES ARE MADE IN ACCORDANCE WITH REGULATIONS

The IRB ensures that prompt reporting of changes is being conducted and that such changes are not initiated without review or approval. The following steps have been established in order to assure this:

- All consent forms are stamped and signed by the IRB Chair or designee. Unsigned and unstamped consent forms circulating that do not explicitly demonstrate approval by the IRB are cause for termination or revocation of a research protocol approval.

- All PI(s) must complete and submit evidence of a mandatory CITI online training for the Protection of Human Subjects. (https://www.citiprogram.org/)

- Workshops and lectures are given to new faculty and students in which all steps, time limitations and requirements are discussed.

- Two Blackboard Spaces (one for faculty and one for students) are available with all documentations, IRB calendars, and an e-mail for communication with CAU's IRB Administrator.

- Twice a year the IRB Administrator conducts an internal audit to close protocols that have expired or need continuing review and report the findings to the Institutional Officer.

F. IRB REPORTINGS

Procedures for ensuring prompt reporting of unanticipated problems, serious noncompliance, adverse events, suspensions or terminations to the IRB, Institutional Officer, and/or President and to Office of Human Research Protection (OHRP) have been established.

As established by the OHRP:

OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

OHRP recognizes that it may be difficult to determine whether a particular incident, experience, or outcome is unexpected and whether it is related or possibly related to participation in the research. OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others. Examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem include:

- changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;
- modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- implementation of additional procedures for monitoring subjects;
- suspension of enrollment of new subjects;
- suspension of research procedures in currently enrolled subjects;

- modification of informed consent documents to include a description of newly recognized risks; and

- provision of additional information about newly recognized risks to previously enrolled subjects.

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1

As established by the OHRP:

The HHS regulations at 45 CFR part 46 do not define or use the term *adverse event*, nor is there a common definition of this term across government and non-government entities. In this guidance document, the term *adverse event* in general is used very broadly and includes any event meeting the following definition:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6

Adverse events encompass both physical and psychological harms.

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1

There is also non-compliance situations. Examples of these situations are, among others:

- Research conducted without IRB review and/or approval

- Failure of the PI to obtain the Legally Effective Informed Consent of subjects or of the IRB to appropriately waive the requirements to obtain informed consent.

- IRB meeting convened without quorum (No non-scientist present, lack of a majority)

- IRB Members with conflicting interest participated in IRB review of research

Upon becoming aware of an adverse event, unanticipated problem or noncompliance the Principal Investigator must report it promptly to the IRB (45 CFR 46.103(b)(5)). He/she should follow the guidelines to determine if an adverse event is an unanticipated event (http://www.hhs.gov/ohrp/policy/advevntguid.html).

The Institutional Officer is responsible for reporting any unanticipated problems, serious noncompliance, adverse events, suspensions, or terminations to the OHRP following the guidelines found at http://www.hhs.gov/ohrp/compliance/reports/index.html. Regulations 45 CFR 46.113 do not specify a time frame for reporting, except "promptly". It is established that a serious incident, must be reported to OHRP within days.

Preventive actions to avoid these types of situations have been established by the CAU's IRB. These are the following:

- Workshops and lectures are given to new faculty and students in which all steps, time limitations and requirements are discussed. These include that every PI must report any change, complaint and/or adverse situation that happens or that is a direct or indirect result of their research project.

- Every Legally Informed Consent must include a statement with the names, e-mails and phone number of the person to contact by participants in case of any change, complaint and/or adverse situation that happens or that is a direct or indirect result of their research participation.

- Every Legally Informed Consent must include a statement, which establishes that in case of any situation, or adverse situation a written referral must be given and an "Adverse Effect Protocol" is to be followed by the PI or any project staff.

In accordance with the regulations provided by the HHS: "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects."

Research Misconduct Policies are found at https://ori.hhs.gov/federal-research-misconduct-policy

III. OTHER CONSIDERATIONS

A. CONFLICT OF INTEREST

The IRB is responsible for ensuring that members who review research have no conflicting interest. Therefore, no IRB member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest must be part of the Committee or is allowed to emit a vote, except to provide information requested by the IRB. IRB members with conflict of interest for any project must excuse and abstain of any vote or discussion of that specific project.

The IRB is also responsible to ensure that investigators engaged in human subjects' research have no financial interests that could compromise the protection of

research subjects. Special questions and deliberations could be addressed if financial conflict results as part of a research project. Guidelines are found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html

Possible actions in case of financial conflict of interest could be:

- Including information in the Informed Consent document, such as the source of funding and funding arrangements to conduct and review research, or information about a financial arrangement to an institution or an investigator and how it is being managed.

- Using special measures to modify the Informed Consent process when a potential or actual financial conflict exists, such as having another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.

- Using independent monitoring of the research.

Others conflicts of interest could be addressed by the IRB and special questions and deliberations could be addressed if conflict results as part of a research project.

B. INSTITUTIONAL EDUCATIONAL REQUIREMENTS AND AVAILABILITY

- It is required by CAU's IRB that every PI (s) (faculty or student) submitting a proposal to the IRB be certified with the CITI online training for the protection of human subjects. (https://www.citiprogram.org/)

- Lectures and workshops are given to new faculty and students in which all steps, time limitations and requirements are discussed.

- Two Blackboard Spaces (one for faculty and one for students) are available with all documentations, calendars, and an e-mail for communication with the IRB Administrator.

- IRB Members should complete the CITI online training for the protection of human subjects. (https://www.citiprogram.org/)

C. IRB RESOURCES AVAILABILITY

CAU's IRB Federal Wide Assurance number (FWA), IRB identification number, minutes and required forms are available in the San Juan Campus at the Research Training Program Office on the third floor of the Carlos Albizu University building located at 151 Tanca St., San Juan, PR.

Requirements, online training, educational links, and other documents are available on CAU's blackboard. DHHS official page is available at http://www.hhs.gov/ohrp/. Official required online training is available at https://www.citiprogram.org/

The Regulation of HHS Title 45, public welfare- part 46, protection of human subjects is available at http://www.hhs.gov/ohrp/. All records are accessible for IRB and HHS inspection.

D. PROCEDURES FOR SELECTING AND APPOINTING THE IRB CHAIRPERSON AND MEMBERS

CAU's Institutional Officer is the person responsible for selecting the IRB Chairperson and members. The IRB Chair is selected among faculty members and is required to at least comply with the following:

- Be a core faculty member of CAU with a Ph.D., Psy.D., or M.D. degree or its equivalent.
- Have at least five years' experience as researcher or as part of research teams.
- Knowledge of the ethics code of the profession established by APA, local regulatory agencies and DHHS.
- Be available for required DHHS IRB trainings.

IRB scientific members must at least comply with the following:

- Be a core or adjunct faculty member of CAU with a Ph.D., Psy.D, or M.D. degree or its equivalent.
- Have experience in scientific research.
- Be available on scheduled dates for convened meeting and local training.

IRB non-scientific members must at least comply with the following:

- Be active community members from the local area or UCA's non-scientific employee
- Be available on scheduled dates for convened meeting and local training.

IRB non-affiliated members must at least comply with the following:

- Be active community members from the local area

- Be not otherwise affiliated with CAU and who is not part of the immediate family of a person who is affiliated with the institution

- Be available on scheduled dates for convened meeting and local training.

The Institutional Officer may request other requirements that he/she understands benefits the IRB to comply with the DHHS requisites.

IV. STATEMENT OF ETHICAL RESPONSIBILITY FOR RESEARCH INVOLVING HUMAN SUBJECTS

Carlos Albizu University faculty engaged in research and/or supervising students' research projects should be aware of the University's responsibility for ethical conduct in any project involving human subjects. Faculty is responsible for research done by students under their supervision with respect to these matters. Each research design must be examined for possible risk to subjects. If even minor risk of physical, psychological, sociological, or other harm may be involved, the faculty member must determine that: the risks to the subject are so outweighed by the sum of the benefit and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks; the rights and welfare of any such subjects is guaranteed and clear Legally Effective Informed Consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part; and the conduct of the activity will be reviewed at timely intervals.

In addition to questions of risk and informed consent, the subjects' rights of privacy must be protected. If a faculty member, researcher, or student has any doubts regarding the ethics of a project or steps taken to protect research subjects, he or she should refer them to the IRB. In any case, the IRB should be informed of all research projects involving human subjects.

If a faculty member, researcher, or student is supported by a governmentally funded fellowship or has other, independent, governmental funds for research, he or she must submit the regulation proposal form for review by the IRB. The faculty and students will be guided by the Ethical Principles in the Conduct of Research with Human Participants of the American Psychological Association.

Note: The enclosed documents should be read carefully for full explanation of the ethical guideline and procedures. It is required by CAU'S IRB that every PI (faculty or student) submitting a proposal to the IRB be certified with the CITI online training for the protection of human subjects provided at https://www.citiprogram.org/

APPENDIXES

Appendix A: PROPOSAL TO INTERNAL REVIEW BOARD (IRB) OF THE CARLOS ALBIZU UNIVERSITY (Form IRB-1)

Appendix B: PROPOSAL FOR RENEWAL/CHANGES TO INSTITUTIONAL REVIEW BOARD (IRB) (Form IRB-2)

Appendix C: INDIVIDUAL INVESTIGATOR AGREEMENT (FORM IRB-3)

Appendix D: EVENTS THAT REQUIRE PROMPT REPORTING TO THE IRB (FORM IRB- 4)

Appendix E: NOTICE OF PROTOCOL TERMINATION

Appendix A

PROPOSAL TO INSTITUTIONAL REVIEW BOARD (IRB)
OF THE CARLOS ALBIZU UNIVERSITY

Principal Investigator _____ Date _____

Research Supervisor (if applicable) _____

Project Title _____

Agency to which submitted (if applicable) _____

Grant No. (if applicable) _____

I have read the Individual Investigator Agreement and unreservedly subscribe to the principles it contains. I present for the IRB's consideration the following information about the proposed research project.

1. **Does your proposed project use vulnerable subjects (children, prisoners, or pregnant women) or subjects "at risk"? Yes _____ No _____**

2. **Location of Study (hospital, outpatient facility, school, or other agency).**

3. **Statement of Purpose: Describe the scientific aims or hypotheses to be tested.**

4. **Describe the nature of the individuals who will be the subjects and describe fully how they will be recruited. Attach copies of recruitment materials. Describe inclusion/exclusion criteria.**

5. **If you are planning to use hospitalized or institutionalized individuals as subjects, describe precisely how you are fulfilling special regulations of the Department of Health, Education and Welfare *(HEW regulations http://www.hhs.gov/ohrp/)* governing such research.**

6. **Research Plan: What tasks will subjects be asked to perform, or what tests will they undergo? Please provide an orderly scientific description of the study design and research procedures as they affect the subjects.**

7. **Specify provisions to be used in safeguarding the rights and welfare of the human subjects in this research; provisions for the medical care of the subject.**

8. **Describe the methods to be employed for securing informed consent of subjects. For research involving minors, explain how parental permission and child assent will be obtained.** ***Attach copies of the form(s) and explanation to be used.***

9. **Describe the risks to the subjects and the potential benefits of this research to subjects and to the public. Describe how risks will be minimized. Describe procedures for monitoring the ongoing progress of the research and reporting adverse events.**

10. **Confidentiality: Describe how research data will be collected and recorded. Describe methods and procedures that will be used to safeguard the confidentiality of subjects and their data. Describe any limits to confidentiality. Describe what will be done with the data when the research is completed.**

Should any change in methods become advisable, I will bring this to the IRB before changes are initiated **(Refer to the Renewal/Changes form).**

Date _____

Principal investigator's name _____

Principal investigator's signature _____
(Signature)

Supervisor's name (if applicable) _____

Supervisor's signature (if applicable) _____

Department _____

Telephone (Day) _____ **(Evening)** _____

E-mail _____

Address _____

PLEASE ATTACH ONE COPY OF YOUR PROPOSAL TO THIS FORM AND SUBMIT BOTH

Revised: January 29, 2019

(Note: This document is available in Blackboard under IRB-student and IRB-faculty courses)

Appendix B

**PROPOSAL FOR RENEWAL/CHANGES TO INSTITUTIONAL REVIEW BOARD (IRB)
OF THE CARLOS ALBIZU UNIVERSITY**

Principal Investigator: _____

Date: _____

Research Supervisor (if applicable): _____

Project Title: _____

Agency to which submitted (if applicable): _____

Grant No. (if applicable): _____

IRB Number: _____

Effectiveness Period: From _____ **to** _____
Date (month/day/year) **Date (month/day/year)**

I have read the Individual Investigator Agreement and unreservedly subscribe to the principles it contains. I present for the IRB's consideration the following information about the proposed research project.

1. Does your proposed project use vulnerable subjects (children, prisoners, or pregnant women) or subjects "at risk"? Yes ___ No ___

2. Describe any changes in the nature of the individuals who will be subjects and describe fully how they will be recruited this year including if the sample size will be increased.

3. If you are planning any changes in the use of hospitalized or institutionalized individuals as subjects this year, describe precisely how you are fulfilling special regulations of the Department of Health, Education and Welfare *(HEW regulations https://www.hhs.gov/ohrp/)* governing such research.

4. Please report the current status of your investigation including a detailed explanation of the current phase and a brief description of the previous phases. Please explain the difficulties that you have found completing the investigation.

5. Specify any changes in the provisions to be used in safeguarding the rights and welfare of the human subjects in this research; provisions for the medical care of the subject. Please inform any changes in the methodology or procedures.

6. Describe if there have been any changes in the methods to be employed for securing informed consent of subjects. Attach copies of the form and explanation to be used.

7. Describe any changes in the risks to the subjects and the potential benefits of this research to subjects and to the public.

8. Please report any adverse effects and unforeseen events and their management.

Should any change in methods become advisable, I will bring this to the IRB before changes are initiated.

Date _____

Principal investigator's name _____

Principal investigator's signature _____
(Signature)

Supervisor's name _____

Supervisor's signature _____
(Signature)

Department _____

Telephone (Day) _____ **(Evening)** _____

E-mail _____

Address _____
_____

PLEASE ATTACH ON COPY OF YOUR PROPOSAL TO THIS FORM AND SUBMIT BOTH

(Do not write below this line)

IRB CHAIR OR COMMITTEE MEMBERS WHO EVALUATE CHANGE OR RENEWAL:

_____	_____	_____
NAME	**SIGNATURE**	**DATE**
_____	_____	_____
NAME	**SIGNATURE**	**DATE**
_____	_____	_____
NAME	**SIGNATURE**	**DATE**

APPROVAL DATE: _____

(Note: This document is available in Blackboard under IRB-student and IRB-faculty courses)

Appendix C

Institutional Review Board
Carlos Albizu University

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): Carlos Albizu University

Applicable FWA #: 00003384

Individual Investigator's Name:

_____

Specify Research Covered by this Agreement:

_____

---

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) designated under the above FWA and will accept the final authority and decisions of the IRB/IEC, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB/IEC prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB/IEC any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research

without prior IRB/IEC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB/IEC any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB/IEC.

(9) The Investigator acknowledges and agrees to cooperate in the IRB/IEC's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB/IEC in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB/IEC.

(11) Emergency medical care may be delivered without IRB/IEC review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date _____
Name: _____ Degree(s): _____
(Last) *(First)* *(Middle Initial)*
Address: _____ phone #: _____

_____
(City) *(State/Province)* *(Zip/Country)*

Supervisor Signature (if applicable): _____ Date _____

Name: _____ Degree(s): _____
(Last) *(First)* *(Middle Initial)*
Address: _____ phone #: _____

_____
(City) *(State/Province)* *(Zip/Country)*

FWA Institutional Official (or Designee): _____ Date _____

Name: _____Institutional Title:_____
(*Last*) (*First*) (*Middle Initial*)

Address: ____ (*City*)_____ (*State/Province*) _____(*Zip/Country*) _____

Phone #: _____

(Note: This document is available in Blackboard under IRB-student and IRB faculty courses)

Appendix D

REPORTING FORM FOR EVENTS THAT REQUIRE PROMPT REPORTING TO THE IRB

This form should only be used to report events that appear on the **List of Events that Require Prompt Reporting to the IRB** (see Section II below).

Additional Requirements

1. If this event report applies to multiple studies, complete a form for each study.
2. Attach any supporting documentation to the report.

Section I: Investigator Information

Principal Investigator:_____IRB Study Number:_____

Building/Room No.:_____

_____Department: _____

Phone:_____Fax Number:_____E-Mail:

_____

Contact Information:

Name:_____Address:_____Phone:

_____

Fax:_____E-Mail:

_____

Project Title:

Sponsor/Funding Agency:

_____

_____

Section II: List of Events that Require Prompt Reporting to the IRB *(SELECT EVENT TYPE)*

A. ☐ Event (including adverse events, injuries, side effects during a study) that caused harm to one or more subjects or others, or placed one or more subjects or others at increased risk of harm, **and** was unexpected, **and** related (e.g. > 51% chance) to the research procedures.

1. Did the event cause harm or place a subject at increased risk of harm?

   ☐ Yes

   ☐ No

2. Was the event unexpected at the time of its occurrence?

   ☐ Yes

   ☐ No

3. Is it more likely than not (e.g. > 51% chance) that this event was related to the research?

☐
Yes

☐ No

If you answered "**No**" to **ANY** of the above questions, **DO NOT REPORT THE EVENT ON THIS FORM;** it does not meet the IRB's prompt reporting requirements. You should, however, report it at the time of continuing review. If, however, you answered "**Yes**" to **ALL** of the above questions, continue to Sections III and IV.

B. ☐ Protocol deviation/violation (an unintentional or accidental change to the IRB-approved protocol) that placed one or more subjects at increased risk, or has the potential to occur again without intervention (on-site only). Continue to Sections III and IV.

C. ☐ Change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject (e.g. purposeful and for subject safety) (on-site only). Continue to Sections III and IV.

D. ☐ Complaint of a subject that indicates unexpected risks or that cannot be resolved by the research team (on-site only). Continue to Sections III and IV.

E. ☐ Interim findings or safety monitoring reports that indicate an unexpected change to the risks or potential benefits of the research, in terms of severity or frequency. Skip to Section IV.

F. ☐ Publication in the literature that indicates an unexpected change to the risks or potential benefits of the research. Skip to Section IV.

G. ☐ Other: Please explain:

Continue to sections III and IV, as appropriate.

Section III: Event Information

1. Date of Event:_____ Date Notified of Event:

2. Event Site: ☐ On-site Subject ID (if applicable):
☐ External Site

3. Event Report: ☐ Initial Report
☐ Follow-up Report

4. Provide a brief description of the event or list an event term:

5. Explain the corrective measures taken to prevent the event from occurring in the future (if possible), how the event was (or will be) resolved, and whether the sponsor was notified of the event (if applicable):

Section IV: Investigator Action

1. Is the event consistent with the informed consent document and is the severity and/or frequency of the event consistent with available literature (e.g. drug brochure, protocol, publications)?
   ☐ Yes. Either attach a copy of the applicable page(s) of the approved informed consent document with the description highlighted or underlined or cite the event description from the informed consent document:

   ☐ No. Explain why not:

2. Should the informed consent document be revised?
   ☐ Yes. Submit an amendment and the revised informed consent document with this event report for IRB review. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

   ☐ No. Explain why not:

3. Should the protocol be revised?
   ☐ Yes. Submit an amendment and the revised protocol with this event report for IRB review. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

   ☐ No. Explain why not:

4. Should currently enrolled subjects be notified?
   ☐ Yes. Attach a copy of the notification with this event report for IRB review.
   ☐ No. Explain why not:

5. Did the event compromise the validity of the data?
   ☐ Yes. Please explain:

   ☐ No.

Statement of Principal Investigator. I have personally reviewed this report and agree with the above assessment.

Signature of Investigator:_____ Date:_____

FOR IRB OFFICE USE ONLY

This information has been reviewed and the following action is recommended:

☐ 1. Event report determined to **NOT** meet reporting requirements. IRB staff initials: _____ date:

Reason(s):

_____

☐ 2. Event report sent to ☐ full IRB for review / ☐ IRB Chair or designee for expedited review as a possible unanticipated problem involving risks to subjects or others.

IRB, IRB Chair, or designee determination:

☐ Event report does **not** represent an unanticipated problem involving risks to subjects or others and can be filed with the IRB study. **No further action is required.**

☐ Event report does **not** represent an unanticipated problem involving risks to subjects or others; however, **further action is required. See below or refer to the IRB minutes for additional information.**

Action Required:

_____

_____

_____

☐ Event report **does** represent an unanticipated problem involving risks to subjects or others and can be filed with the IRB study. **No further action is required.**

☐ Event report **does** represent an unanticipated problem involving risks to subjects or others and **further action is required. See below or refer to IRB minutes for additional information.**

Action Required:

_____

_____

Additional Comments:

_____

_____

_____

IRB Signature: _____ Date: _____

Recorded in the Minutes of: _____

(Note: This document is available in Blackboard under IRB-student and IRB-faculty courses) (FORM IRB-4)

Appendix E

Carlos Albizu University
San Juan Campus
Institutional Review Board

Notice of Protocol Termination

I. Title of the Investigation

II. IRB Protocol Number

III. Principal Investigator and Co-Investigator(s)

Name: -

Telephone: _____ Fax:

Address: _____ E-mail:

Name: -

Telephone: _____ Fax:

Address: _____ E-mail:

IV. Current Status of Investigation (check all that apply)

- ☐ Study is permanently closed to enrollment
- ☐ All subjects have completed all study-related interventions and/or procedures
- ☐ Collection of private identifiable information is complete
- ☐ Analysis of private identifiable information is complete
- ☐ Remaining study activities are limited to data analysis
- ☐ Study remains active only for long-term follow-up of subjects
- ☐ Other (e.g., subjects were never recruited)

V. Study Participants

Item	Write # or N/A
1. Anticipated number of participants according to the protocol approved by IRB	

2. Number of participants enrolled (consented) since the last review by the IRB	
3. Number of participants enrolled (consented) at the end of the investigation	
4. Number of participants randomized	
5. Number of participants who dropped out of the study	
6. Number of participants who completed the study	
7. Number of participants who were withdrawn from the study	

VI. Adverse Events or Unanticipated Problem

Item	Circle one
1. Any adverse events (e.g., worsening of emotional symptoms or behavioral problems) occurred?	**Yes or No**
2. Any serious adverse events (e.g., hospitalizations, death, life-threatening event) occurred?	**Yes or No**
3. Any unanticipated problems occurred?	**Yes or No**

If any adverse events or unanticipated problems identified, please explain what happened, whether the IRB was notified, and what corrective measures were taken.

VII. Storage Of Data (check all that apply)

☐ The original data or data collection documents have been destroyed.

☐ Any connection between existing data and the original source of information has been destroyed.

☐ No individual can be identified from existing data and materials (i.e., data has been de-identified)

Investigator will retain data with identifiers.

Explain why you will retain data identifiers and indicate where and how long the data will be stored, and who will maintain the records.

Publications and Presentations

Include a bibliography of publications or presentations generated by this investigation.

VIII. Signatures

Signature of Principal Investigator _____ Date _____

Signature of Supervisor or Co-Investigator (if applicable) _____ Date _____

If applicable:

Month	Day	Year

Thesis defense date, project or dissertation: