UNIVERSIDAD CENTRAL DEL CARIBE

RULES AND REGULATIONS

2018

Universidad Central del Caribe
Institutional Review Board

Rules and Regulations
2018

This manual contains the general standards for the composition, operation and responsibilities for our Institutional Review Board (thereafter referred to as the IRB), as mandated by the Federal Food and Drug Administration (FDA) and the Department of Human Health and Services (DHHS).

Definitions:

a. **Institutional Review Board:** refers to any board, committee or other group formally designated by an institution to review, to approve the initiation of, monitor and conduct periodic review of biomedical and behavioral research involving human subjects. These are governed by Title 45 CFR part 46(1) and Title 21 parts 56 and 312 (FDA). The IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical and regulatory. The primary purpose of this review is to assure the protection of the rights and welfare of human subjects
b. **Research:** refers to a systematic investigation (includes research development, testing and evaluation) designed to contribute to generalizable knowledge. 45 CFR 46.102 b. The following are NOT research:
    a. Scholarly and journalistic activities (oral history, biographies, literary criticism, legal research and historical scholarship
    b. Public health surveillance activities
    c. Criminal investigations
    d. Intelligence, homeland security

c. **Clinical Investigation:** a research study in which one or more human subjects are prospectively assigned to one or more interventions (including placebo or other control), to evaluate the effects of the interventions on biomedical or behavioral related outcomes.

d. **Human Subject:** Refers to a living individual about whom the researcher obtains data through intervention and/or interaction with the individual or through identifiable information or biospecimens or obtains, uses, analyzes or generates identifiable private information or identifiable bio- specimens. The subject may be the recipient of a test or a procedure or a control, and may be an ill or healthy individual. Intervention includes:

1. Communication or interpersonal contact between the investigator and the subject. Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place. Information that has been provide for specific purposes by an individual with the expectation that it will not be made public.

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

3. Identifiable biospecimen is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated to the specimen.

e. **Institution:** may be any public or private entity or agency (including federal, state or other).
f. **Emergency use:** means the use of a test article, drug or intervention on a human subject in a life threatening situation in which there is no standard acceptable treatment available, and in which there is not sufficient time to obtain IRB approval.
g. **Investigator:** refers to an individual who conducts a clinical investigation, or in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.
h. **Benefit:** a valued or desired outcome: an advantage. In research represents a probability.
i. **Risk:** probability of harm or injury and may refer to chances that specific individuals are willing to take to achieve a goal or conditions that make a situation dangerous per se.
j. **Minimal Risk:** a risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed 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. **Sponsor:** means a person or other entity that initiates an investigation but that does not actually conduct the investigation or research
l. **Sponsor-investigator:** refers to an individual who both initiates and carries out, either alone or with others, research. The obligations of a sponsor- researcher or investigator include both that of a sponsor and that of an investigator.
m. **Test article:** refers to any drug, device, biological product, food additive, color additive, electronic product or any other article subject to regulation under the FDA.

A. Exemptions from IRB Review:

1. The following are exempt from the requirements of IRB review:

a. Any investigation or research which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date; or any investigation commenced before July 27, 1981 that was not otherwise subject to IRB review under the FDA before that date.
b. Emergency use of an article provided that such use is reported to the IRB within 5 working days. Any subsequent use of the article at the institution is subject to IRB review.(See Guidance Charts)
c. Research not prohibited and research is conducted in such a way that the identity of the subjects remains protected, disclosures would not place the subject at criminal risk, financial risk, loss of employability, of educational advancement or of loss of reputation.
    i. Research conducted in established or commonly accepted educational settings, specifically involving common educational practices that are not likely to adversely affect student opportunity to learn or their outcomes. Includes studies that compare educational techniques classroom management methods or curricula.
    ii. Research involving educational tests, survey procedures, interview procedures or observation of public behavior
    iii. Research involving collection or study of existing data, documents, and records, pathological or diagnostic specimens.
    IV. Research studying or examining public benefit or service programs
    IV. Research involving taste and food evaluation or consumer acceptance studies. Note that there are other requirements
    V. Information recorded in such a way that the identity of the subject cannot be ascertained.

These exemptions apply to subparts B, some apply for subpart D (children), but not C (Prisoners).

d. The HHS has prohibited exemption of research involving prisoners and most research involving children (Some exceptions are permitted). Interventions involving deception likewise.

e. Secondary research for which consent is not required: Secondary uses of identifiable biospecimens or private information if:

    a. Private information or biospecimens are already publically available.
    b. Information or biospecimens recorded by the investigator is such a manner that the identity of the human subject cannot be readily ascertained directly or through identifiers *linked to the subject.* The

investigator cannot backtrack and identify the subject and the investigator does not contact the subjects.

c. Research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45CFR parts160 and 164, Subparts A and B.

B. Administration of the IRB:

1. Jurisdiction and authority of the IRB:

a. The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities under the auspices of the institution (Universidad Central del Caribe) with which it is affiliated. It functions in coordination, but independently of other committees and has the authority to approve, disapprove, suspend or modify all research activities that fall under its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been approved by the IRB may be subject to review and disapproval by the top official (president) of the Institution, however, this official cannot approve research that has been disapproved by the IRB.

b. The IRB functions independently of but in cooperation with other institutional committees that may evaluate protocols for different purposes.

2.IRB Membership:

a. The IRB must have at least five (5) members with varying backgrounds to provide complete and adequate review of research activities commonly conducted by the Institution.

b. The IRB must be sufficiently qualified by the experience and expertise of its members' backgrounds. The IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable laws and standards of professional conduct and practice. And therefore must include persons knowledgeable in these areas. The IRB must have members that are knowledgeable and primarily concerned with vulnerable categories of populations (children, prisoners, pregnant women and the mentally disabled).

c. Members cannot be of a single gender, race or profession. Election, however, must not be based exclusively on any of these categories.

d. The IRB must have at least one member whose primary concerns are scientific, and at least one member whose primary concern is not scientific. There must also be at least one member who is not affiliated to the institution (and is not immediate family of an affiliated individual). One individual may assume more than one function. The IRB can invite individuals with specific expertise to assist in the review of study protocols which may require expertise beyond that of the IRB: these individuals cannot vote. When evaluating FDA regulated research, there must be at least one physician member present for quorum.

e. If the IRB regularly reviews research involving a vulnerable category of Subjects (Children, prisoners, handicapped or mentally disabled), the membership must include one or more individuals who are knowledgeable about and experienced in working with these subjects. (34 CFR 350.3(d)2): 34CFR356.3(c) (2))

f. No IRB member may participate in the review of protocols in which the member has a conflicting interest (directly involved as a researcher, research involving the member's department or family member) except to provide information at the IRB's request.

g. A list of the current members of the IRB must be submitted to the OPPR and also kept in the IRB's records. The list must identify members by name, gender, earned degrees, representative capacity, indications of expertise or experience sufficient to describe the member's chief anticipated contributions to IRB deliberations as well as any employment between each member and the institution.

h. Changes in membership must be reported to the head of the agency or institution and the OPPS.

i. The secretary will be present in all IRB meetings and will be responsible for the written documentation of meeting minutes, establishment of the "quorum" and of voting actions by the members of the IRB including number of members voting for, against and abstaining. Minutes will be transcribed from meeting recordings and distributed in subsequent meetings.

3. IRB Functions and Operations:

In order to fulfill the requirements of federal regulations, the IRB shall:

a. Follow and document written procedures (1.) for conducting the initial and continuing review of research and for reporting its findings and actions to the investigator and to the institution. (2.) For determining which projects require review more frequently than annually, and (3) for insuring prompt reporting to the IRB for changes in research activity, (4.) ensuring prompt reporting to the IRB of unanticipated problems involving risks to subjects and others.

b. In order for research to be approved by the IRB, it shall receive the approval of a majority of votes of those members present at the meeting. A "majority" being defined as 50% plus one of members present at the meeting.

c. Be responsible for reporting to the institutional officials and ,if required, to the FDA any serious or continuing non-compliance by investigators with the requirements and determinations of the IRB.

d. Quorum for meetings will be set at a minimum of half of the active IRB members of which at least one member whose primary concern is a non-scientific area will be present (a community member may meet this requirement) and a physician member for FDA regulated studies. In the event that quorum is not established within 20 minutes after the meeting's scheduled starting time, the meeting will be cancelled and reconvened for a future date.

e. Meetings will be scheduled on the last Tuesday of every month with the following exceptions: Months of July and December due to holidays and vacations.

f. The chairperson of the IRB may convene emergency meetings of the full IRB with 48 hours of prior notification

4. IRB Review of Research

a. The IRB shall review and have authority to approve, require modifications in or disapprove all research activities covered by these regulations. While the President of the Institution may disapprove research approved by the IRB, the inverse is not true: S/he cannot approve research that has been disapproved by the IRB.

b. The IRB shall require that information be given to participants as part of the informed consent process and may require that additional information be given to participants when in the IRB's judgment the information would meaningfully add to the protection of participant

rights and welfare. The IRB may waive documentation of the informed consent in accordance to Sec.46.117 (see chart 10 and 11)

c. The IRB may for some or all participants or the participant lawfully representative, waive the requirement of a signed informed consent document if it finds that the research represents no more than minimal risk of harm to participants, , involves no procedures for which a consent would be required, it would not be practical to conduct the study without the waiver and the waiver or altering the informed consent will not adversely affect the participants' rights and welfare and when appropriate pertinent information will be provided to participants later (see decision chart 10).

d. The IRB will notify the investigators and may notify the Institution in writing of its decision to approve or disapprove the proposed research activity and of modifications required to secure IRB approval of the research activity. When the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for the decision and give opportunity to respond in person or in writing. The institution may disapprove studies approved by the IRB, but the Institution may not approve studies disapproved by the IRB

e. The IRB shall conduct continuing review of research approved and covered by these regulations at interval appropriate to the degree of the risk, but not less frequently than once per year, and shall have authority to observe or have a third party observe the consent process and the research. Intervals for progress reports will be based on the risks, the investigator's experience and will be included in the voting process. This information must be included in the minutes as well as in the correspondence with the researcher.

f. All study projects approved by the IRB will be approved with the requirement that a progress report of all study subjects, results, and problems be summarized on a yearly basis at most or earlier if so required for approval. In addition, it is the responsibility of the principle investigator to promptly notify in writing of any unexpected problems or adverse events or reactions in any participant during the course of the study within five working days. This initial report may be informative about the event, followed by an in-depth analysis and report. Progress reports must include the summary, a copy of the current Informed Consent document, flyers, survey instruments, scripts, handouts or educational material, and any other document affecting the study.

g. The IRB will evaluate all approved projects on at least a yearly basis along with the progress report to ensure that the study has been carried

out as approved. The IRB will not allow a study to continue if the report is not filed on time. The IRB can temporality approve an extension of a study while the report is completed.

h. The IRB may approve some studies through the process of expedited review. This type of review is as rigorous and applies the same criteria as in full review. After a protocol has been approved by expedited review, the president will report this to the full committee. A study cannot be disapproved by expedited review: when expedited review cannot approve a protocol, the study will be presented to the full IRB for review. This type of review is carried out by the chairperson or delegate(s) when the following conditions are met. (45 CFR 46.110)

(1). Minimal risk to participants, no vulnerable populations and involves only procedures included in categories 1 to 7
(2). Research involves the following procedures:
i. Some clinical studies without IND/IDE requirements
ii. Prospective non-invasive collection of biological samples
iii. Blood sample collections (routine methods and discreet amounts)
iv. Data collection through non-invasive methods (as routinely collected for non-research purposes).
v. Material collected for non-research purposes
Voice digital or video data collection for research
vi. Individual and group behavior, surveys, interviews and oral histories.
(3). Participants are not at risk of criminal or civil liability or at social or economical damage or if so, are measures in place to protect participants to make these risks at no more than minimal?
(4). Does the review involve a minor change in approved research during the period of approval?
(5). Protocols previously review by expedited review and conditions have not changed (Ex. still minimal risk)
(6). Protocols reviewed through the full IRB but conditions have changed so that the research is now eligible for expedited review.
(7). When the research is permanently closed to enrollment of new participants and all participants have completed research related.
(8). When all activity left at this site is follow-up of research participants or
(9). No participants have been enrolled at this site and no additional risks have been identified at other sites
(10). Remaining activity at this site is limited to data analysis
(11). Research is not conducted under the FDA (IND or IDE)

5. Criteria for IRB review of research

a. The first step shall be to determine whether the submitted protocol is research and research with human participants according the established criteria (see guidance chart 1).
b. The IRB will consider the qualifications of the researcher for the proposed trial, as documented by a current curriculum vitae and/or other relevant documentation, as requested by the IRB.

c. In order to approve research covered by these regulations, the IRB shall determine that all of the following elements are satisfied:

(1). Risks to participants are minimized through sound study design.

(2). Risks to subjects are reasonable in relation to Risk/Benefit ratios

(3). Selection of subjects is equitable and appropriate for the study design.

(4). Informed consent will be sought from each prospective participant or his/her legally authorized representative. The IRB has the authority to waive documentation of the informed consent when the criteria are met

(5). Informed consent must be appropriately documented and contain all the required elements.

(6). Where appropriate, the research plan must include provisions for data monitoring to ensure and enhance the safety of the participants.

(7) There must be appropriate provisions to protect the privacy of the participants to the degree required by the nature of the protocol

(8). There will be additional safeguards in place in protocols where some or all of the participants may be vulnerable to coercion or undue influence with the purpose of providing additional protection for these participant's rights and welfare.

(9). When non-therapeutic trials are to be carried out with the consent of the participant (or legally acceptable representative) the IRB should determine if the proposed protocol and/or other documents adequately address relevant ethical concerns and meet applicable regulatory requirements for such trials.

(10). The IRB should review both the amount and method of payment to participants to assure that neither presents problems of coercion or undue influence on trail participants. Payments to participants should be prorated and not paid wholly ob the completion of the trial by the participant.

(11). The IRB should ensure that information regarding payment to subjects, including the methods, amounts, schedules of payment to trial participants, is set forth in the Informed Consent form and any other written information to be provided to participants. The way payment will be prorated should be described.

c. Suspension or termination of IRB approval of research:

(1). The IRB shall have the authority to suspend or terminate approval in research that is not being conducted in accordance with IRB requirements or that has been associated to unexpected serious harm to subjects. The decision will be reported promptly to the investigator, to the appropriate institutional officers and the FDA, if required.

d. Cooperative research:

In complying with these regulations, institutions involved in multi-institutional studies may use joint review; rely on another qualified IRB or similar arrangements aimed at the avoidance of duplication of efforts. The IRB will comply with the final statutes for Single IRB review once these become mandated (in three years)

e. Continuing Review:

Upon evaluation for approval the IRB will determine the intervals for continuing review (progress report) at intervals not greater than one year. Continuing review, unless the IRB determines otherwise, is NOT required in the following circumstances:

i. Research eligible for expedited review (__. 109(F))
ii. Research reviewed in accordance with limited review as described in __.10(d)(2)(iii)
iii. Research that has progressed to the point that the researchers are only involved in data analysis, assessing follow-up data from procedures that subjects would undergo as part of clinical care

f. The IRB shall have the authority to, or have a third party, observe the consent process and the research.

5. Institutional Responsibilities:

a. The Institution must provide the DHHS with a written FWA ASSURANCE that it will comply with the requirements of the Policy.

b. Specification of quality standards in the written policies of the Institution so that the Institution supports only well-designed and properly executed research.

6. Records and Reports

a. The IRB will prepare and maintain adequate documentation of all IRB activity including the following:

(1). Copies of all research proposals , reviews, scientific evaluations, samples of approved Informed Consents, flyers, promotional materials, telephone scripts, questionnaire, survey sheets, data collections sheets, educational material, etc.
(2). Minutes of IRB meetings shall contain sufficient details to show attendance, member composition, actions taken by the IRB, vote on these actions (including the number of votes for, against and abstained); the basis for controverted issues and their resolution; the basis for the required changes. This record will be preferably a verbatim report or a summary of the more important aspects when a verbatim report is not feasible.
(3). Records of continuing review activities,
(4). Copies of all correspondence between the IRB and investigators.
(5). A list of all IRB members identified by name, earned degrees, representative capacity, indications of experience, such as Board certifications, licenses, etc. in sufficient detail to describe each members' chief anticipated contributions to the IRB deliberations and any employment or other relationship with the institution, and/or other members. (See appendix).
(6). The rational for an expedited reviewer's determination under (__.110(b)(1)(i)) that research appearing on the expedited review list (__. 110(a) is more than minimal risk.

6. Informed Consent:

a. No investigator may involve a human being as a participant in research covered by these regulations unless the investigator has obtained a legally effective informed consent from the prospective participant or his/her legally authorized representative. A researcher should pursue such consent only under circumstances that provide the prospective participant with sufficient time or opportunity to consider whether or not to participate and that minimize the opportunity of coercive or undue influence. The information given to the prospective participant should be in a language understandable to the subject or the representative. No informed consent , whether written or oral, may include exculpatory language through which the participant or the representative is made to waive any legal rights, or releases or appears to release the investigator, the institution, the sponsor or its agents from liability for negligence.

Broad consent may be obtained in lieu of informed consent obtained. See below.

b. Elements:

(1). A statement that the study involves research; an explanation of the purpose of the research and the expected duration of the participant's involvement; a description of the procedures to be followed and an identification of the procedures that may be experimental.

(2). A description of any reasonably foreseeable risks or discomforts to the participant.

(3). A description of any benefits to the subject or others which may reasonably be expected from the research.

(4). A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the participant.

(5)A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, and that notes the possibility that the FDA may inspect the records.

(6). A statement that participation is voluntary; that refusal to participate or withdrawal from participation in the study will involve no penalty, no loss of benefits to which the participant is otherwise entitled to.

(7). A statement with information about whom to contact with questions about adverse events: to whom to contact with questions about participant rights and to whom to contact with questions about the study.

(8). 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 should occur and, if so, what they consist of and where further information may be obtained

(9). In research that involves the collection of identifiable private information or identifiable biospecimens, either a statement that even if identifiers are removed the data or biospecimen will not be used in other studies, or alternately, that de-identified data /biospecimens could be used for other unrelated studies, by other or the same researcher, without additional informed consent from the subject or legal representative (if this were a possibility). Statements that biospecimens devoid of identifiers, can be used for commercial purposes and the extent of subject rights to commercial profits; general description of types of research that can be carried out with these biospecimens or identifiable data; a description of the identifiable private information/biospecimen to be

used so that the subject has a general idea of the types of institutions /researcher that may have access to and whether sharing of private identifiable information or biospecimens may occur. The length of time during which private identifiable information/biospecimens may be stored or used for other research; whether the subject (or representative) will be told about the other research in which his/her private identifiable information will be involved or a statement that this information will not be shared with the subject. If an individual were asked to provide broad consent for the storage, maintenance and secondary research use of private identifiable data or biospecimens, the IRB CANNOT waive consent

(10). Additional elements:

i. Statement that a particular treatment or procedure may pose risks for the subject (or fetus) if the subject would to become pregnant, that are unforeseeable

ii. Additional costs to the subject and under what ciircumstances

iv. Consequences of subject withdrawal from participation (lab tests, follow-ups for safety reasons).

v. Statement that if important additional significant new findings related to a subject's willingness to participate, that these will be provided to the subject

vi. Number of participants

vii. Whether clinical results during the study will be shared with the participant or not

(11) Waiver of consent:

i. An IRB can waive the consent in research involving public benefit programs, procedures for obtaining benefits, possible changes to those programs and research cannot be carried out without the waiver for practical reasons.

ii. An IRB can waive or alter consent if risk is minimal, cannot be carried out for practical reasons, the waiver will not adversely affect the rights or safety of the subjects and whenever appropriate, subjects will be given additional pertinent information after participation.

ii. An IRB can waive a signed informed consent form when the risk is less than minimal, the only link to the study would be the signed document and the principal risk is a breach in confidentiality and involves no procedures for which an informed consent would be required. The IRB can require the

researcher to provide written information to the subjects and if the subjects are members of a group, culture where informed consents are not the norm.

iii. Screening, recruiting or determining eligibility: The IRB may approve a research proposal in which an investigator will obtain information or biospecimens with the purpose of screening, recruiting or determining eligibility if: the investigator will obtain oral or written information with the prospective participant, the investigator will obtain identifiable private information, or biospecimens by reviewing records or stored biospecimens. Informed consents of clinical trials must be posted on the federal web site.

c. Documentation of the Informed consent:

(1) The informed consent must be documented by a written document approved by the IRB, and signed by the participant or the participant's legal representative at the time of the consent. A copy should be given to the person signing the form.

(2). The consent form may be either of the following:

i. A written document that embodies the elements of informed consent required by section 50.25/__.116(a)(5). This form may be read to the participant or the participants' legally authorized representative, but in nay event, the investigator will provide the participant or the participant's legal representative sufficient time to read the form before it is signed.

ii. Short form written consent document stating that the elements of informed consent required by section 5025 have been presented to the prospective participant or his/her legal representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the representative in addition to a copy of the short form.