	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
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INITIAL REVIEW – FULL IRB REVIEW

Purpose:

To describe the process of full IRB review at the UPR/MSC.

Introduction:

During the initial review of research, the IRB assesses the proposed protections of the rights and welfare of human subjects participating in research. In order for a project to be approved, it must meet the DHHS Criteria for IRB approval of research as defined at 45 CFR 46.111, 21 CFR 56.111 and receive the approval of a majority of the quorum.

Source:

45 CFR 46.111; 45 CFR 46 Sub parts B, C and D
21 CFR 56.111; 21 CFR 50 Sub part D

Applicability:

IRB Staff, IRB Members

Policy:

To ensure a thorough review and to provide the greatest protection to our research participants, initial review of research is conducted at a convened

meeting where quorum is present, except where expedited review is allowable under the Federal Regulations.

The IRB chair or a designated member shall determine if a research activity meets the criteria for expedite review.

Procedure:

Reviewer system

The UPR MSC IRB utilizes a primary reviewer system. The protocols on agenda for full board evaluations are distributed among the members taking in consideration their expertise, so that each protocol will have a primary and secondary reviewer. The secondary reviewer will substitute the primary reviewer if the latter is absent at the meeting, and will otherwise provide an additional level of review and discussion. Treatment protocols will have a physician, nurse or other qualified healthcare professional as the primary reviewer.

Documents distributed to IRB Members before a meeting

Each member will receive an electronic version of the complete agenda and protocols to be reviewed through the IRBWISE system. Each reviewer will be provided an IRB evaluation worksheet to be used as a guide for presenting the protocol during the meeting and given to the office staff after the meeting finalizes.

All the IRB members have special access privileges to the IRBWISE system; therefore they can review all the documents for each study on agenda. At least one week prior to the IRB meeting, each primary reviewer will receive an agenda packet containing paper copies of the application and protocol (refer to policy for IRB submission).

Primary reviewer may request additional information from the Principal Investigator. This can be accomplished directly or through the IRB Office staff. The primary reviewers will present the research project to the convened board at the IRB meeting and address all of the following issues:

(a) Research design and methods

(b) Risk identification and assessment

(c) Benefits identification and assessment

(d) Disclosure of risks and benefits

(e) Plan for data collection storage and analysis

(f) Privacy and confidentiality issues

(g) Equitable selection of subjects

(h) Adequacy of provisions for monitoring and observation of research participants

(i) Adequacy of content, expression and process of informed consent

(j) Requirements for assent

After the primary and secondary reviewers have presented their comments, all Board members discuss the documents received for review and add their comments.

Research or clinical investigations involving pregnant women, human fetuses and/or neonates

For research involving pregnant women, human fetuses and/or neonates**,** the committee will determine compliance with additional protections of CFR sub- part B.

Research or clinical investigations involving children

In the case of research or clinical investigations involving children as subjects, IRB will assess the risk category that applies to the study (as defined on 45 CFR 46 subpart D and if applicable 21 CFR 50 subpart D) and the requirement for parental permission and child assent as follows:

- Studies not involving greater than minimal risk to the children or studies involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research: Parental permission (one parent maybe sufficient) and child assent according to age guidelines described on

"Informed Consent and Child Assent" section of this manual.

- Studies involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition: Parental permission (both parents unless one is deceased, unknown, incompetent or not reasonably available and child assent according to age guidelines described on "Informed Consent and Child Assent" section of this manual.

- Studies that the IRB believes does not meet the conditions described above, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children This special cases may not be approved by local IRB and must be referred to DHHS if DHHS funded and/ or to the Commissioner of Food and Drugs, for review.

Research involving prisoners as subjects

For research involving **prisoners**, a special checklist will be utilized to assure compliance with CFR sub-part C of CFR.

Determination of Quorum & Voting

Please refer to "IRB Meetings Policies and Procedures" section.

Criteria for IRB approval of Research

The IRB reviews research in accordance with current Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations. The main purpose of the IRB is to protect the rights and welfare of human subjects who take part in research. More specifically, the IRB assures that:

(1) Risks to subjects are minimized.

(2) Risks to subjects are reasonable in relation to any benefits that might be expected from taking part in a research study and to the importance of the knowledge that may result.

(3) Selection of subjects is fair and equitable.

(4) Participation is voluntary and informed consent is obtained from each prospective subject or where appropriate, from the subject's legally authorized representative.

(5) The research plan provides for monitoring the data collected to ensure the safety of subjects.

(6) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Determining frequency of continuing review

When IRB votes to approve a protocol, they decide the period for which IRB approval is to be granted. This determination is based on their assessment of the degree of risk to participants, as defined in 45CFR 46.103(b) and 109 (e). When the risk is significantly higher in relation to the risk of alternative procedures, IRB will consider requiring more frequent continuing review (periods shorter than a year), or one year with case by case reporting. The approval period begins the day that either the full committee approves the study, or the day the Chair or designated reviewer approves the response to stipulations and must not be longer than a year.

Determining which studies need verification from sources other than the investigators

Investigators are expected to provide all relevant information regarding the conduct of the research to the IRB. This system is based on trust between the investigators and the IRB. The IRB also relies on Data and Safety Monitoring Boards' (DSMB) reports as an external source of data verification.

In order to assure that the research is conducted in compliance with all regulations for human subject's protection, IRB may require at their discretion verification of information from other sources. Verification of information provided to the IRB may be requested by the convened committee or by the IRB chairpersons during the process of carrying out reviews.

Independent verification may include request and verification of correspondence between sponsor and or FDA and the investigator; including sponsor's audit reports, or direct audits by an IRB-delegated team. This may be considered in the following situations:

- Projects involving unusual levels or types of risk to subjects
- Studies conducted by investigators who had previous non-compliance with regulations
- Unclear or contradictory information noticed during continuing review
- Complaints from subjects or whistleblowers