	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
		Rev. 07/01/2014

MATERIALS REQUIRED FOR IRB SUBMISSION

Purpose:

To define the IRB submission requirements.

Sources:

45 CFR 46
21 CFR 56

Applicability:

Investigators, Students, IRB Members and Staff

Background:

UPR MSC utilizes an electronic system for IRB submission. The protocol review application was developed taking into consideration federally mandated criteria as well as local institutional policies and practices. The application requires that investigators respond to questions and issues that are pertinent to evaluate the significance of the research and making a risk/benefit determination. It also includes the opportunity to address institution-specific requirements.

Policy:

The development of a comprehensive protocol review application by an investigator is essential. Investigators must carefully review IRB submission requirements. Incomplete applications will not be accepted for IRB review.

Procedure:

Applications for approval to conduct research activities involving human participants must be submitted to the Human Research Subjects Protection Office and must be approved by IRB prior to initiation of any research activity. Materials required for submission include:

- **Completed IRBWISE electronic application:**

  This application has been designed to meet the needs of the researchers that utilize the UPR MSC's IRB. **All items in this application must be answered**. Please read each question carefully, if the question does not apply to your research answer "NO" or "N/A" as appropriate. Please do not use cross references such as "Refer to Protocol" or "Refer to Informed Consent Document." Applications, containing incomplete answers or blanks will be returned to the Principal Investigator. This could ultimately delay the review of your protocol.

  Please make sure to use the appropriate application for the specific activity you want to submit (initial review, continuing review, amendment, etc.).

- **Electronic signatures are required:**

  (1) Signature of the investigator (PI) in the IRBWise endorsement section, who ensures accuracy of the information contained within the submitted materials and, upon approval, assures compliance with all aspects of the section titled "Endorsement".

  (2) If the investigator is a faculty member, the signature of the Department Chair warrants that he/she is aware that the Principal Investigator intends to conduct the proposed research in his/her department. If the Division Chief is unavailable, a deputy or acting chief may electronically sign

the application.

(3) If the investigator is a student or resident, must have the signature of the faculty advisor and the Department Director, who assume **complete responsibility** for the student's research including ensuring accuracy of the information contained within the submitted materials and assuring compliance with all aspects of Section entitled "Endorsement".

- **Attachments:**

If applicable, the following documents should be attached in the IRBWISE system: (Not all research studies will need all of these elements)

(1) Research proposal/protocol (required for all studies)

(2) Data Collection Forms

(a) You will need to attach questionnaires, surveys, medical history forms, demographic forms, phone screens, etc. and copies of data collection forms(s) to the Application. Questionnaires that will be administered via telephone interview will require submission of the interviewer's text.

(3) If surveys are being used, a cover letter to the participant is required and a copy of the survey and cover letter must be attached to the application. The cover letter must contain the following:

(a) Explanation of why the research is being conducted (i.e. fulfillment of master degree's thesis, dissertation, etc.);
(b) The purpose of the study;
(c) A statement that the subject's responses will be kept anonymous or confidential and that they do not have to answer all of the questions;
(d) If participants will be students, then include a statement that class standing or grades will not be affected by refusal to participate

or withdrawal from the study; and

(e) A statement that participation is voluntary.

(4) Data and safety monitoring plan (for studies with more than minimal risk that are not monitored by a DSMB).

(5) Consent and Assent Forms (Refer to templates at **http://irbrcm.rcm.upr.edu/**)

(6) Approval by other regulatory committees or other institutions' IRB

(a) If a proposed project involves a component of research that falls under the jurisdiction of the Animal Care and Use and/or the Biosafety Offices, approval must be obtained from the appropriate Compliance Office(s).

(7) If applicable, include evidence of IRB approval of other IRB that might have jurisdiction in the research.

- **Supplemental Materials:**

(1) If access to research subjects is gained through other institutions, those institutions must be identified on the IRBWISE application and an authorization letter or IRB approval must be provided.

(2) All advertisements related to recruitment (i.e., newspaper, radio, flyers, etc.) to be used.

(3) Interview or focus group protocols, scales, all the instruments to be used for the research must be attached electronically to the IRBWISE application, e.g. complete research proposal.

(4) When the research involves a new drug or device, a copy of the investigators brochure and IND should also be included.