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

EXTERNAL INSTITUTIONAL REVIEW BOARD
WESTERN IRB

Purpose:

To recognize the availability of an external IRB as alternative for industry sponsored or externally funded protocols conducted at the UPR MSC.

Sources:

WIRB Services Agreement Document

Applicability:

Investigators with Industry Sponsored or externally funded Protocols

Background:

On September 15, 2005, Western IRB (WIRB®) was been established as an affiliate MSC IRB. MSC IRB is required by its policies and by the Federal Wide Assurance, to review and maintain files on all clinical research conducted within the institution. This includes the industry-sponsored protocols that are reviewed by Western IRB per contract between the institution and Western IRB.

Policies:

The University of Puerto Rico Medical Sciences Campus has affiliation with the Western Institutional Review Board (WIRB) as an alternative for the review and oversight of externally funded projects conducted at the UPR MSC.

The MSC IRB has the right to decide to keep any new research protocol at the UPR MSC for review by the internal IRB.

No other commercial IRB review will be allowed for MSC projects. Projects previously approved by the UPR MSC IRB's will NOT be transferred to WIRB.

Procedures:

Principal Investigators will determine whether they want to submit the research protocols to Western IRB or to the IRB of the University of Puerto Rico Medical Sciences Campus.

All industry-sponsored protocols that will be submitted to the Western IRB, should initially be submitted to the Western IRB Liaison Officer (MSC IRB Office, Office A-236, Main Building) prior to its submission to WIRB.

The Initial Submission documents will include MSC site specific needs to meet institutional requirements (Compensation and Privacy Language) and to provide the MSC IRB with all the information needed for our files.

Information on required documents is available at IRB website (**http://irbrcm.rcm.upr.edu/**). The Western IRB Liaison Officer will retain copies of necessary documents and then will provide a letter of authorization to the Principal Investigator to submit the Initial Submission documents to Western IRB for full board review. After this Initial Submission to the MSC IRB, all other correspondence, including renewals, amendments, and adverse events, will be sent directly to Western IRB by the Principal Investigator. MSC IRB will maintain its files by receiving copies of approvals directly from Western IRB.

The MSC IRB charges a one-time fee of $750.00 for the processing of industry- sponsored protocols submitted to the Western IRB for review. This fee provides funds to the MSC IRB to assist in the costs associated with the review. The MSC IRB uses the fee to pay for the staff time involved in the pre-review of the protocol for institutional and WIRB requirements. The fee also covers the maintenance and update of the file throughout the life of the protocol at MSC.

Studies may be submitted to WIRB® only if they meet ALL of the following conditions:

(a) The trial is externally or industry-sponsored, industry-written; FDA regulated and meets the definition of a clinical trial "A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions".

(b) The investigator has not previously submitted the clinical trial to another MSC IRB.

(c) The proposed research does not involve gene transfer or embryonic stem cell Research.

(d) The individual responsible for the conduct of the study (the PI) must be an MSC faculty member or a MSC associated member. MSC students are not allowed to submit research projects to WIRB even if it meets the above conditions.

The UPR MSC may decide to retain a protocol for the internal IRB review if the protocol has significant local context issues such as a unique vulnerable population, involves an investigative team that has had previous serious and/or continuing noncompliance issues, or if the research design or intervention adds unusual risk for the subjects.