Institutional Review Board

Application to Submit Protocols for Western IRB Review

IMPORTANT NOTICE: Before submitting this application to the OPPHI/IRB, please verify that it has all the required signatures.

PROTOCOL INFORMATION

Project Title:	
Sponsor:	
Sponsor Protocol Number:	

PRINCIPAL INVESTIGATOR (PI) INFORMATION

Principal Investigator	
School	
Department	
Telephone	Fax
Mailing Address	
E-mail	

STUDY COORDINATOR INFORMATION

Study Coordinator: (designated contact for this research other than the PI)	
Telephone	Fax
Mailing Address	
E-mail	

I intend to submit this new research protocol to WIRB. The following documents are enclosed to meet institutional requirements and to provide the MSC IRB with all the information needed to open a study file. I also understand the UPR MSC Human Research Subjects Protection Office will invoice a **$750.00** standard processing fee.

DOCUMENTS SUBMITTED (all these documents must be sent electronically to wirb.rcm@upr.edu):

- ☐ UPR MSC Submission Form (signed by the PI and the Department Director)
- ☐ WIRB Submission Form with PI's Signature
- ☐ Research Proposal
- ☐ Letter of Authorization from the Performance Site
- ☐ Informed Consent Document (English Version)
- ☐ Informed Consent Document (Spanish Version)
- ☐ FDA 1572 Form
- ☐ Investigator Brochure
- ☐ Diaries and Questionnaires
- ☐ Copy of the required training certificates for all personnel (Human Subjects Protection, HIPAA, Good Clinical Practices and Biosafety).
- ☐ Certification as evidence that the study was submitted to the Office of Contracts.
- ☐ Certification as evidence that the study was submitted to the Institutional Biosafety Committee (IBC).
- ☐ Other (Specify)

_____ _____

Signature of Principal Investigator Date

DEPARTMENT DIRECTOR ASSURANCE STATEMENT

This is to certify that I have reviewed this research protocol and I attest to the competency of the investigator(s) to conduct the project. I authorize the Principal Investigator to conduct the Study under this Faculty/ Department.

Department Director (Printed Name) _____

Date _____

Department Director's Signature _____

To be completed by the Office of Compliance

Date Reviewed: _____

Name of Reviewer: _____

After reviewing this research protocol the following decision was made:

☐ Protocol qualifies for submission to WIRB.

☐ Protocol does not qualify for submission to WIRB.

Reason for disapproval:

_____
_____
_____
_____

_____
_____
Signature of Liaison Person

Date