University of Puerto Rico
Medical Sciences Campus
Human Research Subjects Protection Office

PROTOCOLS FOR WESTERN IRB REVIEW CHECKLIST

PI:
Title:
Sponsor:
Sponsor Protocol Number:
NUM_OPPHI:

☐ MSC Submission Form (signed by the PI and the Dept. Director)

☐ WIRB_Initial Review Submission Form

☐ FDA 1572 Form (Signed by Investigator)

☐ Research Protocol

☐ Informed Consents
- ☐ English
- ☐ Spanish
- ☐ Information required about **ClinicalTrial.gov** (Informed Consents)

☐ Diaries and Questionnaires
- ☐ English
- ☐ Spanish

☐ Investigator's Brochure

☐ Log of Research Personnel (Including name, Institution of Affiliation, role, etc.)

☐ Evidence that the protocol was submitted to the Institutional Biosafety Committee (IBC) and CITI Program_Certificate of Biosafety

☐ Evidence protocol processing with Office of Contracts [(Lcda. Rosa I. Martínez Addarich -Letter or Email). Recuerde que una vez tenga la aprobación del IRB que evalúa el protocolo debe

llevar copia de la carta a la Oficina de Contratos para continuar el proceso y presentarlo para la firma del Rector.]

☐ Other:

Revised by:

_____ _____

Name Sign

Date: _____