



WORKSHEET: External IRB review of UM Human Subject Research

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HRP-335	03.20.2019	1 of 1

The purpose of this checklist is to provide support for IRB staff conducting Pre-review. This checklist or equivalent is to be completed by the IRB staff, signed, dated, and retained.

IRB Number:	
Protocol Name:	
Investigator:	
Funding	
Reviewing IRB:	

- A current, executed Reliance Agreement exists and is
 - The UM Investigator is not included on restricted list.
 - The UM investigator and research team members have completed required training
 - All ancillary reviews have been submitted via eProst
- The following are included in eProst:
- eProst SmartForm with all applicable questions answered
 - Approval Letter from reviewing IRB listing UM/JHS as a site. package includes the abbreviated initial review application, the protocol, subject facing materials, local ancillary approval determinations, other approved documents, approval letter and, when applicable, the reliance agreement.
 - The approval and expiration dates (if applicable) on the approval letter are consistent with the dates listed in Questions 4 and 5 of the External IRB page of the SmartForm.
 - The protocol is complete and understandable.
 - The protocol is consistent with UM requirements and applicable law.
 - If consent is not waived or consent alteration granted, the consent document and process is consistent with UM SOP HRP-090-091, when applicable.
 - The language in the approved informed consent document, if any, is consistent with the language of the CTA
 - If there is a local COI, the language in the consent document is consistent with the management plan.
 - The research is acceptable; there is no apparent error or omission in the approval of the reviewing IRB based on regulatory criteria for approval of human subjects research.

Comments:

- Acknowledgement sent to Relying Investigator