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| The purpose of this worksheet is to provide support for IRB staff conducting screening of submission materials.[[1]](#footnote-1) | | |
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| 1. ALL REVIEWS | | |
|  | Determine the laws that apply to Human Research and indicate in the “Regulatory Oversight” section of HRP-401. | |
|  | Determine whether the Human Research has received all required ancillary reviews and approvals by the appropriate committees and officials, including Scientific Review, use the “WORKSHEET: Ancillary Reviews Matrix (HRP-309).” | |
|  | If the Human Research could be subject to the General Data Protection Regulation (GDPR), send for legal counsel review. | |
|  | Note any missing materials necessary for review in the “Missing Materials” section of HRP-401. | |
|  | Protocol template or Determination Form | Data collection instruments |
|  | Consent document(s), HIPAA Authorization Form, or script(s) | Written material to be seen or heard by subjects |
|  | Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).” | |
|  | Determine whether this submission is related to a study where the UMN IRB is serving as sIRB or a reliance on an external IRB submission. | |
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| 1. INITIAL REVIEW and MODIFICATION FOR STUDIES (when the modification affects one of the following) | | |
|  | If the submission is a request for reliance on an external IRB, use the “WORKSHEET: Local Context Review for Relying on an External IRB (HRP-830).” | |
|  | If the research involves the use of a drug use the “WORKSHEET: Drugs (HRP-306)” and check the protocol or local protocol addendum for an IDS number (IDS numbers will not be included for Gillette research studies). | |
|  | If the research involves the use of a device (including a humanitarian use device) use the “WORKSHEET: Devices (HRP-307).” | |
|  | Note any special determinations that need to be made by the convened IRB or Designated Reviewer in the “Notes” box in the Submit Pre-Review activity. | |
|  | If the device meets the abbreviated IDE requirements, note “Non Significant Risk Device” in the “Notes” box in the Submit Pre-Review activity. | |
|  | If the research is NIH-funded (regardless of whether the investigator has indicated the use of a Certificate of Confidentiality), note the presence of a Certificate of Confidentiality in the Protocol Tracking section of the Pre-Review Checklist. | |
|  | Note any missing materials necessary for review in the “Missing Materials” box in the Submit Pre-Review Activity. | |
|  | Study Team training | Investigator brochure for investigational drug |
|  | Complete sponsor protocol | Package insert for marketed drugs |
|  | DHHS-approved sample consent document (if applicable) | Product information for medical devices |
|  | For a multi-site / cooperative research study where UMN IRB will serve as sIRB, a Communication Plan (HRP-82X) is provided | For the Department of Education (ED) research, ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA. |
|  | Note, if relevant, missing/inappropriately answered protocol template sections in the “Missing Materials” box of the Submit Pre-Review activity; compare the submitted protocol to the appropriate template on the IRB website. | |
|  | For clinical drug trials conducted by the Department of Psychiatry: The protocol includes a plan for:   1. Providing written notification of any research participant’s death or serious injury to be reported to the Ombudsman’s office within 24 hours as directed by the UMN HRPP. 2. Providing all research participants with the Ombudsman Information Sheet (NOTE: The information sheet does not need to be included in the ETHOS record). | |

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|  | Include, as appropriate, the following items in the “Notes” box in the Submit Pre-Review activity. Other notes may also be relevant. | | |
|  | Research is subject to regulations not overseen or conducted by the organization | | There are inadequate provisions to control the device(s) |
|  | Positive financial declaration without a Conflict of Interest report (see **HRP-054 IRB Review of Financial Conflicts of Interest**) | | There are inadequate provisions for an investigator held IND |
|  | Protocol information relates to an item in the list of institutional financial interests | | There are inadequate provisions for an investigator held IDE |
|  | An IND is required and there is no IND | | External site(s) getting federal funds from the organization does not have a federalwide assurance (FWA) |
|  | An IND is required and there is insufficient documentation | | The research involves adults unable to consent and statements by the investigator and legal counsel regarding which individuals are legally authorized representatives do not match. |
|  | An IDE/HDE is required and there is no IDE/HDE | | The research involves children and statements by the investigator and legal counsel regarding which persons do not match. |
|  | An IDE/HDE is required and there is insufficient documentation | | There are inadequate provisions to control the device(s) |
|  | There are inadequate provisions to control the drug(s) | |  |
|  | If NIH GDS certification is required, flag the submission for the IRB Director or Assistant Director. Follow “SOP: NIH GDS Certification (HRP-064). | | |
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| 1. INITIAL REVIEW and MODIFICATION FOR PARTICIPATING-SITES (p-Sites) RELYING ON UMN IRB: | | | |
|  | | The p-Site submission includes all of the following:  Assign the Sr. IRB Analyst supporting sIRB/reliance as an ancillary review.  All questions have been completed on the Basic Information page (e.g. p-Site PI is listed).  All required documents have been uploaded as applicable:  Reliance Agreement (includes both signatures)  Local Context Form  p-Site Informed Consent Document  p-Site Recruitment Material | |
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| 1. OTHER CONTINUING REVIEW | | | |
|  | Note missing Continuing Review items in the “Missing Materials” box in the Submit Pre-Review activity. | | |
|  | Determine whether study is subject to any new Human Research policies enacted since last approval. | | |
|  | If funded by NIH, verify with the investigator whether the NIH COC policy applies. | | |
|  | Identify if there are any unresolved Reportable New Information submissions and determine whether those submissions must be addressed prior to or as part of the continuing review. | | |
|  | For multi-site or collaborative studies for which UMN is serving as the IRB of record, enrollment numbers for each p-site. | | |
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| 1. MODIFICATION   If this is a p-Site related change, see Section 3 “INITIAL REVIEW and MODIFICATION FOR p-SITES RELYING ON UMN IRB.” | | | |
|  | Note missing Change in Protocol materials in the “Missing Materials” section of HRP-401. | | |
|  | Determine whether study is subject to any new Human Research policies enacted since last approval. | | |
|  | Note whether the study is a multi-site or cooperative research study where UMN IRB is serving as sIRB. | | |
|  | Identify if there are any unresolved Reportable New Information submissions and determine whether those submissions must be addressed prior to or as part of the modification review. | | |

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| 1. STUDY CLOSURE | |
|  | Confirm that the research meets the criteria for closure and note in the Study Closure section of HRP-401. |

1. This document satisfies AAHRPP elements I-9, II.2.C [↑](#footnote-ref-1)