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| The purpose of this worksheet is to provide support for HRPP staff conducting screening of submission materials. |
| 1. ALL REVIEWS
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| [ ]  - Determine the laws that apply to the Human Research and indicate in the “Regulatory Oversight” section of “CHECKLIST: Pre-Review (HRP-401)”.[ ]  - Determine whether any investigators or research staff are Restricted. If so, list their names and the reasons in the “Restrictions” section of  “CHECKLIST: Pre-Review (HRP-401)”.[ ]  - Determine whether the Human Research has received all required ancillary reviews and approvals by the appropriate committees and officials. [ ]  - If the Human Research could be subject to EU GDPR, send for legal counsel review. [ ]  - If there is a HIPAA authorization, review using “WORKSHEET: HIPAA Authorization (HRP-330)”.[ ]  - If a HIPAA waiver of authorization is required, grant using “CHECKLIST: HIPAA Waiver of Authorization (HRP-441).”[ ]  - Determine whether the submission is for a Single-Site Study, a Collaborative Study, or a Multi-Site Study. |
| **Note any missing materials necessary for review in the Missing Materials section of “CHECKLIST: Pre-Review (HRP-401)”.** |

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| * [ ] Completed “FORM: Basic Study Information (HRP-211)” including all appendices as applicable
* [ ] Investigator Protocol
* [ ] Consent document(s) or script(s)
 | * [ ] Data collection instruments
* [ ] 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).”
 |
| 1. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following):
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| * [ ] If the research involves the use of a drug use the “WORKSHEET: Drugs (HRP-306).”
* [ ] 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 “Special Determinations” section.
* [ ] If the device meets the abbreviated IDE requirements, note “Non-significant device determination” in the “Special Determinations” section.
 |
| **Note any missing materials necessary for review in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401)”:** |
| * [ ] Qualifications of the key personnel
* [ ] Complete sponsor protocol (including HHS protocol)
* [ ] HHS-approved sample consent document
* [ ] Investigator brochure for investigational drug
* [ ] Package insert for marketed drugs
* [ ] Institutional Profile
* [ ] Executed Reliance Agreement(s)
 | * [ ] Product information for medical devices
* [ ] For the Department of Education (ED) research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA.
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| **Note missing/inappropriately answered Investigator Protocol sections in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401)”:** |
| [ ]  - IRB Review History[ ]  - Objectives[ ]  - Background[ ]  - Setting[ ]  - Resources Available[ ]  - Prior Approvals[ ]  - Study Design[ ]  - Recruitment Methods | [ ]  - Inclusion/Exclusion Criteria[ ]  - Compensation for Injury[ ]  - Local Number of Subjects[ ]  - Total Number of Subjects[ ]  - Study Timelines[ ]  - Study Endpoints[ ]  - Procedures Involved[ ]  - Data and Specimen Banking | [ ]  - Data Management[ ]  - Confidentiality[ ]  - Provisions to Monitor Data[ ]  - Withdrawal of Subjects[ ]  - Risks to Subjects[ ]  - Potential Benefits to Subjects[ ]  - Provisions to Protect Privacy[ ]  - Economic Burden to Subjects | [ ]  - Consent Process[ ]  - Consent Documentation[ ]  - Vulnerable Populations[ ]  - Drugs or Devices[ ]  - Multi-Site Research[ ]  - Community-Based Participatory Research[ ]  - Sharing of Results |
| **“Notes” section:** |
| [ ]  - Research is subject to regulations not overseen or conducted by the organization[ ]  - Positive financial declaration without a Conflict of Interest report[ ]  - Protocol information relates to an item in the list of institutional financial interests[ ]  - An IND is required and there is no IND[ ]  - An IND is required and there is insufficient documentation[ ]  - An IDE/HDE is required and there is no IDE/HDE[ ]  - An IDE/HDE is required and there is insufficient documentation[ ]  - There are inadequate provisions to control the drug(s) | [ ]  - There are inadequate provisions to control the device(s)[ ]  - There are inadequate provisions for an investigator held IND[ ]  - There are inadequate provisions for an investigator held IDE[ ]  - External site(s) getting federal funds from the organization does not have a federalwide assurance (FWA)[ ]  - The research involves adults unable to consent and statements by the investigator and legal counsel regarding which individuals are legally authorized representatives (LAR) do not match.[ ]  - The research involves children and statements by the investigator and legal counsel regarding which persons do not match. |
| 1. CONTINUING REVIEW
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| [ ]  - If continuing review is not required, ask the investigator to withdraw the submission.[ ]  - Note missing continuing review form in the Missing Materials section of “CHECKLIST: Pre-Review (HRP-401).” |
| 1. MODIFICATION
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| [ ]  - Note missing modification form in the Missing Materials section of “CHECKLIST: Pre-Review (HRP-401).” |
| 1. STUDY CLOSURE
 |
| [ ]  - Confirm that the research meets the criteria for closure and note in the Study Closure Section of “CHECKLIST: Pre-Review (HRP-401).” |