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| The purpose of this checklist is to provide support for IRB staff conducting screening of submission materials. |
| 1. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following)
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| * Determine the laws that apply to the Human Research and indicate these in the “Regulatory Oversight” section.
* Determine whether the principal investigator is Restricted. If so, note in the “Restrictions” section.
* Determine risk level of research and note in the “Risk Level” section.
* 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 an humanitarian use device) use the “WORKSHEET: Devices (HRP-307)”
* Determine whether any special determinations are required. If so, note in the “Special Determinations” section.
* Determine whether any protocol tracking items apply. If so, note in the “Protocol Tracking” section.
* If there is a HIPAA authorization, review using “CHECKLIST: HIPAA Waiver of Authorization (HRP-441)”
* If a HIPAA waiver of authorization is required, grant using “CHECKLIST: HIPAA Waiver of Authorization (HRP-441)”
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| **Note any missing materials necessary in the “Missing Materials” section:** |
| * Investigator Protocol
* Point-by-point response
* Evaluation of any Related Financial Interest.
* Application form and appendices
* Materials to meant to be seen or heard by subjects
* Consent documents and scripts
* Sponsor protocol
* DHHS grant application, protocol, and sample consent
 | * Investigator brochure for investigational drug
* Package inserts for marketed drugs
* Product information for medical devices
* For the Department of Energy (DOE) research: “Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements”
* For the Department of Education (ED) research letter attesting FERPA and PPRA compliance.
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| **Note missing/inappropriately answered Investigator Protocol sections in the “Missing Materials” section:** |
| * 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
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|  **Note any of the following in the “Final Contingencies” section:** |
| * The type of research is not conducted or overseen by the institution
* The type of research is reviewed by an external IRB
* 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
* If 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 getting federal funds from the institution does not have a federalwide assurance (FWA)
* The research involves adults unable to consent and statements by the investigator and legal regarding which individuals are legally authorized representatives do not match.
* The research involves children and statements by the investigator and legal regarding which persons do not match.
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| 1. CONTINUING REVIEW or MODIFICATION
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| * Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).”
* Note missing Continuing review form in the “Missing Materials” section:
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| 1. STUDY CLOSURE
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| * Confirm that the research meets the criteria for closure and note in the Study Closure Section.
* Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).”
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