The purpose of this checklist is to provide support for IRB staff conducting screening of submission materials.

1 **ALL REVIEWS**

- 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 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)”.
- Note any missing materials necessary for review in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401)”: Application & appendices A (external sites), B (drugs and devices) □ Data collection instruments
  - Investigator Protocol □ Written material to be seen or heard by subjects
  - Consent document(s) or script(s)
- Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).”

2 **INITIAL REVIEW and MODIFICATION (when the modification affects one of the following)**

- 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)”.
- 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 □ Product information for medical devices
  - Complete sponsor protocol (including DHHS protocol) □ DHHS-approved sample consent document
  - Investigator brochure for investigational drug □ For the Department of Education (ED) research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA.
  - Package insert for marketed drugs
- Note missing/inappropriately answered Investigator Protocol sections in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401)”: IRB Review History □ Inclusion/Exclusion Criteria □ Data Management □ Consent Process
  - Objectives □ Compensation for Injury □ Confidentiality □ Consent Documentation
  - Background □ Local Number of Subjects □ Provisions to Monitor Data □ Vulnerable Populations
  - Setting □ Total Number of Subjects □ Withdrawal of Subjects □ Drugs or Devices
  - Resources Available □ Study Timelines □ Risks to Subjects □ Multi-Site Research
  - Prior Approvals □ Study Endpoints □ Potential Benefits to Subjects □ Community-Based
  - Study Design □ Procedures Involved □ Provisions to Protect Privacy □ Participatory Research
  - Recruitment Methods □ Data and Specimen Banking □ Economic Burden to Subjects □ 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 do not match.
- The research involves children and statements by the investigator and legal counsel regarding which persons do not match.

3 **CONTINUING REVIEW**

- Note missing Continuing review form in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401).”

4 **MODIFICATION**

- Note missing modification form in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401).”

5 **STUDY CLOSURE**

- Confirm that the research meets the criteria for closure and note in the Study Closure Section of “CHECKLIST: Pre-Review (HRP-401).”