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 the Pre-Review Activity.
- Verify funding information and determine if additional criteria are applicable.
- Determine whether any investigators or research staff are Restricted. If so, notify investigator and provide information to resolve restriction.
- Determine whether investigators have completed education requirements or COI disclosures as required.
- Determine whether the Human Research has received all required ancillary reviews (per HRP-309 - WORKSHEET - Ancillary Review Matrix) and approvals by the appropriate committees and officials.
- If the Human Research could be subject to EU GDPR, send to privacy officer for review.
- If there is a HIPAA authorization, review using HRP-330 - WORKSHEET - HIPAA Authorization
- If a HIPAA waiver of authorization is required, grant using HRP-441 - CHECKLIST - HIPAA Waiver of Authorization
- Determine whether the submission is for a Single-Site Study, Collaborative Study, or Multi-Site Study.
- Note any missing materials necessary for review in the “Missing Materials” section of the Pre-Review Activity:

  - Application & appendices as applicable
  - Investigator Protocol
  - Consent document(s) or script(s)
  - Determine whether any new information has been provided. (For example, a new risk.) If so, follow HRP-024 - SOP - New Information.

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

- If the research involves the use of a drug use the HRP-306 - WORKSHEET - Drugs.
- If the research involves the use of a device use the HRP-307 - WORKSHEET - Devices. Note any special determinations that need to be made by the convened IRB or Designated Reviewer.
- If the device meets the abbreviated IDE requirements, note “Non-significant device determination”.
- Note any missing materials necessary for review in the “Missing Materials” section of the Pre-Review Activity:

  - Qualifications of the key personnel
  - Grant application (optional requirement)
  - Complete sponsor protocol (including DHHS protocol)
  - DHHS-approved sample consent document
  - Investigator brochure for investigational drug
  - Package insert for marketed drugs
  - Executed Reliance Agreement when required
  - "Missing Materials” section of the Pre-Review Activity:

  - IRB Review History
  - Objectives
  - Background
  - Setting
  - Resources Available
  - Prior Approvals
  - Study Design
  - Recruitment Methods
  - Inclusion/Exclusion Criteria
  - 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

**“Final Contingencies” section of the Pre-Review Activity:**

- 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 federal wide 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.
### WORKSHEET: Pre-Review

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<thead>
<tr>
<th>NUMBER</th>
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<tbody>
<tr>
<td>HRP-308</td>
<td>5/1/2022</td>
<td>2 of 2</td>
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</tbody>
</table>

3 **INITIAL REVIEW and MODIFICATIONS FOR pSITES RELYING ON THIS IRB** (when the modification affects one of the following)

- [ ] The site record includes all of the following:
  - [ ] Completed Basic Information Page
  - [ ] Completed Local Funding Sources Page (if relevant)
  - [ ] Site Informed Consent Document
  - [ ] All other documents required by the Study

4 **CONTINUING REVIEW**

- [ ] If Continuing review is not required, see if the information can be used for the annual Administrative Check-in.
- [ ] Note missing Continuing review form in the “Missing Materials” section of the Pre-Review Activity.

5 **MODIFICATION**

- [ ] Note missing modification form in the “Missing Materials” section of the Pre-Review Activity.

6 **STUDY CLOSURE**

- [ ] Confirm that the research meets the criteria for closure and note in the Study Closure Section of the Pre-Review Activity.