



## WORKSHEET: External IRB Screening

Document No.:	Edition No.:	Effective Date:	Page:
HRP-470	003	05 Jan 2022	1 of 1

This worksheet is used to review research in advance of external IRB review

IRBNet #:

**1. Check**

- |      |   |
|------|---|
| 1.1  | <input type="checkbox"/> The [Organization] has determined the research to be suitable (See "WORKSHEET: Protocol Suitability (HRP-471)")                            |
| 1.2  | <input type="checkbox"/> All organizational approvals have been or will be obtained before the research starts (e.g., radiation safety, biosafety, or departmental) |
| 1.3  | <input type="checkbox"/> The submission is complete   |
| 1.4  | <input type="checkbox"/> Investigators and research staff are up to date on human research and COI training   |
| 1.5  | <input type="checkbox"/> An executed IRB reliance agreement is in place   |
| 1.6  | <input type="checkbox"/> External IRB policies, SOPs, and/or guidance have been reviewed  |
| 1.7  | <input type="checkbox"/> Investigator agreements are in place   |
| 1.8  | <input type="checkbox"/> FWA is present for federally funded research   |
| 1.9  | <input type="checkbox"/> An agency-specific assurance or assurance addendum is present when required (e.g., DOD, Department of Navy, Air Force)                     |
| 1.10 | <input type="checkbox"/> Procedures to control IND drugs are adequate to prevent use in individuals who are not subjects  |
| 1.11 | <input type="checkbox"/> Procedures to control IDE devices are adequate to prevent use in individuals who are not subjects  |
| 1.12 | <input type="checkbox"/> Procedures are in place to comply with sponsor requirements when an investigator holds the IND or IDE                                      |
| 1.13 | <input type="checkbox"/> Financial declarations have been made  |
| 1.14 | <input type="checkbox"/> A management plan is in place for any positive financial declaration   |
| 1.15 | <input type="checkbox"/> The [Organization] has no financial interest in the research   |
| 1.16 | <input type="checkbox"/> The description of <Legally Authorized Representative> is consistent with laws of the jurisdiction in which the research is conducted      |
| 1.17 | <input type="checkbox"/> The description of <Children> is consistent with laws of the jurisdiction in which the research is conducted                               |
| 1.18 | <input type="checkbox"/> The description of <Guardians> is consistent with laws of the jurisdiction in which the research is conducted                              |

**2. Notes**