

WORKSHEET: External IRB Screening

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Research Administration

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

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1. Check

- 1.1 The [Organization's] policy allows the research
- 1.2 The [Organization] has determined the research to be feasible
- 1.3 The [Organization] has determined the research to be consistent with the [Organization's] mission
- 1.4 All organizational approvals have been or will be obtained before the research starts (e.g., radiation safety, biosafety, or departmental)
- 1.5 The submission is complete
- 1.6 Investigators and research staff are up to date on training
- 1.7 Site agreements are in place
- 1.8 Investigator agreements are in place
- 1.9 Federal assurance is present for federally funded research
- 1.10 A Navy assurance addendum is present for DON-supported research
- 1.11 An Air Force assurance addendum is present for Air Force supported research
- 1.12 Procedures to control IND drugs are adequate to prevent use in individuals who are not subjects
- 1.13 Procedures to control IDE devices are adequate to prevent use in individuals who are not subjects
- 1.14 Procedures are in place to comply with sponsor requirements when an investigator holds the IND or IDE
- 1.15 Financial declarations have been made
- 1.16 A management plan is in place for any positive financial declaration
- 1.17 The [Organization] has no financial interest in the research
- 1.18 The description of <Legally Authorized Representative> is consistent with laws of the jurisdiction in which the research is conducted
- 1.19 The description of <Children> is consistent with laws of the jurisdiction in which the research is conducted
- 1.20 The description of <Guardians> is consistent with laws of the jurisdiction in which the research is conducted

2. Notes