University of Central Florida

| WORKSHEET: External IRB Screening | | |
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| HRP-308 | 8/19/2015 | 1 of 1 |

The purpose of this worksheet is to provide support for Designated Reviewers reviewing research in advance of external IRB review. This worksheet is to be completed by the Designated Reviewer, signed dated and retained in the electronic record.

| 1 | Questions for Principal Investigator |
|---|---|
| ☐ Yes ☐ No | Is the research funded? |
| ☐ Yes ☐ No | Does the research involve any sites where the principal investigator is responsible for the research (i.e., personally conducts or oversees the research) and does not ordinarily have privileges to conduct the research? |
| ☐ Yes ☐ No | Is the research covered by an IND? |
| ☐ Yes ☐ No | Is the research covered by an IDE? |
| ☐ Yes ☐ No | Does the research involve adults unable to consent? |
| ☐ Yes ☐ No | Does the research involve obtaining consent for children from their parents or guardians? |

| 2 | Check for all the apply |
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| ☐ | The IRB (or Designated Reviewer) has determined the research to be suitable (See 3 "Protocol Suitability"). |
| ☐ | All institutional approvals have been or will be obtained before the research starts (e.g., radiation safety, biosafety, or departmental). |
| ☐ | The submission is complete. |
| ☐ | Investigators and research staff are up to date on human research and COI training. |
| ☐ | Site agreements are in place. |
| ☐ | Investigator agreements are in place. |
| ☐ | Executed IRB authorization agreements are in place. |
| ☐ | FWA is present for federally funded research. |
| ☐ | An agency specific assurance or assurance addendum is present when required (e.g., DOD, DON, Air Force). |
| ☐ | Procedures to control IND drugs are adequate to prevent use in individuals who are not subjects. |
| ☐ | Procedures to control IDE devices are adequate to prevent use in individuals who are not subjects. |
| ☐ | Financial declarations have been made. |
| ☐ | A management plan is in place to comply with sponsor requirements when an investigator holds the IND or IDE. |
| ☐ | The Institution has no financial interest in the research. |
| ☐ | The description of "Legally Authorized Representative" is consistent with laws of the jurisdiction in which the research is conducted. |
| ☐ | The description of "Children" is consistent with laws of the jurisdiction in which the research is conducted. |
| ☐ | The description of "Guardians" is consistent with laws of the jurisdiction in which the research is conducted. |

| 3 | **Protocol Suitability** (Unsuitable research will not advance to the external IRB without further administrative review and approval. If any item is checked, the protocol is considered unsuitable.) |
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| ☐ | The research is not allowed by the Institution's policy. |
| ☐ | The research is not consistent with the Institution's mission. |
| ☐ | The research holds out unacceptable risk to the Institution. |
| ☐ | The research holds out unacceptable risk to the investigator. |
| ☐ | The research holds out unacceptable risk to the subjects. |
| ☐ | There are insufficient resources to support this research. |
| ☐ | The research should not be conducted due to concerns with the sponsor. |
| ☐ | The research will have a negative effect on subjects. |
| ☐ | The proposed reimbursement for services is insufficient. |
| ☐ | The research should not be conducted due to concerns with the sponsor. |

| 4 | Notes |
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| Sign | | Date | |
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