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| The purpose of this checklist is to support the review of requests to determine when the organization, employee, or agent1 of Spectrum Health (SH) is engaged in Human Research.  This checklist is to be completed by the IRB Analyst and the Designated Reviewer, signed, dated, and retained in the submission attachments in IRB Manager. | | | | | | | | | | |
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| **Study Title:** | | | $$ProtocolTitle$$ | | | | | | | |
| **Investigator:** | | | $$piformattedname$$ | | | | | | | |
| 1. Pre-Review: This section is to be completed by the IRB Analyst. | | | | | | | | | | |
| **1.1 Regulatory Oversight:** Check all that apply | | | | | | | | | | |
|  | | None | |  | DHHS (NIH, etc.) |  | FDA (drug/device/ biologic) |  | Other: | |
|  | | The SH employee or agent is a direct awardee of a federal grant, award, or contract involving human research (even if no human research activities are being carried out by SH). STOP: If checked, SH is engaged in this research and an IRB Initial xForm is to be submitted. Complete Section 1.4. | | | | | | | | |
| * 1. Conditional Engagement Criteria: Check all that apply. SH is engaged if any of the following are true, *unless* criterion in Section 2 are met). | | | | | | | | | | |
|  | SH employees or agents will obtain informed consent of subjects to take part in the research. | | | | | | | | | |
|  | SH employees or agents will obtain data about subjects through interaction for research purposes2. | | | | | | | | | |
|  | SH employees or agents will obtain data about subjects through intervention for research purposes2. | | | | | | | | | |
|  | The SH employee or agent is obtaining, using, studying, or analyzing private identifiable information from ANY source (whether from another institution or already in possession of the investigator). | | | | | | | | | |
|  | For Research that is FDA regulated (skip if N/A): | | | | | | | | | |
|  | The SH employee or agent is identified in the protocol as a sub-investigator and will be collecting data for research purposes. | | | | | | | | | |
|  | The SH employee or agent is administering a test article and will conduct protocol-specific and/or data collected that will be sent to the Sponsor. | | | | | | | | | |
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| * 1. **Engagement Exclusion Criteria:** The organization is not engaged if all of Section 1 criteria are situations where one or more of the following are true. | | | | | | | | | | |
|  | | SH employees or agents will perform commercial, or other services, for investigators, where **all** of the following are true:   1. The services performed do not merit professional recognition or publication privileges; 2. The services performed are typically performed by those organizations for purposes other than research; and 3. SH employees or agents do not administer any study intervention being tested or evaluated under the protocol. | | | | | | | | |
|  | | SH was not selected as a research site, but employees or agents will provide clinical trial-related medical services that are dictated by the protocol and are typically performed as part of routine clinical monitoring or follow-up of subjects enrolled at a study site by clinical trial investigators, where **all** of the following are true:   1. SH employees or agents do not administer the interventions being tested or evaluated under the protocol; and 2. The clinical trial-related medical services are typically provided by the organization for clinical purposes; and 3. SH employees or agents do not enroll subjects or obtain the informed consent of subjects to take part in the research; and 4. When appropriate, investigators from an engaged organization retain responsibility for both:    1. Overseeing protocol-related activities and    2. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required by the protocol. | | | | | | | | |
|  | | SH was not initially selected as a site, but SH employees or agents will administer the interventions being tested or evaluated under the protocol on a one-time or short-term basis, where **all** of the following are true:   1. The investigator from the engaged organization determines that it will be in the subject's best interest to receive the interventions being tested or evaluated at SH; and 2. SH employees or agents do not enroll subjects or obtain their informed consent to take part in the research; and 3. Investigators from the organization engaged in the research retain responsibility for **all** of the following:    1. Overseeing protocol-related activities; and    2. Ensuring the interventions are administered in accordance with the protocol; and    3. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including, the reporting of safety monitoring data and adverse events as required by the protocol; and    4. The IRB of Record is informed that interventions being tested or evaluated have been administered at the SH site (documented by IRB of Record’s approval of this activity at SH). | | | | | | | | |
|  | | SH employees, or agents, activities will be limited to the following:   1. Informing prospective subjects about the availability of the research; and/or 2. Providing prospective subjects with information about the research but do not obtain subjects’ consent to take part in the research or act as representatives of the investigators; and/or 3. Providing prospective subjects with information about contacting investigators for information or enrollment; and/or 4. Seeking or obtaining the prospective subjects' permission for investigators to contact them.   *Note: If a subject provides permission to allow a SH employee or agent to send investigators their contact information (even if collected from the medical record upon permission), this is an acceptable use of PHI and a HIPAA Authorization waiver is not required.* | | | | | | | | |
|  | | The organization will permit investigators from another organization to use its facilities for research. | | | | | | | | |
|  | | SH employees or agents will release identifiable private information (PII), identifiable private health information (PHI), and/or identifiable biospecimens about subjects to investigators at another organization, where the following are true:   1. The receiving Institution has current IRB approval and has met the informed consent requirements as determined by that IRB. *Documentation of IRB Approval must be added to the submission file in IRBManager.*   **If SH employees or agents will access or release PHI; complete CHECKLIST: Waiver or Alteration of HIPAA Authorization (HRP-427)** | | | | | | | | |
|  | | The organization's employees or agents both:   1. Obtain coded private information from another organization involved in the research that retains a link to identifiable private information; and 2. Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens. 3. The SH employee or agent is not collaborating on other activities related to the conduct of the research with the investigators who receives such information or biospecimens (e.g., the study, interpretation, or analysis of the data resulting from the identifiable information or biospecimens, authorship of presentations or manuscripts related to the research3.) | | | | | | | | |
|  | | Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study. | | | | | | | | |
| **1.4 Pre-Review Comments/ Contingencies to be Met:**  If the Engagement Exclusion Criteria cannot be determined, request further clarifications or documentation from the Investigator. Attach to the submission file all supporting documentation and email correspondence. Document a short summary of the project and/or relevant notes to the reviewer below. | | | | | | | | | | |
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| If the organization, employee, or agent is Engaged in the Human Research. Instruct the Investigator to submit an IRB Initial xForm. Sign and attach this checklist to the submission, note in the Instance “Determined to be Engaged” and mark the event complete. | | | | | | | | | | |
| Analyst Completing Checklist: | | | |  | | | | | Date: |  |

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| 1. Designated Reviewer Determination: This section is to be completed by the Designated Reviewer when the IRB Analyst’s pre-review indicates that the organization, employee, or agent is not engaged in the Research. | | | | | | |
| 2.1 Reviewer Criteria: All must be “Yes”. If a conflict of interest exists, a different Designated Reviewer is to be selected. If pre-review contingencies are not met; return to IRB Analyst to obtain required information. | | | | | | |
| Yes No | | I do **not** have a Conflicting Interest. | | | | |
| Yes No | | All pre-review contingencies noted above have been met. | | | | |
| * 1. Final Determination: Select one of the following. | | | | | | |
|  | The organization, employee or agent is not Engaged in the Human Research. | | | | |
|  | The organization, employee or agent is Engaged in the Human Research. | | | | |
| * 1. **Designated Reviewer Notes:** | | | | | |
| **Designated Reviewer Completing Checklist:** | | |  | **Date**: |  |

1 Employees or agents refer to individuals who: (1) act on behalf of the organization; (2) exercise organizational authority or responsibility; or (3) perform organizationally designated activities.

2 In this worksheet, "research" means <Research as Defined by HHS> involving <Human Subjects as Defined by HHS> and "subject" means <Human Subject as Defined by HHS>

3 <https://www.hhs.gov/ohrp/coded-private-information-or-biospecimens-used-research.html>