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| The purpose of this checklist is to provide support for individuals in determining whether an activity is Human Subjects Research (HSR) and subject to IRB review and approval. If the activity is Human Research as defined by DHHS or FDA regulations, it is Human Research per organizational policy.  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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| Investigator: | | $$ProtocolTitle$$ | | | | | | |
| Study Title: | | $$piformattedname$$ | | | | | | |
| 1. Pre-Review: This section is to be completed by the assigned IRB Analyst. | | | | | | | | |
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| 1.1 Is the Project Research? | | | | | | | | |
| 1.1.1 Excluded Research: The following types of activities are [Excluded](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102)[[1]](#footnote-1) from the requirement of IRB Review. | | | | | | | | |
| Yes  No | | | | Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. | | | | |
| Yes  No | | | | Public health surveillance activities**, i**ncluding the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. | | | | |
| Yes  No | | | | Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes | | | | |
| Yes  No | | | | Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security mission. | | | | |
| If ‘No’ is marked to all above – Complete the next section. | | | | | | | | |
| 1.1.2 Criteria for Research: | | | | | | | | |
| Yes  No | | | | Is the project a systematic investigation; including research development, testing and evaluation of data? Is the project attempting to answer a question or hypothesis and has a stated methodology? | | | | |
| Yes  No | | | | Is the ***primary intent*** of the project to develop or contribute to ***Generalizable Knowledge***? [Generalizable Knowledge](https://www.spectrumhealth.org/-/media/spectrumhealth/documents/clinical-research/policies/irb-guidance-on-quality-improvement.pdf?rev=3bdad038282b4629a693f809b1ccd3ed&hash=ADB207DE4C78C2BF78519401C6C6F3CE) is knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences. These activities draw *general* conclusions, inform policy, or generalize beyond a single individual or an internal program, or are created to make a broad statement. | | | | |
| If ‘Yes’ is marked for both of the above, The project is Research, Go to Section 1.2  If ‘No’ is marked for either above; Complete the next section. | | | | | | | | |
| 1.1.3 Criteria for Quality Projects: | | | | | | | | |
| Yes  No | | | | The purpose of the project is to improve conformance to existing standards of care, operational processes, policies and/or procedures or to establish internal benchmarks | | | | |
| Yes  No | | | | The project does not increase risk to patients, with exception of possible privacy/confidentiality concerns. | | | | |
| Yes  No | | | | The project includes the use of QI/QA methods/models such as benchmarking/surveillance activities; all participants receive standard care; does not include any experimental activities; implementation of care practices and interventions that are consensus-based or evidence-based. | | | | |
| If ‘Yes’ is marked for all of the above, this is a Quality project - **STOP**. Go to Section 1.4.  If ‘No’ is marked for any of the above – Go to Section 1.2. | | | | | | | | |
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| * 1. Does the Research include Human Subjects[[2]](#footnote-2)? | | | | | | | | |
| Yes  No | | | | If the Research is supported or funded by an agency which is a signatory to the Common Rule, has the federal agency made a determination that this Research is required to have IRB review? (If not supported by a federal agency, select No) | | | | |
| If ‘Yes’ is marked above – **STOP:** the activity is Human Research under DHHS regulations and an IRB Initial xForm is to be submitted. Complete Section 1.4.  If ‘No’ is marked above – proceed below | | | | | | | | |
| Yes  No | | | | Does the Research include collecting information or specimens aboutliving individuals? | | | | |
| If ‘No’ is marked above – **STOP.** Go to Section 1.3.  If ‘Yes’ is marked above – Proceed | | | | | | | | |
| Yes  No | | | | Will the investigator conducting the Research use, study, or analyze information or biospecimens obtained through any of the following mechanisms (Select Yes if any of the below apply):  Physical procedures or manipulations of those individuals or their environment for research purposes (“intervention”).  Communication or interpersonal contact with the individuals ("interaction”).  Obtain, access, use, study, or generate identifiable private information or identifiable biospecimens[[3]](#footnote-3) | | | | |
| If ‘No’ is marked above – **STOP**: the activity is not human subject research. Complete Section 1.4.  If ‘Yes’ is marked above – The project is research involving human subjects– Go to section 1.4. | | | | | | | | |
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| **1.3 Research on Decedents Information:** The following Section is to be completed when the Research includes PHI from deceased subjects. Skip if Not Applicable. | | | | | | | | |
| Yes No | | | | Has the Investigator provided a rationale and/or the aims/goals for the Research and why access to Protected Health Information (PHI) from decedents is necessary? | | | | |
| Yes No | | | | Has the investigator completed the necessary attestations for the use and disclosure of PHI for research on decedents (HRP 203)? | | | | |
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| **1.4 Pre-Review Comments/ Contingencies to be Met:**  Request further clarification or information from the Investigator if determinations cannot be made. 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 (e.g., resolution of requested items from pre-review, important areas relevant to DR review, etc.) | | | | | | | | |
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| If the Research is determined to be Human Subjects Research. Instruct the Investigator to submit as a research project. Sign and attach this checklist to the submission, note in the Instance “Determined to be HSR” 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 project is potentially Non-Human Subjects Research. | | | | | | | | |
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| **2.1 Reviewer Criteria:** All must be “Yes”. If a conflict of interest exists, a different Designated Reviewer is to be selected. If additional information is needed to make a determination, email the IRB Analyst to obtain required information. | | | | | | | | |
| Yes No | | | I do not have a Conflicting Interest. | | | | | |
| **2.2 Final Determination:** Select one of the following | | | | | | | | |
|  | The submission is Research that does not include Human Subjects. | | | | | | | |
|  | The submission is Not Research involving Human Subjects. | | | | | | | |
|  | The submission is a Quality Project. | | | | | | | |
|  | The submission is Human Subjects Research. (*Inform Analyst upon return of checklist).* | | | | | | | |
| * 1. **Designated Reviewer Notes:** | | | | | | | | |
| **Reviewer Completing Checklist:** | | | | |  | | **Date:** |  |

1. See the list of Excluded research definitions at: 45 CFR 46.102(l) [↑](#footnote-ref-1)
2. For an activity to be considered *Human Subjects Research* and require the review by the IRB; the activity must meet the definition of “research” and involve the collection of data or biospecimens from or about “human subjects”. [↑](#footnote-ref-2)
3. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, OR information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

   *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. [↑](#footnote-ref-3)