**Guidance: Submitting Formative/Pre-Clinical/Pilot Research Activities to the JHU IRBs**

The JHU IRBs apply the principles of the federal Common Rule to all of the human subjects research studies conducted by its faculty and students, regardless of funding source. The definition of “research” under the Common Rule is as follows:[[1]](#footnote-1)

***Research*** *means a systematic investigation,* ***including research development, testing, and evaluation,*** *designed to develop or contribute to generalizable knowledge.* [Emphasis added.] 45 CFR 46.102(e).

Any activity that falls within the definition of “research” requires IRB oversight. Researchers may have questions about the types of formative activities that constitute “research” that requires prospective IRB approval. For example, may an investigator ask research staff to review a questionnaire for readability; is it ok to ask a child whether or not they understand what a question means; can an investigator ask volunteers to help train study staff on how to conduct a medical scan or collect specimens; what about collecting pilot data from volunteers using study tools, but not planning to retain the data for analysis? These are all examples of formative activities that involve collection of information that will not be used in the final study analysis.

The Common Rule definition of “research” includes “development” activities involving volunteers and/or their identifiable data or biospecimens. The following are examples of development activities that fall within the definition of “research” under the Common Rule, and thus require IRB approval prior to starting:

1. Any activity that involves volunteers where participation by a volunteer may trigger risk (including physical, societal, stigmatic, etc.) or legal concerns, including, but not limited to:

a. Any activity involving a minor.

b. Any activity involving an adult with cognitive impairment.

c. Any activity where there is a potential for exposure to possible criminal prosecution in the region where the research takes place (sex work, MSM), or embarrassment or harassment if the volunteer was identified as engaging in the activity.

2. Any activity that involves collecting or obtaining private information[[2]](#footnote-2) or biospecimens from an adult volunteer regardless of whether the private information is retained for analysis or is identifiable. Note that obtaining data and/or biospecimens from employees or students raises issues of potential undue influence if a direct supervisor, teacher, or advisor is involved with the study.[[3]](#footnote-3) Obtaining personal information and biospecimens raises questions about data security, privacy, and the ultimate disposition of the materials. This includes testing to calibrate equipment.

3. Any activity that uses volunteers to train study staff in clinical procedures for research purposes only. For example, training research staff on the use of a Fibroscan machine using human volunteers requires IRB approval.

4. Any activity involving procedures with volunteers that may generate diagnostic information.

Adults, including JHU Students and Employees MAY NOT be involved as volunteers in formative activities without IRB approval if they:

• Provide biospecimens.

• Complete test data collection tools with responses that disclose personal information.

• Serve as volunteers for training purposes.

• Serve as volunteers to help calibrate medical devices.

• Generate diagnostic information, even if not shared with clinical providers.

Adults, including JHU employees and students MAY be involved as volunteers in formative activities without IRB approval if:

• Reviewing language and completing data collection tools or consent forms to see if the wording is understandable and conveys the concepts intended.

• Reviewing a questionnaire for readability.

• Trying on external medical devices to ensure proper fit.

When in doubt, please contact your JHU IRB office.

1. For FDA regulated studies, "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. 21 CFR 56.102. [↑](#footnote-ref-1)
2. 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, and 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). 45 CFR 46.102(e)(4). [↑](#footnote-ref-2)
3. Note that JHU has institutional policies regarding when JHU students or JHU/JHHS employees may be involved in research at JHU. [↑](#footnote-ref-3)