

## **Not Human Subjects Research (NHSR)/Not Engaged (NE) in Research**

The BSPH IRB is authorized to interpret the federal human subjects research regulations and determine which activities require BSPH IRB oversight. IRB review is required when BSPH investigators are “engaged” in human subjects research activities. IRB determinations are governed by the following definitions and concepts:

1. A “human subject” is a “a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” 45 CFR 46.102(e)(1).
2. “Research” is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102(l).
3. “Engaged” in human subjects research is a concept explained by guidance from the Office of Human Research Protection (OHRP) (<http://www.hhs.gov/ohrp/policy/engage08.html>). It means that the institution/investigator is not:
  - The primary grant recipient of federal dollars funding the activity;
  - Contacting human participants (consenting, interacting, intervening); or
  - Accessing or using identifiable human biospecimens or data for research purposes. In such cases, if collaborators are “engaged” in these activities, their institution’s IRBs will be responsible for overseeing their human subjects research activities.

IRB oversight is required when the activity involves human subjects, meets the definition of “research”, AND a BSPH investigator is “engaged” in the human subjects research activity, as opposed to providing technical advice or playing some other peripheral role. When an investigator is “not engaged” in human subjects research, and when the activities do not meet the definition of “human subjects research”, the IRB will provide documentation that no IRB oversight is needed for those activities.

### **The IRB will document determinations as follows:**

#### **1. Not Engaged in Human Subjects Research**

While the project itself is human subjects research, BSPH faculty, staff, or students are not the primary grantee of federal funding, consenting participants, collecting

data/biospecimens or otherwise interacting with human subjects, or obtaining or using identifiable (or linkable) private information/biospecimens.

2. **Research/Not Human Subjects Research** activities may use research methods but do not include “human subjects”, have no research question, or are not intended to be generalized.
  - **Key Informant Research** involving information from individuals about something other than themselves, disclosing no personal opinions, and not exposing respondents to employment or other risks. “**Key Informants**” are people who provide objective information about something associated with their work or their community, but not about their personal or subjective knowledge, opinions, attitudes, and practices. This determination should be made by the IRB and will require submission of the questions proposed. Here are some examples: □If you ask a person to provide a subjective opinion about their work (e.g., WHAT THE PERSON THINKS about policies, effective practices, etc.),
    - Questions of an organization employee about how well an organization responded to COVID is potentially politically charged. It involves critical opinion by the respondent and could trigger employment risk. It is human subjects research and requires IRB review. HSR
    - Questions of clinicians about demographic data of patients they see is not opinion; it is objective data that involves no opinion and does not expose the respondent to risk, so they are not human subjects. NHR
    - If you ask a person an objective question about how an organization operates, that person is a key informant, and the project is not human subjects research. NHR
    - If you ask a person to provide a subjective opinion about their work (e.g., WHAT THE PERSON THINKS about policies, effective practices, etc.), those questions may include employment related risks; respondents are human subjects. HSR
  - **Secondary Data Analysis** involving the use of existing, de-identified and unlinkable data/specimens, including publicly available data. The investigator must not be able to “reasonably ascertain” the identity of the individuals from whom the data/specimens originated.
    - **EXCEPTION:** HIPAA Limited Data Sets (Protected Health Information “PHI”, including age, dates of service, zip code) are considered to be human

subjects research, even if the investigator cannot reasonably ascertain the identity of the individual participant.

3. **Not Research/Public Health Practice** involving “program development or evaluation” in the delivery of public health practice services.”
4. **Not Research/Public Health Surveillance** involving activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
5. **Not Research/Quality Assurance** involving an organization, government entity, clinic or practice conducting a self-evaluation to determine whether it meets identified standards of quality in the delivery of a service or product. There is no research question.

### **OBTAINING PERMISSION:**

Consent in the NHR/NE context is more of an “agreement” or “permission” than “legally effective informed consent”. The complete list of elements is not required. Elements of consent to consider –

1. Who is conducting the study?
2. A description of the study’s purpose.
3. An explanation about why you are asking the person to participate.
4. A description of study procedures, how long they will take, etc.
5. How the data will be stored, protected, shared, how long the data will be kept, etc.
6. Possibility of re-contact for follow-up or data quality assurance.
7. Participation is voluntary.

Although an activity may not constitute human subjects research, the IRB encourages the use of an oral consent form in the process of obtaining permission. It’s a “best” practice and a courtesy to the participant that:

1. Allows the investigator to use the form as a guide for the verbal explanation of the study,
2. Gives the participant adequate information concerning the study,
3. Provides adequate opportunity for the participant to consider all options,
4. Responds to the participant’s questions,
5. Ensures that the participant has comprehended this information,
6. Obtains the participant’s voluntary agreement to participate, and
7. Provides the PI’s contact information to the participant.

### **STUDENT PROJECTS:**

All student-initiated projects must have a preliminary review by the IRB Office to determine whether they are human subjects research requiring IRB oversight unless the BSPH PI is adding you as a student investigator to an existing, BSPH IRB-approved study.

### **TIPS:**

1. If you need IRB documentation of a NHR determination, a new application through the PHIRST system is required. The BSPH IRB will provide documentation of its determination.
2. If your proposed activity will involve participation of Johns Hopkins clinical providers, students, University staff or other employees, even though it may be “not” human subjects research, a new application through the PHIRST system is required.
3. If your proposed activity will involve identifiable health information (“Protected Health Information” or “PHI”) generated and stored electronically by certain health organizations (covered entities), a new application through the PHIRST system is required.
4. When the BSPH IRB decides that a project does not qualify as human subjects research, the IRB does not need to be informed of minor administrative changes such as adding/deleting study personnel, **but it will need to see substantive amendments to ensure that the changes do not alter the IRB determination.** The PI may submit an Amendment Application through the PHIRST system.
5. **NHR/NR Determinations:** No Continuing Review Application/Progress Report is required.
6. **When in Doubt:** Please submit your questions to the BSPH IRB Office email address at: [bspb.irboffice@jhu.edu](mailto:bspb.irboffice@jhu.edu).