



Office of Research Use Only

IRB Number:

Date received:

Date of Determination:

## Determination of Human Subject Research Office of Research

The NWH IRB is required to review and approve all research involving human subjects. This application helps determine if your project involves human subject research as defined by federal regulations.

### INSTRUCTIONS for INVESTIGATORS:

1. Please complete this form in its entirety and submit with any applicable project descriptions, statements of work, survey instruments or questionnaires via email attachment to [mcymerman@partners.org](mailto:mcymerman@partners.org) or [delek@partners.org](mailto:delek@partners.org) in the Office of Research.
2. The Office of Research will determine whether your project or activity needs additional review by the IRB and will notify you with a Determination Memo in an email attachment.
3. Do **NOT** begin project activity or data collection prior to receiving a Determination Memo.
4. If you have any questions or need further instructions, please call us at 617-243-6211 or 6493.

### INVESTIGATOR INFORMATION

Investigator Name:

Title:

Department:

Email:

### PROJECT INFORMATION

Project Title:

Is project supported by external funding?

No

Pending \* Please identify your anticipated funding source:

Yes \* Please identify your funding source:

\* If funded, provide copy of grant proposal with this form.

State the purpose of the project and what you hope to learn:

Describe all project procedures including any data collection activities, methodological designs and plans for analysis:

Describe the participant population (age range, gender, ethnic background, type of participant such as student, faculty, health care professionals, etc.), an approximate number of participants, and the location where the project will take place :

**\*NOTE:** Please include copies of any project AND surveys/questionnaires, interview questions, etc. with this form

**Instructions:** Complete Section A as applicable to determine if activities in which you will be engaged meet the definition of human subject research.

**SECTION A: Activities Determined by the Newton-Wellesley Hospital IRB not to Represent Human Subject Research**

1.  **Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.

2.  **Program evaluation /Quality Improvement/Quality Assurance Activities:** The activity is conducted to assess, analyze, critique, and improve current processes within the institutional setting to include projects designed to improve current processes involving health care delivery in the institutional setting. The intent is not to generate conclusions that can be applied universally outside of the immediate environment where the project occurred.

a.  The activity does not involve randomization into different treatment groups.

b.  The activity is not designed to be applied to populations beyond the specific study population.

**Note: Quality improvement** projects are designed to improve the performance of any practice in relation to an established standard. **Quality assurance** projects are activities that are designed to determine if aspects of any practice are in line with established standards. Service surveys issued or completed by Newton-Wellesley Hospital personnel for the purposes of improving Newton-Wellesley Hospital services/programs or for developing new services or programs for student, employees or alumni may fall into this category. Investigators who plan to conduct a QI/QA project, should ensure that they have receive approval from any applicable committees within their department or the site in which the activity will occur.

3.  **Evidence Based Practice Intervention:** The project or activity is designed to use best available evidence to make patient care decisions. The project is focused exclusively on translating evidence and applying it to clinical decision-making to improve health care delivery, i.e. it is designed to close the gap between research being conducted and the practice.

**Note:** “Practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.

4.  **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. Public use data sets (such as portions of U.S. Census data, data from the National Center for Educational Statistics, General Social Survey, Bureau of Labor Statistics, etc.) are data sets prepared with the intent of making them available for the public and not individually identifiable, therefore their analysis would not involve human subjects.

**NOTE:** IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of subjects. In both cases, Exempt Category #4 may apply.

5.  **De-Identified Private Information or Human Biological Specimen:** The project is limited to the use of existing de-identified private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if you can confirm the following:

a.  The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**

b.  The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were collected; **and**

c.  The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any identifying information (names, SSN, DOB, PHI, etc.) and any codes that would enable linkage of the information or specimens to individual identifiers do not exist.

**NOTE:** To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers.

6.  **Coded Private Information and/or Human Biological Specimens:** The project is limited to the use of existing coded private information and/or human biological specimens (hereafter referred to as “specimens”). IRB

Approval is not required if all of the following conditions apply to the project:

- a.  The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**
- b.  The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because for example the specimen provider has agreed not to release the key to the code.

**NOTE:** If a contractual agreement or Data Use Agreement is required in order to gain access to the information, typically agreements are signed by Newton-Wellesley Hospital officials and not individual researchers. Please provide a copy of any contractual agreement/DUA with your submission.

7.  **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research.

**NOTE:** This exception may not be available for decedent Information that contains Psychotherapy notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse.

8.  **Oral History:** The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

**NOTE:** IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test health, economic, sociological, or anthropological models/theories).

9.  **Journalism/Documentary Activities:** The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

**NOTE:** IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

10.  **Information-gathering interviews:** The activity focuses exclusively on interviewing or surveying participants about his or her expert knowledge about products or policies rather than people or their thoughts regarding themselves (e.g. interviewing pharmacists about xenobiotic metabolism of a specific drug).

**NOTE:** Interview questions will need to be reviewed by the Office of Research. If the activity involves collecting demographic information about participants it may require IRB approval.

\*\*\*\*\*End of Section A\*\*\*\*\*

**IMPORTANT:** If your activity does not fall into the categories described in Section A, continue to Section B to assess whether your activity is defined as research per regulations. NOTE: If your project falls under FDA regulations, please call our office at 617-243-6211.

**Section B. Activities Defined as Research and Subject to Review by the Newton-Wellesley Hospital IRB**

1. **Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?**

TIP: If the activity is characterized by a plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question AND the intent of the investigation is to generate conclusions that can be applied outside of the immediate environment where the investigation occurred, then the activity meets the definition of research. *If you plan on presenting findings at a professional conference or publishing your results in an academic journal, your project may meet the definition of generalizable.* If you have questions about this, please contact our office at 617.243.6493.

<input type="checkbox"/> Yes, Go to #2	<input type="checkbox"/> No, IRB review is not required
<b>2. Does the research involve obtaining information about LIVING individuals?</b>	
<input type="checkbox"/> Yes, Go to #3	<input type="checkbox"/> No, IRB review is not required
<b>3. Does the research involve collecting data through <u>intervention</u> (i.e., physical procedures or manipulation of the environment) or <u>interaction</u> (i.e., communication or interpersonal contact between investigator and person) with the individuals?</b>	
<input type="checkbox"/> Yes, <b>IRB review required.</b>	<input type="checkbox"/> No, Go to #4
<b>4. Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?</b>	
<input type="checkbox"/> Yes, Go to #5	<input type="checkbox"/> No, IRB review is not required
<b>5. Is the information <u>private</u>? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)</b>	
<input type="checkbox"/> Yes, <b>IRB review required</b>	<input type="checkbox"/> No, IRB review is not required

<b>Section C. Investigator Responsibilities and Assurances</b>	
<ul style="list-style-type: none"> <li>I certify that the information provided in this determination form and in all attachments is complete and accurate.</li> <li>I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants and for the ethical conduct of this activity.</li> <li>I certify that the proposed project has not yet been done, is not currently underway, and will not begin until IRB determination and/or approval has been obtained.</li> </ul>	
<b>Investigator Signature</b>	
Name: _____	Date: _____

<b>Office of Research USE ONLY</b>	
<input type="checkbox"/> <b>Project does NOT need IRB review.</b>	<input type="checkbox"/> <b>Project DOES need IRB review.</b>
Date: _____ Initials: _____	Date: _____ Initials: _____
<b>(Office of Research use only)</b> Determination based on the following rationale:	