**Human Research Determination Form**

Northwestern University’s IRB Office is required to review Human Research for which Northwestern University and those entities where Northwestern University has an agreement for IRB services (e.g., Northwestern Memorial HealthCare and the Shirley Ryan Ability Lab) are engaged, and investigators are required to submit applications for review prior to the initiation of any human research activities. Northwestern University, its affiliated institutions, and those institutions for which Northwestern University provides IRB services are henceforth referred to as the “Institution(s).” Only activities that meet the definition of “research” involving “human subjects” as defined in the DHHS, FDA, or other applicable regulations require IRB review (see Sections 1/2 below).

Researchers can self-determine whether their activities are human research. If you are unable to determine whether your activities meet the regulatory definition of “research” with “human subjects,” OR if you would like/need the IRB to evaluate your study to provide an official determination with documentation that your activity is not human subjects research, complete the **Activity Information** detailed in Section 3 below and submit this form in place of a full protocol in a new study application in the Northwestern University [eIRB+ system](https://irb.northwestern.edu/submitting-to-the-irb/eirb/index.html).

If, while reviewing this form, you determine that your proposed activity is Human Research, submit a new study application in the Northwestern University [eIRB+ system](https://irb.northwestern.edu/submitting-to-the-irb/eirb/index.html). Create and upload a protocol and, if appropriate, an informed consent form using the current IRB-provided [protocol](https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/index.html) and [consent](https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/index.html) templates.

Please review the Appendix at the end of this document for examples of activities generally considered not to be Human Research that must be reviewed by the IRB.

**NOTE**: The IRB can only make this determination **PRIOR** to the beginning of the activity. The IRB will not make a determination after the activity has already begun. The IRB Office uses “WORKSHEET: Human Research Determination” (HRP-310) to make its Human Research determinations. Please consult that worksheet as a guide before you submit your application.

If the Institution(s)(i.e., Northwestern University or its affiliated institutions) is the primary recipient of a federal award (e.g., NIH, NSF, DoE, DoD), and one or more external entities will engage in human subject research, then the human research determination form is NOT appropriate because the Institution(s) is also engaged in human subjects research (see Appendix 1.8 for more information). If the Institution(s) (i.e., Northwestern University or its affiliated institutions) is the primary awardee and the grant application designates this as being human subject research, then this would be considered human research and this form must be submitted with a [human research application](https://irb.northwestern.edu/submitting-to-the-irb/index.html) and study related documents.

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| **SECTION 1:**  Use the information in parts A and B of this section to determine if your activity is human subjects research as defined by the federal regulations for those [federal agencies](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) that adopted the [Revised Common rule](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46). NOTE: Northwestern University’s IRB applies the Revised Common rule to review research that does not fall under the purview of another federal oversight agency. |
| **PART A: DETERMINATION OF “RESEARCH”** |
| **CFR 46.102(d)*: Research***- a ***systematic investigation***, including research development, testing, and evaluation, ***designed to develop or contribute to generalizable knowledge***.  A ***systematic*** approach involves a predetermined system, method, or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory. A systematic approach includes collecting information or biospecimens and performing quantitative or qualitative analysis.  Activities ***designed to develop or contribute to generalizable knowledge*** are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable). |
| 1. Does the proposed activity involve a ***systematic*** *approach*?   **YES\***   **NO**   1. Is the intent of the proposed activity to ***develop or contribute to generalizable knowledge***?   **YES\***   **NO**  **\*If YES to both 1 & 2, the activity constitutes research**. |
| **PART B: DETERMINATION OF “HUMAN SUBJECT”** |
| **CFR 46.102(f)*: Human subject*** - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: **(1)** data through***intervention*** *or* ***interaction*** with the individual; or **(2)** ***identifiable******private information***.  ***Intervention*** includes both physical procedures by which information is gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.  ***Interaction*** includes communication or interpersonal contact between investigator and subject.  ***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 which the individual can reasonably expect will not be made public (e.g., medical record information). Private information must be individually identifiable.  ***Identifiable***is where the identity of the subject is or may be ascertained by the researcher, or will be associated with the information. The research could involve the use of ***coded*** data/specimens.  ***Coded*** means a living individual’s identifiable information, such as name or social security number, has been replaced by a code, such as a number, letter, or combination thereof, ***and*** there isa key to link the code to the identifiable information of that individual. *Coded data are considered identifiable under the Common Rule.* |
| ***Use the definitions above to answer the following questions.*** |
| 1. Does the activity involve obtaining information about *living individuals* through ***intervention*** or ***interaction*** with the individuals?   **YES\***   **NO**  **\*If YES to #1, the activity involves human subjects.**  **If NO to #1,** does the activity involve obtaining protected health information (PHI) about deceased individuals?  **YES\***   **NO**  **N/A**  **\*If YES, the following must be true:**   1. The use or disclosure is solely for research on the PHI of decedents; and 2. The PHI is necessary for research purposes. 3. If requested by the covered entity, the Lead Researcher will be required to provide documentation of the death of the individual(s). 4. Does the activity involve obtaining ***identifiable***and ***private information*** **about** living individuals?   **YES\***   **NO**  **\*If YES to #2, the activity involves human subjects.**   1. Does the activity involve the use of ***coded*** private information/specimens?   **YES\***   **NO**   1. **If YES to #3**, the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information/specimens pertain because: 2. The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances until the individuals are deceased. **Provide a copy of this agreement (an informal email exchange is sufficient). *OR***   **YES**   **NO\***   1. The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances until the individuals are deceased. **Provide documentation of the written policies and operating procedures. *OR***   **YES**   **NO\***   1. There are other legal requirements prohibiting the release of the key to the investigators until the individuals are deceased. **Provide documentation of the legal requirements.**   **YES**   **NO\***  **\*If YES to 3, and NO to 4a, 4b, or 4c, the activity involves human subjects. If YES to 3, and YES to 4a, 4b, or 4c, then the activity does not involve human subjects.** |

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| **SECTION 2:**  **Answer the questions below to determine if the proposed activity is human subjects research as defined by the FDA** |
| **PART A: DETERMINATION OF “HUMAN SUBJECT”** |
| **21 CFR 50.3(g):** *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. |
| ***Use the definition above to answer the following questions.*** |
| 1. Does the activity involve human subjects as defined by FDA regulations? 2. An individual will be a recipient of any test article (i.e., drug, biologic, or medical device) or as a control.   **YES\***   **NO**   1. An individual on whose specimen**+** a test article will be used (21 CFR 812.3(p))*(i.e., In vitro diagnostic (IVD)***++** *device, drug, biologic)*   **YES\***   **NO**  **Note:** The FDA regulations (21 CFR Parts 50 and 56) apply to all clinical investigations regulated by the FDA and other clinical investigations that support applications for research or marketing permits. Therefore, all studies of investigational IVDs that will support applications to the FDA are subject to 21 CFR Parts 50 and 56, even if they are not subject to most requirements of 21 CFR Part 812. See the [FDA Guidance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-diagnostic-ivd-device-studies-frequently-asked-questions) on[**In Vitro Diagnostic Device Studies - FAQs**](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=irb%20and%20in%20vitro&utm_content=1) for more information.  **+** Specimen – including use of leftover specimens that are not individually identifiable (e.g., a remnant of a human specimen collected for routine clinical care or analysis that would otherwise have been discarded).  **++**In vitro diagnostic products (IVD) are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, to cure, mitigate, treat, or prevent disease or its sequelae. |

If **YES** to any of the above, STOP HERE.



Your activity is human subjects research and requires IRB approval before you may begin. Develop a full protocol and [submit a Human Research Application](https://irb.northwestern.edu/submitting-to-the-irb/index.html) in eIRB+.

IF **NO**, complete the form below to provide detailed activity and funding information

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| **SECTION 3: ACTIVITY INFORMATION FORM** |
| 1. Describe the **purpose** of the proposed activity. (Describe the intent behind what you are doing, why you are doing it) |
| 1. Provide a description of the **procedures**. |
| 1. Describe the **subject** population or the **type** of information/specimens to be studied. |
| 1. Were the data/specimens **originally** **collected solely for research purposes?**   **YES\***   **NO**  **N/A**  **\*If YES to #4,** the IRB *may* request a copy of the IRB Approval Letter and Consent Form from the original study. The IRB will review this information to confirm that the use of the data/specimens conforms to what the participant agreed to in the informed consent form. |
| 1. Explain where the data/specimens were collected/obtained (i.e., identify the source of data/specimens).   **Not Applicable – *Activity does not involve the use of data/specimens.***  ***Research Biorepository/ Registry will be used [Provide the IRB Project STU number or the name of the outside Repository/Registry]***  **Northwestern Medicine’s Enterprise Data Warehouse (EDW)**  **AND/OR** |
| 1. Explain how the data/specimens will be provided to the investigator (e.g., the investigator will ask the EDW to provide de-identified data; the investigator will be provided an already existing, de-identified data set, etc.). Indicate who will de-identify the data and/or specimens, and how the data and/or specimens will be de-identified.   OR  **N/A** |
| 1. Describe all the **data points, variables, or information** that will be collected or analyzed for this project   OR  **N/A**  Notes:   * Access is limited to the items included in this section. The IRB must be notified of any additions to the above. * Please confirm that the information you have provided here does not include private identifiable information (i.e., [18 PHI Identifiers](https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/consent-hipaa/hipaa.html)). |
| **FUNDING** |
| Will the activities be supported by Federal funding (e.g., NIH, NSF, DoE, DoD) awarded directly to the Institution(s)(i.e., Northwestern University or its affiliated institutions is the primary awardee)?  **YES\***   **NO**  **\*If YES to #1, link the applicable InfoEd Number on the Funding Information page in the eIRB+ system. If Northwestern University is not a recipient of funds (i.e., SRALab is the prime or sub, and Northwestern is not involved), include the originating funder (i.e., NHLBI), prime award recipient, and sub award recipients in the protocol you submit in the eIRB+ system.**  NOTE: If the Institution(s) (i.e., Northwestern University or its affiliated institutions) is the primary recipient of a federal award (e.g., NIH, NSF, DoE, DoD), and one or more external entities will engage in human subject research, then the human research determination form is NOT appropriate because the Institution(s) is also engaged in human subjects research (see Appendix 1.8 for more information). Please [complete a Human Research Application](https://irb.northwestern.edu/submitting-to-the-irb/index.html). |
| Does the grant, contract, or cooperative agreement application designate this as being human subject research?  **YES**   **NO**  NOTE: If the Institution(s) (i.e., Northwestern University or its affiliated institutions) is the primary awardee and the grant application designates this as being human subject research, this must be submitted with a human research protocol and study related documents. This would be considered human research. |

**APPENDIX**:

The following are examples of activities that are generally considered **not** to be Human Research according to the definitions in Sections 1 and 2 above. If your activity is limited to one of the examples below, then it is likely not Human Research which would not require IRB review.

Note that publication is not a determining factor for whether an activity is Human Research.

* 1. **Quality Assurance/Improvement and Program Evaluation Projects**: The activity is limited to quality assurance/improvement activities or program evaluation designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.

See the IRB [Guidance on Quality Improvement and Program Evaluation Projects](https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html) for more information about how these activities are distinguished from research activities and more detailed considerations.

* 1. **Case Report or Case Series**: A case report is information collected and presented to highlight an interesting experience, observation, treatment, presentation, relationship, or outcome. A case series is a small collection of case reports, about 2-5 cases. It typically (but not always) results from a retrospective review of patients’ records. It may alternatively involve a prospective intervention or prospective collection of specimens or data that is not part of standard service or care. Testing of a patient’s biospecimen (e.g., special stain, immunohistochemistry, molecular studies) is not typically permissible as part of a case report. A critical component is that nothing was done to the patient(s) with prior “research” intent.

Note that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance. The use of Protected Health Information (PHI) to prepare a case report does not require IRB review for HIPAA Privacy Rule purposes. However, anyone who wishes to publish information that includes HIPAA identifiers or may identify the patient because of a description of a unique disease, condition, or outcome will need to obtain a signed HIPAA authorization from the patient. This authorization does not need to be submitted to the IRB for review, but consultation with the Northwestern Memorial HealthCare Privacy Officer is recommended. Additionally, those publishing case reports are strongly encouraged to obtain consent from any patients about whom the information will be published. In the case of deceased individuals, consent might be obtained from the next of kin.

Many journals require acknowledgement from an IRB prior to publication of a single case report or a case series. If asked to provide acknowledgement from the IRB prior to publication, either use this guidance as documentation from the IRB or contact the Northwestern University IRB office for assistance.

* 1. **Course-Related Activity**: The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of Human Research in Section 1.0.

Student class assignments that are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge meet the federal regulatory definition of “research.” These class assignments fall under the jurisdiction of the IRB and require IRB application, approval, and oversight. Instructors wishing to use such assignments must apply to the appropriate IRB for review and approval of these assignments before they begin.

Class assignments may be considered IRB-regulated research if the faculty member or the students change their plans about how to use the data. If the faculty member or students plan to use data collected from class assignments for research and publication, the faculty member must submit the activities to the IRB and obtain approval before beginning the activities.

* 1. **Journalistic or Documentary Activity (including Oral History)**: The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium (e.g., print newspaper, documentary video, online magazine).

**Oral History**:

OHRP has explained that “oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and therefore do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB).”

This does **not** mean that using oral history methods always makes IRB review unnecessary because whether this OHRP policy applies to a specific project depends on the scholar’s intent. Using oral history methods within a systemic investigation that seeks generalizable conclusions about living people would constitute “human subjects research” as defined in federal law.

* 1. **Research Using Public or Non-Identifiable Private Information about Living Individuals**: The activity is limited to analyzing data about living individuals (1) where the data have been retrieved by the investigator from public, non-restricted data sets or (2) where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.
  2. **Research Using Health Information from Deceased Individuals**: This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Note that deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions above for clarification. Note also that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.

* 1. **Preliminary Activities (exploratory and developmental work):**

Preliminary activities are small-scale activities intended to create and refine the study plan or aspects of the study plan (e.g., design, method, instrument(s)) prior to performance of a larger study.

Instrument/Questionnaire Development is limited to interacting with individuals to obtain feedback on the types of questions that could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the topic of the instrument, survey, or questionnaire. The instrument/questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as human subject research.

**Note:** If you or your team asks the participant to provide additional information unrelated to instrument/questionnaire construction, such as demographic information, that will be analyzed as part of a research study, the project may need to be submitted to the IRB for review.

Occasionally, preliminary activities do not meet the definition of research because they are not part of a systematic investigation. For example:

-Going to a potential site to see if the research is possible

-Going through a consent process with friends to see if the information is comprehensible

-Sending your new survey to a few experts in the field for their feedback as to whether the questions are appropriate for the topic and/or study population

-Obtaining feedback from colleagues and peers about research design

-Consulting a community advisory board (i.e., a tribal committee/council) about what you propose to study and/or how best to conduct your study

* 1. **Institutional Engagement:**

Per [OHRP](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html), an institution is considered engaged in a particular non-exempt human research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

The Institution is also considered engaged in non-exempt human research when it receives “an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.” As a result, the Northwestern University IRB must either serve as the Single IRB for all sites engaged in non-exempt human research or cede IRB review to an external IRB. Contact [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu) for more information.

Some examples of when the Institution is not engaged include if the Institution’s employees:

-Communicate with prospective subjects about the availability of research

-Provide prospective subjects with written information about research, which may include a copy of the relevant informed consent document, and other IRB-approved materials) but do not obtain subjects’ consent.

-Provide prospective subjects with the contact information of the investigators

\* For a full list of examples, please refer to the worksheet on Engagement- HRP-311