IRB Pre-Application-Decision Tree

This document is intended to help you identify if your project represents research involving human participants. Use this tool to determine whether you need to submit an IRB research proposal or request a determination from the IRB before developing an IRB proposal and creating a project in IRBNet. (*For faculty who will be teaching a research methods class, please see page 34 of the IRB Procedure Manual)

"Research", as defined by the Department of Health and Human Services (DHHS,) is a systematic investigation, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**." A systematic investigation is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Program evaluation and monitoring and quality assurance and improvement activities involve the systematic collection of information from or about human participants to ensure or enhance service delivery for the benefit of program recipients. However, while these types of activities often involve the systematic access, review, collection, analysis, and/or use of information from human participants like research, these are designed to benefit a single individual or organization and its program recipients rather than contribute to generalizable knowledge. If you would like the IRB to make a determination if your project is a program evaluation/ quality improvement project and not human subjects research, please submit your materials to IRBNet.

Other examples of activities that typically are not generalizable (not research) include biographies, oral histories, journalistic activities, legal research, and historical scholarship that focus directly on the specific individuals about whom the information is collected. "Research" is intentionally devised to contribute to broader knowledge rather than for the direct benefit of individuals or organizations. The intent to disseminate or share results beyond the individual or organization is an indicator of work designed to contribute to generalizable knowledge, while work that remains closely held by or for the individual or organization is an indicator that the work is not research.

Note: If a non-research activity is anticipated to also have the potential to contribute to generalizable knowledge with dissemination of the findings, submission of an IRB application for review prior to the start of the activity is recommended. **IRB approval cannot be provided retroactively for activities involving data (information or biospecimens) collected from human participants for non-research purposes.** It is not advisable to classify an activity as a non-research activity with the intention of re-classifying it as research contingent upon whether the findings offer a contribution to general knowledge. If a proposed activity is designed primarily for non-research purposes and IRB approval is not sought in advance, it cannot be later reclassified as research for IRB approval purposes. If a non-research activity reveals interesting insights, an IRB application may be submitted to start a new research project to access, review, collect, analyze, use, or disclose information collected from new human participants to replicate the non-research findings.

NO	YES	1. Is the proposed activity a **systematic** investigation **designed** to contribute to **generalizable knowledge** with data (i.e., information or biospecimens) from human participants?

- If the answer to question 1 is **NO**, **stop here**. Activities that are **not research** do not require IRB review.
- If the answer to question 1 is **YES**, **proceed** to the following questions.

NO	YES	2. Will this research be **limited** to accessing **existing data sets** for secondary analysis of data collected for other purposes?
NO	YES	3. Are the existing data sets to be accessed **public** (Such as data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges)?
NO	YES	4. Will the data sets **exclude** all **personally identifiable information** (name, address, date of birth, social security or other identification number, or some combination of information that allows for identification of an individual) from human participants? (See complete list of 18 HIPAA identifiers)

- If questions **2,3, and 4 are all answered YES**, stop here.

Accessing and analyzing publicly identifiable, de-identified data sets does not constitute human subjects research. If your program of study requires a letter from the IRB with this determination, please submit a brief statement that lists the sources of existing data and includes the attestation: "This research will utilize data from [insert the name of the data set(s) and the original owner or sponsor here] which is publicly available and does not require any special qualifications, permissions or privileges to access it. This research is limited to the secondary analysis of existing data sets without personally identifiable information. A determination that this activity is considered, "not human subjects research" is requested from the IRB."

Administrative review of the descriptive summary of the research may result in a determination that the research is **not human subjects research**, a request for additional information in order to make a determination, or a determination that the research is human subjects research requiring IRB application and IRB review.

- If **any or all** of questions 2, 3, or 4 are answered **NO**, **proceed** to the following questions.

NO	YES	5. Will the research involve any **interactions** (i.e., face-to-face, remote, or digital communications or contact of any kind) with living human subjects?
NO	YES	6. Will the research involve any invasive or noninvasive **interventions** (e.g., administration of treatments, manipulations of the environment, delivery of therapeutic or educational programs, or collections of biospecimens) with living human subjects?
NO	YES	7. Will the research team access, review, collect, analyze, use, or disclose any **personally identifiable information** (e.g., name, address, date of birth, social security or other identification number, or some combination of information that

		allows for identification of an individual) from living human subjects? (See complete list of 18 HIPAA identifiers)
NO	YES	8. Will the research team access, review, collect, analyze, use, or disclose any **identifiable private information** (i.e., identifiable information related to health, mental health, or other private characteristics or behavior such as sex, substance use, criminal activity) from living human subjects?

- If questions 5, 6, 7, and 8 are **all** answered **NO**, **stop here,** and **submit** a statement with a brief descriptive summary of the research activity in an abstract form, preferably under 500 words, and concludes with the attestation below:
  - "This research proposal does not involve any interaction or intervention with living human subjects and does not involve any personally identifiable information or identifiable private information. A determination that this activity is not human subjects research is requested from the IRB."
  - For de-identified private data sets that come to the principal investigator de-identified by someone not on the research team, please include permission to access the private data set, a list of data fields that will be accessed, and confirmation of who will be de-identifying the information.
  - Administrative review of the descriptive summary of the research may result in a determination that the research is **not human subjects research**, a request for additional information in order to make a determination, or a determination that the research is human subjects research requiring IRB application and IRB review.
- If **any or all** of questions 5, 6, 7, and 8 are answered **YES**, **proceed** to the application wizard in the Designer section of IRBNet.