What Needs an IRB Review?

All research projects that will involve human participants must be submitted for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

Human subjects are "living individuals about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, identifiable private information."

> Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g, providing stimuli to gauge reaction and response).
>
> Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews).
>
> 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of a participant is associated with the information or may readily be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

IRB Review Categories: Exempt, Expedited, and Full

The IRB reviews all human subjects research and classifies the types of review into three categories.

- Exempt review includes human subjects research in which there is minimal risk to participants. Please note that exempt review DOES NOT mean exempt FROM review. See categories below.
  - The IRB typically processes exempt review applications in about two weeks.
- Expedited review includes human subjects research in which there is more than minimal risk to participants. There is more than minimal risk when the sample size is small and/or the participants are audio or video recorded. See categories below.
  - The IRB typically processes expedited review applications in about 2 weeks.

- Full review includes human subjects research in which there is more than minimal risk to participants and does not fall into one of the expedited categories. Additionally, full review is required of research targeting special populations (ie. children under 18, prisoners, institutionalized individuals, pregnant women, etc.).
    - The IRB typically processes full review applications in about 1-2 months.

Exempt Review

The categories below are classified as exempt review. Please use Form A when submitting your IRB application for exempt review category research.

- **Research in Educational Settings (Category 1)**
    - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
        - (a) research on regular and special education instructional strategies; or
        - (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
- **Tests, Surveys, Interviews, Observation of Public Behavior – Part 1 (Category 2)**
    - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
        - *NOTE: If the information obtained is recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants; and any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. Please complete IRB FORM B for Type 2 Research instead.*
- **Tests, Surveys, Interviews, Observation of Public Behavior - Part 2 (Category 3)**
    - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 above if: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- **Use of Existing Records (Category 4)**
    - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through

identifiers linked to the participants.

- **Public Benefits/Service Programs (Category 5)**
  - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
    - (a) public benefit or service programs;
    - (b) procedures for obtaining benefits or services under those programs;
    - (c) possible changes in or alternatives to these programs or procedures; or
    - (d) possible changes in methods or levels of payment for benefits or services under those programs.
- **Consumer Acceptance (Category 6)**
  - Taste and food quality evaluation and consumer acceptance studies:
    - (a) if wholesome foods without additives are consumed; or
    - (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environment Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

Expedited Review and Full Board Review

The categories below are classified as expedited review. Please use Form B when submitting your IRB application for expedited review and full board review category research.

- Category 1 - Drugs or devices not needing investigational new drug or device exemptions
- Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Category 3 - Collection of biological specimens by noninvasive means (hair, saliva, sweat, nail clippings, etc.)
- Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples include weight, height, eye-color and moderate exercise by healthy volunteers.
- Category 5 - Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Category 6 – Collection of data from voice, video, digital or image recordings made for research purposes
- Category 7 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, that includes:
  - i) Information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;

- ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
- iii) The human subjects are elected or appointed public officials or candidates for public office;
- iv) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

➢ Special Populations - Research involves a special population (eg. children under the age of 18, prisoners, pregnant women, institutionalized individuals, etc)

Examples of Activities Generally Considered NOT to be Human Research

The following are examples of activities that are generally considered NOT to be Human Research according to the definitions above. If your activity is limited to one of the examples below, then it is likely not Human Research which would need to be reviewed by the IRB.

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

- Note: The purpose of a QA study is to assure known quality. The purpose of Program Evaluation (PE) is to assess that a program is doing what it is intended to do. Generally QI is designed for the purpose of improving the quality of a service, a program, a process, etc.. A QA, QI or PE study should present NO CHANGE in RISK to participants. These studies are mechanisms to assure that a service, a program or process functions optimally. Such projects are usually for internal auditing purposes only.
- If you can answer "yes" to all of the following questions, the activity is most likely not human research:

1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. For biomedical or Social Behavioral QA or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?
3. Does the study involve collection of data to which the investigator routinely has access as part of his or her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?

- **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.
    - 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.
- **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 above.
    - Note that some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB Office for review.
- **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.
- **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.
- **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.
    - 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.
- **Instrument/Questionnaire Development:** This activity is limited to interacting with individuals in order to obtain feedback on the types of questions which 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.

- Note that 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 also that if the participant is asked 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 will need to be submitted to the IRB for review.

If, after reviewing the information above, (1) you are unclear as to whether your activity is Human Research and would like for the IRB Office to make a determination for you or (2) you believe that your activity is not Human Research but would like for the IRB Office to provide documentation that it agrees with your assessment, then please email the IRB at irb@manhattan.edu.