IV. What is/isn't Human Subject Research?

The first question an investigator should consider with respect to an IREC application is whether the project fits the definition of **human subject research**. In order to do so, the project must meet the IREC definitions of both **research** and **human subjects** in order to require IREC approval.

Research

The IREC defines research as "*a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*" *(45CFR46.102 (d))*.

"Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond that studied.

As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective."

Human subject research generally does not include journalism, political polls, or public health surveillance. However, some of these activities may include or constitute human subject research in circumstances where there is a clear intent to contribute to generalizable knowledge – and the study collects data about the subjects themselves. If this is the case then the entire project must reviewed and approved by the IREC.

Human Subjects

A human subject is defined by the IREC as "*a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.*"

The following list contains brief explanations of the terms found in the definition of human subjects.

• The term **living individual** refers to the state of the subject. The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from non-living subjects are not subject to the human subject protection regulations.

• **"About whom"** indicates that the data received from the living individual is *about* the person. A human subject research project requires that the data received from the living individual is *about* the person. Some interactions with people for the purpose of collecting information do not collect any information about that person. For example, a researcher may contact a non-governmental organization to ask about its sources of funding. A researcher might also contact individuals in order to collect information about a product or a service. In both cases, the data being collected is not *about* the individual. Therefore, in these cases the individuals would not be considered human subjects.

• **Intervention** includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.

• **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

• **Identifiable private information**[1] includes 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) and information about behavior that occurs in a context in which an individual can reasonably expect that no recorded observation is taking place (such as a locker room or public restroom).

• **Identifiable** means the information contains one or more data elements that can be used alone or combined with other reasonably available information to identify an individual (e.g. IID number, birthdate, home address). Please note that studies based on data collected for non-research purposes may not constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

NOTE: Observational studies of public behavior (including watching television or observing conversation in internet chat rooms) are **not** human subject research if they do not involve intervention or interaction with the subjects and if the behavior is not private.

In light of the potential consequences of not obtaining IREC review and approval, the investigator should err on the side of caution and consult the IREC when he/she is uncertain if a project is human subject research.

[1] Disclosure of private information may place subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation. Researchers must use caution with collections of identifiable data of a sensitive nature.

Determining if a Study is Human Subject Research

Determining whether a project requires review by the IREC is sometimes difficult and for this reason it is always best to consult with the IREC for guidance.

The IREC makes the determination whether or not a project meets the definition of human subject research. Nazarbayev University policy requires that proposed research involving human subjects be reviewed and approved by the Institutional Research Ethics Committee prior to project initiation.

If you are unsure if your project meets the definition of research or if you require documentation that your project does not require IREC review, complete and submit the Institutional Research Ethics Committee (IREC) Application/Protocol Form found in Appendix A of this document.

The determination of whether or not a project or activity is defined as human subject research rests on the answers to the following three questions:

1. Is it research? The IREC defines research as a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge. Research is usually described in a protocol, a formal document that describes the research question or hypothesis and how it is to be tested (methodology) to establish facts and reach conclusions.

2. **Is the intent to produce generalizable knowledge?** The ***intent*** to develop or contribute to generalizable knowledge makes an activity research. Generalizable knowledge is knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences. Activities designed to contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. The information is collected to share with others in a discipline and is created to make a broad statement (conclusion) about a group of people, procedures, programs, etc.

If the activity is not a systematic investigation designed to contribute to generalizable knowledge, the activity does not meet the definition of research.

Generalizable knowledge includes one or more of the following concepts:
(1) The information contributes to a theoretical framework or an established body of knowledge; (2) The primary beneficiaries of the study are other researchers, scholars, and

practitioners in the field of study; (3) Publication, presentation or other distribution of the results is intended to inform the field of study; and, (4) The results are intended to be replicated in other settings.

3. Does it involve human subjects? Although a seemingly straight-forward question, whether or not an activity involves human subjects can be somewhat confusing, especially when using coded private information or specimens. Human subjects are defined as "living individuals *about whom* an investigator conducting research obtains:

- Data through intervention or interaction with the individual, **or**
- Identifiable private information

Intervention includes both physical procedures by which data are gathered (for example, 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 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 the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

For purposes of this document, ***coded*** means that:

- Identifying information (such as name or IID number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Determinations of what does or does not involve human subject research must be made by the IREC or individuals designated by the IREC Chair who have sufficient training and expertise in making such determinations.

In analyzing a particular activity under this question, it is important to focus on **what is being obtained by the investigators**. If the investigators are not obtaining either data

through intervention or interaction with living individuals, **or** identifiable private information, then the research activity does not involve human subjects.

What about Research Involving Coded Private Information or Biological Specimens?

Whether or not an activity is classified as "not involving human subjects" or qualifies for exemption under 45 CFR 46.101(b)(4) is determined by the following:

- the source of the data (primary or secondary data)

- the ability or inability of the investigator to link data or specimens to specific individuals either directly or indirectly through coding systems

Research involving **only** coded private information or specimens is not considered human subject research if **both** of the following conditions are met:

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals (i.e. it is pre-existing data); **and**

2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

a. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;

b. There are IREC-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; **or**

c. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

The exemption under 45 CFR 46.101(b)(4) applies to research involving private information and specimens when:

1. Data is already existing at the time the research is proposed and is available publicly, **or**

2. The information is recorded by the investigator(s) in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects.

This exemption would not apply if the investigators, having obtained identifiable private information or specimens from existing records or specimens, record the data or

information in a coded manner, since the code would enable subjects to be identified through identifiers linked to the subjects.

NOTE: If it is determined that the research does NOT require IREC approval, the investigator, will receive a letter to confirm the decision was made by the IREC.

Identifying Studies that Are Human Subject Research

Certain studies may have the characteristics of research but do **not** meet the definition of human subjects research. The IREC policies state that the definition of human subjects and research must **both** be met in order for a study to be considered human subject research.

Examples of activities that are Human Subject Research:

1. Utilizing test subjects for new devices, products, drugs, or materials. Examples of this type of research may include testing the effectiveness of a new drug treatment or testing the effectiveness of a newly developed exercise machine.

2. Collecting data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.

3. Using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question. An example of this type of research would be an investigator performing a chart review of patient health records as part of data collection.

4. Using bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the key. An example of this type of research would be collection of saliva samples from participants in order to measure changes in cortisol levels during a specific task.

5. Producing generalizable knowledge about categories or classes of subjects from individually identifiable information. Much research falls into this category. One example would be collecting data regarding the eating habits of university students in hopes of generalizing the findings to university students in Kazakhstan. Another example would be data collection from individuals undergoing a particular cancer treatment in order to make generalizations about the treatment and how it will work for others diagnosed with cancer.

6. Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living, working space or test chamber.

Identifying Studies that Are *Not* Human Subject Research (Do Not Need IREC Review):

Examples of activities that are Not Human Subject Research (NHSR):

1. Data collection for internal departmental, school, or other university administrative purposes. *Examples: teaching evaluations, customer service surveys.*

2. Service surveys issued or completed by university personnel for the intent and purposes of improving services and programs of the university or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This would include surveys by professional societies or university consortia. *Example: A university-issued survey regarding employee use of and satisfaction with Parking Services.*

Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IREC review may be required before the data could be released to the new project.

3. Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves.
Example: canvassing librarians about inter-library loan policies or rising journal costs.

4. Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques. For more detailed information on course-related activities/class projects, please see the end of this chapter.

Note: The IREC is only required to review studies that meet the definitions of "research" and "human subject"[2].

5. Biography or oral history research involving a living individual that is not generalizable beyond that individual. *Example: Interviewing an individual about their experience during a past event, such as the September 11th terrorist attacks.*

[2] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

6. Independent contract for procedures carried out for an external agency.
Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.

7. Research involving cadavers, autopsy material or bio-specimens from now deceased individuals. *Example: Obtaining organs from deceased individuals for use in biology research.*

Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IREC review.
Please contact the IREC for further information.

8. Innovative therapies except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) *Example: Based on a growing recognition that "a moist wound healing environment predisposes surgical incisions to a faster healing and better patient outcome" a surgeon uses an advanced wound care technology on a patient who underwent a radical mastectomy to improve patient outcomes.*

9. Quality improvement projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge ***and*** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. *Example: Institutional research conducts a campus wide survey of students regarding their assessment of food services in the campus dining facilities.*

Note: Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the
IREC for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IREC.

10. Case histories (medical) which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.

11. Publicly available data[3] do not require IREC review. *Examples: census data, labor statistics.*

Note: Investigators should contact the IREC if they are uncertain as to whether the data qualifies as "publicly available".

12. Coded private information or biological specimens that were **not** collected for the currently proposed projects do not need IREC review as long as the investigator cannot link the data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator.

Note: Investigators are not allowed to make this determination. These projects require verification from the IREC.

Class Projects

Class projects are designed to provide students an opportunity to practice various research methods such as interview, observation, and survey techniques, as well as data analysis. They do not require IREC review. Research conducted by students (graduate or undergraduate) as part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to nor will it likely lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures including research methods (interviewing, observation and survey techniques) as well as data analysis.

Class projects that meet ALL of the conditions stated below may be conducted under the supervision of the faculty member without submitting a protocol to the IREC. Projects that do not meet all of these conditions must be submitted to the IREC for review.

The class project must meet the definition of classroom research. This is defined as a project which:

[3] Publicly available refers to record sets that are readily available to the broad public, such as census data, health, labor, or educational statistics. An investigator should not assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

- is a normal part of the student's coursework
- is supervised by a faculty member
- has as its primary purpose the development of the student's research skills
- does not present more than minimal risk to participants or to the student investigator
- does not include as research subjects any vulnerable populations as classified in Subparts B,C, or D of 45 CFR 46 such as fetuses, neonates, prisoners, and individuals under the age of 18.
- Is not "genuine research" that is expected to result in generalizable data or expected to result in publication or some other form of public dissemination.

The above refers to student class projects only. Independent research projects conducted by students such as honors projects, theses, dissertations, and independent study projects that collect data through interactions with living people or access private information ***DO*** *fall under the jurisdiction of the IREC. These projects will require that a protocol be submitted to the IREC for review.*

PLEASE NOTE: Even if it is not the intent of a class project to produce generalizable knowledge, if the project involves more than minimal risk to participants or involves a sensitive topic area, it WILL require IREC review and approval. Categories of sensitive topics include information:

- relating to sexual attitudes, preferences or practices
- relating to the use of alcohol, drugs or other addictive products
- pertaining to illegal conduct
- that if released could reasonably damage an individual's financial standing, employability, or reputation within the community
- that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination
- pertaining to an individual's psychological well-being or mental health

genetic information.