Definitions and terms used in human subject research

This document provides definitions for terms as they apply to human subject research.

Accrual

The number of subjects that have completed or are actively in the process of completing a research study. It is the number of subjects enrolled in a study. It does include drop-outs.

Adverse effect

An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).

Adverse event

Any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio; Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Approval period

The period in which the study can be conducted

Assent

A child's affirmative agreement, verbal or written, to participate in research. Mere failure to object should not, absent affirmative agreement, to be construed as assent. This means the child must actively show their willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way

Assurance

A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with the applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved

Authorized Institutional Official

An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral science research

Autonomy

Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others

Baseline

The initial time point in a clinical trial that provides a basis for assessing changes in subsequent assessments or observations. At this reference point, measurable values such as physical exam, laboratory tests, and outcome assessments are recorded.

Belmont Report

A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1970

Beneficence

An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (i) do not harm; and (ii) to protect from harm by maximizing possible benefits and minimizing possible risk of harm

Benefit

Evaluate our desired outcome; an advantage. I human subject research compensation is not considered a research benefit.

Biologic

Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries. Biologics include vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, and allergenics.

Case report or case study

A case report is one in which three or fewer records are accessed. Case reports do not meet the definition for human subjects research and do not require submissions to the IRB if the project meets the following criteria:

- Nothing was done to the patient(s) with prior research intent.
- The case report does not contain elements of a systematic investigation (e.g. statistical methods).
- The case report describes an interesting treatment, presentation or outcome.
- The published article will not contain any identifiable information or authorization has been obtained.

Centers for Disease Control (CDC)

Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.

Certificate of Confidentiality

A document that provides additional protection of data from legal subpoena. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research.

Children

In Massachusetts, children, or minors, are individuals under 18 years of age.

Clinical Trial

A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

Clinical Investigation (FDA definition)

Any experiment that involves a test article and one or more human subjects and is subject to requirements for submission to the Food and Drug Administration. Clinical investigations must not be initiated unless that investigation has been reviewed and approved by an IRB.

Clinical Research (NIH Definition)

The NIH defines clinical research as:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
- Epidemiologic and behavioral studies.
- Outcomes research and health.

Closure

An IRB protocol may be closed out after data collection is complete; interaction with participants is complete and all data has been de-identified.

Code of Federal Regulations (CFR)

The Code of Federal Regulations is an annual codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. The CFR is divided into 50 titles representing broad areas subject to Federal regulation. Each Title is divided into chapters that are assigned to agencies issuing regulations pertaining to that broad subject area. Each chapter is divided into parts and each part is then divided into sections -- the basic unit of the CFR. The purpose of the CFR is to present the official and complete text of agency regulations in one organized publication and to provide a comprehensive and convenient reference for all those who may need to know the text of general and permanent Federal regulations (National Archives).

Coded data

Identifying information (such as name or social security 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.

Coercion

The use of express or implied threats of violence, reprisal, or other intimidating behavior to compel a person to act against his or her will. Under coercion, a person has no choice

Cognitively impaired

Individuals having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

Collaborative IRB Training Initiative (CITI)

An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the country and is administered by the University of Miami (see: www.citiprogram.org).

Common Rule

The Common Rule, which governs research with human subjects conducted or supported by 15 federal departments and agencies establishes a comprehensive framework for the review and conduct of proposed human research to ensure that it will be performed ethically. The central requirements of the Common Rule are:

- Those who participate as subjects in covered research are selected equitably and give their fully informed, fully voluntary written consent; and
- That proposed research be reviewed by an independent oversight group referred to as an Institutional Review Board (IRB) and approved only if risks to subjects have been minimized and are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.

Compensation

Payment for participation and research.

Competence

Capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

Confidentiality

Refers to subjects' data and the study safeguards that will protect the data.

Conflict of Interest (COI)

The real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships. A conflict of interest occurs when individuals involved with the conduct, reporting, oversight, or review of research also have financial or other interests, from which they can benefit, depending on the results of the research.

Consent Document

Documents presented to a subject or parent guardian prior to beginning a study. Most studies will have this document submitted with the proposal, unless requesting a Waiver (see below). The IRB has provided a template on the web site for investigators to prepare their documents.

- ***Adult Informed Consent:*** This is required when subjects are 18 years and older. This should be written to the subject using appropriate language ("you").
- ***Parental Permission Document:*** This is required when subjects are 17 years and younger. This should be written to the parent/guardian using appropriate language ("your child").
- ***Assent Document:*** Assent is an agreement by an individual not competent to give legally valid informed consent (e.g., a child aged 7+ or cognitively-impaired person) to participate in research. This is required for children enrolled in studies that are 7-17 years of age. If the board deems appropriate, this can be requested for younger children.

Data Safety Monitoring Board (DSMB)

A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial

or notification of subjects about new information that might affect their willingness to continue in the trial.

Data Safety Monitoring Plan (DSMP)

Data and Safety Monitoring means the process to ensure and maintain the scientific integrity of human subject research and to protect the safety of human subjects, a system for appropriate oversight and monitoring to ensure the safety of participants and the validity of the data. The section of a protocol that describes the steps to identify physical, social, or psychological occurrences that may result from participation in the research study and explains in detail how such occurrences will be handled and reported. A DSMP describes the timing, tools and/or method(s) for monitoring and evaluation, procedures for treatment or resolution (including circumstances which would result in halting or terminating research), procedures for and timing of reports to oversight bodies, and description of oversight bodies involved with the study (e.g. FDA, IRB, or Data and Safety Monitoring Board). A study does not need to have a Data and Safety Monitoring Board to have a DSMP.

Data Transfer Agreements/Data Use Agreements (DTA/DUA)

A Data Use Agreement (DUA) is a contractual document used for the transfer of data that has been developed , where the data is nonpublic or is otherwise subject to some restrictions on its use. Often this data is a necessary component of a research project and it may or may not be human subject data from a clinical trial, or limited data set information as defined in HIPAA. Universities will want to ensure that DUA terms protect confidentiality when necessary, but permit appropriate publication and sharing of research results in accordance with institution policies, applicable laws and regulations, and federal requirements. DUAs are similar to confidentiality agreements.

Debriefing

Giving subjects previously undisclosed information about the research project following completion of their participation in research.

Deception in Research

Deception is the intentional misleading of subjects or the withholding of full information about the nature of a research experiment or procedure. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental.

Declaration of Helsinki

A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries.

DHHS

Department of Health & Human Services

Drug

A drug is defined as: A substance recognized by an official pharmacopoeia or formulary. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (other than food) intended to affect the structure or any function of the body. A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device. Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

Equitable

Fair or just; Used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

Exculpatory

Pertaining to that which relieves of a responsibility, obligation, or hardship; clearing from accusation or blame.

Exempt

Six categories of minimal risk research that are exempt from federal oversight. However, these categories of research are not exempt from review by Northeastern's HRPP; rather applications are to be submitted and the HRPP will be an exempt determination.

Expedited review

Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Expired Study

When a continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the informed consent document. No activities can occur on the expiration date or after.

Federal Wide Assurance

Assurance of compliance with Department of Health and Human Services (DHHS) regulations pertaining to the protection of human subjects. The federal Office for Human Research Protections (OHRP) requires that an institution/organization have an OHRP-approved assurance of compliance with the DHHS regulations (45 CFR 46.103) if the institution/ organization is engaged in human subjects research that is conducted or supported by any agency of the DHHS.

Northeastern University:

- Federalwide Assurance Number: FWA00004630
- Registration with OHRP: IRB00000356
- Institutional Organization Number: IORG0000211

Food & Drug Administration (FDA)

An agency within the U.S. Department of Health and Human Services (DHHS) responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, nation's food supply, cosmetics, and products that emit radiation.

Family Education Rights & Privacy Act (FERPA)

A federal law of 1974 that protects the privacy of student education records.

Full board review

Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Generalizable

Quietly applicable or universally applicable.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Grant

Financial support provided for research study designated and proposed by the investigators.

Guardian

An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. It also means an individual who is authorized to consent on behalf of a child to participate in research.

Health Insurance Portability & Accountability Act (HIPAA)

The first comprehensive Federal protection for the privacy of personal health information. The Privacy Rule regulates the way certain health care groups, organizations, or businesses, called covered entities under the Rule, handle the individually identifiable health information known as protected health information (PHI).

Human subject/participant

A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information (no intervention or interaction required.)

Identifiable

When an investigator can readily ascertain or associate the information with the individuals' identities. Examples of identifiers include names, social security numbers, medical record

numbers, OR any code that permits the data to be linked to individually identifiable living individuals.

Individual Investigator Agreement (IIA)

Document to be completed by an individual community Investigator who is collaborating with an UI Principal Investigator on a CBR study but is not serving as a representative of a community organization, rather is participating as an individual independent investigator and is requesting UI IRB oversight for their activities.

Informed consent

A process by which a participant or legal guardian voluntarily confirms his or her willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form approved by an IRB, unless such documentation is waived by the IRB (45 CFR 46).

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25] (OHRP).

Informed consent form

A document that describes the rights of a study participant and provides details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document.

IRB of Record

A reviewing IRB that assumes IRB oversight for another organization that meets the regularity definition of engaged in human subjects research. If federal funds are supporting this research, the organization is designated to do so through an approved Federalwide Assurance (FWA) on file with the Federal Office of Human Research Protection (OHRP).

Institutional Review Board (IRB)

An independent body constituted of medical, scientific, and nonscientific members whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, protocols and amendments, and of the methods and material to be used to obtaining and documenting informed consent of the trial participant.

Institution

Any public or private entity or agency (including federal, state, and local agencies).

IRB Authorization Agreement (IAA)

A type of reliance agreements between two institutions in which one IRB agrees to serve as the Reviewing IRB (or IRB of record) and one IRB agrees to serve as the Relying IRB.

Institutionalized

Confined, either voluntary or involuntary(e.g., hospital, prison, or nursing home.)

Interaction

Communication or interpersonal contact with individuals.

Intervention

Physical procedures and manipulations of those individuals or their environment for research purposes.

Justice

An ethical principle discussed in the Belmont Report requiring fairness and distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Legally authorized individual

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Limited data set

A limited data set could include the following (potentially identifying) information:

- Admission, discharge, and service dates;
- Dates of birth and, if applicable, death;
- Age (including age 90 or over); and
- Five-digit zip code or any other geographic subdivision, such as state, county, city, precinct and their equivalent geocodes (except street addresses).

Covered entities must condition the disclosure of the limited data set on execution of a "data use agreement," which

- establishes the permitted uses and disclosures of such information by the recipient, consistent with the purposes of research, public health, or health care operations;
- limits who can use or receive the data; and
- requires the recipient to agree not to re-identify the data or contact the individuals.

In addition, the data use agreement must contain adequate assurances that the recipient will use appropriate physical, technical and administrative safeguards to prevent use or disclosure of the limited data set other than as permitted by HIPAA and the data use agreement, or as required by law.

Material Transfer Agreement (MTA)

A document that is used by scientists and their institutions to transfer materials to other scientists and institutions. MTAs provided by outside organizations may contain clauses that are not consistent with the University of Utah policies and procedures and/or federal law. Signing one of these agreements could severely impede a scientist's ability to carry out his or her research or to publish in a timely fashion. It is important that all MTAs are evaluated and signed by an authorized TVC representative. The Technology Venture Commercialization Office handles and processes these agreements.

Medical device

A diagnostic or therapeutic article that does not achieve any of its principal intended purposes through chemical action within or on the body. The FDA defines "devices" very broadly. For example, devices include, but are not limited to, diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

Minimal risk

the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).

For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. This is not interpreted to include the inherent risks certain categories of human subjects face in their everyday lives. For example, the risks imposed in research focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone).

In addition, the IRB generally subscribes to the recommendations related to 45 CFR 46.404 from SACHRP regarding research involving children.

Modification

A change to an approved study. An Modification form must be submitted that describes the proposed modifications to an approved study. All new and revised documents are to be submitted with the form. Modifications must be approved before these are implemented.

Multi-site

A multi-site study is research that takes place at more than one entity and each entity has an IRB.

National Institutes of Health (NIH)

A federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research

Nonaffiliated member

Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community.

Noncompliance

Failure to follow the federal regulations with respect to protection of human subjects in research or failure to follow the determinations of the IRB with respect to conduct of the research as approved by the IRB.

Not human subject research

An activity that does not meet the definitions of "research" and "human subject" under either FDA or DHHS regulations.

Nuremberg Code

A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

Obtains

In addition to obtaining, this term includes using, studying, analyzing, collecting, gathering, and viewing information.

Office for Human Research Protection (OHRP)

A federal government agency within the Department of Health and Human Services (DHHS) charged with the protection of human subjects participating in government funded research. It issues assurances and oversees compliance of regulatory guidelines by research institutions.

Permission

The “agreement of parent(s) or guardian to the participation of their child or ward in research.” The term “parent” means a “child's biological or adoptive parent.”

Post Approval Monitoring (PAM)

A program to ensure that ethical and regulatory requirements are followed by investigators. This program is also designed to improve the quality of research by ensuring congruence between what is described in the research protocol and what is occurring during the actual performance of research activities. PAM methods include: protocol review; laboratory visits; observation of selected procedures; and follow-ups to concerns. All studies, even those determined to qualify for exempt status, are subject to PAM.

Principal Investigator (PI)

The person who is ultimately responsible for the conduct of the study. For student-initiated research, the student’s faculty advisor serves as the PI and is ultimately responsible for the conduct of the study.

Prisoner

An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution. The definition of "minimal risk" for research involving prisoners differs somewhat from that given for non-institutionalized adults.

Common examples of the application of the regulatory definition of “prisoner” are as follows:

Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these population.

Privacy

Respecting an individual’s right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing and circumstances of obtaining personal information from or about them. For example, individuals may not want to conduct the consent process in an open area or may not want to be seen entering a study site that might stigmatize them.

Private

The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place OR the individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will not be made public, e.g., medical record, educational record, tax record.

Procedures

Activities that subjects will undergo as part of their participation or investigators will follow to conduct the study. For example, in a data analysis study, the procedures would include an investigator reviewing subjects' records. In a study involving interaction or intervention with subjects, procedures would describe the nature of the intervention or interaction, such as administering surveys or questionnaires. Study procedures need to be described in detail.

Protocol

The portion of the IRB Application form that describes how the Principal Investigator (PI) will conduct the study.

The formal design or plan of an experiment or research activity, specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Protected Health Information (PHI)

Information about the past, present, or future physical or mental health of an individual that identifies or could be used to identify the individual and is created or received by a Covered Entity. (45 CFR 160.301, 164.501; information about the provision of health care and payment for health care is included; some educational and employment records are excluded.)

Quality Assurance/Quality Improvement (QA/QI)

These are activities designed to improve the quality of a process or assess its overall function. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

Quorum

Greater than half of the IRB members are present at an IRB meeting and the following criteria are met: at least one member whose primary concerns are in scientific areas is present at the meeting; at least one member whose primary concerns are in non-scientific areas is present at the meeting; and at least one unaffiliated member is present at the meeting. A Board member may fulfill more than one criterion.)

Research

A systematic investigation designed to develop or contribute to generalizable (widely applicable) knowledge. These terms are defined elsewhere in this glossary. Note that if the research activity involves a drug, device, or biologic, other regulations and definitions may apply. Please contact the IRB for further clarification.

Research Misconduct

Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data or creative innovations that are nonetheless ethical, legal and meet professional standards.

Research team/personnel

Those involved in the design, conduct, or reporting of the research. Research personnel can include students and those outside Northeastern University.

Respect for persons

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Risk

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." These can include:

- ***Moderate Risk:*** The subject will undergo procedures that will increase their risks above those normally encountered in daily life. Equivalent term is "more than minimal risk." These can include, but are not limited to: clinical drug trials, device trials, genetic studies, and risks that include insurability and employability.
- ***Minimal Risk:*** The subject will undergo procedures that do not appear to increase the risks above those normally encountered in daily life. These can include but are not limited to studies that involve survey, questionnaire, interview, medical records review, observation of behaviors, drawing a small amount of blood from a healthy individual, etc.
- ***Exempt:*** These studies are not usually reviewed by board members, but are reviewed by the chairman. These have been determined to fit certain federal regulations as exempt from IRB review.

Secondary Data

Secondary data is data collected by someone other than the user. Common sources of secondary data for social science include censuses, surveys, organizational records and data collected through qualitative methodologies or qualitative research. Primary data, by contrast, are collected by the investigator conducting the research.

Serious Adverse Event (SAE)

Any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects

Is another condition which investigators judge to represent significant hazards

Site Visit

A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

Systematic

Having or involving a system, method, or plan.

Tissue/Specimen banking

Specimen collection banks, whether they are described as "banks" or not, are many and varied. They cover the spectrum from individual clinicians' research specimen collections, (often gathered with no specific project in mind) to institutional "Tissue Banks" (such as cancer center shared resource banks) to multi-center, industry-sponsored drug trials which usually collect at least some blood or tissue for unspecified future research.

Unanticipated Problem (UP)

Unanticipated problems are defined as any incident, experience or outcome that occurs during the course of a study that meets all of the following criteria:

-
  - Unforeseen (not expected by the researcher or the research participant) given the research procedures and the subject population being studied.
  - Related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
  - Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

Undue influence

Exceeding the influence that is appropriate or normal; excessive. It is fine to influence or sway individuals to participate in your study. The issue is whether that influence is undue. This will vary by study. For example, $10 may not be unduly influential compensation in America for 3 hours of participation. However, in other countries, $10 may be the equivalent of a month's salary and may be unduly influential.

Vulnerable populations

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Voluntary

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Waiver of documentation of consent

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Waiver of informed consent

Occasionally there are reasons to waive written consent or to alter the requirements of consent. Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements. In order to qualify for a Waiver of Consent, the following conditions should be met: 1) that the research pose no more than minimal risk to subjects; 2) no adverse effects as a result of the waiver or alteration; 3) without the waiver or alteration the research in question could not be carried out; and 4) information will be provided after participation is completed, if appropriate.

Wards of State

A ward means a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law. The term “ward of State” may be used interchangeably with “ward” in this document. For inclusion in a study, a number of additional considerations must be made.

Resources

ClinicalTrials.gov

Department of Health & Human Services

Federal law (45 Part 46)

Food & Drug Administration Regulations (50 CFR Part 21)

National Institutes of Health (NIH)

Office of Human Research Protection (OHRP)