

## Definitions

The purpose is to provide definitions of the most common terms used by the Institutional Review Board (IRB) or Exempt Review Committee (ERC) at Marywood University.

### **ADVERSE EVENT**

Any untoward or unfavorable physical or psychological occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research; while occurring mostly in the context of biomedical research, it may occur in the context of social and behavioral research.

Adverse events that occur during clinical trials or multi-site studies can be either internal or external.

**Internal AE** means that the event involved a participant enrolled by the investigator at Marywood University or at a site conducted by an investigator affiliated with Marywood University (within MU-IRB's purview).

**External AE** means that the event involved a participant enrolled by an investigator at another institution participating in a multi-study or trial (i.e., clinical trials that have arms in other countries – not within the IRB's purview, but may affect local participants).

### **ADVISOR (RESEARCH ADVISOR OR FACULTY ADVISOR)**

An individual who mentors a student investigator (advisee). The individual shares the responsibility for the ethical conduct of research, making adequate time for consultation with the advisee and monitoring research progress.

### **AGENT**

An individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities. Agents can include employees such as faculty or staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

### **ANNUAL CHECK-IN REPORT**

A required report for research projects which are still open one year from approval but which do not require official, regulatory continuing review.

### **ANONYMOUS**

A status of research information where a subject's identity is not known by the investigator(s) or may not be associated with the information or biospecimens collected

### **ASSENT**

An agreement to participate in a research study by subjects who are not competent to give legally valid informed consent (e.g., children or cognitively impaired individuals); does not involve mere *failure to object* by the individual, absent affirmative agreement

### **AUDITOR (EVALUATOR, OUTSIDE REVIEWER OR PEER DEBRIEFER)**

An individual, often externally located and utilized in qualitative research, who reviews research data and results for accuracy

## **AUTONOMY**

Freedom of choice and the right of an individual to determine in what activities he/she will or will not participate

## **BENEFITS**

Valued or desired outcomes that will be advantageous to the subjects participating, and/or to the field of study; compensation or other incentives cannot be considered benefits for subjects to weigh against risks when deciding whether or not to participate

## **CERTIFICATE OF CONFIDENTIALITY**

Coverage issued by the National Institutes of Health (NIH) and other HHS agencies prohibiting forced disclosure of identifiable, sensitive research information to any court, such as through a subpoena, or other person not connected with the research, except when the subject consents or in a few other specific situations; automatically applied to NIH awardees; may be requested for some non-funded studies if health-related; see [NIH's COC page](#)

## **CHILDREN**

Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted, and who are usually under the age of eighteen (nineteen in Alabama and Nebraska, or twenty-one in Mississippi)

## **CLINICAL TRIAL**

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes

### **CLOSURE OF A RESEARCH PROJECT**

An official action taken by the Institutional Review Board (IRB) or Exempt Review Committee (ERC) to finalize its IRBNet history and to set a date of destruction for all electronic and hard copy records maintained by the Office of Planning and Institutional Research (OPIE)

### **CODE OF FEDERAL REGULATIONS**

The codification of the general and permanent rules (administrative law) published in the Federal Register by the departments and agencies of the Federal Government of the United States, which is divided into 50 titles representing broad areas subject to Federal oversight

### **COERCION**

Overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance

### **CO-INVESTIGATOR**

An individual with shared responsibility for the oversight of a research study, including (1) design, development and implementation of the study plan, (2) affirmation that all members of the research team are appropriately qualified, trained and supervised, and (3) maintenance of all administrative and compliance aspects of the study, but who is not identified as the lead

### **COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)**

A provider of high quality, peer-reviewed, and web-based educational courses in research ethics, regulatory oversight, research administration, and other topics pertinent to the interests of member organizations and individual learners

### **COMMON RULE (45 CFR 46, SUBPART A)**

The Federal regulations governing the protection of human subjects in research and adopted by twenty, U.S. Federal departments and agencies

### **COMPENSATION (or INCENTIVE)**

Payments or other rewards given to human subjects as motivation to participate in research and granted in either monetary (cash, check, gift card, voucher, etc.) or non-monetary format (gift, promotional item, course credit, etc.); may not be considered as a benefit for subjects to weigh against risks when deciding whether to participate

### **CONFIDENTIAL**

A status of research information where a subject's identity is known by the investigator, but is protected from release.

### **CONFLICT OF INTEREST**

In research, refers to situations in which financial or other personal considerations may compromise or appear to compromise an investigator's professional judgment in conducting or reporting research, or in an IRB/ERC member's review of research. It arises when the primary interest is influenced by a secondary interest that may harm professional judgment and objectives.

## **CONTINUING REVIEW**

An official review which is conducted at a designated interval after a project has received initial review and approval by the Institutional Review Board (IRB) or Exempt Review Committee (ERC)

## **DATA**

Information that is collected for analysis or used to reason or make a decision

## **DEBRIEFING**

A part of the informed consent process where the investigator provides subjects with previously undisclosed information (e.g., research employing deception or incomplete disclosure) about the research project following completion of their participation

## **DECEPTION**

An intentional misleading of others through misrepresentation or falsehood, which may happen when an investigator provides research subjects with false information in order to obtain unbiased results

## **DE-IDENTIFY**

The removal and separation of any and all data points that help establish or indicate an individual, or any other unique items of individually identifying information, from data or specimens

## **DEVIATION**

Any major or minor divergence or departure from approved research, which is under the investigator's control and which takes place without prospective IRB or

ERC approval. Approved research encompasses all approved materials and documents such as the application/protocol, informed consent or assent form, recruitment materials, questionnaires/data collection forms or any other information relating to the study.

A **major deviation** is one that impacts (1) the research risks and benefits, (2) subject well-being or safety, (3) the integrity or validity of study data, or (4) a subject's willingness to participate in the research. Examples include enrolling an ineligible subject, failure to obtain informed consent prior to any study-specific tests/procedures, incorrect dosage, etc.

A **minor deviation** is one that does not impact (1) the research risks and benefits, (2) subject safety, (3) the integrity of study data, or (4) a subject's willingness to participate in the research. Examples include failure to collect specific measures (e.g., questionnaire, baseline weight, etc.), unapproved advertisements used for recruitment, collecting signatures for an exempted study, etc.

### **DIETARY SUPPLEMENT (NUTRITIONAL SUPPLEMENT)**

A product taken by mouth that contains a "dietary ingredient" intended to supplement the diet, such as vitamins, minerals, herbs or other botanicals, amino acids, enzymes, organ tissues, glandulars, or metabolites; may be considered by the Food and Drug Administration (FDA) as a drug if intended to diagnose, cure, mitigate, treat or prevent a disease in humans

### **DOCUMENTATION OF INFORMED CONSENT**

Refers to use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative

## **DRAWING (RAFFLE or LOTTERY)**

Occurs when human research subjects are offered a chance to win a prize or something of value in return for their participation as subjects in a research activity

## **ENGAGED IN HUMAN RESEARCH ACTIVITIES**

When an institution's employees or agents, for the purposes of research, obtain (1) data about human subjects through intervention or interaction with them, (2) identifiable, private information about human subjects, or (3) the informed consent of human subjects

## **EVALUATOR (AUDITOR, OUTSIDE REVIEWER OR PEER DEBRIEFER)**

An individual, often externally located and utilized in qualitative research, who reviews research data and results for accuracy

## **EXCLUSION CRITERIA**

Those characteristics that disqualify prospective subjects from participation in a study

## **EXEMPT REVIEW**

A classification of human subject research review which fits into one or more Federal categories for exemption, and (1) does not involve more than minimal risk to subjects, (2) does not involve a population prohibited from exemption, and (3) is conducted by trained individuals as part of, or as assigned by, the [Exempt Review Committee](#) (ERC)

## **EXPEDITED REVIEW**

A classification of human subject research review permitted by the Federal regulations at [45 CFR 46.110](#) for certain types of non-exempt research involving no more than minimal risk, or for minor changes in approved research, which is carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB

## **FEDERALWIDE ASSURANCE (FWA)**

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

## **FOOD AND DRUG ADMINISTRATION (FDA)**

A Federal agency housed within the U.S. Department of Health and Human Services that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. While FDA regulations differ from the Common Rule, the FDA is required to harmonize with the Common Rule whenever permitted by law (e.g., section 1002 of the 21st Century Cures Act, Public Law 114-255).

## **FULL REVIEW**

A classification of human subject research review required in the Code of Federal Regulations at [45 CFR 46](#), [21 CFR 50](#) and [21 CFR 56](#) and performed at a convened monthly meeting of the Institutional Review Board (IRB) for research posing greater than minimal risk to subjects, clinical investigations regulated by the FDA, or for research involving any activities which are not allowed under an [expedited process](#) or [exemption](#)

## **GENERAL DATA PROTECTION REGULATION (GDPR)**

Effective May 25, 2018, a broad-scale regulation in European Union law covering data protection and privacy for all individuals located within the European Union (EU) and the European Economic Area (EEA), regardless of citizenship, and also addressing the export of personal data outside the EU and EEA areas

### **GENERALIZABLE KNOWLEDGE**

Information contributing to a theoretical framework of an established body of facts and experiences, with the expectation that it may be broadly applied to a larger population beyond the site of data collection or the population studied; results intended to be replicated in other settings

### **GUARDIAN**

An individual who is authorized under applicable State or local law to consent on behalf of a child to research or general medical care.

### **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**

United States legislation, signed into law in August 1996, which provides data privacy and security provisions for safeguarding individually identifiable health information for both the living and the deceased; applies to organizations that are considered HIPAA-covered entities, including health plans, healthcare clearinghouses and healthcare providers

### **HUMAN SUBJECT (or PARTICIPANT)**

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

## **IDENTIFIABLE BIOSPECIMEN**

A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

## **IDENTIFIABLE PRIVATE INFORMATION**

Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information

- If subjects' identities are inseparable from data, then data are **directly** identifiable.
- If subjects' identities are kept separate from data, with information connecting them maintained by a code or a master list, then data are **indirectly** identifiable.
- Research data or records which retain indirect identifiers only are still considered identifiable.

## **IDENTIFIERS**

Data points that help establish or indicate an individual and may include items such as (1) name; (2) address; (3) elements of dates related to an individual (e.g., date of birth); (4) email address; (5) numbers, such as telephone/fax, social security, medical record, health plan/beneficiary, certificate/license, vehicle identifiers (e.g., license plate), accounts (e.g., bank/credit card), device ID/serial; (6) web URLs; (7) Internet Protocol (IP) addresses; (8) biometric identifiers (e.g., voice, fingerprints); (9) full face photographs or comparable images; (10) or any other unique identifying number, characteristic or code not assigned by the investigator for coding purposes (e.g., Global Positioning System readings)

## **INCENTIVE (or COMPENSATION)**

Payments, compensation or other rewards given to human subjects as motivation to participate in research and granted in either monetary (cash, check, gift card, voucher, etc.) or non-monetary format (gift, promotional item, course credit, etc.); may not be considered as a benefit for subjects to weigh against risks when deciding whether to participate

## **INCLUSION CRITERIA**

Those characteristics that prospective subjects must have if they are to be included in a study

## **INCOMPLETE DISCLOSURE**

Withholding of information about the specific purpose or nature of the research, usually to prevent bias in results

## **INFORMED CONSENT (see also PERMISSION)**

A process by which a knowing, legally effective agreement to participate in research is made by any individual or the individual's legally authorized representative, and which may only be obtained under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence; the process begins with advertising/recruitment

## **INSTITUTIONAL REVIEW BOARD (IRB)**

An administrative body established in response to the National Research Act of 1974 to protect the rights and welfare of human subjects recruited to participate in biomedical, social, behavioral or educational research

## **INTENTIONALLY IDENTIFIED**

Subjects' names are identified in connection with the data when the research results are presented to the public; common for journalistic-type interview studies, where subjects are public figures or in oral histories; in such cases, the investigator should seek explicit consent from the subjects for the use of their names in connection with their data

## **INTERACTION**

Actions, including communication or interpersonal contact, between an investigator and subject, and which may take place in person or remotely (e.g., online surveys)

## **INTERNATIONAL RESEARCH**

Research which is proposed to take place outside of the United States, including activities which take place on foreign soil, which access foreign human subjects remotely (e.g., Internet), or which access data about human subjects from the foreign location.

## **INTERPRETER (see also TRANSLATOR)**

An agent of the investigator who assists in the facilitation of communication between the investigator and subjects who are not fluent in the language of the investigator(s), and who performs such communications live in real time

## **INTERVENTION**

Physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes

## **INVESTIGATIONAL NEW DRUG (IND)**

A request for authorization from the FDA to administer an investigational drug, dietary supplement (if studied as a drug) or biological product to humans

## **INVESTIGATOR (OR RESEARCHER)**

An individual who contributes significantly to the design and implementation of a study protocol; for the purposes of the HHS regulations, the Office of Human Research Protections refers to any individual responsible for the conduct of research involving human subjects, either for the study as a whole or for an individual site, with involvement such as:

- obtaining information about living individuals by intervening or interacting with them for research purposes
- obtaining identifiable private information about living individuals for research purposes
- obtaining the voluntary informed consent of individuals to be participants in research
- studying, interpreting, or analyzing identifiable private information or data for research purposes

## **IRB APPROVAL**

The determination by the Institutional Review Board (IRB) that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB, and other institutional, state and Federal requirements

## **LEGALLY AUTHORIZED REPRESENTATIVE (LAR)**

An individual, 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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by

institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

### **LOTTERY (DRAWING or RAFFLE)**

Occurs when human research subjects are offered a chance to win a prize or something of value in return for their participation as subjects in a research activity

### **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.

### **MINIMAL RISK FOR PRISONERS**

The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons

### **MODIFICATIONS (AMENDMENTS)**

Changes or additional information requested by the Institutional Review Board (IRB) or Exempt Review Committee (ERC) to any part of a research application or supplementary materials after review has been conducted, but before approval has been granted

### **NEONATE**

A newborn, whether viable or non-viable

### **NOT RESEARCH (see Research)**

A determination that a project does not fit the Federal definition of research, no further review is required so long as no changes are made, and an investigator may begin the project, assuming that the institution has not disapproved it

### **NOT RESEARCH WITH HUMAN SUBJECTS (see Human Subject)**

A determination that a project does fit the Federal definition of research, but does not involve human subjects as defined in the same Federal regulations, and where no further review is required so long as no changes are made, and an investigator may begin the project, assuming that the institution has not disapproved it

### **OFFICE OF HUMAN RESEARCH PROTECTIONS (OHRP)**

Housed within the U.S. Department of Health and Human Services (HHS), a Federal agency which provides oversight of the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the HHS or nineteen other agencies which follow the Federal Policy for the Protection of Human Subjects (Common Rule).

### **ORAL HISTORY**

A method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life [National Oral History Association], and which is biographical in nature; includes a recorded conversation about the past with named individuals in which knowledge about specific events and individual lives is narrated in story form and made available to the public through deposit in archives

### **OUTSIDE REVIEWER (AUDITOR, EVALUATOR, OR PEER DEBRIEFER)**

An individual, often externally located and utilized in qualitative research, who reviews research data and results for accuracy

**PARENT**

A child's biological or adoptive parent

**PEER DEBRIEFER (AUDITOR, EVALUATOR, OR OUTSIDE REVIEWER)**

An individual, often externally located and utilized in qualitative research, who reviews research data and results for accuracy

**PERMISSION (INFORMED CONSENT OF PARENT/GUARDIAN)**

A process by which a knowing, legally effective agreement for a child to participate in research is made by any individual's parent(s) or guardian(s); the process begins with advertising/recruitment

**PERSONALLY IDENTIFIABLE HEALTH INFORMATION**

Health or medical data or information that can be linked directly or inferentially to an individual

**POPULATION**

A group of people in society meeting certain criteria to be eligible as subjects in a research project

**PREGNANCY**

Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

## **PRINCIPAL INVESTIGATOR (PI)**

An individual with primary responsibility for the oversight of a research study, including (1) design, development and implementation of the study plan, (2) affirmation that all members of the research team are appropriately qualified, trained and supervised, and (3) maintenance of all administrative and compliance aspects of the study

## **PRISONER**

Any individual involuntarily confined or detained in a penal institution, and encompassing individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing

## **PRIVACY**

Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others

## **PRIVATE INFORMATION**

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 that the individual can reasonably expect will not be made public (e.g., a medical record)

## **PRO RATE**

To divide something in a proportional way, based on time

## **PROTECTED HEALTH INFORMATION**

Individually identifiable health information recorded in any form or medium that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual

## **PROTOCOL**

The formal design or plan of a study's activity, which includes a description of the design or methodology to be employed, the eligibility requirements and recruitment details for prospective subjects and controls, the informed consent process, the proposed methods of data analysis, and a description of records retention

## **PUBLICLY AVAILABLE DATA**

Public sources of data, such as census data

## **RAFFLE (LOTTERY or DRAWING)**

Occurs when human research subjects are offered a chance to win a prize or something of value in return for their participation as subjects in a research activity

## **RESEARCH**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; a project designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge, which may be expressed in theories, principles, and statements of relationships

Systematic investigations may include, but are not limited to:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of educational or social programs
- cognitive and perceptual experiments
- medical chart review studies

Research activity would normally include the following:

- Persons or programs requesting extramural (federal, state, or private) funds for research or training
- Individual faculty members (as well as members of the staff and administration) engaged in research as part of their professional role within the University or as part of their job assignment
- Graduate and doctoral students doing research, which is of the nature of a thesis or dissertation and is part of a degree program
- Students performing research as part of an independent study or the honors program
- Individuals (including students or persons from outside the University other than faculty, staff, or administration) conducting research at Marywood University or with Marywood University populations

### **RESEARCH ADVISOR (See ADVISOR)**

### **RESEARCH ASSISTANT (RA)**

An individual who contributes to the implementation of a research study by performing limited activities, including interaction with subjects and/or access to data, but who does not participate in the design and development of the study protocol

## **RESEARCH MISCONDUCT**

Fabrication, falsification, or plagiarism that is committed while proposing, performing or reviewing research or while reporting results, and which does not include honest error or differences of opinion

## **REVISIONS**

Changes requested by the Principal Investigator (PI) or funding sponsor to a project which was previously approved by the Institutional Review Board or Exempt Review Committee

## **RISK**

The probability and magnitude of harm or injury (physical, psychological, social or economic) occurring as a result of participation in research, and which may vary from minimal to significant

## **SAFETY REPORT (also see ADVERSE EVENT)**

A type of adverse event report used in clinical trial studies of drugs, biologics and devices, which is required by the Food & Drug Administration (FDA) to be sent by trial sponsors to the FDA and all investigators for any serious and unexpected adverse event taking place during a trial, regardless of the location of the event; must also be reported to the IRB

## **SIGNIFICANT RISK**

A potential for serious probability of harm or injury (physical, psychological, social or economic) to the health, safety or welfare of the subjects

## **SECURE SOCKETS LAYER (SSL)**

A cryptographic protocol that provides authentication and data encryption between servers, machines and applications operating over a network (e.g. a client connecting to a web server) in order to provide security

## **SYSTEMATIC**

A step-by-step, methodical procedure presented or formulated as a coherent body of ideas or principles

## **TRANSLATOR (see also INTERPRETER)**

An agent of the investigator who assists in the facilitation of communication between the investigator and subjects who are not fluent in the language of the investigator(s), by means of translation of written documents into a written format that may be read and understood by the subjects

## **TRANSPORT LAYER SECURITY (TLS)**

A cryptographic protocol that provides authentication and data encryption between servers, machines and applications operating over a network (e.g. a client connecting to a web server) in order to provide security; replaced SSL in 1999

## **UNANTICIPATED PROBLEM**

Any incident, experience, or outcome that meets *all* of the following (1) unexpected event (in terms of nature, severity, or frequency) given the described procedures and characteristics of the subject population being studied, (2) related or possibly related to participation in the research (where there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), and (3) 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**

An offer of excessive or inappropriate compensation or other overture in order to obtain compliance

### **VOLUNTARY**

The decision to participate, or to continue participation, in a research activity while being free of coercion, duress, or undue inducement

### **WAIVER OF DOCUMENTATION OF INFORMED CONSENT**

Waiver of the requirement to obtain a signature of the subject or subject's LAR to participate in research under certain circumstances; may be appropriate where a signed document could have a negative consequence for the subject (breach of confidentiality as primary risk), for minimal risk research with telephone or Internet procedures, or where subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm

### **WAIVER OR ALTERATION OF INFORMED CONSENT**

Waiver of the requirement to obtain informed consent in its entirety from a subject, a parent/guardian, or a subject's LAR, or alteration of one or several elements of informed consent, but only if all general requirements for informed consent and the following five points are met: 1) research involves no more than minimal risk to the subjects, 2) research could not practicably be carried out without the requested waiver or alteration, 3) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format, 4) the waiver or alteration will not adversely affect the rights and welfare of the subjects, and 5) whenever appropriate, the subjects or

legally authorized representatives will be provided with additional pertinent information after participation.

### **WITHDRAWAL OF A SUBJECT**

Occurs when a subject voluntarily removes his or her consent to participate in a study, or when an investigator ends a subject's study participation

### **WITHDRAWAL OF A RESEARCH PROJECT**

A type of closure which is requested by a Principal Investigator (PI) or automatically made by the IRB or ERC under certain circumstances, usually because the project has not begun or because it was abandoned

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## **History**

07/18/2017 - Added definitions

08/31/2017 - Added definitions

05/31/2019 - Updated definitions as a result of the Revised Common Rule

06/24/2019 - Added a definition

09/03/2019 - Corrected error links

10/16/2019 - Added a definition

08/31/2021 - Added a definition

09/28/2021 - Added definitions

10/06/2021 - Added definitions

01/25/2022 - Adjusted definition