GLOSSARY:

HUMAN SUBJECTS PROTECTIONS TERMS

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Overview:

This glossary is a compilation of frequently used terms and resource links related to human subjects protections.

Intended Audience:

- **Tribal Institutional/Research Review Board members and Coordinators** are encouraged to use the glossary as a reference in the course of their work.
- **Research investigators and other members of a research team** might particularly benefit from links to relevant external sources of information (for ex. 'Human Subject Decision Charts', 'The HIPAA Privacy Rule for Researchers' and other documents from OHRP, NIH, HIPAA, and the FDA)

A

ABSTAIN

An action that an Institutional Review Board (IRB) member can take, indicating that he or she chooses not to vote on a protocol under review.

ACCRUAL

The number of individuals who have undergone the informed consent process. This term may be used interchangeably with enrollment. For research studies with a screening phase, the accrual number may be less than the enrollment, as individuals are deemed ineligible for the study, or choose to withdraw. Many Institutional Review Boards (IRBs) do not permit investigators to 'accrue' more participants than what was written in the approved protocol.

Modified from definition at this external resource: Mayo Clinic Institutional Review Board Definition of Terms

ADVERSE EVENT

A term used to describe an unintended physical, psychological and/or social harm resulting from, or that occurred during participation in research. While there are no HHS regulations regarding the reporting of 'adverse events'; most Institutional Review Boards (IRBs) have policies specific to 'adverse events'. Investigators should refer to individual IRBs for reporting requirements. *Modified from definition at this*

external resource: OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

AMENDMENT

Planned changes to a research study approved by an Institutional Review Board (IRB). Federal regulations require IRB review prior to implementation of protocol revisions

ANONYMIZED DATA

Data that is stripped of all identifying information (all identifiers) for patients or subjects, with all codes and links destroyed. This differs from de-identified data or information.

For further understanding of 'codes' and 'links', see related term: CODED DATA

ANONYMOUS DATA

Data that were collected without identifiers and that were never linked to an individual (for example anonymous surveys). Note: This does not include "coded data". Coded data are not anonymous.

ASSENT

Agreement to allow a child's participation in research. The IRB(s) relevant to a research project typically determines if an 'assent' is needed or if it can be waived. The relevant IRB will also determine if assent needs to be a written agreement. A parental or guardian 'informed consent' usually accompanies the 'assent'.

For more information, see the following external sources, from the OHRP Human Research Protection FAQs:

What is child assent, and how do the requirements vary with the age of the research subjects?

When does child assent have to be obtained for research and can it be waived?

What happens when there is a disagreement between a child and his/her parents about research participation?

ASSURANCE

A written commitment submitted by an institution to a federal agency, promising to comply with applicable regulations governing research with human subjects.

See related term: FEDERAL WIDE ASSURANCE

AUTHORIZATION

See related terms: HIPAA AUTHORIZATION, IRB AUTHORIZATION AGREEMENT

B

BELMONT REPORT

A statement of fundamental ethical principles for research involving human volunteers. The three principles identified in the Belmont Report are 'respect for persons', 'beneficence', and 'justice'. The Belmont Report was the basis for U.S. federal regulations for research with human volunteers. It was issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978.

For more information, see external resource: Belmont Report

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: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

Modified from defintion at this external resource: Belmont Report

BIOBANK

A collection of human biological materials and associated data used for research purposes.

C

CERTIFICATE OF CONFIDENTIALITY

A document that provides protection to an investigator against compelled disclosure of identifying information of a participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. An example of 'compelled disclosure' is a legal authority (like the police) requesting information on a research participant, or verification of an individual's participation in a research project.

For more information, see external resource: NIH FAQs on Certificate of Confidentiality

CHILD/CHILDREN

Individual(s) who is/are not of legal age for consent to treatment or procedures involved in a research project. The specifics, like age, are determined by the applicable jurisdictional laws where the research is being conducted. In order for a 'child' to participate in a research study, typically parental or guardian permission must be granted and documented, utilizing an informed consent form. An additional form, an 'assent' indicating the child's willingness and agreement to participate may also be required by the relevant IRB.

For more information, see the following external resources from the OHRP Human Research Protections FAQs:

How do the human subject research regulations define "children"?

Does research involving children include special requirements?

What is parental permission in the context of research involving children?

If by law a child is able to consent to treatment without parental permission, can they also consent to participate in research related to that treatment?

Are exemptions different for research involving children?

Also see this external resource relevant to clinical trials:

FDA Code of Federal Regulations – CFR 21, regarding children in research

CLINICAL TRIAL

A human subjects research study designed to test the effectiveness of drugs, devices, and treatments.

For more information, including an explanation of the 'Phases of clinical trials', see these external resources:

FDA Information for Consumers: Inside Clinical Trials

COERCION

An extreme form of undue influence, involving a threat of harm or punishment if an individual doesn't participate in research.

See the following external resources from OHRP related to this topic:

What does it mean to minimize the possibility of coercion or undue influence?

What constitutes coercion or undue influence when students are involved in research in a college or university setting?

What constitutes coercion or undue influence when employees are the subjects of research?

CODED DATA

Data for which identifiers have been replaced with a code (such as a number, or symbol) to protect participant confidentiality. Coded data is linked to identifiers via a key. As long as a link exists, data is considered to be identifiable.

For more information, see external resource: OHRP Guidance on Research Involving Coded Private Information or Biological Specimens

CODE OF FEDERAL REGULATIONS (CFR)

A compilation of the general and permanent rules published by the Executive departments and agencies of the U.S. Federal Government. Regulations related to research with human subjects are included.

For more information see external resource: U.S. Government Printing Office Information on Code of Federal Regulations

COMMON RULE *See related term:* THE COMMON RULE

CONFLICT OF INTEREST (COI)

A situation in which financial or other considerations (such as personal beliefs or relationships) have the potential to compromise or bias professional judgment and objectivity. For example, a 'conflict of interest' can influence an IRB member's ability to be objective with regard to a particular research project.

CONFIDENTIALITY

The ethical principle that a health care professional and/or investigator will treat all patient or participant information as secret, unless given specific permission or consent outlining how the information should be disclosed.

CONSENT *See related term:* INFORMED CONSENT

CONTINUING REVIEW

Periodic review of research activities, by an Institutional Review Board (IRB)

D

DATA (research data)

Research data is information or materials used for, or resulting from the systematic investigation of a topic (designed to contribute to generalizable knowledge). Some examples are as follows:

written observations	photographs	measurements
questionnaires	videotapes	computer program
spreadsheets	hand-written notes	audio recordings
factual records (e.g. public records)	biological specimen	

Raw data is data as collected or measured directly from the source. The *use* of the information is what defines it as 'research data'. Analyses, numerical information, and written conclusions created using information from *raw data,* are also considered to be 'research data', and are often referred to as *processed data.*

See related terms: PRIMARY DATA, SECONDARY DATA, QUANTITATIVE DATA, QUALITATIVE DATA, ANONYMIZED DATA, ANONYMOUS DATA

DATA AND SAFETY MONITORING BOARD (DSMB)

A group of individuals who monitor the safety and scientific integrity of some research studies. The membership of a board will depend on the specific scientific skills and knowledge relevant to a study. The group can recommend that a research study be stopped. A 'data and safety monitoring board' is often required for multi-site and/or higher risk clinical trials.

DATA LINKAGE

The merging of two or more separate data sets (e.g. health information and education information about the same individuals), for research purposes.

DATA SET

An organized collection of data, that is typically numeric or encoded, if used for research. The 'data set' should include documentation files (e.g. a codebook, report, or data dictionary) so that it can be used by a second party.

There are specific types of data sets, such as the Limited Data Set

DATA USE AGREEMENT (DUA)

A legally binding agreement between two entities, required by federal regulations, for the sharing of limited data sets (data sets with some identifiers). The agreement specifies terms and conditions for the use, protection and transfer of data. In addition, copies of 'data use agreements' must be submitted to the Institutional Review Board(s) relevant to the research project. The IRB does not approve the 'data use agreements' but needs to maintain copies of them.

Modified from definition at this external resource: 45 CFR § 164.514(e)

Also see this external resource: NIH: How can Covered Entities Use and Disclose Protected Health Information for Research and Comply with the Privacy Rule?

DATA SHARING AGREEMENT

See DATA USE AGREEMENT. *'Data sharing agreement' and 'Data use agreement' are terms that are used interchangeably.*

DECLARATION OF HELSINKI (DoH)

A code of ethics for clinical research approved by the World Medical Association in 1964 and revised thereafter, with the latest revision published in October 2013.

See the newly released, 2013 revision of this document at this external resource: Declaration of Helsinki

DE-IDENTIFIED INFORMATION

Health information that has been stripped of elements that could identify the research subject. De-identification of information, according to the HIPAA Privacy Rule, means 18 specific 'identifiers' must be removed from the data. This differs from anonymized data, in that a link or code to identifiable information about the subject is kept.

For more information, see these external resources: HHS Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the HIPAA Privacy Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES *See related term:* HHS

DEVIATION *See related term:* PROTOCOL DEVIATION

DHHS *See related term:* HHS

E

ENGAGEMENT (of institutions in human subjects research)

An organization is considered engaged in human subjects research when its employees or agents, for the purposes of the non-exempt research project, obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research;
- The informed consent of human subjects for the research; or
- When the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor (that is, employees or agents of another institution).

Modified from the definition at this external resource: OHRP Guidance on Engagement of Institutions in Human Subjects Research

For information on school involvement in research, see this external resource: U.S. Department of Education Guidance on Engagement of Institutions in Human Subjects Research

ENROLLMENT

The number of individuals who have undergone the informed consent process to participate in a research project. *See related term:* ACCRUAL.

EPIDEMIOLOGY

Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.

See this external resource: IRB Considerations Regarding Epidemiologic Studies (Institutional Review Board Guidebook Chapter IV)

EXEMPT HUMAN SUBJECTS RESEARCH

This is a status granted to a research project involving human participants, by an Institutional Review Board (IRB) in the initial review process. 'Exempt' status means that the research project is does not require continuing IRB review, as the risk to participants in the research study is considered minimal. OHRP recommends that an IRB (and not the investigator) make the final determination to assign 'exempt' status.

See the following from the external resource, the 'OHRP Human Research Protections FAQs':

Who may determine that research is exempt?

Human Subjects Research exemptions

What should investigators do when considering changes to an exempt study that could make it nonexempt?

Also see these external resources, HHS 'Human Subject Regulations Decision Charts' regarding 'Exemption':

Chart 2: "Is the Research Involving Human Subjects Eligible for Exemption under 45 CFR 46.101(b)?"

Chart 3: "Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?"

Chart 4: "Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?"

Chart 5: "Does Exemption 45 CFR 46.101(b)(4)(for Existing Data Documents and Specimens) Apply?"

Chart 6: "Does Exemption 45 CFR.46.101(b)(5)(for Public Benefit or Service Programs) Apply?"

Chart 7: "Does Exemption 45 CFR 46.101(b)(6)(for Food Taste and Acceptance Studies) Apply?"

EXPEDITED REVIEW

This type of review is generally for research that involves no more than minimal risk and/or for minor changes to an approved research study. An IRB chair or designated voting board member, or a select group of individuals from the board - can review the study, rather than the entire IRB.

See these external resources, HHS 'Human Subject Regulations Decision Charts' Regarding Expedited Review:

Chart 8: "May the IRB Review Be Done by Expedited Procedures?"

Chart 9: "May the IRB Continuing Review Be Done by Expedited Procedures?"

EXPIRATION

A research study 'expires' when continuing review approval is not obtained. All research activities must stop until the protocol is renewed.

F

FDA HUMAN SUBJECTS PROTECTIONS REGULATIONS

Regulations established by the U.S. Food and Drug Administration (FDA) for the protection of human subjects (human volunteers) in research. These typically apply to clinical trials.

See these external resources:

FDA Regulations for Protection of Human Subjects

Comparison of FDA and HHS Human Subject Protection Regulations

FEDERAL WIDE ASSURANCE (FWA)

A formal written agreement in which an institution ensures, the Office for Human Research Protections (OHRP), that it will comply with applicable regulations governing research with human subjects.

See the following external resources:

Terms of the Federal Wide Assurance for the Protection of Human Subjects

OHRP Instructions for filing an FWA

OHRP database for checking status of an institution's FWA or IRB registration

FERPA

(Family Education Rights and Privacy Act)

A set of regulations that applies to those institutions that receive funding from the Department of Education. FERPA was written specifically for students and outlines student rights with regard to disclosure of educational records. It also outlines the terms and conditions under which research investigators may be given access to students' home contact information.

For more information see these external resources:

Family Education Rights and Privacy Act

U.S. Department of Education Guidance on Engagement of Institutions in Research

FOCUS GROUP

A group convened to discuss a specific topic, conduct an evaluation, or test new ideas. Questions are usually asked in an interactive group setting such that participants are encouraged to talk with other group members. Sessions are also often audio-recorded. Focus groups can be used in research for a variety of reasons; for example to help generate ideas and questions for research, or to help with evaluation.

FULL BOARD REVIEW

This term applies to research studies reviewed by full convened IRB with a recorded vote and corresponding minutes to document the discussion.

G

GENERALIZABILITY

In human subjects research, this is the extent to which research findings and conclusions, from a study conducted on a sample population, can be applied to the population at large or groups outside of the original research study. To be considered research, a study must aim to contribute to 'generalizable' knowledge.

GENETICS and GENETICS RESEARCH *See related term:* HUMAN GENETIC RESEARCH

GINA (The Genetic Information Nondiscrimination Act of 2008)

The federal law that prohibits discrimination in health insurance coverage and employment based on 'genetic information'. GINA is not applicable to certain forms of health insurance coverage; examples are: the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, and the Federal Employees Health Benefits Program.

For more information on GINA, see these external resources:

NIH National Human Genome Research Institute FAQs on the Genetic Information Nondiscrimination Act of 2008

The Genetic Information Nondiscrimination Act of 2008 Information for Researchers and Health Care Professionals

GINA HELP: Interactive Educational Resource for the Lay Person

H

HHS U.S. Department of Health & Human Services

The United States government's agency for protecting the health of all Americans; and providing essential human services, especially for those who are least able to help themselves.

See this external resource: U.S. Department of Health and Human Services

HIPAA

The Health Insurance Portability and Accountability Act of 1996, and the privacy regulations under the Act. For details of the privacy regulations, see related term HIPAA PRIVACY RULE.

HIPAA AUTHORIZATION

A document that gives permission to use specified protected health information (PHI) for a designated purpose. It can also be used to grant permission to disclose PHI to a specified third party for a use other than treatment, payment or health care operations. An IRB can require that 'HIPAA authorizations' be signed by all participants in a research study or it can grant a waiver of authorization.

HIPAA IDENTIFIERS *See related term:* IDENTIFIERS

HIPAA PRIVACY RULE

Also known as the 'Standards for the Privacy of Individually Identifiable Health Information', it was issued by the U.S. Department of Health and Human Services (HHS). It establishes national standards to protect individuals' medical records and other personal health information. It also establishes the conditions under which protected health information (PHI) may be used for research purposes.

For more information see the following external resources:

NIH: Institutional Review Boards and the HIPAA Privacy Rule

NIH HIPAA Privacy Rule Information for Researchers

HHS Health Information Privacy: Guidance for Consumers

HIPAA PRIVACY AUTHORIZATION *See related term:* HIPAA AUTHORIZATION

HIPAA SECURITY RULE

A rule that establishes standards for how entities store, transmit, and safeguard protected health information that is in electronic form. *See this external resource:* Summary of the HIPAA Security Rule.

HIPAA WAIVER *See related term:* WAIVER OF (HIPAA) AUTHORIZATION

HITECH ACT

The Health Information Technology for Economic and Clinical Health (HITECH) Act, implemented in 2009**.** It aims to encourage the use of electronic medical records and to develop standards for the nationwide electronic exchange and use of health information, for improved quality of care. Subtitle D of this bill addresses the privacy and security concerns associated with the electronic transmission of health information.

See these external resources: HITECH Act.

HHS 2013 Omnibus Rule that implements provisions of the HITECH ACT

HUMAN SUBJECTS (human participants) *See related term:* PARTICIPANTS

HUMAN GENETIC RESEARCH

Human genetics research is the study of diverse internal and external factors responsible for human traits, their interaction with each other, and with the environment. In medicine and public health, the focus is on factors related to health and disease. Identifiable genetic information receives the same level of protection as other health care information under the HIPAA Privacy Rule.

For information on related terms such as: genotype, genome, genome sequencing, DNA, DNA sequencing, epigenetics, SNP, CNV, *See the following external resource:* Genome.gov: Talking Glossary of Genetic Terms

Also see this external resource: NCAI American Indian and Alaska Native Genetics Research Resource Guide: Tools for Tribal Leaders and Citizens

I

IDENTIFIERS or **IDENTIFYING INFORMATION**

Any item or combination of items in the data that could lead directly or indirectly to the identification of a research participant.

According to the HIPAA Privacy Rule, the identifiers are as follows:

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Phone numbers
5. Fax numbers

6. Electronic mail addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

See these external resources for more information:

HHS Guidance Regarding Methods for De-identification of the Protected Health Information in Accordance with the HIPAA Privacy Rule

45 CFR § 164.514

INCENTIVE

Anything offered to participants, monetary or otherwise, to encourage participation in research.

INCIDENTAL FINDINGS

Unexpected discoveries made in the course of research that are outside the scope of the research and may or may not be clinically significant.

INDIRECTLY IDENTIFIABLE

Data that does not include direct identifiers (e.g. name, social security number), but contains enough information about an individual to identify the person. This data is still considered identifiable by 'The Common Rule'.

INDIGENOUS KNOWLEDGE *See related term:* TRADITIONAL KNOWLEDGE

INFORMED CONSENT

An individual's agreement to participate in research, given without coercion or undue influence. Typically individuals are asked to sign a document, called a 'consent form' which outlines the terms of the agreement.

An individual's agreement should be based upon the individual's clear understanding of what their participation will involve. Individuals should be given adequate time to consider participation in research. Technical and medical language should be explained in lay person's terms and for an eighth grade level of comprehension. Non-English speaking individuals must have information presented in a language they understand.

See related terms: WAIVER OF INFORMED CONSENT, WAIVER OF DOCUMENTATION OF INFORMED CONSENT

See these external resources:

OHRP FAQs on Informed Consent

FDA Code of Federal Regulations Regarding Informed Consent

INSTITUTIONAL REVIEW BOARD (IRB)

A body formed to protect both individuals participating in research. Institutional review boards and particularly community and Tribal Nation research review boards are increasingly advocating for and administering community protections as well.

For more information on relevant federal regulations, see these external resources:

HHS Institutional Review Board Guidebook

OHRP Guidance on Written IRB Procedures

INVESTIGATOR (research investigator)

Anyone involved in conducting a research project. Investigators are not only scientists, but can include administrative staff and students involved in a particular project. One investigator, usually is designated 'principal investigator' and is responsible for the project overall. All 'investigators' are responsible for the ethical treatment of human subjects.

Modified from definition provided by OHRP at this external resource: Investigator Responsibilities- FAQs

IRB APPROVAL

Permission to conduct research, granted by an Institutional Review Board (IRB) authorized to review the research project. *For further information on specific types of approvals, see related terms:* FULL BOARD REVIEW, EXPEDITED REVIEW, EXEMPT HUMAN SUBJECTS RESEARCH

IRB AUTHORIZATION AGREEMENT (IAA)

A written agreement defining a relationship between 2 or more Institutional Review Boards (IRBs) that are assigned to review the same research protocol. It is an agreement intended to reduce the burden of review for IRB's and investigators. An authorization agreement allows an institution to delegate IRB review to another IRB.

IRB OF RECORD

The name for the IRB designated to review a research protocol or protocols on behalf of another entity's 'institutional review board' (IRB). A written agreement, called an 'authorization agreement' is drafted to formally define the relationship between the IRBs and to define the terms of the review responsibilities.

J

JUSTICE

An ethical principle discussed in the specified in *The Belmont Report*. It's emphasis is on the need for fairness in determining who should receive the benefits of research and who should bear its burden. For example, specific groups of research participants should not be made to bear more risks than another group of participants, and disadvantaged individuals should not be recruited to participate in research that is of little benefit to them. *Modified from definition at this external resource:* Belmont Report

K

KEY STUDY PERSONNEL

Members of the research team who contribute in a substantive way to the scientific development, design, or conduct of the study. Funding agencies and institutional review boards may have their own definition for 'key study personnel'. *Modified from definition at this external resource:* NIH Grants & Funding, Frequently Asked Questions: Senior/Key Personnel

L

LIMITED DATA SET (LDS)

This refers to a dataset containing some identifiers (protected health information), but excluding 16 specific identifiers. The exclusion of these identifiers enables the data to be legally used or disclosed for research, public health, or healthcare operations; without a patient or participant's authorization. Researchers must draft a data use agreement in order to share a 'limited data set'.

See this external resource for a listing of the 16 identifiers that must be excluded: "NIH: How can Covered Entities Use and Disclose Protected Health Information for Research and Comply with the Privacy Rule?"

Also see this external resource: 45 CFR § 164.514(e)(federal regulations language regarding the limited data set)

M

MATERIAL TRANSFER AGREEMENT (MTA)

A contract that is used by scientists and their institutions for the transfer of research materials. The MTA outlines the rights of the provider and the recipient with regards to the research materials and the derivatives of the research materials.

MINIMAL RISK

A risk is 'minimal' if the probability of harm is not greater than that ordinarily encountered in daily life or in a routine physical or psychological test. *See related term:* RISK

Modified from definition at these external resources: Federal Regulations: 45 CFR 46.102(i) and Institutional Review Board Guidebook

N

NONAFFILIATED MEMBER

Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty.

NUREMBERG CODE

A code of research ethics developed during the trials of Nazi war criminals following World War II. This code informed the current federal regulations for the protection of human subjects in research.

Modified from definition at this external resource: OHRP 1993 Institutional Review Board Guidebook Glossary.

Also see this external resource: The Nuremberg Code

O

OHRP (Office for Human Research Protections)

The office under the Department of Health and Human Services responsible for implementing regulations governing biomedical and behavioral and/or social science research involving human subjects. *See external resource:* OHRP Website

P

PARTICIPANTS

Individuals who volunteer to participate in a research study. They are also referred to as 'human subjects'. Under the federal regulations, 'human subjects' are defined as: living individuals about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information. Several regulations exist to protect people who volunteer to participate in research studies.

Modified from definition at this external resource: 45 CFR part 46

Also see related term: THE COMMON RULE

PHI *See related term:* PROTECTED HEALTH INFORMATION

PILOT ACTIVITIES

Also referred to as 'Pilot Studies' and 'Pilot Research', these are small-scale studies intended to test out a research design or to test a research instrument, as well as to provide information on the feasibility of a larger study.

PRIMARY DATA

Research data collected 'first-hand' by the investigator in the course of a research project, for example through observation, experimentation, and surveys. *See related term:* SECONDARY DATA

PRINCIPAL INVESTIGATOR (PI)

The investigator with primary responsibility for the design, conduct, and management of a research project. Principal Investigators must ensure that all aspects of their research project adhere to federal regulations, state and local laws, institutional policies, and relevant IRB policies and procedures - regarding the safety and protection of human subjects. *Modified from definition at this external resource:* Mayo Institutional Review Board 'Definition of Terms'

PRIVACY RULE *See related term:* HIPAA PRIVACY RULE

PROSPECTIVE RESEARCH STUDY

A study designed to follow a population (or cohort) over time in order to identify or determine the specific factors contributing to positive and/or negative future health outcomes.

See related term: RETROSPECTIVE RESERCH STUDY

PROTECTED HEALTH INFORMATION (PHI)

Any information in the medical record that can be used to identify an individual; and that was created or used in the course of providing a health care service. (See related term 'identifiers'.) This information is protected by the HIPAA regulations. The HIPAA Privacy Rule also specifies when health information used by researchers is considered to be PHI.

PROTOCOL (research protocol)

In research, this is the formal design or plan of an experiment or research activity. 'Research protocols' must be submitted to an IRB for review and/or to agencies for research support. The protocol includes a description of the research design or methodology, the eligibility requirements for prospective participants, the plan for research activities, the proposed methods of analysis that will be performed on the data collected, and information on how participants will be protected in the study.

PROTOCOL DEVIATION

An **unplanned** change or alteration to an Institutional Review Board (IRB) approved protocolthat was made without IRB or sponsor approval. Federal regulations require investigators to report protocol deviations to the IRB or IRBs relevant to their study. Investigators should refer to individual IRBs for reporting requirements.

PROTOCOL VIOLATION

An intentional or planned act in which an IRB approved protocol is not followed.

PUBLIC HEALTH

Public health is the science of protecting and improving the health of entire populations. It focuses largely on preventing disease and promoting health. Some examples of public health achievements are: the fluoridation of water for the prevention of tooth decay; family planning services, screenings for specific illnesses, vaccinations, roads that are safer for driving, anti-smoking campaigns, and programming to provide better nutrition to children.

See these external resources:

"What is Public Health?" by the CDC Foundation

WHO Definition of Public Health

Q

QUALITATIVE DATA

Information collected for research purposes, usually collected through focus groups or interviews. It answers 'quality' questions, or questions that are difficult to quantify numerically. An example use of 'qualitative data' is categorizing participant responses and reporting their exact responses in quotes. This data is often gathered with smaller numbers of participants to gain meaning on a topic.

QUANTITATIVE DATA

Information collected for research purposes that answers 'quantity' questions like 'how much?' and 'how many?'. For example, Body Mass Index (BMI), blood sugar level, or number of cigarettes smoked in the last 30 days.

QUORUM

This term refers to a majority of the Institutional Review Board (IRB) voting members. At IRB meetings, a quorum must be established and maintained for vote on all matters needing full board review.

R

RECRUITMENT

The process of finding potential subjects to participate in a research study. It can include distributing or presenting information that describes the research project and eligibility criteria.

RESEARCH

A systematic investigation of a topic, that aims to develop or contribute to generalizable knowledge.
Modified from definition at this external resource: HHS definition of 'research': 45 CFR 46.102

RESEARCH DATA *See related term:* DATA

RESEARCH MISCONDUCT

Any fabrication, falsification, or plagiarism, on the part of the research investigator and team in proposing, conducting the research, or in reporting research results.

RESPECT FOR PERSONS

One of three ethical principles specified in *The Belmont Report*. It calls for the autonomy (or self-determination) of the individual in the context of human subjects research, and requires protections for individuals with diminished autonomy (such as children or individuals with disability). It describes 'informed consent' as key to facilitating individual autonomy in the context of research.

Modified from the definition at this external resource: Belmont Report

RETROSPECTIVE RESEARCH STUDY

A research study that is conducted after the outcome of interest has occurred. It can involve review of records from the past (*e.g.*, birth and death certificates, medical records, school records, employment records), or obtaining information about past events through interviews or other means. *See related term:* PROSPECTIVE RESEARCH STUDY

RISK

In research, this is the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. *See related term:* MINIMAL RISK

Modified from definition at this external resource: OHRP 1993 Institutional Review Board Guidebook

S

SECONDARY DATA

Data that was not collected by the investigator using it, but resulted from a past research study, and/or was made available via a public database. *See related term:* PRIMARY DATA

SIGNATORY OFFICIAL

The individual selected to sign the Federal-Wide assurance (FWA) filed with OHRP to ensure compliance with human subjects' protections regulations. This must be a high-ranking individual who has the authority to represent the institution named in the FWA.

SUBJECTS (HUMAN) *See related term:* PARTICIPANTS

SUSPENSION (of IRB Approval)

An IRB action that temporarily halts some or all research activities for a previously approved research project. Suspension must be accompanied by a report outlining the reasons for the action, and the report must be given to the principal investigator of the study, as well as any other relevant institutional officials. *See related term:* TERMINATION

Modified from this external resource: 45 CFR 46.113: Federal regulations regarding 'Suspension or termination of IRB approval of research'

T

TABLE

An IRB action that postpones review of a research protocol. An IRB may choose this action for several reasons. For example, the board may 'table' review if it needs additional information to review the protocol, or needs to bring in an expert to assist with review.

TERMINATION (of IRB approval)

An IRB action that permanently halts and closes all activities for a previously approved research project. Termination' must be accompanied by a report outlining the reasons for the action; and the report must be given to the principal investigator of the study, as well as any other relevant institutional officials. *See related term:* SUSPENSION

See this external resource: 45 CFR 46.113: Suspension or termination of IRB approval of research

TRADITIONAL KNOWLEDGE

The knowledge unique to a given culture or society. It does not stem from knowledge generated by universities and research institutions. Traditional knowledge is usually specific to place, transmitted orally, and rooted in the historical experience of a people. Indigenous peoples, local communities and governments are increasingly advocating for protections, equivalent to 'intellectual property protections', for traditional knowledge.

Modified from definitions at these external resources:

UN: World Intellectual Property Organization (WIPO): "Traditional Knowledge and Intellectual Property"

Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous People

World Bank Indigenous Knowledge Program'

THE COMMON RULE

Another name for 45 CFR 46 Subpart A, the United States Federal regulations governing the protection of human research participants. Eighteen federal departments and agencies have adopted 'The Common Rule' and require institutions that receive support from these federal departments and agencies to comply with these regulations.

See these external resources: 45 CFR 46

List of Departments and Agencies that comply with The Common Rule.

OHRP Human Research Protections FAQs:

How does HHS ensure that regulatory requirements for human research are met?

U

UNANTICIPATED PROBLEM OR EVENT

All of the following criteria must be met for a problem or occurrence to be classified as an 'unanticipated problem or event':

1. unexpected (in terms of nature, severity, or frequency) given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means 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.

Note: it is also possible to have 'unanticipated problems or events' that are not 'adverse events'.

Modified from definition at this external resource: OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

UNDUE INFLUENCE

The impact of an unequal power relationship on an individual's decision to consent to participate in a research project. This may occur when prospective participants are recruited by individuals in a position of authority over them. *See related term*: COERCION

See the following external resources from OHRP Human Research Protections FAQs:

What does it mean to minimize the possibility of coercion or undue influence?

When does compensating subjects undermine informed consent or parental permission?

What constitutes coercion or undue influence when students are involved in research in a college or university setting?

What constitutes coercion or undue influence when employees are the subjects of research?

V

VOLUNTARY

This term is used in research to refer to an individual's willingness and corresponding agreement to participate (or continue to participate) in a research project, free of coercion or undue influence. *See related term:* INFORMED CONSENT

VULNERABLE POPULATIONS or PARTICIPANTS

Vulnerable populations need special protections in research. Federal regulations define 9 groups as vulnerable - pregnant women, human fetuses, neonates, children, prisoners, persons with physical and/or mental disabilities, and the economically or educationally disadvantaged. *Modified from definition provided in Institutional Review Board Member Handbook Second Edition by Robert Amdur and Elizabeth Bankert.*

See these external resources:

Subpart B of 45 CFR 46: Additional Protections for Pregnant Women, Human Fetuses & Neonates Involved in Research

Subpart C of 45 CFR 46: Additional DHHS Protections Pertaining to Biomedical & Behavioral Research Involving Prisoners as Subjects

Subpart D of 45 CFR 46: Additional DHHS Protections for Children Involved as Subjects in Research

WAIVER OF (HIPAA) AUTHORIZATION

An IRB can waive the requirement for a research HIPAA Authorization Form if use of the health information is no more than a minimal risk. There are regulations regarding investigator disclosure of information protected under the HIPAA waiver of authorization.

For more information on 'accounting of disclosures', *See these external resources:* HHS FAQs on 'Right to Accounting of Disclosures' and 45 CFR Parts 160 and 164 (HIPAA Privacy Rule Accounting of Disclosures).

WAIVER OF DOCUMENTATION OF INFORMED CONSENT

An IRB can waive the requirement for a signed consent in certain situations. An IRB may choose to provide a 'waiver' if, for example, the consent is the only link identifying the subject with the research project and it could pose a privacy risk.

See this external resource from the OHRP Research Protections FAQs:

When may the requirement for documentation of informed consent or parental permission be waived or altered?

WAIVER OF INFORMED CONSENT

An IRB can waive the requirement for informed consent if all the conditions below are met:

- The research involves no more than minimal risk
- The waiver will not adversely affect the rights of the subject
- The research cannot be practicably carried out without the waiver
- When appropriate subjects will be provided with additional pertinent information after participation

See this external resource from the OHRP Research Protections FAQs:

May the requirement for obtaining informed consent or parental permission be altered or waived?

REFERENCES

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