GLOSSARY AND DEFINITIONS

This document was developed for both the National Comprehensive Cancer Network Best Practices For the Design, Implementation and Management of Repositories, Registries, And Databases and the Great Lakes Biorepository Network (GLBRN) Project.

The following definitions were adapted or derived verbatim from the Office of Civil Rights Guidance Document for De-identification of Protected Health Information in Accordance with the Health Insurance Portability, Accountability Act (HIPAA) Privacy Rule, the NCI Best Practices for Biospecimen Research, Black's Law Dictionary, Taber's Medical Dictionary, Merriam-Webster's Dictionary, Wikipedia, Federal Government Websites such as the Food and Drug Administration and the Department of Health and Human Services, the International Society for Biological and Environmental Repositories (ISBER) 2012 Best Practices for Repositories--Collection, Storage, Retrieval and Distribution of Biological Materials for Research, U.S. Departments of Labor and Statistics, U.S. Department of Patent and Trademark, Centers for Disease Control, the National Cancer Institute, the Office for Human Research Protection Guidance documents, Boston University Libraries, Babylon Business Dictionary, and from various institutional policies and procedures, including The Dana-Farber Cancer Institute, Fred Hutchinson Cancer Research Center, Roswell Park Memorial Institute, University of Nebraska Medical Center, Van Andel Institute, and Yale University.

Term	Definition
Accreditation	Voluntary method of quality assurance designed to assess an organization's adherence to a set of standards required by the accrediting organization.
Aliquot	(1) Pertaining to a portion of the whole; any one of two or more samples of something, of the same volume or weight. (2) A process wherein a biospecimen is divided into separate parts, which are typically stored in separate containers as individual samples.
Anonymized or Anonymous Data or Samples	Identifying information has been forever stripped from the data or specimen (i.e., anonymized) and there is no way for anyone to go back and find out the identity of the individual for whom the specimen or data was obtained. Re-identification of anonymized data is intended to be impossible (i.e., even when combined with other data found as a result of testing).
Assay	Examination and determination as to characteristics (as weight, measure, or quality); analysis (as of a drug) to determine the presence, absence, or quantity of one or more components.
Associated Data	Any descriptive information affiliated with a biospecimen or the individual from whom it is derived, including but not limited to research, phenotypic, clinical, epidemiologic, and biospecimen-resource procedural data.
Audit	**(**1) A documented review of procedures, records, personnel functions, equipment materials, facilities, and/or vendors to evaluate adherence to written standard operating procedures or government laws and regulations, (2) to perform an audit.
Barcode	A machine-readable code in the form of numbers and a pattern of parallel lines of varying widths, printed on and identifying a product.
Best Practice	A technique, process, or protocol that has been shown or is otherwise believed to be state-of-the-art in that it provides superior results to those achieved by any other technique, process, or protocol. Best practices may evolve as new evidence emerges. While best practices are consistent with all applicable ethical, legal, and policy statutes, regulations, and guidelines, they differ from guidance, policy, or law in that they are recommendations and are neither legally enforceable nor required.
Bioassay	The determination of the relative strength of a substance (as a drug) by comparing its effect on a test organism with that of a standard preparation.
Biohazard	A risk to human health or the environment arising from biological work, especially with microorganisms**.**
Biologic Specimen (Biospecimen)	Tissue, fluids (such as blood or urine), or other human-derived material taken from a single donor at a specific time that may be used in research. This material may be fresh or frozen samples, formalin-fixed paraffin-embedded bocks, slides, blood spots, or in other formats. "Samples" are portions or aliquots of biospecimens (see **Sample**).
Biological	Of, relating to, caused by, or affecting life or living organisms: biological processes such as growth and digestion.
Biorepository	An organization, place, room, or container (a physical entity) where biospecimens are received, stored for potential research use, processed, and/or disseminated (which include derivatives and relevant data). The biorepository may also include the physical structure, policies, procedures, governance, and activities associated with the operation of a Biorepository.
Biosafety in Microbiological and Biomedical Laboratories (BMBL)	BMBL has become the code of practice for biosafety—the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The principles of biosafety introduced in 1984 in the first edition of BMBL1 and carried through in this fifth edition remain steadfast. These principles are containment and risk assessment. The fundamentals of containment include the microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms that are handled and stored in the laboratory. Risk assessment is the process that enables the appropriate selection of microbiological practices, safety equipment, and facility safeguards that can prevent laboratory-associated infections (LAI).

GLOSSARY AND DEFINITIONS

Term	Definition
Biospecimen	Tissue, fluids (such as blood or urine), or other human-derived material taken from a single donor at a specific time that may be used in research. This material may be fresh or frozen samples, formalin-fixed paraffin-embedded bocks, slides, blood spots, or in other formats. "Samples" are portions or aliquots of biospecimens (see Sample).
Biospecimen Use Committee	A committee that determine appropriate use/sharing of biospecimens in accordance with the documents that guide the collection and distribution of the biospecimens.
Bloodborne Pathogens	Pathogenic microorganisms that are present in human blood and can cause disease in humans.
Business Associate	A person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity's workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity.
Cancer Registry	A Cancer Registry is a systematic collection of data about cancer and tumor diseases. The data are collected by Cancer Registrars. Cancer Registrars capture a complete summary of patient history, diagnosis, treatment, and status for every cancer patient in the United States, and other countries as well.
Certificate of Confidentiality	Issued by the National Institutes of Health (NIH) to protect identifiable research information from compelled disclosure. It allows the Investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, State, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Effective October 1, 2017 Certificates of Confidentiality are issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016. In these cases, the Certificate will be issued as a term and condition of award. (Certificates of Confidentiality Kiosk Web site, http://grants.nih.gov/grants/policy/coc/).
Chain of Custody	Chain of custody refers to the chronological documentation or paper trail, showing the seizure, custody, control, transfer, analysis, and disposition of physical or electronic evidence. It encompasses the procedures that ensure that, at all times in the process, the sample is correctly associated with the donor, with available donor clinical information (at the time of collection and in the future), with all aliquots of the sample and with all derivatives of the sample. Also encompasses the quality control/quality assurance procedures that check to be sure the procedures are working. Chain of custody is essential for accurate and high quality research.
CLIA	Clinical Laboratory Improvement Amendments – A set of standards administered by the federal Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) that certifies specific laboratories that have a standard of reliability for decisions about diagnosis and treatment of patients. Many laboratories that test specimens for research purposes are not CLIA certified. It is generally understood that research results, if not generated from a CLIA certified laboratory, are not returned to patients and cannot be billed based on the CMS rules.
Clinical Laboratory Improvement Amendments	Clinical Laboratory Improvement Amendments – A set of standards administered by the federal Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) that certifies specific laboratories that have a standard of reliability for decisions about diagnosis and treatment of patients. Many laboratories that test specimens for research purposes are not CLIA certified. It is generally understood that research results, if not generated from a CLIA certified laboratory, are not returned to patients and cannot be billed based on the CMS rules.
Clinical Research	Research conducted with human subjects or on materials of human origin. An investigator may interact directly with human subjects or may not have direct contact (such as in pathology studies examining improved diagnostic techniques). Clinical research includes development of new technologies, study of mechanisms of human diseases, therapy, clinical trials, epidemiology, behavior, and health services research (NCI Thesaurus).
Clinical Trial Management System	A web-based software system designed to streamline operations within a clinical research site. A software that manages critical functions of the research site such as patient recruitment, study tracking, financial accounting, scheduling, reporting and more.
Code of Federal Regulations (CFR)	The annual collection of executive-agency regulations published in the daily *Federal Register*, combined with previously issued regulations that are still in effect. See https://www.govinfo.gov/help/cfr for more information.
Coded Data or Samples	Personal identifying information has been replaced with a number, letter, symbol, or combination (i.e., a code). An investigator who receives coded samples/information is not able to readily ascertain the identity of the individual from whom the sample/private information pertains. The code or linkage allows the holder of the code (e.g., an Honest Broker, see below) to re-identify the donor, the data, or specimen. Re-identification is necessary if additional samples or follow up information from the same patient are required by the research team. Coded samples/data permit a high level of protection of protected health information (as the research team does not have direct access to this information). IRB review is required if coded specimens are reidentified.
Commercialization	The process cycle of introducing a new product or production method into the market. For example, cells derived from a hairy cell leukemia patient were used to develop GM-CSF that was commercialized and sold as a medication used to reduce the risk of infection in patients receiving chemotherapy.

GLOSSARY AND DEFINITIONS

Term	Definition
Commercialized	*see* **Commercialization.** The process cycle of introducing a new product or production method into the market. For example, cells derived from a hairy cell leukemia patient were used to develop GM-CSF that was commercialized and sold as a medication used to reduce the risk of infection in patients receiving chemotherapy.
Comparative Genomics	The study of the comparison and relationship of genome structure and function across different biological species or strains, e.g., human, mouse and a wide variety of other organisms from yeast to other warm blooded animals.
Confidentiality	Treatment of information so that it is not divulged in ways that are inconsistent with the understanding of the original disclosure. Particularly, the ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient, unless the patient gives consent permitting disclosure.
Confidentiality Pledge	An agreement by study personnel pledging to adhere to the confidentiality requirements of the approved protocol. Such documentation is required for access to certain restricted access data sets, e.g., an agreement not to attempt to identify the source of the specimen.
Conflict of Interest (COI)	A COI occurs when there is a divergence between an individual's private interests and his/her professional obligations, such that an independent observer might reasonably question whether the individual's professional actions or decisions appear to be or are materially influenced by considerations of personal gain, financial or otherwise. A critical question in this regard is whether the design, conduct, and reporting of research is free from bias.
Covered Entity	Any entity that is: • A health care provider that conducts certain transactions in electronic form (called here a 'covered health care provider'); • A health care clearinghouse; or • A health plan
Custodianship	The caretaking responsibility for biospecimens that extends from collection through research use. Responsible custodianship requires careful planning and transparent policies to ensure the long-term physical quality of the biospecimens, the privacy of human research participants, the confidentiality of associated data, and the appropriate use of biospecimens and data. Custodianship is generally part-and-parcel of a Biorepository's Operating Procedures.
Data repository	A repository of data (electronic or paper). Health information that originates from a medical record is a common example of data that is included in a data repository. Data may be de-identified or identified with oversight provided by the repository gatekeeper.
Data Security	A comprehensive system that controls access to information and ensures data integrity with appropriate audit and report functions that enable the ability to determine compliance with standards. The comprehensive data security system covers physical and electronic network access, server access, access rights, audit trails and has the ability to validate limited data items.
Data Use Agreement (DUA)	A DUA entered into by both the custodian organization and the researcher that enables the organization to disclose a limited data set (LDS) to the researcher for research, public health, or health care operations. 45 CFR 164.514(3). AN LDS excludes specific direct identifiers of the individual, relatives, employers, or household members of the individual. The DUA must: • Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which MAY NOT include any use or disclosure that would violate the rule if done by the covered entity • Limit who can receive the data • Require the receiver of the data to agree to the following: ◦ Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law. ◦ Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the agreement. ◦ Report to the organization any use or disclosure of the information not provided for by the agreement, of which the receiver becomes aware. ◦ Ensure that any agents, including a subcontractor, to whom the receiver provides the information agrees to the same restrictions and conditions that apply to the recipient with respect to the LDS. ◦ Not to identify or contact the individual
Database	Collection of information elements (data). A structured collection of records or data that is stored in a computer system so that a computer program or person using a query language can consult it to answer queries.

GLOSSARY AND DEFINITIONS

Term	Definition
dbGaP	The **d**ata**b**ase of **G**enotypes **a**nd **P**henotypes (dbGaP) archives and distributes the results of studies that have investigated the interaction of genotype and phenotype. Such studies include genome-wide association studies, medical sequencing, molecular diagnostic assays, as well as association between genotype and non-clinical traits. Investigators can submit study data/results and request study data/results for their current research needs. dbGaP is a National Center for Biotechnology Information (NCBI) data distribution service.
De-identification methods	The process used to prevent a person's identify from being connected with specimens or information/data. The HIPAA Privacy Rule identifies two methods to achieve de-identification: (1) the Expert Determination method and (2) the Safe Harbor method.
De-identified	Specimen(s)/data that do not identify an individual and with respect to which there is no reasonable basis to believe can be used to idenitfy an individual.
De-identified Data Set	A dataset that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.
Delegation Log	A log that provides a comprehensive list of study staff members and the duties that have been delegated to them by the Principal Investigator. It is required for both observational and interventional clinical research studies.
Deoxyribonucleic acid (DNA)	A self-replicating material present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information.
Department of Health and Human Services	The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Food and Drug Administration, Office of Human Research Protections and Office of Civil Rights (which oversees the HIPAA regulations) are all agencies within DHHS.
Derivative	Biospecimen that is prepared through laboratory manipulation either with or without the addition of chemical substances by the laboratory technician.
Deviation	An intentional or unintentional event that is a departure from a procedure or a normal practice. For example, an activity that is different from what is set out in an IRB approved protoocol.
DHHS	The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Food and Drug Administration, Office of Human Research Protections and Office of Civil Rights (which oversees the HIPAA regulations) are all agencies within DHHS.
Disclosure	A disclosure of Protected Health Information (PHI) is the sharing of that PHI outside of a covered entity or outside of the health care component of a covered entity.
Distribution	A process that includes receipt of request for samples, selection of appropriate samples, and final inspection, in conjunction with subsequent shipment and delivery of samples to another biospecimen resource, biospecimen collection center, or laboratory. Distribution may also include policies that require an evaluation of scientific merit prior to release.
Donor	Living or deceased individual who is the source of the specimen in accordance with established medical criteria, procedures and privacy regulations.
Electronic Medical Record (EMR)	An EMR is a digital version of a paper chart that contains all of a patient´s medical history from one practice. An EMR is primarily used by providers for diagnosis and treatment. Also referred to as an Electronic Health Record (EHR).
Encryption	The process of encoding messages or information in such a way (called a ciphertext) that only authorized parties can read it.
Environmental Monitoring System	An automated, centralized monitoring system that monitors environmental conditions and alarms in conjunction with remote access, security features and electronic data storage.
Exempt Research	Exempt research involves very little risk, if any, and that would meet one of the six categories described in the DHHS regulations at 45 CFR 46.101(b). Exempt research categories do not apply to certain types of research (e.g., prisoner research, survey research involving children, etc.). IRB review is not required for exempt research.
Existing Specimens or Data	Leftover samples/data that were collected for routine clinical care or from a prior research study, not entirely used in the original study and thus potentially available for other research projects.
Expedited (IRB) Review	Expedited review is a type of review that can be conducted by the IRB Chair or designated IRB member(s) for research that meets minimal risk criteria and the categories of research described at 63 FR 60364-60367, 11-09-1998. The criteria for approval are the same as for a protocol requiring review at a fully convened IRB meeting.
Expert Determination (De-identification) Method. (45 CFR 164.514(b))	A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable: 1. Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information by an anticipated recipient to identify an individual who is a subject of the information; and 2. Documents the methods and results of the analysis that justify such determination

GLOSSARY AND DEFINITIONS

Term	Definition
External Collaborating Investigators	Investigators from various external sites that work with a lead investigator at another site, commonly referred to as the coordinating site or hub.
Firewall	In computing, a firewall is a software or hardware-based network security system that controls the incoming and outgoing network traffic by analyzing the data packets and determining whether they should be allowed through or not, based on a rule set.
Food and Drug Administration (FDA)	The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. The FDA is also responsible for the safety and security of most of our nation's food supply, all cosmetics, dietary supplements, tobacco products and products that give off radiation.
Gatekeeper	The individual or institutional body who has the responsibility to ensure that all regulations and policies have been followed prior to approval of an activity. In biobanks, the gatekeeper might help the biorepository to ensure that appropriate IRB approvals are in place as well as MTA agreements along with appropriate intended use of a sample prior to the release of a sample for research. A gatekeeper could also fulfill the role of the Honest Broker.
Genome Wide Association Study	In genetic epidemiology, a genome-wide association study (GWA study, or GWAS), also known as whole genome association study (WGA study, or WGAS), is an examination of many common genetic variants in different individuals to see if any variant is associated with a trait. GWAS typically focus on associations between single-nucleotide polymorphisms (SNPs) and traits like major diseases. Genome-wide data sets are increasingly being used to identify biological pathways and networks underlying complex diseases, and in drug development process.
Genomics	The study of the complete genetic complement of an organism or organ (Taber's Medical Dictionary).
Genotype	The genetic constitution of an individual organism. Also known as your complete heritable genetic identity and is revealed by personal genome sequencing**.**
Greater Than Minimal Risk	Greater than minimal risk protocols place participants at higher risk than those ordinarily encountered in daily life or during the performance of routine physical care and include such examples as chemotherapy, or bone marrow aspirations. These protocols typically involve investigational drugs, new treatment methods or invasive procedures. The study may result in information that will yield generalizable knowledge about the disease or subject population.
GWAS	In genetic epidemiology, a genome-wide association study (GWA study, or GWAS), also known as whole genome association study (WGA study, or WGAS), is an examination of many common genetic variants in different individuals to see if any variant is associated with a trait. GWAS typically focus on associations between single-nucleotide polymorphisms (SNPs) and traits like major diseases. Genome-wide data sets are increasingly being used to identify biological pathways and networks underlying complex diseases, and in drug development process.
Hazardous	In the context of biohazardous it refers to biological substances that pose a threat to the health of living organisms.
Health Information	Any information, whether oral or recorded in any form or medium, that: 1. 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 2. 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. 3. Genetic information is considered health information.
Health Insurance Portability & Accountability Act	Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.
HIPAA	Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.

GLOSSARY AND DEFINITIONS

Term	Definition
HIPAA Identifiers	The Privacy Rule defines eighteen (18) identifiers as follows: 1. Names, 2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three (3) digits of a zip code, if according to the current publicly available data from the Bureau of the Census: • The geographic unit formed by combining all zip codes with the same three initial digits contain more than 20,000 people; and • The initial three digits of a zip code for all such geographical units containing 20,000 or fewer people is changed to 000. 1. 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 such ages and elements may be aggregated into a single category of age 90 or older; 2. Telephone numbers; 3. Fax numbers; 4. Electronic mail addresses; 5. Social Security Numbers; 6. Medical Record Numbers; 7. Health Plan beneficiary numbers 8. Account numbers; 9. Certificate/license numbers; 10. Vehicle Identifiers and serial numbers, including license plate numbers; 11. Device identifiers and serial numbers; 12. Web Universal Resources Locators (URLs) 13. Internet Protocol (IP) address numbers; 14. Biometric identifiers' including finger and voice prints; 15. Full face photographic images and comparable images; and 16. Any other unique identifying number, characteristic, or code; and the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.
HIPAA Privacy Rule	The regulations establish national standards to protect individuals' medical records and other personal health information and apply to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.
Honest Broker	An individual, organization, or system acting for, or on behalf of, a covered entity to collect and provide health information to research investigators in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients-subjects directly or indirectly. The honest broker cannot be one of the investigators. The information provided to the investigators by the honest broker may incorporate linkage codes to permit information collation and/or subsequent inquiries (i.e., a "re-identification code"); however, the information linking this re-identification code to the patient's identity must be retained by the honest broker and subsequent inquiries are conducted through the honest broker. In addition, linkages and requests to re-identify the source would require IRB review and approval.
Human Biological Specimens	Any biological material that comes from human bodies. This includes sub-cellular structures (e.g., DNA), cells, tissues (e.g., blood, bone, muscle, connective tissue, teeth, and skin), organs (e.g., liver, bladder, heart, kidney, and placenta), gametes (e.g., sperm and ova), and waste (e.g., hair, nail clippings, urine, feces, saliva, and sweat, which often contains shed skin cells).
Human Leukocyte Antigen (HLA) Typing	A series of tests done before a transplant to determine how closely the tissues of a donor and recipient match.
Human Research Protection Program (HRPP) Accreditation	A process that reviews the practices of organizations involved with research that involves human subjects and measures a program's compliance to the standards set by the accrediting organization.
Human Subject	A living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR § 46.102(e)(1)).
Human Subject Research	Research involving a human subject. (See "human subject" and "research.")
Identifiable	The identity of the subject is or may readily be ascertained by the investigator or associated with the information (45 CFR § 46.102(f)).
Identification Risk	The degree to which a data set can be linked to a data source that can reveal the identity of an individual.

GLOSSARY AND DEFINITIONS

Term	Definition
Identifying Information	Information (e.g., name, social security number, medical record or pathology accession number, etc.) that would enable the identification of the subject. For some specimens this information might include the taxon name and collection number.
In Vitro Diagnostic Device (IVD)	Broadly defined, IVD is a device intended for use for the in-vitro examination of specimens derived from the human body to provide information for diagnostic, monitoring or compatibility purposes. Examples of IVDs include blood glucose meters, home pregnancy tests, test kits used in hospital laboratories, reagents, and analytic.
Incident	Any unplanned occurrence that deviates from Standard Operations Procedures (SOPs) or applicable government laws and regulations during specimen retrieval, processing, labeling, storage or distribution that may affect subsequent use of those specimens.
Incidental Findings	A discovery concerning an individual research participant that: 1) is discovered in the course of research, but was not the focus of the research study, 2) is beyond the information required to achieve the aims of the study, and 3) may have potential safety, health, or welfare importance. Incidental findings may or may not be anticipated to be found in a portion of the research participants. Likewise, incidental findings may or may not surpass the frequency of results necessitating communication to participants expected within the studied population.
Individually Identifiable Health Information	Health or demographic information collected from an individual, and that: 1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and 2. 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 the individual; and • That identifies the individual; or • With respect to which there is a reasonable basis to believe the information can be used to identify the individual.
Informed Consent	A decision to participate in research, by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.
Institutional Review Board (IRB)	A specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral research. The relevant regulatory requirements for an IRB are provided at 45 CFR Part 46 and 21 CFR 56.
Intellectual Property	A commercially valuable product of the human intellect, in a concrete or abstract form, such as a copyrightable work, a protectable trademark, a patentable invention or a trade secret.
Interaction	Includes communication or interpersonal contact between the investigator and subject.
International Air Transport Association (IATA)	IATA is the trade association for the world's airlines, representing approximately 240 airlines or 84% of total air traffic, supporting various areas of aviation activity as well as assisting to formulate industry policy on critical aviation issues.
International Society For Biological and Environmental Repositories (ISBER)	A professional society of individuals and organizations who share an interest in promoting consistent, high quality standards, ethical principles and innovation in biospecimen banking by uniting the global biobanking community.
Intervention	Includes both 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.
Inventory	A complete list of items.
Investigator	A scientist or engineer for a particular well-defined science (or other research) project, such as a laboratory study or clinical trial.
Investigator Agreement	Generally refers to an agreement between an IRB and an outside investigator for review of that investigator's research.
Investigator Alone	Unique funding for specific study purpose by investigator alone.
Investigators in same institution	Thematic research involving multiple laboratories and physicians for fulfilling research objectives.
Label	Any written, printed or graphic material on or affixed to a specimen container or package.

GLOSSARY AND DEFINITIONS

Term	Definition
Limited Data Set (LDS)	Removal of direct identifiers and use of a data use agreement. Direct identifiers that must be removed are as follows: 1. Name 2. Street/Postal Address 3. Phone/Fax Number 4. E-mail Address 5. Social Security Number 6. Certificate/License Number 7. Vehicle ID and Serial Number 8. URL's and IP Addresses 9. Full Face Images and Biometric Identifiers 10. Medical Record Number, Health Care Plan Number, Other Account Numbers 11. Device ID and Serial Numbers An LDS can include: • City, State, Zip Code • Date of Birth, Date of Death • Age in Years, Months, Days or Hours as Necessary for the Research
Linkages	Linkages are a connection or relationship between two or more things, e.g., the relationship between genes on the same chromosome that causes them to be inherited together or two or more linked data points that may help to identify an individual.
Longitudinal Data	Data in which the same units are observed over multiple time periods.
Material Transfer Agreement (MTA)	An agreement that governs the transfer of tangible research materials and data between two organizations, when the recipient intends to use it for his or her own research purposes. It defines the rights and obligations of the provider and the recipient with respect to the use of the materials.
Minimal Risk	The risk of harm in research no greater than encountered in daily life or routine physical or psychological examinations or tests.
Minimum Necessary	HIPAA requires that no more than the minimum necessary PHI be disclosed for the intended purpose of the research.
Non-Human Subject Research	Activities that, according to 45 CFR 46 and agency guidance, meet the regulatory definition of research, but do not involve human subjects. In non-human subjects research, biological materials to be used have been de-identified prior to being given to the researcher, who also signs a written agreement not to attempt to re-identify the specimens. Research that involves coded, de-identified, or anonymized information and/or specimens that were not collected specifically for the proposed research activity and the investigator cannot readily ascertain the identity of the individual to whom the information or specimen pertains is considered non-human subjects research. Collection: includes collection of de-identified specimens, already coded specimens, autopsy specimens; (ii) Release: includes release of de-identified samples or coded samples without access to the code.
Occupational Safety and Health Administration (OSHA)	OSHA is a federal organization (part of the Department of Labor) that ensures safe and healthy working conditions for Americans by enforcing standards and providing workplace safety training.
Paraffin Embedded	A method of preserving biospecimens where they are chemically or otherwise fixed and then infiltrated with molten wax, which later solidifies.
Patent	A property right granted by the U.S. Government to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention when the patent is granted.
Personally identifiable Information (PII)	Any information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means. PII is further defined as information: (i) that directly identifies an individual (e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc.) or (ii) by which an agency intends to identify specific individuals in conjunction with other data elements, i.e., indirect identification. (These data elements may include a combination of gender, race, birth date, geographic indicator, and other descriptors). Additionally, information permitting the physical or online contacting of a specific individual is the same as personally identifiable information. This information can be maintained in either paper, electronic or other media.
Phenotype	The set of observable characters of an individual resulting from the interaction of its genotype with the environment.
Preservation	Use of chemical agents, alterations in environmental conditions, or other means during processing to prevent or retard biological or physical deterioration of a biospecimen.
Prevalence	The total number of cases of a given disease in a specified population at a designated time. It is differentiated from "incidence," which refers to the number of new cases in the population at a given time.

GLOSSARY AND DEFINITIONS

Term	Definition
Primary Research	Primary research is new research, carried out to answer specific issues or questions. It can involve questionnaires, surveys or interviews with individuals or small groups.
Principal Investigator (PI)	The PI is the lead scientist , engineer or specialist for a particular well-defined science (or other research) project, such as a laboratory study or clinical trial.
Privacy	1. The condition or state of being free from public attention to intrusion into or interference with one's acts or decisions; 2. The ability of a person to control the availability of information about and exposure of him- or herself.
Privacy Board	The committee set out in the HIPAA regulations as responsible for ensuring compliance with the regulations for the protection of health information.
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 which the individual can reasonably expect will not be made public (for example, a medical record) (45 CFR § 46.102(f)).
Procedure	A series of steps designed to result in a specific outcome when followed in order.
Process Validation Studies	Scientific measurable evidence that a product meets specification consistently and the process performance meets an acceptance criteria and is reproducible.
Processing	Any procedure employed after specimen collection but prior to its distribution, including preparation, testing, and releasing the specimen to inventory and labeling.
Prospective	A study or collection maintained for expected or likely use in the future.
Protected Health Information (PHI)	Individually identifiable health information: 1. Except as provided in paragraph (2) of this definition, that is: • Transmitted by electronic media; • Maintained in electronic media; or • Transmitted or maintained in any other form or medium. 1. PHI excludes individually identifiable health information in: • Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; • Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and • Employment records held by a covered entity in its role as employer. PHI is information, including demographic information, which relates to: • The individual's past, present, or future physical or mental health or condition • The provision of health care to the individual, or • The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.
Proteomics	The global analysis of cellular proteins. Proteomics uses a combination of sophisticated techniques including two-dimensional (2D) gel electrophoresis, image analysis, mass spectrometry, amino acid sequencing, and bio-informatics to resolve comprehensively, to quantify, and to characterize proteins. The application of proteomics provides major opportunities to elucidate disease mechanisms and to identify new diagnostic markers and therapeutic targets.
Quality	Conformance of a biospecimen or process with pre-established specifications or standards.
Quality Assurance (QA)/Quality Management System (QMS)	An integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process or item is of the type and quality needed for the project. Same as quality management system.
Quality Control (QC)	Specific tests defined by the QA or QMS Program to be performed to monitor procurement, processing, preservation, distribution and storage; biospecimen quality, and test accuracy. These may include, but are not limited to performance evaluations, testing, and controls used to determine accuracy and reliability of the biospecimen resource's equipment and operational procedures as well as monitoring of the supplies, reagents, equipment, and facilities.
Quality Management System (QMS)	Same as Quality Assurance (QA).
Readily Identifiable Information (DHHS)	Information is not considered readily identifiable if (i) investigators and holder of the key enter into an agreement prohibiting the release of the key; (ii) IRB-approved policies and procedures prohibit the release of the key to investigators; (iii) other legal requirements prohibit the release of the key.
Registry	Centralized collection of information elements (data) or databases, also known as a "Data Bank".

GLOSSARY AND DEFINITIONS

Term	Definition
Re-identification	Ascertainment of the individual associated with a biospecimen, sample, or data by translation of a code or linkage.
Repository	Also called a "biobank or biorepository" is a collection of biological specimens and/or data.
Repository Gatekeeper	The individual responsible for oversight of repository access utilizing defined policies and procedures.
Research	1. Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (CFR 45 § 46.102(d)). 2. Systematic investigation about a subject in order to discover facts, establish or revise a theory, or develop a plan of action based on the facts discovered.
Research Data	Data that is collected, observed, or created, for purposes of analysis to produce original research results.
Research Protocol	Research Protocols (protocols) are research studies that test something for a specified condition or purpose, e.g., a drug or medical device, or may review previous studies or record the history of a disease or condition.
Retrieval	The removal, acquisition, recovery, harvesting, or collection of biospecimens.
Retrospective	Relating to or being a study or collection (as of a disease) that looks back on or deals with past events or situations.
Revocation of Authorization	Participants have a right to revoke their authorization for use of their PHI. This must be done in writing. Exceptions to revocation of authorization are: 1. PHI already collected prior to the revocation may still be used. 2. Mandated reporting of PHI, such as to the FDA, investigations of scientific misconduct, and/or adverse event reporting.
Safe Harbor (De-identification) Method. (45 CFR 164.514(b)	The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed: 1. Names, 2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three (3) digits of a zip code, if according to the current publicly available data from the Bureau of the Census: • The geographic unit formed by combining all zip codes with the same three initial digits contain more than 20,000 people; and • The initial three digits of a zip code for all such geographical units containing 20,000 or fewer people is changed to 000. 1. 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 such ages and elements may be aggregated into a single category of age 90 or older; 2. Telephone numbers; 3. Fax numbers; 4. Electronic mail addresses; 5. Social Security Numbers; 6. Medical Record Numbers; 7. Health Plan beneficiary numbers 8. Account numbers; 9. Certificate/license numbers; 10. Vehicle Identifiers and serial numbers, including license plate numbers; 11. Device identifiers and serial numbers; 12. Web Universal Resources Locators (URLs) 13. Internet Protocol (IP) address numbers; 14. Biometric identifiers' including finger and voice prints; 15. Full face photographic images and comparable images; and 16. Any other unique identifying number, characteristic, or code; and the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.
Safety	Processes, procedures and technologies to ensure freedom from danger or harm.

GLOSSARY AND DEFINITIONS

Term	Definition
Sample	1. A portion of a biospecimen; 2. A single unit containing material derived from one biospecimen. 3. Serving as an illustration or example.
Scientific Advisory Board or Committee	A Scientific Advisory Board (SAB) is a body of independent scientific experts (physicians, scientists, statisticians and others) established to render specialized advice in science and technology
Secondary Research	Any research use beyond the scope of the primary study. See Primary research.
Shipping Manifest	A written description of the contents of the shipped package.
Simple Letter Agreement (SLA)	Material transfer agreement approved for use at the NIH and which the NIH encourages for use in exchanges between academic institution.
Specimen	Same as **Biospecimen.**
Stakeholder	One that has an interest in an enterprise. In the context of the *NCI Best Practices*, the term stakeholder includes research participants, patient advocates, researchers, clinicians, and biospecimen resource operational/managerial personnel.
Standard Operating Procedure	An established procedure to be followed in carrying out a given operation or in a given situation (NCI Thesauras).
Standard Operating Procedure (SOP)	An established procedure to be followed in carrying out a given operation or in a given situation.
Standard Operating Procedures (SOPs) Manual	A collection of SOPs detailing specific policies of a repository and the procedures required to be used by the staff/personnel.
Standard Precautions	Familiar name of the CDC publication titled "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007." The guidelines are based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes may contain transmissible infectious agents, and include a group of infection-prevention practices. These include: hand hygiene, use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure, and safe injection practices. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents.
Storage	Maintenance of biospecimens under specified conditions for future use.
Suppression	Withholding information in selected records from release.
Sustainable	Of, relating to, or being a method of using a resource so that the resource is not depleted.
Tissue	An aggregate of cells with different specialized characteristics that are organized anatomically, usually in the fixed framework of an organic matrix. The architectural organization that is maintained contributes to the performance of a specific collective function. Tissues are parts of organs. The term tissue is most often referred to in the context of solid tissue, as originating from a solid organ; however, tissue also can be defined broadly to include collections of cells and the extracellular matrix and/or intercellular substances from bodily fluids such as blood.
UBMTA	A Master Agreement used among the NIH, universities, and other nonprofit research facilities to expedite transfer of research materials among noncommercial entities. More information about the terms of the UBMTA and its signatories is available at https://grants.nih.gov/grants/guide/notice-files/not95-116.html
Uniform Biological Material Transfer Agreement	A Master Agreement used among the NIH, universities, and other nonprofit research facilities to expedite transfer of research materials among noncommercial entities. More information about the terms of the UBMTA and its signatories is available at (https://grants.nih.gov/grants/guide/notice-files/not95-116.html).
Unique Identifier	A set of characters used as a code that is unique in the context or the system for which it is created. It serves as a means of identification and reference (often instead of a name) for an entity, person, thing, function, procedure, activity, variable, or body of data.
Validation (of Procedures or Equipment)	1. The act of confirming a product or service meets the requirements for which it was intended; 2. A statistical method of partitioning a sample of data into subsets such that the analysis is initially performed on a single subset, while the other subsets are retained for subsequent use in confirming and validating the initial analysis.

GLOSSARY AND DEFINITIONS

Term	Definition
Waiver of HIPAA Authorization	The following criteria must be satisfied for an IRB or Privacy Board to approve a waiver of HIPAA authorization under the Privacy Rule [45 CFR 164.512(i)(1)(i)]: 1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: • an adequate plan to protect the identifiers from improper use and disclosure; • an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and • adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart; 2. The research could not practicably be conducted without the waiver or alteration; and 3. The research could not practicably be conducted without access to and use of the protected health information.
Waiver of Informed Consent	The HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research (45 CFR 46.116(d) when the IRB finds and documents that: 1. The risk to the subjects is minimal, 2. Subjects' rights and welfare will not be adversely affected by the waiver, 3. Conducting the research without the waiver is not practicable, and 4. If appropriate, subjects are provided with additional pertinent information after their participation.
Withdrawal of Consent	In research, a person agrees to be part of a research study and later decides to withdraw from participation, hence withdrawing their consent to continue in the study.