Research Glossary

Affiliated Covered Entity- legally separate covered entities that are affiliated by common ownership or control may designate themselves (including their health care components) as a single covered entity for Privacy Rule compliance

Authorization- a specific type of permission given by the individual to use and/or disclose protected health information about the individual. The requirements of a valid authorization are defined in the HIPAA regulations.

Breach- the unauthorized acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed, would not reasonably have been able to retain such information.

Breach of Data Use Agreement- unauthorized or improper access, use, disclosure, or handling of data that is governed by an agreed-upon set of terms and conditions. Agreement typically outlines specific rules and restrictions regarding how the data should be accessed, utilized, stored, and shared.

Business Associate- generally an entity or person who performs a function involving the use or disclosure of Protected Health Information (PHI) on behalf of a covered entity (such as claims processing, case management, utilization review, quality assurance, billing) or provides services for a covered entity that require the disclosure of PHI (such as legal, actuarial, accounting, accreditation)

Business Associate Agreement- a written contract between a covered entity and a business associate (BA) that establishes the permitted and required uses and disclosures of protected health information by the BA

Classified Research- research conducted with or on behalf of a government agency, or service provided to or on behalf of a government agency, that will require government-issued security clearances for participation.

Confidential Business Information- any private financial or commercial information relating to the amount or source of any income, profits, losses or expenditures of a person, including data relating to cost, price, or customers. "Confidential business information" does not include the financial terms of a contract or the identity of a contractor, except in extraordinary circumstances where state or federal law or regulation may require the non-disclosure of such information.

Confidential Research Information- includes, but is not limited to any and all records of an institution that have been created, developed, discovered, disclosed to, or received by or on behalf of faculty, staff, employees, or students of the institution concerning research that have not been published, patented or otherwise disclosed such as: (1) Information contained in research proposal funding applications and human, animal, or clinical research protocols; (2) Preliminary research data and memorandum discussions regarding preliminary data; (3) Unpublished manuscripts or unpublished lecture notes, data, and other information relating to research; (4) Creative works in process; or (5) Intellectual property disclosures, laboratory notebooks and computer records

associated with confidential research information, and scholarly correspondence prior to official publication of research results.

Copyrightable Works- title 4, cpt 12

Covered Entity- individuals and/or organizations that are subject to the Privacy Rule:

Healthcare provider Examples include: doctors, clinics, dentists, nursing homes, pharmacies, etc.	*Health plans* Examples include: health insurance companies, HMOs, company health plans, government programs (Medicare, Medicaid, etc.)
Healthcare clearinghouses Examples include: billing service, repricing company, etc.	*Business associates* Examples include: lawyers, consultants, claims processing vendors, cloud vendors, etc.

Covered Functions/ Non Covered Functions- any activity that would make the entity a healthcare provider, a health plan, or a healthcare clearinghouse, and also performs some business functions that a covered entity does not perform ("non covered functions").

Data Classification Levels:

High Risk/Restricted Data- Data that is required by law or regulations, protection is necessary to meet compliance obligations, or the unauthorized disclosure, access, alteration, loss or destruction of those data may have a material impact on the University and is affiliates.

Moderate Risk Data- Data where the unauthorized disclosure, access, alteration, loss or destruction of those data would be expected to have an adverse but not material impact on the University and its affiliates' mission, assets, operations, finances, or reputation, or only limited harm to individuals. Such data can be made available to members of the University community or close collaborators at other institutions with a related research interest, and is not restricted by local, state, national, or international statute regarding disclosure or use.

Low Risk Data- Data where the unauthorized disclosure, access, alteration, loss or destruction of that data would not be expected to have any effect on the University and its affiliates', would not be expected to pose any harm to individuals, or where such data are intended for public disclosure.

Data Safety Monitoring Board (DSMB)- an independent group of experts that objectively evaluates trial data periodically for integrity and to assure the safety of clinical trial participants.

Data Use Agreement- an agreement between a covered entity (the holder of the PHI) and the recipient of the PHI (such as a research investigator) in which the covered entity discloses a limited data set for purposes of research, public health or healthcare operations.

Decedent- deceased individual.

De-identified Data- health information 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.

Direct Identifiers- information that relates specifically to an individual

Disclosure- the release, transfer, provision of access to, or divulging in any other manner of protected health information outside of the entity holding the information.

Electronic Protected Health Information (EPHI)- PHI in electronic form.

Family Educational Rights and Privacy Act (FERPA)- a federal law that affords parents the right to have access to their children's education records, the right to seek to have the records amended, and the right to have some control over the disclosure of personally identifiable information from the education records.

Health Insurance Portability and Accountability Act (HIPAA)- a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

Hybrid Covered Entity-a single legal entity that performs both covered and non-covered functions. services. Only those entities designated as healthcare components ("covered functions"), are subject to the Privacy Rule.

Individual- the person who is the subject of the PHI.

Individually Identifiable Health Information- a subset of "health information," including demographic information, (1) that is created or received by a health care provider, health plan, employer, or health care clearinghouse; 2) that relates to the physical or mental health or condition of an individual; the provision of health care to an individual; or the payment for the provision of health care to an individual; and (3) that identifies the individual, or might reasonably be used to identify the individual. Defer to the 18 data elements

Institutional Research- Also called internal research, is the gathering of data from or about UNLV students, faculty, and staff by university offices or organizations, with the sole intent of using the data for internal informational purposes or for required data-collection purposes. This data would not be made generalizable. Examples include surveys to improve university services or procedures; ascertain the opinions, experiences, or preferences of the university community; or to provide necessary information to characterize the university community. This kind of data gathering does not require IRB review unless respondents are queried about sensitive aspects of their own behavior. For debatable projects, investigators should submit an exclusion review form to the ORI-HS.

Institutional Review Board (IRB)- an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

Intellectual Property-a category of property, which are creations of the mind and their embodiment; the tangible and intangible result of research (including but not limited to data, lab notebooks, charts, biological material, cell lines and samples), compilations and original works of art, literature or music and includes Inventions and Works, Trademarks and Trade Secrets.

Internal Research- see definition for Institutional Research

Inventions- refer to all innovations, discoveries, technological advances, compilations, potentially patentable computer software, tangible research property, trade secrets and proprietary information, mask works, processes, methods, uses, products, or combinations of any of the

foregoing, whether or not patented or patentable at any time under the U.S. Patent Act, as now existing or hereafter amended or supplemented.

Limited Data Set- protected health information that excludes all of the 16 HIPAA specified direct identifiers of the individual or of relatives, employers, or household members of the individual, but retains geographic subdivisions larger than the postal address and elements of dates. Limited data sets may only be used for research, public health or for health care operations; and only with a data use agreement that limits the use of the data by the recipient.

Minimum Necessary- refers to reasonable efforts made to limit use, disclosure, or requests for PHI to the minimum necessary to accomplish the intended purpose

Organized Health Care Arrangement (OHCA)- an organized health system of health care in which more than one covered entity participates and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement and participate in certain join activities.

Personal Identifiable Information (PII)- any data or information that can be used on its own or with other information to identify, contact, or locate an individual. PII includes, but is not limited to, information such as name, personal identification number (e.g. SSN, passport number, etc.), address, telephone number, biometric data, financial information, date of birth, other identifying information

Privacy Board- a review board that is responsible for approving HIPAA waivers of authorization

Proprietary Research- includes, not limited to, *trade secrets*, *confidential business information,* and all other *intellectual property*, *inventions* and *copyrightable works*.

Protected Health Information (PHI)- any individually identifiable health information, including genetic information and demographic information, collected from an individual, whether oral or recorded in any form or medium that is created or received by a covered entity

18 data elements:

1. Patient names	2. Geographical elements	3. Dates related to health or identity of individuals
4. Telephone numbers	5. Fax numbers	6. Email addresses
7. Social security numbers	8. Medical record numbers	9. Health insurance beneficiary numbers
10. Account numbers	11. Certificate/license numbers	12. Vehicle identifiers
13. Device attributes or serial numbers	14. Digital identifier, such as website URLs	15. IP addresses
16. Biometric elements including finger, retinal and voiceprints	17. Photographs of a patient's face	18. Other identifying numbers or codes

Research- any systematic investigation designed to develop or contribute to generalizable knowledge.

Research Misconduct- the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Trademark- defined under both state and federal law. Under state law, Trademark is defined as "any word, name, symbol or device, or any combination of them" that identifies and distinguishes the source of the goods made or sold by one party from those of others. In addition, "service marks" are used to identify and distinguish the source of a service rather than goods and "trade names" are used to identify a business, occupation or vocation and distinguish it from others. Under the federal Trademark Act of 1946, a Trademark is defined in 15 United States Code Section 1127 as a word, name, symbol, device or any combination thereof that is used by a person in commerce, or which a person intends to use in commerce and which may be registered, to identify and distinguish goods from those manufactured or sold by others, and to indicate the source of the goods.

Trade Secret- information, including, without limitation, a formula, pattern, compilation, program, device, method, technique, product, system, process, design, prototype, procedure, computer programming instruction or code that: (a) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means, by the public or any other persons who can obtain commercial or economic value from its disclosure or use; and (b) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Use- the sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an entity that holds such information.

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