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Protecting a Subject's Privacy and Confidentiality

Volumes have been written regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as healthcare entities grapple with the complexities of complying with the standards. The regulations, entitled "Standards for Privacy of Individually Identifiable Health Information", are more commonly referred to as the Privacy Rule. The Privacy Rule offers individuals greater control over their own protected health information (PHI) while imposing new limits upon the ways in which health care providers may use or disclose PHI.

Privacy, confidentiality, anonymity, linked, de-linked and the list goes on. The maintenance of privacy and confidentiality helps to protect subjects from a variety of potential harms, including psychological distress, being denied or losing their health insurance, loss of employment or the damage to social standing that could occur as the result of a breach of confidentiality. Indeed, it is an important function for the IRB to determine how the privacy and confidentiality of research subjects will be protected when reviewing a new protocol.

Privacy can be defined in terms of having control over the extent, timing and circumstance of sharing oneself with others. *Confidentiality* pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to other without permission. Privacy concerns people, whereas confidentiality concerns data.

In determining the degree of privacy of the information, the IRB should use the standard of a reasonable member of the population, and consider whether such a reasonable member would consider the information collected in the research to be private and would that member consider the release of the information without permission to be an invasion of privacy.

If the data was collected *anonymously*, there were no identifies ever recorded. *Identifiable data* can easily link back to the subject by one or more of the 18 identifiers listed in the HIPPA Privacy Rule or a code. If the data is *de-identified,* all of the 18 identifiers have been removed from the data. A *limited data set* contains only a few of the HIPPA identifiers. If the data has been *de-linked*, there were identifier(s) and they continue to exist. However, the code that links the identifiers to an individual no longer exists. Therefore, the data can no longer be linked to the subject.

The 18 HIPAA identifiers include;

1. Names;
2. All geographic subdivisions smaller that a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code;
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 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. Telephone 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 (URL)
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographs and any comparable images;
18. Any other unique identifying number, characteristic, or code.

The Investigator is asked a series of questions on the Submission Form regarding how the data will be collected and managed; how it will be entered into a data base, i.e., identifiable verse de-identified, and the overall security of the data after it is collected. The data collection forms are reviewed to verify the information reported by the investigator.

After the IRB has determined that there are adequate provisions in the protocol to protect the privacy and confidentiality of the subjects, it must also ensure that the consent form accurately provides the subject with information about how their indefinable private information or identifiable biospecimens will be stored, who may have access to it and how it may be disseminated.

Under the Privacy Rule, the CHS CIRB is not required to review the HIPAA authorization. However, the CHS CIRB does review the consent form to ensure that it contains the Privacy Rule core elements and thoroughly explains the subject's right to safeguard their Protected Health Information (PHI).

The Privacy Rule requires core elements of authorization to be included in the Informed Consent Form (ICF).

1. A specific description of the information to be used or disclosed.
2. The name or other specific identification of the person or class of persons authorized to release the information.
3. The name or other specific identification of the person or class of persons to whom the covered entity may make the requested use or disclosure.
4. A description of each purpose of the requested use or disclosure.
5. An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure.
6. The signature and address of the individual and date.
7. A statement telling the patient of their right to revoke their authorization at any time.
8. A statement telling the patient that their treatment is not conditioned on their agreement to sign the authorization.
9. A statement telling the patient that if their information is disclosed based on their signed authorization that there is the potential for that information to be re-disclosed by the recipient whose actions may not be regulated by HIPAA.
10. The authorization must be in plain language.

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