CONFIDENTIALITY OF DATA AND HIPAA PRIVACY RULE

P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
4.05	02.12.2020	4.05	02.08.2020

When the research involves collection of data which might be harmful to subjects if disclosed to third parties in an individually-identifiable form, the investigator must be attentive to the adequacy of provisions to protect the confidentiality of data. The investigator must limit the collection of personal information to that which is essential for the research. Depending upon the degree of sensitivity of the data, the methods for protecting the confidentiality of data may include coding or removal of identifiers as soon as possible, limitation of access to data to the investigator and authorized staff, the use of locked file cabinets, the use of password-protected computers and computer servers, encryption of data on computers, and plans for the ultimate disposition of data.

The investigator should be aware of the extensive vulnerability of research data to subpoena, particularly in studies that collect data that would put subjects in legal jeopardy if disclosed. The subject names should be recorded only when necessary and subjects must be informed that their identity can be protected only to the extent allowed by law.

Certificates of Confidentiality

When and where possible Certificates of Confidentiality should be requested for investigator-initiated studies including projects establishing data and tissue repositories where personal identifiers or codes to identifiers are maintained. When research is funded in whole or in part by the NIH and involves collection of identifiable sensitive information, the research is automatically covered by a certificate of confidentiality. See OHRP guidance on Certificates of Confidentiality at http://www.hhs.gov/ohrp/policy/certconf.html and the Certificate of Confidentiality Kiosk on the National Institutes of Health website http://grants.nih.gov/grants/policy/coc/index.htm.

The investigator is responsible for informing subjects of the protections and limitations of the certificate of confidentiality in the consent. Subjects that were previously notified of these protections do not have to be notified when the protections change unless mandated by the IRB. If a certificate is issued while the study is ongoing, any subjects recruited prior to the issuance of the certificate that are no longer participating in the study do not have to be notified of the of the protections afforded by the certificate unless mandated by the IRB.

When research is covered by a certificate of confidentiality, researchers may not disclose or provide in any federal, state, local civil, criminal, administrative, legislative or other proceeding, the name of an individual or any such information, document, or biospecimen that contains identifiable sensitive information about the individual that was created or compiled for the purposes of research, unless such disclosure or use is made with the consent of the individual to whom the information pertains. This information also cannot be disclosed to any person who is not connected with the research.

Names of individuals or any information, documents, or biospecimens that contain identifiable sensitive information may be disclosed when:

- Required by federal, state, or local laws, excluding instances of disclosure in any federal, state, or local, civil, criminal, administrative, legislative, or other proceeding.
- Necessary for medical treatment of the individual to whom the information pertains, and made with consent of such individual.
- Made with the consent of the individual to whom the information pertains.

- Made for the purposes of other scientific research that is in compliance with applicable regulations.

When conducting any research covered by a certificate of confidentially, including NIH-funded and non-federally-funded research, the investigator must ensure that if identifiable sensitive information is provided to other researchers or organizations, the other researchers or organizations must comply with applicable requirements of the certificate of confidentiality.

Examples of research that are automatically covered by a certificate of confidentiality include:

- Biomedical, behavioral, clinical, or other research where information obtained is recorded in a manner so that individuals cannot be identified or their identity cannot be readily ascertained, directly or through links.
- The collection or use of biospecimens that include identifiable sensitive information.
- The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that individuals can be identified or their identity can be readily ascertained.
- Any other research that involves identifiable sensitive information about an individual.

HIPAA

Where appropriate, all studies must adhere to regulations concerning privacy at 45CFR Parts 160 and 164 (Standards for Privacy of Individually-Identifiable Health Information or **HIPAA Privacy Rule**.) If HIPAA Authorization is required of subjects, the signed authorization document must be maintained with the signed informed consent document for the study (attach these two documents together). In addition, the LSU Notice of Privacy Practices must be provided to all subjects enrolled into a study in which HIPAA Authorization is required. Acknowledgement procedures must be followed and documented as described at the Office of Research Services webpage "HIPAA and Research".

Investigators are directed to http://www.lsuhsc.edu/administration/academic/ors/hipaa.aspx for additional information related to these regulations.

Definitions

Certificates of Confidentiality: Protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in few other specific situations.

Identifiable Sensitive Information: information about an individual that is gathered or used during biomedical, behavioral, clinical, or other research where the following may occur:

- An individual is identified; or
- For which there is at least a very small risk that, some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of the individual.