1. CERTIFICATE OF CONFIDENTIALITY

The purpose of this policy is to describe the process of applying for a Certificate of Confidentiality. It is the policy of the IRB that a Certificate of Confidentiality may be required for certain research proposals where the potential of disclosure of sensitive, personally identifiable information creates significant risk of harm or damage to the participant.

2. PURPOSE

2.1. Certificates are issued for the purpose of protecting identifiable research information from compelled disclosure. The certificate 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.

2.2. Federal funding of the research is not a prerequisite.

2.3. A Certificate does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in case of child abuse.

2.4. A research protocol cannot rely on a Certificate to withhold data if the participant consents in writing to the disclosure.

3. APPLICABLE RESEARCH

3.1. The project must be categorized as research (see IRB Policy 101, About the IRB for a definition of research).

3.2. The research must be IRB-approved.

3.3. The information collected must be "sensitive" (e.g., disclosure will involve significant harm or damage to the participant).

3.3.1. Per NIH Policy, identifiable sensitive information means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research where the following may occur:

a) An individual is identified; or

b) 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 an individual.

3.4. Personally identifiable information is collected during the research.

3.5. The investigator and/or the IRB determine that a Certificate is necessary to minimize risk to participants.

3.6. Certificates are issued for single, well-defined research projects rather than groups or classes of projects. Occasionally a Certificate can be issued for cooperative multi-site projects. A coordinating center or "lead" institution can apply on behalf of all institutions involved in the protocol. The lead institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the Certificate, its protections, and circumstances in which voluntary disclosures would be made.

4. SENSITIVE RESEARCH CATEGORIES

4.1. Information relating to sexual attitudes, preferences, or practices.

4.2. Information relating to the use of alcohol, drugs, or other addictive substances.

4.3. Information pertaining to illegal conduct.

4.4. Information that, if released, could damage a participant's financial standing, employability, or reputation within the community.

4.5. Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.

4.6. Information pertaining to an individual's psychological well-being or mental health.

4.7. Genetic information.

5. APPLICATION PROCESS

5.1. Some research is automatically covered by a CoC those include:

5.1.1. Research funded by the NIH if the researcher is conducting research in which identifiable, sensitive information is collected or used.

5.1.2. Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a manner that human participants cannot be identified, or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

5.1.3. The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.

5.1.4. 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 human subjects can be identified or the identity of the human subjects can readily be ascertained.

5.1.5. Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

5.2. A CoC may be issued for research that:

5.2.1. Meets the definition of human subjects research, including exempt research in which subjects can be identified;

5.2.2. Is collecting or using human biospecimens that are identifiable or

that have a risk of being identifiable;

5.2.3. Involves the generation of individual level human genomic data;

5.2.4. Involves any other information that might identify a person.

5.3. For research funded by CDC, FDA, HRSA, and SAMHSA, the researcher will need to work through these agencies to determine the mechanism to apply for a CoC.

5.4. For HHS agencies other than those noted in Section A and B above, the researcher can apply for a CoC through the NIH using the NIH online application system. The NIH may issue a CoC for specific health-related projects using sensitive identifiable information.

5.5. If the research is funded by a non-HHS agency or a non-federally funded agency, NIH may grant a CoC for research projects that are:

5.5.1. Collecting or using identifiable, sensitive information

5.5.2. On a topic that is within the HHS health related research mission

5.5.3. Storing the research information collected or used in the US

5.5.4. And for research that:

5.5.4.1. Meets the definition of human subjects research, including exempt research in which subjects can be identified;
5.5.4.2. Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable;

5.5.4.3. Involves the generation of individual level human genomic data;

5.5.4.4. Involves any other information that might identify a person.

5.6. For non-NIH funded research, in addition to the completed application, the PI will be required to provide documentation of IRB approval and a copy of the informed consent form(s) as it would read if a Certificate of

Confidentiality is obtained (e.g., explains the Certificate, its protections and the circumstances in which voluntary disclosures might be made).

5.7. Both the PI and the IO are required to sign the Certificate application.

5.8. Additional information and detailed instructions may be found on the National Institutes of Health website at: https://humansubjects.nih.gov/coc/index

6. FINAL IRB APPROVAL

6.1. Investigators must provide final approval of the Certificate of Confidentiality to the IRB.

6.2. If the Certificate applies to Creighton only, no additional documentation is required after final submission to the Creighton IRB.

6.3. If the Certificate applies to multiple sites and Creighton is the lead institution, the HRPP staff will maintain accurate records to include but not limited to:

6.3.1. List of all participating sites agreeing to uphold the Certificate of Confidentiality

6.3.2. All approved consent documents from each participating site

6.3.3. All executed authorization agreements

7. CERTIFICATE OF CONFIDENTIALITY

7.1. When research is covered by a certificate of confidentiality, researchers:

7.1.1. May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

7.1.2. May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

7.2. May disclose information only when:

7.2.1. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

7.2.2. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

7.2.3. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

7.2.4. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

7.3. When research is covered by a certificate of confidentiality, researchers must inform participants (by using Creighton IRB informed consent template language within the consent documents) of the protections and limitations of certificates of confidentiality

7.3.1. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.

7.3.2. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect participants consented prior to the change in

authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform participants.

7.4. Researchers conducting NIH-supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other researchers or organizations, regardless of whether or not the research is federally funded, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.