1.0 Purpose:

1.1 The purpose of this policy is to outline the types of research to which a Certificate of Confidentiality (CoC or “Certificate”) may apply, its scope and limitations, and responsibilities of the recipient.

2.0 Definitions:

2.1 **Identifying characteristic -** any characteristic such as name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research subject for which there is at least a very small risk that it could lead to the deduction of the identity of the individual.

2.2 **Sensitive Information -** any information which could be of interest to the court in civil, criminal or other judicial proceedings. Examples include: use of alcohol, illegal drugs or addictive products and illegal behavior.

2.3 **Significant Change -** any major change in the scope or aim of the research protocol, change in personnel having major responsibilities in the project, or change in the drugs being administered (if any) and the persons who will administer.

3.0 Background:

3.1 In accordance with Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, the Secretary of Health and Human Services is required to issue a Certificate of Confidentiality to investigators or institutions engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected, to protect the privacy of individuals who are subjects of such research, if the research is funded wholly or in part by the Federal Government. Also specified are the prohibitions on disclosure of the names of research participants or any information, documents, or biospecimens that contain identifiable sensitive information collected or used in research by an investigator or institution with a Certificate.

3.2 The updated protections and requirements apply to all Certificates, including those issued prior to the law’s enactment.

3.3 The purpose of a CoC is to provide additional protection of the confidentiality of human subjects participating in research that may be collecting sensitive information. A CoC is issued to protect identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants even for civil, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level. Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d).

3.4 CoCs 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.

3.5 Research is considered "sensitive" if it involves the collection of information such as sexual attitudes, preferences, practices; personal use of alcohol, drugs, or other addictive products; or illegal conduct.

3.6 Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).

3.7 Individuals who participate as research subjects in the specified project during any time the Certificate is in effect are protected permanently. If the IRB allows enrollment prior to receipt of the CoC, study subjects are not protected until the CoC is issued. Once the CoC is issued, all information given to researchers is protected including any that was given prior to issuance.

3.8 Applicability:

3.8.1 NIH-funded Research:

3.8.1.1 Any research funded wholly or in part by the NIH that collects or uses identifiable, sensitive information, automatically is deemed to be issued a CoC by NIH as part of the award.

3.8.1.2 Certificates issued in this manner no longer will be issued as a physical document. To document that a study is under CoC protection, investigators may reference the Notice of Award and the NIH Grants Policy Statement.

3.8.2 Non-NIH-funded Research:

3.8.2.1 Research funded by HHS agencies other than NIH, including the CDC and FDA, or research under the authority of the FDA, may request a Certificate from the funding agency.

3.8.2.2 Research that is funded by HHS agencies that do not issue a Certificate, is funded by non-HHS federal agencies, or is funded by non-federal organizations may request a Certificate via the NIH online system application at https://humansubjects.nih.gov/coc/apply . A CoC will be issued for non-federally funded studies at the discretion of NIH.

4.0 Procedure:

4.1 Institutions and their investigators are responsible for determining whether research they conduct is subject to this Policy and therefore issued a Certificate.

4.2 This Policy applies to research supported by NIH if collecting sensitive information, and if the activity is biomedical, behavioral, clinical or other research, and any of the following questions can be answered “yes”:

4.2.1 Does the research involve human subjects as defined in 45 CFR 46?

4.2.2 Is the research collecting or using biospecimens that are identifiable to an individual, or for which there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identify of an individual?

4.2.3 Does the research involve the generation of individual level, human genomic data?

4.2.4 Does the research involve any other information that might identify a person?

4.3 The recipient of a Certificate shall not:

4.3.1 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.

4.3.2 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.

4.4 Personally identifiable information protected by a Certificate may be disclosed only under the following circumstances:

4.4.1 Voluntary disclosure of information by study participants themselves or any disclosure that the study participant has consented to in writing, such as to insurers, employers or other third parties.

4.4.2 Disclosure necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of the individual.

4.4.3 Disclosure by the researcher in compliance with reporting requirements of federal, state, or local laws, such as knowledge of child abuse or communicable disease, provided such intention to report is specified in the informed consent form.

4.4.4 Disclosure for the purpose of other scientific research that is in compliance with applicable federal regulations governing the protection of human subjects in research.

4.5 Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. It is imperative that other appropriate mechanisms and procedures are in place to protect the confidentiality of identifiable private information that is obtained in the proposed research.

4.6 Recipients conducting research subject to this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with federal statutes, regulations, and the terms and conditions of award.

4.7 Recipients are required to ensure that any investigator or institution not funded by NIH or any subrecipient of NIH funding who receives a copy of identifiable, sensitive information protected by a Certificate under this Policy understands that they are also subject to these requirements. This includes any down-stream, secondary users of data or biospecimens.

4.8 Participants of research subject to this Policy, for which informed consent is sought, must be informed of the protections and the limits to protections provided by a Certificate according to this Policy.

4.9 If NIH-funding will or has ended but a study will continue to recruit new research participants without NIH funding, a new CoC will have to be requested for continuity of protections, using the CoC online system. If the NIH funding will or has ended, but the study has completed all enrollment and data collection, there is no need to extend the Certificate.

4.10 For non-NIH funded research for which a CoC is desired, an online application must be submitted. This is generally submitted after the IRB approves the research since IRB approval or approval conditioned upon issuance of a CoC is a prerequisite for issuance. As the informed consent must include language describing the Certificate and any voluntary disclosures specified by the investigator, the investigators must inform the IRB that they are applying for a CoC and have included appropriate language in the informed consent.

4.11 The IRB may determine that a study can commence concurrent with the investigator applying to the appropriate agency (federal or other) for the CoC or it may require that no subjects be enrolled until the investigator has obtained a CoC. This is dependent on the need for the protection offered by the CoC in relation to the type of sensitive information being collected.

4.12 When a CoC must be requested for a non-NIH federally funded study, a non-federally funded study, or for an extension of a CoC previously issued, an application must be submitted to NIH via their online system at https://humansubjects.nih.gov/coc/apply .

4.12.1 The institution's Federal wide-Assurance number will be required (HHC's number is FWA00021932).

4.13 Upon receipt of the CoC, notify the IRB and inform all subjects already enrolled that the protection offered by the CoC is now in effect. Update research records to note that subjects were informed. Subjects who are no longer actively participating in the research may be informed by mail with a copy of the letter retained in the research file.

4.14 Submit an amendment to the IRB along with revised consent documents that are modified to say that the CoC is obtained.

4.15 Protocol amendments must be submitted to the IRB for any changes to an approved protocol prior to implementation.

4.16 The sample language for the consent that follows may be modified as necessary:

4.16.1 "A Certificate of Confidentiality (CoC) has been [applied for/obtained] from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information."

4.16.2 "This protection will not be in effect until we have obtained the CoC, which may take a few months. You will be informed when the CoC has been received."

4.16.3 "If you decide to take part in this research study, you will be required to give us information about your [substance use/genetic information/criminal behavior, etc]. Any of your identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission, with the following exceptions: We will disclose to appropriate authorities reportable diseases, known or suspected abuse of a child or elderly person, or if you become a danger to yourself or others."

4.16.4 "The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA)."

4.16.5 "You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information."

4.16.6 "When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained."

5.0 Documentation:

1.1 The HHC HRPP office maintains all records related to the implementation of this policy, electronic communications, and notifications to investigators, funding or regulatory agencies, etc.

1.2 Records are archived for a period of at least six (6) years following the termination or completion of the research activities.

6.0 References:

6.1 Public Health Service Act §301(d), 42 U.S.C. §241(d): *Protection of privacy of individuals who are research subjects*

6.2 45 CFR 46.111(a)(7)

6.3 NOT-OD-17-109 NIH Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality, September 7, 2017

6.4 NIH Certificates of Confidentiality website at https://humansubjects.nih.gov/coc/index

6.5 U.S. Department of Health and Human Services, Health Resources and Services Administration application information: http://www.hrsa.gov/humansubjects/certificates.htm

6.6 Institutional Review Board Management and Function, Bankert, E. A., Amdur, R. J., 2nd Edition, 2006

7.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	PMJ/EHP	7/1/11	Conversion to new policy template; significant expansion of policy
02	SMH	3/15/20	Significant revision to reflect change in NIH policy in response to new requirements included in the 21st Century Cures Act

Element II.3.E.