NIH Certificate of Confidentiality (CoC) Policy

Effective Date: October 1, 2017

Summary: Policy applies to all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, or other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information for certain covered research activities. See NIH COC Kiosk for more information.

Topic	Summary	Principal Investigator Action	IRB or ORC Action	Institution Action
Issuance of a Certificate of Confidentiality	**NIH funded projects subject to the policy commenced or ongoing on or between December 13, 2016 and September 30, 2017** will be deemed to be issued a CoC. Actual certificates will NOT be issued.	PI submits a modification to the IRB protocol updating the informed consent for any project open for participant enrollment. The informed consent would include protections and limitations of the CoC.	ORC will review active IRB protocols to identify projects subject to the policy and inform IRB. Upon IRB concurrence, PI will be notified. Following submission by PI, IRB will review modification. ORC documents CoC in protocol file and notifies OSP.	Agreements (subawards, DUA, DTA, MTA, etc.) must include a statement that the human data/specimens are subject to a CoC.
	NIH funded projects subject to the policy commenced on or after October 1, 2017 will be deemed to be issued a CoC. Actual certificates will NOT be issued. CoC will become a term and condition of new and non-competing awards.	PI should reference CoC if applicable as precaution in protocol and include appropriate CoC language (protections and limitations) in the proposed informed consent.	During review of IRB protocol, IRB will determine if project meets CoC policy requirements. IRB will review informed consent for appropriate language. ORC documents CoC in protocol file and notifies OSP.	
	Non-NIH funded projects commenced on or after October 1, 2017 may be issued written certificates from NIH following an online application process.	**No change** – Following ORC review, PI submits application to appropriate NIH institute via online system with copy of IRB approved consent describing protections and limitations and assurance letter signed by PI and Institutional Official. When issued, PI provides copy of CoC to ORC for IRB protocol file.	**No change** - During review of IRB protocol, IRB will determine if project needs a CoC. ORC reviews draft CoC application and facilitates signature of Institutional Official. ORC documents CoC in protocol file with copy of CoC provided by PI, and notifies OSP if applicable.	
Identifiable, sensitive information	Information about an individual gathered or used during the course of research where: 1. An individual is identified or 2. There is at least a very small risk that other information could be used to deduce the identity of the individual	PI submits IRB protocol with sufficient detail to determine if identifiable, sensitive information will be collected or used.	IRB determines if IRB protocol involves collection or use of identifiable, sensitive information.	No action needed.

Created by: AU Office of Research Compliance – 10.11.2017

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Topic	Summary	Principal Investigator Action	IRB or ORC Action	Institution Action
Covered Research	1. Human Subject Research as defined in (45 CFR 46) including exempt research that is not anonymous 2. Involves collection or use of biospecimens that are identifiable or at least a very small risk that other information could be used to deduce the identity of the individual 3. Involves the generation of individual level, human genomic data from biospecimens or use of such data 4. Any other research involving information about an individual with at least a very small risk of deducing the identity of an individual	PI submits IRB protocol with sufficient detail to determine if project involves covered research.	IRB determines if IRB protocol involves covered research.	No action needed.
Certificate Requirements	1. For legal proceedings, shall not disclose name, information, document, or biospecimen that contains identifiable, sensitive information created or compiled for the purpose of the research without individual's consent 2. Outside of the research team, shall not disclose name, information, document, or biospecimen that contains identifiable, sensitive information about an individual created or compiled for the purposes of research	1. PI along with institution will use the certificate to deny disclosure of information. 2. PI will not disclose information unless it is a permitted disclosure identified below.	1. No action needed. 2. Not applicable.	1. Institution along with PI will use the certificate to deny disclosure of information. 2. Not applicable
Permitted Disclosures	1. Required by Federal, State, or local laws excluding legal proceedings. (ex. child abuse or communicable disease) 2. Necessary for medical treatment of the individual and with individual's consent 3. With the consent of the individual 4. For purposes of other scientific research in compliance with Human Research Regulations	PI files event notice with IRB prior to disclosure 1. PI may disclose per law. 2. PI may disclose for medical treatment with consent 3. PI may disclose with consent 4. PI may disclose for research purposes with IRB approval and notice to recipient of COC	IRB reviews event notice and responds to PI. ORC files event notice and IRB comments with approved IRB protocol.	Item 4:Agreements (subawards, DUA, DTA, MTA, etc.) must include a statement that the data/specimens are subject to a CoC.