**GUIDANCE 2**

**CERTIFICATE OF CONFIDENTIALITY GUIDANCE**

1. **Obtaining a “Certificate of Confidentiality" to Protect Against Compulsory Disclosure of Confidential Information**

In certain studies, protection against compelled disclosure of identifying information about research subjects may be required. In such circumstances, the NIH/HSS may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, and/or the use and effect of alcohol and/or other psychoactive drugs) to protect the privacy of subjects by withholding from all persons not connected with the conduct of the research their names or other identifying characteristic and other information derived from the research. Persons so authorized to protect the privacy of subjects may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. This protection is given in the form of “Certificate of Confidentiality” issued for a particular project upon application. The guidance for Certificate of Confidentiality and the blank form is provided in the following website: http://www.hhs.gov/ohrp/policy/certconf.pdf. Prior IRB approval is mandatory for obtaining this certificate. . For further information and Policy go to: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>.

1. **Purpose**

Certificate of Confidentiality (CoC) protects 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 a few other specific situations. NIH funded researchers are automatically issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research

1. **Obtaining Certification of Confidentiality for NIH and Other HHS Agencies (Non-NIH).**

Effective October 1, 2017, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting and using identifiable, sensitive information is automatically issued a CoC. Awardees no longer have to apply for CoC. This policy applies to NIH funded grants, Cooperative Agreements, R & D contracts, Other Transaction Awards and NIH own intramural research. If the NIH-funded research project meets any one of the criteria listed below then such research data is automatically protected by a CoC from NIH.

Several non-NIH HHS agencies, including CDC, FDA, HRSA, and SAMHSA, issue Certificates of Confidentiality (CoCs). If your research is funded by one of these agencies or is operating under the authority of the FDA, please contact the Certificate Coordinators at the funding agency to determine how to obtain a CoC.

If research is funded by an HHS agency other than NIH, CDC, FDA, HRSA or SAMHSA, that do not issue CoCs Health-related research you may request a Certificate of Confidentiality for specific health-related projects using sensitive, identifiable information, using the NIH online application system using the following link: <https://humansubjects.nih.gov/coc/apply>. NIH issues CoCs on behalf of these agencies.

Please direct your CoC request to the NIH Institute or Center (IC) that supports similar research. Please verify that you have the correct NIH IC with the appropriate IC coordinator at https://humansubjects.nih.gov/coc/contacts. before submitting an application. If you are unsure about which IC is most appropriate for your research topic, you may contact the NIH Central Coordinator at:

**NIH-COC-Coordinator@mail.nih.gov****.**

1. **Obtaining Certification of Confidentiality for NON-NIH-HHS Federal Funders.**

If research is funded by a non-HHS Federal Agency other than HHS, you may request a Certificate of Confidentiality for a specific project that involves sensitive, identifiable information, using the NIH online application system at <https://humansubjects.nih.gov/coc/apply>. Please direct your CoC request to the NIH Institute or Center (IC) that supports similar research. However, please verify this with the appropriate IC coordinator before submitting an application. If you are unsure about which IC is most appropriate for your research topic, you may contact the NIH Central Coordinator at NIH-COC-Coordinator@mail.nih.gov. Issuance of a CoC is at the discretion of NIH. Such CoCs are issued for research projects that are collecting or using identifiable, sensitive information are issued such as:

**•** Meets the definition of human subjects research, including exempt research in which subjects can be identified

• Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable

• Involves the generation of individual level human genomic data

• Involves any other information that might identify a person

* On a topic that is within the HHS health-related research mission and storing the research information collected or used in the US.

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