HARVARD UNIVERSITY

GUIDANCE FOR ISSUING CERTIFICATES OF CONFIDENTIALITY

Guidance Title:	NIH CoC Policy Implementation
Responsible Office:	OVPR
Effective Date:	June 1, 2018
Revision Date:	

NIH CoC POLICY STATEMENT

The NIH Policy for Issuing Certificates of Confidentiality ("NIH CoC Policy") applies to all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH that was commenced or ongoing on or after December 13, 2016, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information[i]. This Policy will be included in the NIH Grants Policy statement as a standard term and condition of award effective October 1, 2017 for new and non-competing awards. The Policy also acknowledges that the NIH will continue to consider request for Certificates for non-federally funded research in which identifiable, sensitive information is collected or used.

Institutions and their investigators are responsible for determining whether research they conduct is subject to this Policy and therefore issued a Certificate. Certificates issued in this manner will not be issued as a separate document.

This policy and procedures guidance outlines the responsibilities of the Harvard investigator, the relevant Grants and Contracts Office, and the relevant IRB in identifying the need for Certificates of Confidentiality and ensuring compliance with the NIH CoC Policy.

NIH CoC POLICY APPLICABILITY

The NIH CoC Policy applies to all Harvard investigators awarded NIH-funding for research in which identifiable, sensitive information is collected or used. This includes:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects, including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving 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;
- Research that involves 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 as defined in the Federal Policy for the Protection of Human Subjects; or
- 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, as defined in subsection 301(d) of the Public Health Service Act.

The NIH CoC Policy also applies to the relevant Grants and Contracts Office and IRB.

DEFINITIONS

NIH POLICY FOR ISSUING CERTIFICATES OF CONFIDENTIALITY (NIH CoC Policy): The policy that automates the issuance of Certificates of Confidentiality as a standard term and condition for any new and non-competing NIH award effective October 1, 2017. Other Department of Health and Human Services (HHS) agencies issue CoCs to investigators they fund. Investigators not funded by HHS can apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research. Further information on the NIH CoC Policy and/or how to obtain a CoC for non-NIH funded research can be found at https://humansubjects.nih.gov/coc/index

Certificates of Confidentiality (CoC; Certificate): 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 a few other specific situations.

Relevant IRB: The Harvard IRB that reviews human subjects research proposals from the PI's School. The Harvard University Area IRB, the Committee on the Use of Human Subjects (CUHS), serves as the Institutional Review Board for Schools located on the Cambridge and Allston campuses at Harvard. The Harvard Longwood Medical Area (LMA) IRB serves as the Institutional Review Board for the Harvard T.H. Chan School of Public Health (HSPH), Harvard Medical School (HMS), and Harvard School of Dental Medicine (HSDM). The submitting office for the Harvard LMA IRB is the Office of Human Research Administration (OHRA) at Harvard Longwood Medical Area.

Relevant Grants and Contracts Office: The Harvard Grants and Contracts Office that reviews sponsored proposals from the PI's School. The Harvard University Office for Sponsored Programs (OSP) serves as the Grants and Contracts Office for Schools located on the Cambridge and Allston campuses at Harvard. The Harvard T.H. Chan School of Public Health Sponsored Programs Administration serves as the Grants and Contracts Office for the Harvard Chan School. The Harvard Faculty of Medicine Sponsored Programs Administration serves as the Grants and Contracts Office for the Harvard Medical School (HMS) and Harvard School of Dental Medicine (HSDM).

PROCEDURES

All new and non-competing NIH-funded research awards primed at Harvard are automatically issued a Certificate of Confidentiality. The responsibilities of key stakeholders are outlined to follow.

Relevant Grants and Contracts Office will notify and ensure that any subrecipient receiving funds to carry out part of the NIH award understand they are also subject to subsection 301(d) of the Public Health Service Act.

Harvard investigator is responsible for (a) submitting a complete application to the relevant IRB, when the research award describes human subjects research as defined in the Federal Policy for the Protection of Human Subjects and (b) informing research participants of the protections and the limitations of the Certificate. Further information on how to prepare an IRB submission, including template disclosure language, can be found by visiting the website for the relevant IRB.

Relevant IRB is responsible for conducting review according to Federal Policy for the Protection of Human Subjects. The IRB will indicate the issuance of a CoC in their system of record, *Electronic Submission, Tracking, and Reporting (ESTR)* for all NIH-funded research, and ensure that research participants are informed of the protections and limitations of the Certificate in applicable IRB-approved

consent documents.

CONTACTS AND SUBJECT MATTER EXPERTS

The Office of the Vice Provost for Research
http:///www.vpr.harvard.edu

Longwood Medical Area IRB
http://www.hsph.harvard.edu/ohra/irb-operations/

University Area IRB
http://cuhs.harvard.edu/

Harvard Faculty of Medicine Sponsored Programs Administration
https://hlcra.harvard.edu/

Harvard T.H. Chan School of Public Health Sponsored Programs Administration
https://www.hsph.harvard.edu/financial-services/sponsored-programs-administration/

Harvard University Office for Sponsored Programs
https://osp.finance.harvard.edu/

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[i] For the purposes of this Policy, consistent with subsection 301(d) of the Public Health Service Act (42 U.S.C 241), the term "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: 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 an individual.