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Owner Stephanie
Madrigal: Dir Clin
Rsrch Admin/Ops
Category/
Chapter Compliance
Applicability OSF All Operating
Units
Areas/Depts Research

Certificate of Confidentiality in Research

DEFINITIONS:

1. **Certificates of Confidentiality (CoC):** protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research.
2. **Human Subject:** a living individual who is or becomes a participant in Research, and about whom an investigator in the conduct of Research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
3. **Informed Consent for Research (Informed Consent):** the process by which investigators respect autonomy and honor human dignity by ensuring that prospective Human Subjects, to the degree that they are capable, or their legally authorized representative, be given the opportunity to choose whether or not to participate in Research and document appropriately their choice after receiving all relevant information about the Research.
4. **OSF Institutional Official:** an individual authorized to execute CoC applications and assumes on behalf of OSF the obligations imposed by assurances as well as obligations imposed by the Federal laws, regulations, requirements and other conditions that apply to applications for and issuances of CoCs.
5. **Research:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute Research whether or not they are conducted or supported under a program that is considered Research for other purposes.
6. **Identifiable Sensitive Information:** 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.

PURPOSE:

1. To comply with the 21st Century Cures Act, subsection 301(d) of the Public Health Service Act and the National Institutes of Health (NIH) Policy for Issuing Certificates of Confidentiality.
2. This Policy applies to all OSF Mission Partners engaged in Research for which a Certificate of Confidentiality has been issued.
3. This Policy applies to all OSF biomedical, behavioral, clinical, or other Research funded wholly or in part by the National Institutes of Health (NIH) or other federal agencies, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program.
4. This policy also applies to the non-federally funded Research for which NIH has issued a CoC.

POLICY:

1. OSF protects the privacy of individuals who are Human Subjects of NIH or other federally funded research in which identifiable, sensitive information is used in the manner described in this Policy when that research was commenced or ongoing on or after December 13, 2016 and is deemed to be issued a CoC by the NIH or requires one under Section 2012 of the 21st Century Cures Act.
2. OSF investigators conducting non-federally funded research with identifiable, sensitive information, are responsible for determining whether a CoC for that specific project should be requested from the NIH or another Public Health Services agency delegated with the authority to issue a CoC.
 - a. OSF investigators who wish to request a CoC for non-federally funded research must notify Research Administration who will assist in completing the application.
 - b. Research Administration is responsible for ensuring required assurance language is captured in the CoC application and in obtaining the required Institutional Official signature.
3. OSF Mission Partners may never disclose identifiable, sensitive information under a CoC without first contacting and obtaining clearance from Research Administration and OSF Legal Counsel.
4. OSF Mission Partners do not provide identifiable, sensitive information protected by a CoC in response to a subpoena. OSF Mission Partners consult OSF Legal and Research Administration in the event they are presented with a subpoena.
5. Research information protected by a CoC and all copies thereof are protected in perpetuity and are subject to the protections and the disclosure requirements noted above.

PROCESS:

Identifying Research in which Identifiable, Sensitive Information is used

OSF considers the following types of Human Subjects Research (including research deemed exempt by an IRB or other appropriate institutional review) to be research in which identifiable, sensitive information is used in that it entails:

1. the collection of identifiable information;
2. 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, and other available data sources could be used to deduce the identity of an individual;
3. the generation and/or use of individual level, human genomic data from biospecimens; or
4. information about an individual for which there is at least a very small risk that some combination of the information and other available data sources could be used to deduce the identity of an individual.

Determining whether or not federally-funded Research is deemed to have been issued a CoC

1. OSFHC Principal Investigators may ask the following questions to determine whether a CoC has been issued by the NIH or another federal agency when conducting research supported in any manner by the federal government:
 - Is the activity biomedical, behavioral, clinical, or other research?
2. If the answer to this question is no, then a CoC is not automatically issued by a federal agency. If the answer is yes, then investigators answer the following questions:
 - a. Does the research involve Human Subjects?
 - b. Does the research involve collecting or using biospecimens that are identifiable to an individual as part of the research?
 - c. If so, is there any risk that some combination of the biospecimen and other available data sources could be used to deduce the identity of an individual?
 - d. Does the research involve the generation of individual level, human genomic data?
3. If the answer to any one of these questions is yes, then the requirement for issuance of a CoC applies to the research and the Investigator shall inform participants about the protections and limitations of the Certificate for any research in which informed consent is sought, including when documentation of consent has been waived, such as oral consent or opt in methods.
4. OSFHC Research Administration may contact the appropriate federal funding agency (FDA, other HHS agencies) in the event clarification on a study's CoC status is needed.

REFERENCES:

1. 21st Century Cures Act, Section 2012. (2016). <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>.

2. NIH Policy for Issuing Certificates of Confidentiality. (2017). <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>.
3. Public Health Service Act (42 U.S.C 241), Subsection 301(d). <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section241&num=0&edition=prelim>.
4. 45 CFR 46 Protection of Human Subjects. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>.
5. NIH Grants & Funding: Certificate of Confidentiality. <https://grants.nih.gov/policy/humansubjects/coc.htm>.

This policy is in effect for OSF Healthcare System, OSF Healthcare Foundation and all OSF Healthcare System subsidiaries and affiliates, except as limited in the header or body of this policy. For purposes of this policy, the terms "subsidiaries" and "affiliates" mean facilities or entities wholly owned or wholly controlled by OSF Healthcare System. The hospitals covered by this policy are:

		Name as listed with Medicare:
X	OSF St. Mary Medical Center	ST MARY MEDICAL CENTER
X	OSF Saint Francis Medical Center	SAINT FRANCIS MEDICAL CENTER
X	OSF Saint James – John W. Albrecht Medical Center	SAINT JAMES HOSPITAL
X	OSF St. Joseph Medical Center	ST JOSEPH MEDICAL CENTER
X	OSF Saint Anthony's Health Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Anthony Medical Center	SAINT ANTHONY MEDICAL CENTER
X	OSF St. Francis Hospital & Medical Group	ST FRANCIS HOSPITAL
X	OSF Holy Family Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Elizabeth Medical Center	Ottawa Regional Hospital & Healthcare Center
X	OSF Saint Luke Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Paul Medical Center	Mendota Community Hospital
X	OSF Heart of Mary Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Sacred Heart Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Little Company of Mary Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Clare Medical Center	OSF HEALTHCARE SYSTEM

Approval Signatures

Step Description	Approver	Date
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Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	8/28/2023
Executive Steering Committee	Amy Olsen: Coord Clinical Policy RN	8/24/2023
President, OSF Healthcare	Sister Diane Marie: President-Sister	7/28/2023
System Chief Medical Officer	Ralph Velazquez: System CMO	7/27/2023
Regulatory/Policies Council	Michael Theisen: Resource Document Spec [AO]	7/19/2023
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	7/10/2023
Notification	Heidi Vermillion: Coord Research Admin	7/10/2023

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