

Certificates of Confidentiality and 21st Century Cures: Part I

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Objectives

- Describe the purpose of a Certificate of Confidentiality (CoC)
- Identify key historical events in the evolution of CoCs
- Describe VHA Handbook 1200.05 Requirements for VA studies issued CoCs
- Describe legislation changes to CoCs based upon Section 2012 of the 21st Century Cures Act
- Identify some of the key requirements in NIH's implementation of Section 2012 of the 21st Century Cures Act

What is a Certificate of Confidentiality?

- Issued by several Department of Health and Human Services agencies:
  - The National Institute of Health
  - U.S. Food and Drug Administration
- Prevents investigators and institutions from being forced or compelled to release individually identifiable information or identifiable characteristics of research subjects.
- Allows the holder (investigator and institution) to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
- Issued in accordance with Section 301(d) of the Public Health Service (PHS) Act 42 U.S.C. 241(d).

Why are Certificates of Confidentiality Applied for in Human Subjects Research?

- Developed to encourage participation in research by granting protections to a subject divulging possible compromising (sensitive) information.
- Does not exempt investigators from performing ethical research.
- Cannot be used to prevent disclosure to state or local authorities of child abuse and neglect, harm to self or others.
- Does not prevent self-disclosure (voluntary).

History of Certificates - 1970-up to December of 2016

- **1970: PHS Act, subsection 303(a)**
  - Permitted Secretary to authorize researchers conducting research on the use and effect of psychoactive drugs to withhold names or other identifying characteristics of research subjects in civil, criminal, legislative, administrative, or other proceedings
- **1979: 42 Part 2a regulations**
  - Expanded the scope of the protection to include research on mental health and the use of alcohol.
  - Established procedures for researchers to apply for the protection
  - Named the protection "Certificates of Confidentiality"
- **1988: Amendment to PHS Act, subsection 301(d)**
  - Expanded the authority to include "biomedical, behavioral, clinical, or other research (including mental health)"

- ***Note***: *NIH presented a timeline of the legislation and policies that authorized and expanded the scope and applicability of certificates of confidentiality to the Secretary's Advisory Committee on Human Research Protections (SACHRP). The complete timeline can be found in the handout provided for this presentation.*

How Have the Protections of the Certificate of Confidentiality been Used?

- Protection with Freedom of Information (FOIA) Requests for individual line data
- Protection against disclosure of subjects' names to outside requesting parties
- *People v. Newman*, 298 N.E.2d 651(N.Y. 1973)
- VA Cooperative Studies Program #519: Integrating tobacco cessation into mental health care for posttraumatic stress disorder: a randomized controlled trial

21st Century Cures Act

21st Century Cures Act

- Enacted December 13, 2016
- Amended Subsection (d) of Section 301 of the Public Health Service Act (42 USC 241)
- Section 2012: Privacy Protection for Human Research Subjects
  - Revises provisions regarding disclosure by researchers of identifiable, sensitive information of research subjects
- Section 2013: Protection of Identifiable Sensitive Information
  - Allows the Secretary of Health and Human Services (HHS) to exempt identifiable information collected for biomedical research from disclosure under the Freedom of Information Act

Sec. 2012 Privacy Protection for Human Research Subjects

- **Requires** that the Secretary of HHS, in coordination with other agencies issue a Certificate of Confidentiality to
  - persons engaged in biomedical, behavioral, clinical , or other research in which **identifiable, sensitive information** is collected and
  - The research is funded wholly or in part by the Federal Government
- Permits the Secretary of HHS to issue Certificates by application, to persons engaged in such research that is not funded by the Federal Government
- All copies of **identifiable, sensitive information** collected are protected under a certificate of confidentiality in perpetuity
- **Identifiable, sensitive information** protected by a Certificate is immune from the legal process and is not admissible as evidence without the individual's consent
- Nothing in the Act limits an individual's access to information about him/herself collected during their participation in the research

Prohibited Disclosures

Prohibits the disclosure of the name or any information, document, or biospecimen that contains **identifiable, sensitive information** about an individual that was created or compiled for research purposes to any other individual not connected to the research, except in the following cases:

- Disclosures required by Federal, State, or local laws except for cases involving civil, criminal, administrative, legislative, or other proceedings.
- Disclosures necessary for medical treatment and made with the individual's consent.
- Disclosures made with the individual's consent.
- Disclosures made for other research purposes in compliance with applicable Federal human subjects regulations.

Identifiable Sensitive Information

Defined as information that is about an individual and that is gathered or used during the course of research and

- through which an individual is identified; or
- 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

Identifiable Sensitive Information

- Definition differs significantly for purposes of the CoC than prior to 21st Century Cures
- Emphasis is on identifiable vs. sensitive

Examples of Research Collecting or Using Identifiable, Sensitive Information

- Research in which identifiable, sensitive information is collected or used, including research that
  - 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

VHA Handbook 1200.5 Requirements: Certificates of Confidentiality

VHA Handbook 1200.05 Requirements

- VHA Handbook 1200.05 currently does not mandate the issuance of a Certificate of Confidentiality for particular types of research.
  - 21st Century Cures Act changes that with its definition of applicability
- Emphasis is now on whether the information is identifiable
  - **Identifiable, sensitive information** is information that is about an individual and that is gathered or used during the course of research and
  - through which an individual is identified; or
  - 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

ORD Documentation for VA Studies Issued a Certificate of Confidentiality: Paragraph 21(d) of VHA Handbook 1200.05

- VA studies with a CoC that do not involve a medical intervention:
  - No annotation may be made in the health record, however subject safety remains a paramount concern
- For VA studies with a CoC that involve a medical intervention:
  - Progress note entry should indicate that an individual has been enrolled in a research study;
  - Health record documentation includes any details that would affect the subject's clinical care; and
  - Health record documentation includes name and contact information for the investigator conducting the study.
- The IRB is not required to "classify" studies as medical vs. non-medical intervention. The Principal Investigator is responsible for the study and determining what is appropriate for inclusion in the medical record.

VA Studies with a Certificate of Confidentiality that Involve a Medical Intervention

- Progress note entry should indicate that an individual has been enrolled in a research study:
  - Avoid specifying the name of the study;
  - Should not include content that would allow someone outside of the research study an ability to know which specific study that patient/subject has been consented
- Subjects' informed consent forms and written HIPAA authorizations are not to be included in the subject's health record.

VA Studies with a Certificate of Confidentiality that Involve a Medical Intervention

Health record documentation includes any details that would affect the subject's clinical care:

- Patient safety is always first priority.
- Principal Investigator (PI) is responsible to make the determination of what should be placed in the subject's health record
- ORD does not prescribe the number of details that can be included in the health record; the PI is responsible for identifying what research information would be needed in the subject's VHA Health Record to ensure appropriate clinical care of the subject who is also a patient.
- ORD cannot specify what the exact content or phrasing can include because it is study specific – it is a PI responsibility.
- VA Form 10-9012 will always be included in the subject's VHA Medical Record if a VA Form 10-9012 is required.

Overview of NIH Implementation of Section 2012

Presented to SACHRP on October 18, 2017

by Taunton Paine, MA, Science Policy Analyst, Office of Science Policy, National Institutes of Health

Implementation Requirement

- The Secretary of HHS must take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with these new requirements
- Certificates issued prior to the date of enactment of the 21st Century Cures Act (December 13, 2016) were converted to the new authority 180 days after enactment
- NIH issued a Notice of Changes (NOT-OD-17-109) to NIH Policy for Issuing Certificates of Confidentiality on 09/07/2017 with an effective date of 10/1/2017
  - (NOT-OD-17-109) located at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Considerations for Developing NIH Policy on Certificates of Confidentiality

- Scope of the new authority requires Certificates to be issued more broadly than before.
- It would not be practical to require applications for Certificates for NIH-funded research to be reviewed by NIH.
- NIH has longstanding policy and guidance for Certificates.

Issuance of Certificates in the NIH Policy

- Under NIH Policy, institutions are responsible for determining whether a research project is within the scope of the Policy
  - The Policy deems such projects to be issued a Certificate by NIH.
  - Investigators and institutions are best positioned to understand the nature of their research and associated privacy risks.

NIH Policy on Certificates of Confidentiality: Scope

The Policy provides examples of research that NIH generally considers to include "identifiable, sensitive information" based on the statutory definition:

1. Human subjects research unless exempt because it is not readily identifiable;
2. Research involving human biospecimens for which there is a "very small risk" that the identity of the participant could be deduced;
3. Research involving human genomic data; and
4. Any other research involving identifiable, sensitive information as defined by the statute.

NIH Policy on Certificates of Confidentiality: Subawards

- Subrecipients of NIH awards receiving funds to carry out part of an award involving information protected by a Certificate are subject to the protections of the Certificate.
- Holders of Certificates are responsible for informing subrecipients.

NIH Policy on Certificates of Confidentiality: Informed Consent

- The NIH Policy expects that if informed consent is obtained, investigators will inform prospective participants of the protections and limitations
  - Institutions are provided flexibility in how best to inform participants—need not be through informed consent as described by 45 CFR 46
  - NIH does not expect that participants who have already provided consent be re-consented or re-contacted
- Sample consent language is provided on the NIH website at https://humansubjects.nih.gov/coc/suggested-consent-language

NIH Policy on Certificates of Confidentiality: Data Sharing

- Disclosure of information covered by a Certificate is permitted for other research "in compliance with applicable Federal regulations" for human subjects protections
  - NIH does not expect recipients using this provision to follow any regulation that they would not otherwise be required to follow.
- NIH Policy expects investigators that share information covered by a Certificate for research not funded by NIH to inform recipients they are also subject to the protections of the Certificate.

NIH Policy on Certificates of Confidentiality: Summary Results

- NIH guidance states that in general, NIH does not consider "summary results" to meet the definition of identifiable, sensitive information
  - Summary results are not typically "about" an individual per the statutory definition of identifiable, sensitive information;
  - Summary results typically pose less than a very small risk that the identity of an individual could be deduced.

Implementation at other Federal Departments and Agencies

- Section 2012 requires Certificates be issued for all federally-funded research
  - Also requires that the Secretary coordinate with other agencies in the development of appropriate policies
- NIH has provided Certificates on request for research supported by other Departments and agencies (e.g., VA, DoD, NSF)
- NIH will continue to provide Certificates for research funded by other Departments and agencies within the NIH mission using the existing system but will not require an assurance or a copy of the informed consent
- NIH's implementation will serve as a pilot that will inform further implementation efforts

NIH Policy on Certificates of Confidentiality: Effective Dates

- NIH Policy states that on October 1, 2017 Certificates were issued to applicable research that was ongoing as of December 13, 2016
- NIH Policy became effective October 1, 2017 and compliance will be a term and condition for new and non-competing awards funded on or after the effective date

Obtaining Certificates of Confidentiality

- NIH awardees no longer have to apply for a CoC
  - All ongoing or new research funded by NIH as of December 13, 2016 that collects or uses identifiable sensitive information is automatically issued a CoC at time of award.
- Research funded by other HHS agencies or operating under the authority of the FDA should contact the CoC Coordinators at the funding agency for direction
- NIH will continue to accept applications for CoCs from recipients of non-federally funded research that meet NIH policy for issuing certificates

VA Implications

- What is currently required for VA studies funded by NIH?
  - NIH policy applies if it involves identifiable, sensitive information.
- What if my study is funded by ORD or other federally funded?
  - Seeking clarification from NIH
- What about studies where the informed consent form is currently being placed in the subject's medical record (studies where a COC was previously not sought)? What are the requirements now?
  - For NIH-funded
  - For other federally funded
- When will you have more information for us on how to implement the new policy?

Questions?