1. PURPOSE

1.1. This guidance outlines answers to common questions about Certificates of Confidentiality (CoC) issued by the National Institute of Health (NIH).

2. GUIDANCE

2.1. What is a Certificate of Confidentiality and which studies are required to have one?
A federal law allows the NIH and other federal agencies to issue Certificates of Confidentiality (CoCs) to persons engaged in sensitive biomedical, behavioral, clinical, or other research, for the purpose of protecting the privacy of research subjects. The authorizing federal law states that anyone who receives a CoC may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify the subjects of research covered by the CoC. Thus, CoCs help minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Certificates will be automatically deemed to be issued to recipients for NIH-funded research that meets the scope of the NIH Policy.

2.2 What information is protected by a Certificate?
Certificates protect names or any information, documents, or biospecimens containing identifiable, sensitive information related to a research participant. This is defined as "covered information" in the policy. In addition, if there is at least a very small risk that information, documents, or biospecimens can be combined with other available data sources to determine the identity of an individual, then they are protected by the certificate.

2.3 What is meant by identifiable, sensitive information?
Identifiable, sensitive information is information about an individual, gathered or used during the course of biomedical, behavioral, clinical, or other research, through which the individual is identified, or 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 determine the identity of an individual. The policy defines this as "covered information."

Identifiable, sensitive information includes, but is not limited to, name, address, social security or other identifying number; and fingerprints, voiceprints, photographs, genetic information, tissue samples, or data fields that when used in combination with other information may lead to identification of an individual.

2.3.1 What if I intend to share identifiable, sensitive information?
Investigators conducting NIH-supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other investigators or organizations, regardless of whether the research is federally funded, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

Investigators conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other investigators or organizations, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

2.4 Can you give some examples of sensitive research topics for studies that may be eligible for a Certificate?

The following is an illustrative but not exhaustive list of sensitive research topic areas:

- Research on HIV, AIDS, and other STDs;
- Studies that collect information on sexual attitudes, preferences, or practices;
- Studies on the use of alcohol, drugs, or other addictive products;
- Studies that collect information on illegal conduct;
- Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community;
- Research involving information that might lead to social stigmatization or discrimination if it were disclosed;
- Research on participants' psychological wellbeing or mental health;
- Genetic studies, including those that collect and store biological samples for future use;
- Research on behavioral interventions and epidemiologic studies.

2.5 What should I do if I receive a subpoena or other demands for research information if I have a COC?

If you receive a subpoena or other demand for information, contact the AdventHealth General Counsel for your location for assistance.

2.6 Are investigators who conduct secondary research with information protected by a Certificate required to apply for a Certificate?

No. Information protected by a Certificate and all copies are subject to the protections of the Certificate in perpetuity. Therefore, if a secondary researcher receives information protected by a Certificate, the secondary researcher is required to uphold the protections of the Certificates. NIH expects that recipients of a Certificate will inform secondary researchers when information disclosed to them is protected by a Certificate.

NIH-Funded Research:

2.7 If the study is funded by NIH, do I need to apply for a Certificate?

No. Eligible research studies that are funded by NIH are automatically deemed to be issued a certificate under the NIH Policy on Certificates of Confidentiality.

Examples of research automatically covered by a certificate of confidentiality:

- Biomedical, behavioral, clinical, or other research, including exempt research, except where 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.
- 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.
- 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.

- 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.

2.8 What NIH-funded research is automatically issued a Certificate?

Effective October 1, 2017, certificates are automatically deemed to be issued by NIH for all research covered by the policy that was commenced or ongoing on or after December 13, 2016. ***You will not receive a separate notice or certificate for NIH-funded research that meets the Certificate qualifications. It is up to the investigator and local institution to determine if the criteria are met.***

- For studies that were previously issued a Certificate, and subjects were notified of the protections provided by that Certificate, NIH does not expect subjects to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform subjects.
- If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer actively participating in the study, NIH does not expect subjects consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that subjects who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform subjects.

2.9 What are the criteria for the automatically issued Certificate?

To determine if this Policy applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a 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?
- Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then this Policy will apply.

2.10 How does the investigator inform research subjects of the protections and limitations of a Certificate of Confidentiality?

The consent form must include the IRB standard Certificate of Confidentiality template language. This required language is provided in the AH IRB Informed Consent Template:

Certificate of Confidentiality from the National Institutes of Health

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information,

documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[*Use the following language as applicable.*] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by **[*THE AGENCY*]** which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.*] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [*list what will be reported, such as child abuse and neglect, or harm to self or others*].

[*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.*] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document **[*restate what will be disclosed, such as including research data in the medical record*]**.

2.11 Are there any exceptions to the protections offered under a Certificate of Confidentiality?

Yes. Certificates do not protect research subjects against the voluntary disclosure by the investigator of identifying information. For example, disclosure of matters such as suspected child abuse, reportable communicable diseases, or subjects' threatened violence to self or others are not protected under a Certificate of Confidentiality.

Also, certain NIH institutes insist that federal agency rights to audit research records are not eliminated by Certificates. The consent form for a research study must inform study subjects that even when a Certificate of Confidentiality has been obtained, the investigator will make certain disclosures.

Finally, if a subject requests in writing that his or her information be disclosed, the researcher cannot refuse to release the information.

2.12 Does the Certificate of Confidentiality for federally funded studies have an expiration date?

No. Certificates of Confidentiality automatically cover research activities and do not need to be extended or amended while the research remains funded by NIH. If there is a lapse in funding for any reason, the Certificate of Confidentiality protections might not apply to information collected during that time period. However, Certificate protections continue for the duration of a no-cost extension.

Non-Federally Funded Studies:

2.12 Are Certificates of Confidentiality limited to federally-funded studies?
No, this protection is not limited to federally funded research. Certificates may be issued to cover any study that the issuing federal agency deems to be appropriate. Generally, research will be considered "sensitive" and eligible for Certificate of Confidentiality protection if the study involves the collection of identifiable information (including enrollment) which, if revealed, could harm the financial standing, employability, insurability, or reputation of a research subject.

2.13 When should an investigator seek a Certificate of Confidentiality for a study?
Before submitting a new application to the IRB, investigators should consider whether a Certificate would be an added protection for study data. If the PI seeks to obtain identifying information of a sensitive nature from research participants, and the disclosure of such information could harm the participants as described above, the PI may wish to apply to the government for a Certificate of Confidentiality. The investigator should state in the protocol to the IRB that he or she will seek a Certificate.

2.14 Will an IRB require an investigator to obtain a Certificate of Confidentiality?
The IRB may also request that an investigator apply for a Certificate if the IRB determines that the data collected from participants should have the additional protections. For instance, sensitive research topics as outlined above in section 2.4.

2.15 How does an investigator apply for a Certificate of Confidentiality?
All Certificate of Confidentiality requests are processed through NIH online CoC system.

https://public.era.nih.gov/commonsplus/public/coc/request/init.era

2.16 Does NIH grant Certificate of Confidentiality for all federal agencies?
No. Investigators whose research is funded by the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and Substance Abuse and Mental Health Services Administration (SAMHSA), or is under the authority of the Food and Drug Administration (FDA) should contact the Certificate of Confidentiality Coordinator at their funding agency for questions on how to obtain a Certificate. Refer to the NIH list of CoC Coordinator Contact Information.

Note: NIH will not issue a Certificate of Confidentiality for Agency for Healthcare Research & Quality- (AHRQ) or Department of Justice- (DoJ) funded research.

Contact AHRQ and DoJ respectively, to obtain information about their privacy regulations.

2.18 Does an investigator still need a HIPAA compliant privacy authorization form if the investigator also has a Certificate of Confidentiality?

Yes. HIPAA and the federal Certificate of Confidentiality statute are two different laws. The HIPAA Privacy Rule applies to any health information collected or used by employees of AdventHealth, and requires that “authorization" (permission) of a specific form be obtained before a person's health information may be collected, used, or disclosed for research. Use of the combined consent/HIPAA authorization template is the mechanism to follow in obtaining written authorization.

2.19 Is the Certificate of Confidentiality still valid if the original Principal Investigator is replaced by another investigator?

No. The Certificate is issued to an individual PI or sponsor. If the PI of a study is replaced by another investigator, the Certificate must be amended to reflect that change.

2.20 Does the Certificate of Confidentiality for non-federally funded studies have an expiration date?

Yes. The Certificate is issued for an explicit period of time. Once it expires, any study information collected after that expiration is not protected. The PI must renew the Certificate of Confidentiality, well in advance of its expiration, so that the entire period of data collection is protected.

2.21 Should the PI notify the issuing federal agency of any changes made to the protocol?

Yes. Most **Certificates of Confidentiality** specify that the holder must notify the issuing agency of any changes to the protocol.

3. REFERENCES

3.1 Certificates of Confidentiality (CoC) | grants.nih.gov