SECTION: RESEARCH
AREA: RESEARCH ADMINISTRATION
SUBJECT: CERTIFICATES OF CONFIDENTIALITY

PURPOSE

To establish the process for obtaining Certificates of Confidentiality for human research studies conducted by employees and students at the University of Arkansas for Medical Sciences ("UAMS").

SCOPE

This policy shall apply to all UAMS employees and students conducting biomedical, behavioral, clinical, or other human research studies.

DEFINITIONS

Certificate of Confidentiality ("CoC") shall mean the certificates issued by the Food and Drug Administration ("FDA"), the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), the Health Resources and Services Administration ("HRSA"), Indian Health Service ("IHS"), the Substance Abuse and Mental Health Services Administration ("SAMHSA"), and the other US Department of Health and Human Services ("HHS") agencies to protect the privacy of research subjects by protecting Investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the Investigator and others who have access to research records to refuse to disclose Identifying Information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level or to any other person not connected to the research.

The Certificate of Confidentiality does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects subjects from compelled disclosure of identifying characteristics by the researcher. The Certificate of Confidentiality is not applicable to disclosures required by Federal, State or local laws. Researchers, therefore, are not prevented from the disclosure of matters such as public health reporting of communicable diseases, child abuse, elder abuse or a subject's threatened violence to self or others. Disclosures may be made with the consent of the subject to whom the data pertains such as when disclosure is necessary for medical treatment of that subject.

Funding through HHS or other federal funding is not a requirement for obtaining a Certificate of Confidentiality.

External Funding Agency shall mean any grantor, private organization, or pharmaceutical company providing funds or resources (to include drugs, devices or components of same) for a

research study.

Identifying Information shall mean any item or combination of items in the research data that could lead, directly or indirectly, to the identification of a research subject.

Identifiable, Sensitive Information shall mean information about an individual that is collected or used during 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. This also applies to the collection or use of biospecimens and human genomic data from biospecimens.

Investigational Device Exemption ("IDE") shall mean an exemption that allows an investigational device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device and allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Investigational New Drug ("IND") Application shall mean a notice of claimed investigational exemption for a new drug which allows an investigational drug or biologic to be studied in humans and exempts the drug or biologic under the IND from the premarketing approval requirements that are otherwise applicable and allows it to be shipped lawfully for the purpose of conducting clinical investigations of that drug.

Investigator shall mean an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject. The responsible leader of a team in the event of an investigation conducted by a team of individuals.

Principal Investigator shall mean the lead Investigator responsible for the conduct of an investigation. The term Principal Investigator or Co-Investigator is not defined in FDA regulations. In the event there are Co-Principal Investigators, each Co-Investigator is fully responsible for fulfilling the Investigator obligations.

Sponsor shall mean an individual, pharmaceutical company, governmental agency, academic institution, private organization, or other organization which takes responsibility for and initiates a clinical investigation. The Sponsor does not actually conduct the investigation.

POLICY

Effective October 1, 2017, Certificates of Confidentiality are automatically issued for fully or partially NIH-funded or CDC-funded projects using Identifiable, Sensitive Information that was ongoing on or after December 13, 2016. The Certificate of Confidentiality will be issued as a term and condition of the award; no physical certificate will be issued. Institutions and Investigators are responsible for determining whether research they conduct is subject to the Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cures Act, P.L.

114-255 (42 USC 241(d)). The protection of these Certificates last in perpetuity; however, data collected after funding ends may not be protected.

The NIH will no longer issue Certificates of Confidentiality for research funded by HRSA, IHS, SAMHSA or operating under the authority of FDA. Certificates of Confidentiality for research funded by these agencies will be issued by the respective funding agency. FDA may issue discretionary Certificates of Confidentiality for research involving an IND, IDE, or other FDA authorized research. The Principal Investigator should contact the Certificate Coordinator of the respective funding agency or FDA.

NIH may issue Certificates of Confidentiality at their discretion for qualifying non-federally funded research or research funded by federal agencies other than AHRQ, CDC, DOJ, FDA, HRSA, IHS, NIH, or SAMHSA. The Principal Investigator should apply for Certificates of Confidentiality using the NIH online CoC system. These certificates cannot be amended (i.e. significant changes to research project) or extended (expired). A new Certificate of Confidentiality request must be submitted.

Note: Certificates of Confidentiality are not applicable for research funded by the Agency for Healthcare Research ("AHRQ") or Department of Justice ("DOJ") as each agency has its own privacy and confidentiality regulations. A Certificate of Confidentiality is not necessary for AHRQ-funded research; the AHRQ confidentiality statue requires the information obtained only be used for the purpose provided. The DOJ will not issue or accept Certificates of Confidentiality issued by NIH or HHS agencies; rather DOJ will approve a request for a Privacy Certificate. The Principal Investigator should refer to each agency official website for additional information, obligations and restrictions.

PROCEDURES

1. Obtain IRB approval before submitting paperwork for a Certificate of Confidentiality.

2. The Principal Investigator is responsible for following the respective HHS agency's Certificate of Confidentiality application procedures. Depending on the agency, the Certificate of Confidentiality application must be signed by the Principal Investigator of the study, or an authorized Institutional Official at UAMS, or both. The designated Institutional Official is the Vice Chancellor for Research and Innovation or their designee. The completed application, including all attachments, must be sent to the appropriate Institutional Official before submission to the HHS issuing agency, NIH or FDA.

3. If applicable, submit consent changes to the IRB in order to comply with NIH (or other agency) Certificate of Confidentiality's consent requirements.

4. Submit documentation to the IRB once the Investigator obtains a Certificate of Confidentiality.

5. It is the Investigator's responsibility to ensure that the Certificate of Confidentiality is obtained either before enrolling any subject or as soon as changes to the research project

necessitate the Certificate of Confidentiality.

6. The UAMS Regulatory Unit of the Office of Research Regulatory Affairs ("ORRA") is available to assist any Principal Investigator in preparing and filing a Certificate of Confidentiality application if one is required for their study.

REFERENCES

42 USC 241(d)

National Institutes of Health, *Certificates of Confidentiality (CoCs) - Human Subjects* https://grants.nih.gov/policy/humansubjects/coc.htm

National Institutes of Health Notice, *Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality*, NOT-OD-17-109, Released September 1, 2017, Effective October 1, 2017 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

National Institutes of Health Notice, *Notice of Transition to New System for Issuing Certificates of Confidentiality for Non-NIH Funded Research*, NOT-OD-20-075, Released February 28, 2020. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-075.html

National Institutes of Health, *How to Get a Certificate of Confidentiality?* https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm

Centers for Disease Control and Prevention, Grants, *Additional Requirement - 36: Certificate of Confidentiality*, https://www.cdc.gov/grants/additional-requirements/ar-36.html

US Food and Drug Administration, Draft Guidance, *Certificates of Confidentiality – Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff*, November 2019.

National Institutes of Health Notice, Electronic Research Administration (eRA), *Certificate of Confidentiality Request*, https://public.era.nih.gov/commonsplus/public/coc/request/init.era

Agency for Healthcare Research and Quality, *Frequently Asked Questions* https://info.ahrq.gov/?page=22

Department of Justice, National Institute of Justice, *Frequently Asked Questions Regarding Confidentiality and Human Subject Protection Requirements* https://nij.ojp.gov/funding/frequently-asked-questions-regarding-national-institute-justices-confidentiality-and-human#field-faqs-890528-11

UAMS Institutional Review Board Policy Number 13.1

Signature:  **Date: November 9, 2022**