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**SECTION: RESEARCH**

**AREA: RESEARCH ADMINISTRATION**

**SUBJECT: CERTIFICATES OF CONFIDENTIALITY**

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## **PURPOSE**

The purpose is to establish the process for obtaining Certificates of Confidentiality for human research studies conducted by UAMS employees and students.

## **SCOPE**

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

## **DEFINITIONS**

**Certificate of Confidentiality** – issued by the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and other 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.

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. Researchers, therefore, are not prevented from the disclosure of matters such as child abuse or a subject's threatened violence to self or others.

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

**Identifying information** - is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.

**IND** – Investigational New Drug application, a notice of claimed investigational exemption for a new drug.

**Investigator** – 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.

**External Funding Agency** – Any grantor, private organization, or pharmaceutical company providing funds or resources (to include drugs, devices or components of same) for a research study.

**Principal Investigator** - The responsible leader of a team in the event of an investigation conducted by a team of individuals.

**Sponsor** – 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**

A Principal Investigator may apply for a Certificate of Confidentiality for qualifying human research studies in accordance with the following:

1. If the research involves an IND (Investigational New Drug application) then the Principal Investigator must apply to the FDA for a Certificate of Confidentiality. If the research does not involve an IND, and is sponsored by a National Institute or Center, the Principal Investigator must apply to the sponsoring Institute or Center that funds the research for the Certificate.
2. If the project is *not* funded by a National Institute or Center, the Principal Investigator may still apply for a Certificate of Confidentiality from the Institute or Center that handles the related area of scientific research. If there is *no* Institute or Center that has an area similar to the research area, the Principal Investigator may submit the application to the central Certificate of Confidentiality resources at the DHHS - the NIMH.
3. If a significant change to the protocol occurs, the Principal Investigator must submit an amended Certificate of Confidentiality application.

## **PROCEDURES**

1. Obtain IRB approval before submitting paperwork for a Certificate of Confidentiality.
2. A Certificate of Confidentiality application must be signed by the Principal Investigator of the study and an authorized Institutional Official at UAMS. The designated Institutional Official is the Vice Chancellor for Research or their designee. The completed application, including all attachments, must be sent to and signed by the appropriate Institutional Official before submission to the NIH or FDA. Once approved, the Principal Investigator is responsible for sending Certificate of Confidentiality application materials to the 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 before enrolling any subject.
6. The UAMS Regulatory Affairs Unit of the Research Support Center is available to assist any Principal Investigator in preparing and filing a Certificate of Confidentiality application if one is required for their study.

## **REFERENCES**

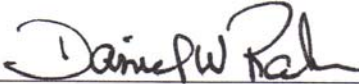
42 U.S.C. 241(d)

National Institutes of Health Certificates of Confidentiality Kiosk  
<http://grants1.nih.gov/grants/policy/coc/index.htm>

National Institutes of Health Guide Notice  
"STATEMENT ON CERTIFICATES OF CONFIDENTIALITY," March 15, 2002.

UAMS Institutional Review Board Policy Number 13.1

Detailed application instructions for certificates of confidentiality: extramural research projects, National Institutes of Health Policy, May 12, 2009

Signature: 

Date: May 11, 2011