



TEXAS A&M UNIVERSITY
SAN ANTONIO

Institutional Review Board

GUIDELINE #10: CERTIFICATE OF CONFIDENTIALITY

I. PURPOSE

This guideline is to ensure that human subjects' research conducted complies with federal, state and local laws, regulations, directives and instructions.

II. STATEMENT

All human subjects research, irrespective of the source of funding, conducted by A&M- SA faculty, staff and students must be submitted and reviewed in accordance with federal research regulations, Texas A&M system guidelines, A&M-SA IRB policies and local consideration.

III. SCOPE

This guideline applies to all research conducted where the A&M- SA IRB serves as the Reviewing IRB.

IV. SUMMARY

Certificates of Confidentiality (CoCs) are intended to protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive information to anyone not connected to the research except when the subject consents, or in limited specific situations. CoCs are issued by the National Institutes of Health (NIH) and other Health and Human Services agencies. All ongoing or new research funded by the NIH (as of December 13, 2016), that is collecting or using identifiable, sensitive information is automatically issued a Certificate of Confidentiality. If your research meets any of the following criteria, then the research data or information is automatically protected by a CoC issued from NIH:

- 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 risk¹ of being identifiable.
- Involves the generation of individual level human genomic data.
- Involves any other information² that identify a person.

Health-related research that is not federally funded in which identifiable, sensitive information is collected or used, may request a CoC but in such situations the CoC is granted at the discretion of the issuing agency. A CoC provides protection for the Investigator and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research. This means that Investigators may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

As part of the informed consent process, research participants consent to the inclusion of research-related data within their medical record. To the extent research information is included in the medical record of a research participant, the CoC will not operate with respect to such information.

¹ At least 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. ² Information about an individual for which there is at least a small risk, as determined by current scientific practice 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 the individual.



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CoCs do not take the place of good data security or clear policies and procedures for data protection, which are essential to the protection of research participants' privacy. Researchers should take appropriate steps to safeguard research data and findings. Unauthorized individuals must not access the research data or learn the identity of research participants.

CoCs do not protect information voluntarily disclosed or information that must be disclosed under mandatory reporting laws. Examples include voluntary disclosures by the participant themselves or disclosures to which the participant has consented. Mandatory disclosures include disclosures on matters such as child abuse, reportable communicable diseases, or possible threat to self or others.

Applications for the new study application must indicate under **Data Monitoring Page, Confidentiality Precautions**: Please select “A Certificate of Confidentiality (from the NIH) will be used”.

Confidentiality: If a Certificate of Confidentiality is valid for your study, briefly provide participants with a clear explanation of the protection that the Certificate of Confidentiality affords, **including the limitations and exceptions**. Also, ensure that an explanation of how identifiable information will be used or disclosed is provided.

REFERENCES

How to Get a Certificate of Confidentiality <https://grants.nih.gov/policy/humansubjects/coc.htm>

What is a Certificate of Confidentiality <https://grants.nih.gov/policy/humansubjects/coc.htm>

Who Can Get a Certificate of Confidentiality <https://grants.nih.gov/policy/humansubjects/coc.htm>

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Title: Certificate of Confidentiality	
Authorized: Dr. Vijay Golla, Vice Provost for Research and Health Sciences	
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