Certificates of Confidentiality Issued by the National Institutes of Health

Effective Oct 1, 2017, NIH automatically issues Certificates of Confidentiality (CoC)s for all research funded by NIH that is collecting or using identifiable, sensitive information. NIH defines "identifiable, sensitive information" as human subjects or biospecimen research where an individual is identified or there is at least a very small risk that a combination of information from multiple sources could be used to identify an individual. NIH posts information about Certificates of Confidentiality.

When this requirement applies, the following language should be added to the consent form in the Privacy/Confidentiality section after the standard HIPAA language:

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.

One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.