Certificates of Confidentiality Issued by the National Institutes of Health

Effective Oct 1, 2017, NIH automatically issues Certificates of Confidentiality (CoCs) 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.

Please refer to the NIH website for more information regarding researchers’ responsibilities: https://humansubjects.nih.gov/coc/NIH-funded
NIH also posts Frequent Asked Questions at: https://humansubjects.nih.gov/coc/faqs

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 in response to a court order. 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 with your name on it. This includes any purposes described 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.