

UNC COC language update and notice for current subjects

The NIH expects that subjects enrolled moving forward and active subjects who will continue to complete research activities be informed when a project meets the new Certificate of Confidentiality (COC) criteria. Consent forms and scripts should include COC language, examples of which are provided below. A sponsor or reviewing IRB may provide alternative language, in which case you may use the alternative language provided to you. UNC IRB retains final approval of any sponsor provided COC language to be used in informed consent forms or scripts at UNC.

The following COC language should be used for all research presenting greater than minimal risk for subjects:

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The following language may be used for research enrolling subjects in the international setting and some minimal risk and exempt research:

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

The following may be used as a notice for previously consented research subjects who will continue with research activities. This notice may be printed and provided to active research subjects at the time of their next study visit or encounter:

Notice of Certificate of Confidentiality

The purpose of this notice is to inform you that the research study that you are participating in is now covered by a Certificate of Confidentiality (COC). The Certificate means that the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States. For example, if there is a court subpoena, the information cannot be disclosed unless you have provided consent for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate will not be used to prevent disclosure as required by federal, state, or local law. These types of disclosures include mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in the informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

If you should have questions about the information provided in this notice, please contact the UNC Office of Human Research Ethics by phone at 919-966-3113 or by email to irb_questions@unc.edu.