

**APPENDIX 8:
CERTIFICATE OF CONFIDENTIALITY
FOR PROVIDERS OF EXPANDED ACCESS INVESTIGATIONAL NEW DRUGS**

[This activity is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention.](#)

Please read the below explanation of what Certificate of Confidentiality (CoC) coverage means for you as a healthcare provider participating in an EA-IND funded by the Centers for Disease Control and Prevention (CDC).

What does CoC coverage mean?

Consistent with the statute (42 U.S.C. 241(d)), CoC coverage means that any researcher, staff, or healthcare provider (hereafter “personnel”) connected with or involved in this Expanded Access to Investigational New Drugs (EA-IND) for therapeutic use must protect the privacy of the participants enrolled in the protocol or use. Personnel receiving information related to the patient cannot disclose or provide to any other person not connected with the EA-IND protocol or use, or the patients’ healthcare needs, the name of the patient or any information, document, or biospecimen that may identify the patient without the specific consent of the patient to who the information pertains or as otherwise permitted by 42 U.S.C 241(d).

Generally, the information covered by a CoC includes names or any information, documents or biospecimens containing *identifiable, sensitive information* related to the patient. Also, if there is at least a very small risk that the information, documents, or biospecimens can be combined with other available data sources to determine the identity of an individual, then they are also protected by the CoC.

Identifiable, sensitive information includes but is not limited to name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information, tissue samples, or data fields that when used in combination with other information may lead to identification of an individual.

[What does this require of me?](#)

Please ensure that patients are informed about the CoC protections and the exceptions to the CoC protections when conducting the informed consent process.

CDC has included an explanation of CoC protections and exceptions to those protections in the informed consent and protocol documents associated with this EA-IND.

Do not release patients’ identifiable sensitive information except under limited circumstances.

As provided in 42 U.S.C. 241(d), the following are the limited circumstances when the personnel may release patients’ identifiable, sensitive information:

- If required by other Federal, State, or local laws, such as for public health reporting of communicable diseases or child or elder abuse reporting;
- If the participant consents; or
- For the purposes of scientific research that is compliant with human subjects’ regulations

This protection lasts in perpetuity for the data collected while the work is funded by or supported by CDC.

[What should personnel do if legal action is brought to release personally identifying information protected by a CoC?](#)

Personnel should immediately seek legal counsel from his or her institution.