

Division of Scientific Investigations
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Certificate of Confidentiality Application Instructions

To apply for a Certificate of Confidentiality from the Food and Drug Administration (FDA) under the Section 301(d) of the Public Health Service Act (42 U.S.C. 241 (d)) to protect against involuntary disclosure of the identities of research subjects, please direct a letter to the following address:

Division of Scientific Investigations (HFD-45)
Attention: Leslie Vaccari
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, Room 5350
Silver Spring, MD 20993

containing the following information using the numbering scheme shown.

1. Investigational New Drug (IND) number
2. Drug name
3. Name and address of IND sponsor (Holder of the IND).
 - For all non-U.S. sponsors, provide the complete contact information for the U.S. Representative for the sponsor of the IND.
 - If the applicant is not the holder of the IND, please attach the signed 1572 provided to the IND sponsor and have the IND sponsor provide documentation (email is satisfactory) that the applicant is the authorized investigator for the study.
4. Name of entity (e.g., university, center, manufacturer, etc.) that should be named as the holder of the certificate.
5. Concise description of the study aims and research methodology; include number, source and description of the human subjects.
6. Reasons for requiring confidentiality.
7. Means used to protect subjects' identities (e.g., coded by number, kept in locked files).
8. Assurances of the following:
 - (a) that for all projects conducted under a FDA investigational exemption (Investigational New Drug Application), all personnel involved with the conduct of the research will comply with the human subject protection requirements of 21 CFR Parts 50, 56, and 312, and that personnel involved in the conduct of the research supported by grants from the Department of Health and Human Services (DHHS) will comply with all the requirements of 45 CFR part 46 "Protection of Human Subjects;"
 - (b) that the Certificate of Confidentiality will not be represented as an endorsement of the project by the FDA or the DHHS or used to coerce individuals to participate in the research project;
 - (c) that the recipient of the Certificate of Confidentiality will use the vested authority to protect the identity of research subjects;
 - (d) that all subjects be informed that a certificate has been issued and that subjects will be provided with a description of the protection covered by the certificate; and
 - (e) that subjects who enter the project after termination of the certificate will be informed of the termination.

The individual primarily responsible for the conduct of the research must sign the letter requesting the Certificate of Confidentiality.

The Certificate of Confidentiality does not govern a disclosure for which the subject gives permission or a researcher's voluntary disclosure of the identifying characteristics of research subjects, but only protects subjects from compelled disclosure of identifying characteristics. For example, a researcher is not prevented from making voluntary disclosure of personally identifiable information related to child abuse or a subject's threatened violence to self or others. However, if a researcher expects to make such voluntary disclosures, the consent form should clearly indicate this [21 CFR 50.25(a)(5)]. The Certificate of Confidentiality also does not govern disclosure of study information without personal identifiers.

Your request will be processed as rapidly as possible. However, if all of the items of information requested above are not provided in the letter, issuance of your certificate may be delayed. Please do not hesitate to contact me, Leslie Vaccari at 301-796-3396 or email Leslie.vaccari@fda.hhs.gov, if you have any questions.