

Essential Elements for a Certificate of Confidentiality Application

A Certificate of Confidentiality can be used for biomedical, behavior, or clinical investigations involving identifiable information of a sensitive nature taken from human subjects such as genetic samples, information on the psychological well being of the subjects, or substance abuse and other illegal behaviors¹. [National Institutes of Health \(NIH\)](#)

A summary of the required information for a Certificate of Confidentiality follows:

- The name and address for the PI and the research institution
 - PI information must include: title/position, mailing address, email address, telephone number, fax
- Title of the IRB approved project, names and titles of other key personnel at the lead site
- Description of project aims and research methods (1-2 paragraphs) including a brief description of procedures for collection and storage of identifiable information, number of subjects, source from which they will be recruited, and description of study population (gender, age, race, etc).
- Reason for requesting a Cert of Confidentiality (description of sensitive information to be collected)
- Documentation signed by an authorized IRB representative attesting to the approval of the project. The NIH will accept an IRB approval that is contingent upon issuance of a Certificate of Confidentiality.
- The OHRP assurance number verifying that the IRB complies with the applicable federal regulations governing research involving human subjects.
- Site(s) where the research will be conducted, description of the facilities, the address and Project Director affiliated with each site. (NIH must be notified of any sites added after the initial application for a Cert of Confidentiality).
- Name and number of supporting grant (if applicable). The name and phone number of the Project Officer responsible for NIH funding (if applicable).

¹ Note: Studies which will be utilizing Investigational New Drugs must contact the FDA to obtain the appropriate Certificate of Confidentiality.

- Beginning date and expected end date for the project. The protection afforded by the Certificate of Confidentiality is permanent however; it will only protect the identifiable information of individuals enrolled in the study or project during the period for which the Certificate of Confidentiality is effective. The applicant may write to the NIH to request an extension if necessary.
- A description of the means used to protect subjects' identities (coding, encrypting data, destructing files)
- A copy of the IRB-approved Informed Consent Form that includes a description of the limitations of the Certificate of Confidentiality and circumstances in which the investigator will disclose voluntarily identifying information (e.g. child abuse, harm to self or others, etc) .