About Certificates of Confidentiality

The application process

1. Applications must address science that is within the scope of NIDA's mission.
    a. Investigational New Drug (IND) –processed by the FDA
    b. Studies in which drug abuse is peripheral are not considered, e.g. study of gangs, but drug abuse is a secondary question.
2. Applications are processed in order of receipt and may take up to 12 weeks for the entire process to be completed. Incomplete applications take more time to process.
3. Applications cannot be processed without IRB approval. If the IRB will not grant approval without the CoC, then a conditional approval or a letter explaining that the CoC is the last step in gaining IRB approval is needed.
4. The application cannot be processed with problematic language in the consent form, as follows:
    a. Consent forms stating or suggesting that there are State laws or regulations, which override the protections of the CoC.
    b. Consent forms that *either* do not outline the exclusions to the protection of the CoC, or do not fully outline the exclusions. In other words, there should be language that says when the researchers will voluntarily release identifying information about study subjects.
    c. Consent forms that do not mention the CoC at all.
    d. Consent forms for that collect biosamples, but do not properly address subject protections. (See Studies that collect biosamples)
5. If the study description is not succinct and clear, NIDA staff spends time re-writing it. The language that describes the study on the front page of the CoC must:
    a. Clearly convey the scientific purpose of the study
        i. What is being done, to whom, in what way, and for what reason?
        ii. Identify a vulnerable study population? E.g. minors (under 21 years), pregnant women, prisoners, men who have sex with men, injecting drug users.
    b. Make grammatical sense

6. To process the application, the following attachments are needed:

    i. If the study is using a controlled substance, then a copy of the current DEA and State licenses must be included.

    ii. Signed assurances from the Authorized Official at the institution. The name, title, and signature of the official must be included in the application before it can be submitted for evaluation.

    iii. The IRB approval letter and the IRB-approved consent form.

Studies that collect biologic samples

1. If the study is collecting biologic samples, such as HIV or other disease testing, or conducting DNA analyses this will be noted in the CoC.

2. Genome-wide association studies, genome sequencing projects, and related genomics research must fully detail how subject identity will be protected in the consent form and not just depend on a CoC to provide the protections. (The IRB usually catches this).

    a. Describe the level of confidentiality of the research data and the measures planned to ensure that confidentiality is maintained.

    b. Participants should know whether their samples will be anonymous/non-identifiable (i.e. personal identifiers will not be kept with their sample and the sample will not have a code number that can be used to identify the participant) or coded and considered de-identified (i.e. any identifying information such as name or SS# will be replaced with a code and only a few authorized people will have access to this code to link samples and data back to personal identifiers).

Multi-site studies

1. If all sites are using the same protocol, or if the sites are using the same or overlapping subjects, or if the enrollment is done at one site and different analyses are done elsewhere, then a single CoC can be issued.

    a. Lead site submits the application on behalf of all sites

    b. Lead site maintains file of all signed assurances, IRB approvals, and approved consent forms to be presented to NIH upon request.

    c. Lead site reviews the consent form language in all consent forms and ensures that they are compliant and consistent.

d. Lead site distributes a copy of the CoC to each site and establishes the protocol that will be used to implement signed assurances if a site receives a demand for disclosure.

2. If all sites are recruiting different subjects and conducting independent studies, then separate CoCs are issued.

3. Simple addition of sites that do not introduce a new protocol, or a new pool of subjects would not require a new CoC.

    a. Lead site to keep track of the study sites.

Requests for Certificates from non-NIH funded studies

1. If the study is supported by another HHS agency that issues CoCs (SAMHSA, HRSA, IHS, CDC), then NIH will not issue the certificate.

2. If the study has an Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA, then it must go to Sherry George at the FDA.

3. The Department of Justice and AHRQ have their own provisions for subject protections so CoCs are not issued for these projects.

4. If there is no funding, NIH can issue a CoC if certain requirements are met:

    a. Is it research? Will it produce publishable results?

    b. Is the research related to the NIH, and more specifically, NIDA's mission?

    c. Who is conducting the study? (Is it being done in a research environment?)

    d. Will the protocol be reviewed by an IRB? Is it ethical?

    e. Will the results contribute to the general body of knowledge versus just the evaluation of a single program?

    f. Is identifiable information being collected?

When you need help with Certificates:

NIH Certificates of Confidentiality Kiosk: http://grants.nih.gov/grants/policy/coc/

NIDA Certificates of Confidentiality Coordinator: Nadine Rogers, PhD
E-mail: rogersn2@nida.nih.gov Phone: 301-443-2105

NIDA Certificates of Confidentiality Team

NIDA Certificates of Confidentiality Lead Administrator: Natisha Rowe
E-mail: natisha.rowe@nih.gov Phone: 301-435-1388

NIDA Certificates of Confidentiality Administrator: Chris Page
E-mail: christina.page@nih.gov Phone: 301-451-7971

Submit NIDA CoC applications to:

NIDACertOfConfident@mail.nih.gov