CERTIFICATES OF CONFIDENTIALITY

Background

The Secretary of Health and Human Services may issue Certificates of Confidentiality under Section 301(d) of the Public Health Service Act (42 USC 241(d)). These Certificates are intended to protect researchers from compelled disclosure of the identities of research subjects. The Secretary has delegated the authority to issue these Certificates to all Public Health Service agencies.

The Health Resources and Services Administration (HRSA) issues Certificates for research that is supported by HRSA funds or related to HRSA programs.

A Certificate of Confidentiality protects all identifiable information for any research subject (i.e., an individual about whom the investigator maintains identifying information) any time the Certificate is in effect. The protection afforded by the Certificate is permanent, meaning that subjects enrolled within the specified study period are protected even after the study ends. However, subjects enrolled in a study outside the specified timeframe of the Certificate are *not* covered by the Certificate.

The Certificate protects against the involuntary disclosure of information that could identify subjects. It does *not* govern the voluntary disclosure of identities of research subjects. Researchers are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if a researcher intends to make such voluntary disclosures, the informed consent form provided to research subjects should clearly indicate this.

Application Instructions

To apply for a HRSA Certificate of Confidentiality, investigators should complete the following steps:

A) Review the Application Requirements listed below.

B) Contact the HRSA Certificate of Confidentiality Coordinator for an initial consultation:

Lisa Wright-Solomon
Health Resources and Services Administration
Office of Planning, Analysis and Evaluation
Email: lwright-solomon@hrsa.gov
Telephone: (301) 443-1984

C) Submit an application letter (via email) to the Coordinator, using the host research institution's letterhead.

The letter should be numbered according to the scheme shown below and should be written in complete sentences, concisely providing the required information in narrative format. Portions of this narrative will be used verbatim to describe the research project in the Certificate.

Requests for Certificates will be processed as rapidly as possible. However, if all of the information requested below is not provided in the application letter, Certificate issuance may be delayed.

Application Requirements

The application letter should include the following elements:

1. **INSTITUTION INFORMATION:** Name and address of the host research institution that will sponsor and oversee the study. This is the institution with which the applicant is affiliated and the recipient of grant support for the research, if there is any.

2. **KEY PERSONNEL:** Name, title, mailing address, email address, and telephone numbers of the applicant as well as the name and title of other key personnel. Include a brief summary of the relevant training and experience and/or curriculum vitae of the applicant and key personnel.

3. **PROJECT TITLE:** Title of the research project. If the project title on the Institutional Review Board (IRB) form is different from the title given here, the applicant must document that the IRB approval pertains to this project.

4. **FUNDING SOURCE:** Source and number of any Federal grant or contract that supports the research directly or indirectly (e.g., "This research is supported by SPNS Grant BRH-xxxxxx from the Health Resources and Services Administration."). If none, state "This study is not supported by Federal funds."

5. **RESEARCH LOCATION:** Name and location where the research will be conducted, and a brief description of the facilities available for the conduct of the research. Please indicate if this is a multi-site project.

The lead site of a multi-site project should apply for a single Certificate to protect participants enrolled at all sites. However, applications for multi-site projects must list each participating unit, address, and project director.

6. **IRB APPROVAL:** Evidence of IRB approval for the research project. A Certificate of Confidentiality will not be issued to an applicant conducting research involving human subjects unless the project has IRB approval.

The approving IRB must be in compliance with applicable Federal requirements. If the applicant institution is receiving HHS funding for research involving human subjects, an IRB registered with the Office for Human Research Protections (OHRP) must approve the project for which a Certificate of Confidentiality is sought. If the host research institution does not receive HHS funding for this research involving human subjects but has an IRB that complies with the requirements for IRBs imposed by another Federal agency, that IRB must approve the research. If the host research institution does not have an IRB, the project should be reviewed by an IRB in accordance with 45 CFR Part 46.

> **(a) Documentation of IRB Approval:** Attach a formal letter or form signed by an authorized IRB representative. Approval must be current and unconditional, or conditioned only upon the

issuance of a Certificate of Confidentiality. If this is a multi-site project, only the lead site IRB approval needs to be submitted; however, the lead site must maintain a copy of the IRB approval from each site, which must be made available to HRSA upon request.

If the project is *exempt* from IRB oversight and approval, attach documentation justifying why it is exempt. If the exempt project is supported by HRSA funds, attach a statement demonstrating compliance with the Policies and Procedures for the Protection of Human Subjects Participating in Research Programs Conducted or Supported by HRSA.

(b) Documentation of IRB Qualifications: Submit the Federal Wide Assurance (FWA) number assigned by OHRP for the IRB that reviewed the project, as well as the associated IRB number. If the IRB is not registered with OHRP, submit a statement that the IRB complies with the applicable Federal regulations governing research involving human subjects.

If this is a multi-site project, the lead site must maintain the OHRP FWA number for the reviewing IRB at each site, which must be made available to HRSA upon request.

(c) Documentation of Informed Consent: Attach copies of the informed consent form(s) to be used in the study, as approved by the IRB. The informed consent form must include a description of the protections and limitations of the Certificate of Confidentiality, including the circumstances in which the investigators may voluntarily disclose identifying information about research participants (e.g., child abuse, harm to self or others, etc.).

Investigators should review the language about confidentiality and data security that is routinely included in consent forms, to be certain that it is consistent with the protections of the Certificate of Confidentiality. OHRP provides guidance on the content of informed consent documents.

Sample informed consent language is provided below. Investigators may adapt the language to the needs of the research participants and to the subject matter under study. However, the language must cover the basic points.

Sample Language

A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

[Include language such as the following if researchers intend to make voluntary disclosure about child abuse, intent to hurt self or others, or other voluntary disclosures.] *The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances.* [State here the conditions under which voluntary disclosure would be made.]

[If no voluntary disclosures will be made, include language stating this.]

7. **PROJECT DATES:** Beginning and expected end dates of the project. Based on the study time period indicated, the Certificate of Confidentiality will state the date upon which it becomes effective and the date upon which it expires. While the protections from the Certificate are permanent, they are only given to subjects whose data are collected within the specified study time frame indicated on the Certificate. See below for information on extensions of Certificates.

8. **PROJECT AIMS AND METHODS:** Concise description (1-2 paragraphs) of the project aims and research methods. Include the number, source, and description of the human subjects.

9. **JUSTIFICATION:** Justification for requesting a Certificate of Confidentiality (e.g., collecting sensitive information, identifying information, etc.). Include a brief description of the sensitive and/or identifying information to be collected.

10. **CONFIDENTIALITY AND SECURITY:** Concise description of the means used to protect research subjects' identities (e.g., coded identifiers, data access restricted to trusted project staff, locked files, secured computer data storage, etc.).

11. **ASSURANCES:** Assurances of compliance with HHS requirements. The following assurances are required and must be inserted verbatim into the Certificate of Confidentiality application letter.

The investigators, the responsible institution, and all collaborating institutions (if applicable) will ensure that:

a. all personnel involved in the conduct of the research will comply with all the requirements of 45 CFR Part 46, "Protection of Human Subjects." (Projects not supported by HHS will comply with 45 CFR 46.103(c) and document legally informed consent in a manner consistent with the principles stated in 45 CFR 46.111);

b. the Certificate of Confidentiality will not be represented as an endorsement of the project by the Secretary of HHS or be used to coerce individuals to participate in the research project;

c. the recipient of the Confidentiality Certificate will use its authority to protect the identity of research subjects;

d. all subjects will 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. subjects who enter the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

If this is a multi-site project, the lead site must indicate in the application that all sites agree to the assurances and that they will maintain copies of the Certificate of Confidentiality. Once the Certificate is issued, the lead site should obtain signed copies of the assurances from each site, which must be made available to HRSA upon request.

12. **SIGNATURES:** The application letter must be signed by both the Principal Investigator (i.e., individual primarily responsible for the conduct of the research) and by the Institutional Official authorized to bind the host research institution. In doing so, they are agreeing to the assurances as stated in the application letter. The name and title of the Institutional Official should be typed below the signature line.

Extensions and Amendments

If the research project will not be completed by the expiration date indicated on the Certificate and/or if an amendment is necessary, the Certificate holder should email the HRSA Certificates of Confidentiality Coordinator at least 3 months prior to the expiration date to request a Certificate extension or amendment. Such requests should include a justification for the extension/amendment, documentation of the most recent IRB approval, and expected date for completion of the research project.

For multi-site projects, if new sites are added after the Certificate is issued, the lead site should provide the HRSA Certificate of Confidentiality Coordinator with an updated list; the accompanying cover letter should include a statement by the lead site indicating that IRB approval has been given at the new site and that the lead site is maintaining a copy of that approval.

If significant changes are made to the informed consent form after the Certificate has been issued, the applicant should contact the Certificate of Confidentiality Coordinator and submit a copy of the revised consent form.

If significant changes are made to the project aims or methods during the course of the study, the applicant should contact the HRSA Certificate of Confidentiality Coordinator, who will then determine if the Certificate can be modified or if the applicant should submit an amended application to obtain a new Certificate.