From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, January 18, 2006 4:45 PM
To: [Redacted]
Subject: RE: Certificate of Confidentiality

Dear [Redacted]:

A Certificate of Confidentiality authorizes a research site to protect the personal identifying information of subjects who participate in biomedical, behavioral, clinical, and other research under the Public Health Service Act. Specifically, the certificate authorizes the research site and the persons engaged in the research to withhold the names or other identifying characteristics of the research subjects from all persons not connected with the conduct of such research. Persons so authorized to protect the privacy of research subjects may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify study subjects.

Protection can be granted only to research (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge). The protection will be granted when the research is of a sensitive nature, and where the protection is judged necessary to achieve the research objectives. Research can be considered sensitive if it involves the collection of information in any of the following categories:

- Information relating to sexual attitudes, preferences, or practices;
- Information relating to the use of alcohol, drugs, or other addictive products;
- Information pertaining to illegal conduct;
- Information that if released, could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
- Information that would normally be recorded in a patient's medical records and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information pertaining to an individual's psychological well-being or mental health;
- Genetic information.

Any person engaged in research collecting sensitive information from human research subjects may apply for a Certificate of Confidentiality. FDA determines whether a study qualifies for a Certificate.

FDA issues Certificates related to studies conducted under an IND, IDE, or PMA. To apply for a certificate for:

--a drug study, please contact:
Julie Unger
Division of Scientific Investigations (HFD-45)
Office of Medical Policy
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
7520 Standish Place, Room 115
Rockville, MD 20855
Telephone: (301) 827-1685
Fax: (301) 594-1204
E-mail: ungerj@cder.fda.gov

--a study involving a biologic or blood product, please contact:

Patricia Holobaugh (HFM-664)
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852
Telephone: (301) 827-6347
Fax: (301) 827-6748
E-mail: holobaugh@cber.fda.gov

--a study involving a medical device, please contact:

Sheila Anne Brown
Investigational Device Exemptions Staff (HFZ-403)
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850
Tel: (301) 594-1190 x 107
Fax: (301) 594-2977
E-mail: mnm@cdrh.fda.gov

To obtain a Certificate of Confidentiality for research studies that do not involve an FDA regulated product, visit the NIH website [http://grants2.nih.gov/grants/policy/coc/contacts.htm] for a list of specific contacts.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [Redacted]

Sent: Monday, January 16, 2006 5:21 PM
To: gcpquestions@oc.fda.gov
Subject: Certificate of Confidentiality

I'm tasked with incorporating requirements for a Certificate of Confidentiality into our clinical SOPs. Among other things I need to address:

* Who decides when this is required?
* How is it obtained?

For a FDA mandated registry, a [Redacted] IRB [Redacted] required this certificate be obtained, from FDA. I could not locate information on who to contact, information needed, etc.

I will very much appreciate any help you can provide in pointing me in the direction of where this information is located.

Thank you

[Redacted]