



POLICY STATEMENT
REGARDING SUBJECT ENROLLMENT
IN STUDIES INVOLVING A
CERTIFICATE OF CONFIDENTIALITY
01/03/2008

The Duke University Health System Institutional Review Board (DUHS IRB) has determined that the following process will be followed for those studies that require a Certificate of Confidentiality ("C of C").

The Principal Investigator shall make the initial determination regarding the appropriateness of obtaining a C of C for his/her protocol. As part of the review process, the Primary Reviewer shall make an independent assessment of the need for a C of C for the protocol. If the Primary Reviewer and Principal Investigator disagree regarding this issue, the Principal Investigator will provide his/her rationale in writing to the Primary Reviewer for expedited review or for presentation at a convened IRB meeting. The IRB will make the final determination regarding the requirement for a C of C, and approval for the study will not be issued until the requirement has been met by the Principal Investigator.

The IRB shall consider the following parameters in making its determination of the need for a C of C: nature of the research activities, characterization of the disease/disorder, age/gender/ethnicity of the subject population, social/legal implications of the results of the research, effect of the results of the research on the individual subject, his/her family, and the local community, and the risks to the subject and his/her family regarding the possibility of loss of confidentiality regarding the research and its results.

If the Principal Investigator seeks to enroll subjects prior to the acquisition of a C of C, the IRB will inform the Principal Investigator that data collected prior to the effective date of the C of C will not have the protection of this document. In such a case:

- 1) A Notification of Approval will be issued by the IRB encompassing only consent forms that do not refer in any way to the C of C. Approval for dual Consent forms, one with C of C language and one without C of C language, will not be granted by the IRB.
- 2) The Principal Investigator will be advised at the time of notification of study approval that, once the C of C has been obtained, an amendment must be immediately filed with the IRB office accompanied by:

- (i) a revised Consent form containing appropriate reference to the C of C and its applicable protections;
and
- (ii) a copy of the C of C

In addition, the Principal Investigator will be reminded that no enrollment under the revised Consent form can begin until IRB approval of the amendment has been obtained.

It is the responsibility of the Principal Investigator to ensure that the C of C is valid at all times during the study. If, at any time during the course of the study, the C of C expires or is terminated, the Principal Investigator must immediately file an amendment with the IRB to remove the C of C wording from the consent form. Furthermore, the Principal Investigator cannot enroll subjects past the termination/expiration date of the C of C until such amendment has been approved, and he/she must inform current subjects through a letter approved by the IRB that data collected during the period of lapsed C of C coverage will not be protected.

C of Cs must be study-specific. A C of C cannot cover a grant, similar studies, or an institute, but must refer specifically to one protocol.

Additionally, Principal Investigators are strongly urged to consult the OHRP Guidance on Certificates of Confidentiality (dated February 25, 2003) found at the following web address:

<http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>