Attachment 4. CDC IRB Approval for Never In Care Project

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Monday, November 13, 2006 3:55 PM
To: Bertolli, Jeanne (CDC/CCID/NCHHSTP)
Cc: NCHSTP Human Subjects (CDC); Milton, Micah (CDC/CCHP/NCBDDD); Jones, James F. (CDC/CCID/NCZVED)
Subject: 4923: Site Restricted - IRB Approval of New Protocol (Convened Board - C)

DATE: 11/13/2006

FROM: IRB Administrator
Human Research Protection Office
Office of Scientific Regulatory Services
Office of the Chief Science Officer, OD/CDC

SUBJECT: Site Restricted - IRB Approval of Protocol #4923, "Surveillance of HIV-Related Events Among Persons Not Receiving HIV Care" (Convened Board - C)

TO: Jeanne Bertolli
NCHSTP/DHAP

New protocol #4923 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 10/18/2007. The IRB has determined that the study involves not greater than minimal risk to subjects.

In accordance with 45 CFR 46, Subpart C, the IRB has determined that this study presents a permissible category of research involving prisoners and qualifies for the waiver of the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2), by virtue of the criteria established by the Secretary of the Department of Health and Human Services. The regulations require CDC, and all other institutions which will involve prisoners in this research, to certify to the Secretary of Health and Human Services that the IRB fulfilled its duties with regard to the additional protections for prisoners, specified in Subpart C. The Human Research Protection Office will submit this certification to the Office of Human Research Protections (OHRP). **Research involving prisoners may not begin until OHRP has indicated its concurrence with the IRB's determination.**

Collaborator Note:

Indiana State Department of Health
New Jersey Department of Health and Senior Services
Philadelphia Department of Public Health
Washington State Department of Health
Seattle-King County Department of Public Health

1) Current IRB Approval Documentation: Study activities may not begin with the above collaborators/sites until documentation indicating current IRB approval has been received by CDC and is on file with this office.

2) Confidentiality statements from each of the study collaborators listed above will be forwarded to CDC. Study activities may not begin

until the requested documentation has been received by CDC and is on file with this office.

3) Please note that all site specific changes made to study documents not previously approved by the CDC IRB, are required to be submitted and approved by the CDC IRB before being utilized at the sites (i.e. consent forms, scripts, recruitment flyers).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 10/18/2007.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

Jennifer McCleary

cc:
James F. Jones
Micah Milton
NCHSTP Human Subjects