

Clinical Indicators of Sexual Violence in Custody

Attachment 6.

IRB Summary and Approval

Voetsch, Drew (CDC/CCID/NCHHSTP)

From: Valosen, John A. (CDC/OD/OCSO)
Sent: Tuesday, May 06, 2008 10:48 AM
To: Heffelfinger, James (CDC/CCID/NCHHSTP)
Cc: Voetsch, Drew (CDC/CCID/NCHHSTP); NCHSTP Human Subjects (CDC); Valosen, John A. (CDC/OD/OCSO); Williamson, Dhelia (CDC/CCHP/NCCDPHP); Campbell, Scott (CDC/CCHP/NCBDDD)
Subject: 5107: IRB Approval of Continuation of Protocol, (Expedited)

DATE: 5/6/2008

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

SUBJECT: IRB Approval of Continuation of Protocol #5107, "Clinical Indicators of Sexual Violence in Correctional Facilities Surveillance System Pilot Study " (Expedited)

TO: James Heffelfinger [IZH7]
NCHHSTP/DSTDP

CDC's IRB A has reviewed and approved your request to continue protocol #5107 for the maximum allowable period of one year and it will expire on 5/14/2009. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Category 8 (b).

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 5/14/2009.

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.

John A. Valosen
Administrator IRB A

cc:
NCHHSTP Human Subjects
Drew Voestch
John Valosen
Dee Williamson
Scott Campbell

Voetsch, Drew (CDC/CCID/NCHHSTP)

From: Valosen, John A. (CDC/OD/OCSO)
Sent: Tuesday, July 17, 2007 4:42 PM
To: Heffelfinger, James (CDC/CCID/NCHHSTP)
Cc: Voetsch, Drew (CDC/CCID/NCHHSTP); Bowles, Kristina E. (CDC/CCID/NCHHSTP);
Dodson, Janella (CDC/CCID/NCHHSTP); Vann, Jerrell (CDC/CCID/NCHHSTP) (CTR);
'Sperling, Charles'; Campbell, Scott (CDC/CCHP/NCBDDD)
Subject: 5107: IRB Approval of New Protocol, (Expedited)

DATE: 7/17/2007

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

SUBJECT: IRB Approval of New Protocol #5107, "Clinical Indicators of Sexual Violence in Correctional Facilities Surveillance System Pilot Study " (Expedited)

TO: James Heffelfinger [IZH7]
NCHSTP/DSTDP

New protocol #5107 has been approved by CDC IRB A for the maximum allowable period of one year and it will expire on 5/14/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 5.

NOTE: Since this protocol deals with prisoners it is required to receive approval from the Office for Human Research Protections (OHRP) and although approved by CDC it is still not released to begin until we receive notification from OHRP. As soon as the notification arrives in our office you will be notified on the clearance to begin.

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 5/14/2008.

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.

John A. Valosen
Administrator IRB A

cc:

Janella Dodson

Jerrell Vann

Drew Voetsch

Kristina Bowles

Charles Sperling

Scott Campbell