ATTACHMENT F: CDC-IRB approval

CDC-IRB approval - Prestest

From: Valosen, John A. (CDC/OD/OCSO)
Sent: Monday, January 22, 2007 3:31 PM
To: Klevens, Joanne (CDC/CCEHIP/NCIPC)
Cc: Gilles, Natalie (CDC/CCEHIP/NCIPC) (CTR); Martindale, Jim (CDC/CCEHIP/NCIPC); Wong, Betty (CDC/CCID/NCIRD) (CTR); Sowell, Anne (ATSDR/DHS/OD)
Subject: 4984: IRB Approval of New Protocol, (Expedited)

DATE: 1/22/2007

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

SUBJECT: IRB Approval of New Protocol #4984, "Feasibility of Different Screening and Referral Strategies for Intimate Partner Violence " (Expedited)

TO: Joanne Klevens, MD, PhD [DZK8]
NCIPC/VP

New protocol #4984 has been approved by CDC IRB A for the maximum allowable period of one year and it will expire on 1/18/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7.

NOTE: This approval does not include the Stroger Hospital of Cook County, Chicago IL until we receive a local approval letter from that institution. Once received in this office they will be permitted to join the study.

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 1/18/2008.

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:
Natalie Gilles
Jim Martindale
Betty Wong
Anne Sowell

CDC-IRB approval – Main Study

From: Valosen, John A. (CDC/OD/OCSO)
Sent: Tuesday, January 30, 2007 1:57 PM
To: Klevens, Joanne (CDC/CCEHIP/NCIPC)
Cc: Gilles, Natalie (CDC/CCEHIP/NCIPC) (CTR); Martindale, Jim (CDC/CCEHIP/NCIPC); Wong, Betty (CDC/CCID/NCIRD) (CTR); Sowell, Anne (ATSDR/DHS/OD)
Subject: 4985: IRB Approval of New Protocol, (Expedited)

DATE: 1/30/2007

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

SUBJECT: IRB Approval of New Protocol #4985, "Randomized Controlled Trial of Routine Screening for Intimate Partner Violence" (Expedited)

TO: Joanne Klevens, MD, PhD [DZK8]
NCIPC/VP

New protocol #4985 has been approved by CDC IRB A for the maximum allowable period of one year and it will expire on 1/29/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7.

NOTE: This approval does not include the Stroger Hospital of Cook County, Chicago IL until we receive a local approval letter from that institution. Once received in this office they will be permitted to join the study.

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 1/29/2008.

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:
Natalie Gilles
Jim Martindale
Betty Wong
Anne Sowell