

From: McCleary, Jennifer
Sent: Thursday, November 03, 2005 8:00 AM
To: Ballesteros, Michael (Mick)
Cc: Booker, Angela; Durant, Tonji; Hatfield-Timajchy, Kendra
Subject: 4636: IRB Approval of New Protocol (Expedited)

DATE: 11/3/2005

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

SUBJECT: IRB Approval of New Protocol #4636, "Human Behavior in Fire Study" (Expedited)

TO: Michael Ballesteros, PhD, MS [ZZB0]
NCIPC/UIP

New protocol #4636 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 11/2/2006. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7.

Please Note: This approval is for the original submission only. There are currently three pending amendments, which will be reviewed and approved separately by the CDC IRB. You will be notified of each amendment's approval by e-mail.

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 11/2/2006.

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: humarecdc.gov.

Jennifer McCleary

cc:

Angela Booker

Tonji Durant

Kendra Hatfield-Timajchy

From: McCleary, Jennifer
Sent: Thursday, November 03, 2005 8:09 AM
To: Ballesteros, Michael (Mick)
Cc: Booker, Angela; Durant, Tonji; Hatfield-Timajchy, Kendra
Subject: 4636: IRB Approval of Amendment # 1 to Protocol #4636, (Expedited)

DATE: 11/3/2005

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

SUBJECT: IRB Approval of Amendment #1 to Protocol #4636, "Human Behavior in Fire Study" (Expedited)

TO: Michael Ballesteros, PhD, MS [ZZB0]
NCIPC/UIP

CDC's IRB "C" has reviewed and approved your request to amend protocol #4636. This amendment requested modifications to the University of Maryland consent form which was requested by the local IRB. The amendment was reviewed using the expedited review process outlined in 45 CFR 46.110(b)(2), "Minor changes in previously reviewed research during the period (of one year or less) for which approval is authorized."

Reminder: IRB approval of protocol #4636 will still expire on 11/2/2006. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other 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:
Angela Booker
Tonji Durant
Kendra Hatfield-Timajchy

From: McCleary, Jennifer
Sent: Thursday, November 03, 2005 8:35 AM
To: Ballesteros, Michael (Mick)
Cc: Booker, Angela; Durant, Tonji; Hatfield-Timajchy, Kendra
Subject: 4636: IRB Approval of Amendment #2 to Protocol (Expedited)

DATE: 11/3/2005

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

SUBJECT: IRB Approval of Amendment #2 to Protocol #4636, "Human Behavior in Fire Study" (Expedited)

TO: Michael Ballesteros, PhD, MS [ZZB0]
NCIPC/UIP

CDC's IRB "C" has reviewed and approved your request to amend protocol #4636. This amendment requested modifications to the consent form that was requested by Battelle's IRB. The additions to the consent form are: inclusion of statements about the risk of confidentiality, a Certificate of Confidentiality will be applied and the form amended once approved; inclusion of contact information for the Battelle IRB; and revision to the agreement line to reflect the first person. The amendment was reviewed using the expedited review process outlined in 45 CFR 46.110(b)(2), "Minor changes in previously reviewed research during the period (of one year or less) for which approval is authorized."

Reminder: IRB approval of protocol #4636 will still expire on 11/2/2006. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other 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:
Angela Booker
Tonji Durant
Kendra Hatfield-Timajchy



Memorandum

DATE: November 14, 2005

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

SUBJECT: IRB Approval of Amendment #3 to Protocol #4636, "Human Behavior in Fire Study" (Expedited)

TO: Michael Ballesteros, PhD, MD [ZZB0]
NCIPC/UIP

CDC's IRB "C" has reviewed and approved your request to amend protocol #4636. This amendment requested the following: waiver of documentation of informed consent and a waiver of authorization of the Privacy Rule (HIPAA). The amendment was reviewed using the expedited review process outlined in 45 CFR 46.110(b)(2), "Minor changes in previously reviewed research during the period (of one year or less) for which approval is authorized." The Board approved a waiver of documentation of informed consent for the telephone screening in accordance with 45 CFR 46.117(c). The Board also approved a waiver of authorization under the Privacy Rule in accordance with 45 CFR 164.512(i) to allow the disclosure of potential protected health information (PHI) from fire departments to study investigators for recruitment.

Reminder: IRB approval of protocol #4636 will still expire on 11/2/2006. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other 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) 639-4954 or e-mail: huma@cdc.gov.


Jennifer McCleary

cc:
Angela Booker
Tonji Durant
Amy Sandul

Santella, Anthony (CDC/CCEHIP/NCIPC) (CTR)

From: Diekman, Shane T. (CDC/CCEHIP/NCIPC)
Sent: Thursday, June 15, 2006 10:27 AM
To: Santella, Anthony (CDC/NCIPC/DUIP) (CTR)
Subject: FW: 4636: Approved Amendment to protocol

Attachments: IRB#4636 Amendment Form #4 1_30_06.pdf; Consent Form 1_27_06 FINAL (with strikethrough).doc; Consent Form 1_27_06 FINAL (without strikethrough).doc

From: McCleary, Jennifer **On Behalf Of** Human Subjects Review-OD
Sent: Wednesday, February 01, 2006 12:39 PM
To: Ballesteros, Michael (Mick)
Cc: Booker, Angela; Diekman, Shane T
Subject: 4636: Approved Amendment to protocol

The Human Research Protection Office has reviewed this amendment and determined that this is an administrative change that could be handled by the IRB Administrator. The revised consent form has been processed and approved, a copy has been filed in the office folder.

The amendment request was approved in our database for documentation purposed but no further action is required from the Center.

Thanks,

Jennifer McCleary
IRB-C Administrator
Human Research Protection Office/OCSCO
Phone: 404-639-4954
Fax: 404-639-4901
MS: D73

From: Diekman, Shane T
Sent: Monday, January 30, 2006 11:37 AM
To: Human Subjects Review-OD
Cc: Coulberson, Sandra L; Booker, Angela; Ballesteros, Michael (Mick); Diekman, Shane T
Subject: amendment to protocol #4636

Due to a staff change, the contact information on our consent form is no longer correct. We have updated our consent form with new contact information.

Shane Diekman

Shane Thomas Diekman, PhD, MPH
Behavioral Scientist
Division of Unintentional Injury Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
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