Richter, Patricia (CDC/CCHP/NCCDPHP)

From: Peterson, Felecia (CDC/OD/OCSO)
Sent: Monday, June 22, 2009 9:06 AM
To: Richter, Patricia (CDC/CCHP/NCCDPHP)
Subject: RE: 4443: Approval of changes, expedited review -- "Human Smoking Behavior Study"

Yes, everything was approved, and you can proceed with the study.

Felecia D. Peterson
IRB Administrator/Program Specialist
Centers for Disease Control and Prevention
Office of the Chief Science Officer
Human Research Protection Office
1600 Clifton Road, N.E. - Mailstop D73
Atlanta, Georgia 30333
Phone: (404) 639-4961
Fax: (404) 639-4901
E-mail: FDP1@CDC.GOV

From: Richter, Patricia (CDC/CCHP/NCCDPHP)
Sent: Monday, June 22, 2009 9:04 AM
To: Richter, Patricia (CDC/CCHP/NCCDPHP); Peterson, Felecia (CDC/OD/OCSO)
Subject: RE: 4443: Approval of changes, expedited review -- "Human Smoking Behavior Study"
Importance: High

Hi Felecia-

Sorry to bother you again about this but I want to make sure everything was approved before we proceed.

Thank you-
Patricia

From: Richter, Patricia (CDC/CCHP/NCCDPHP)
Sent: Friday, June 19, 2009 8:32 AM
To: Peterson, Felecia (CDC/OD/OCSO)
Subject: RE: 4443: Approval of changes, expedited review -- "Human Smoking Behavior Study"

Hi Felecia-

Thank you very much. I notice that the summary below doesn't include the referral bonus (it was highlighted in the modified consent form). I just want to confirm that it was included in the approval.

Thank you-
Patricia

From: Peterson, Felecia (CDC/OD/OCSO)
Sent: Thursday, June 18, 2009 5:55 PM
To: Richter, Patricia (CDC/CCHP/NCCDPHP)
Cc: Redmond Leonard, Joan (CDC/CCHP/NCCDPHP); Bertrand, Jacquelyn (CDC/CCHP/NCBDDD)
Subject: 4443: Approval of changes, expedited review -- "Human Smoking Behavior Study"

Dr. Richter, below is the final approval memo on the amendment request of protocol study 4443. I do apologize for the lengthy review time that it took to approve this amendment, thanks for t

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

DATE: **June 17, 2009**

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

SUBJECT: CDC Approval of Changes to Protocol 4443.0, "Human Smoking Behavior Study." (Expedited)

TO: Patricia Richter, PhD
NCCDPHP/OSH

CDC's IRB G has reviewed and approved the request to make changes to protocol 4443.0, " Human Smoking Behavior Study." These changes included are: **Modification 1.** The PI's are struggling to obtain acceptable rates of participation and retention for the present study. In particular, smokers of "light" and ultra-light" cigarettes have proven very difficult to locate and recruit. In order to increase the effectiveness of our recruiting and enrollment efforts for the present study, we are requesting IRB approval for an extension of existing recruiting methods, materials and participant compensation. ***Modification 2.*** *A. Modify advertisements to target potential study participants. These advertisements will be printed in local newspapers, distributed on cars, gate latches and doors, and handed out to potential participants. B. Add a completion bonus. Every individual who completes the study will receive a $25 dollar bonus payable via a gift certificate for Wal-Mart or local gas stations. C. Distribute flyers to individuals seen smoking near the laboratory with a number to call if they are interested in hearing more about laboratory research opportunities related to smoking. Only a brief overview of the lab and the fact that tobacco research is conducted there would be provided at the direct point of contact. Study specific information or eligibility requirements would be handled directly by laboratory staff answering phones and screening potential participants. None of the above modifications will increase participant burden or risks associated with study participation.*

The action was reviewed in accordance with 45 CFR 46.110(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized. CDC IRB approval of protocol 4443.0 will still expire on 12/8/2009. 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 a request for review of changes to the protocol for IRB review and approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-4721 (or by e-mail at Human Subjects Review - OD on the global CDC global address list or at huma@cdc.gov).

Felecia Peterson

cc:
Joan Redmond-Leonard
Jacquie Bertrand