From: Honein, Margaret (Peggy)
Sent: Sunday, November 06, 2005 10:05 AM
To: Ruuska, Sarah
Subject: Fw: 2087: IRB Approval of Amendment

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Galusha, Pamela <pkg0@cdc.gov>
To: Honein, Margaret (Peggy) <mrh7@cdc.gov>
CC: NCBDDD Human Subjects Review <ncbdddhsr@cdc.gov>; Merritt, Robert <rem2@cdc.gov>
Sent: Sat Nov 05 13:29:43 2005
Subject: 2087: IRB Approval of Amendment

DATE: 11/5/2005

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 to Protocol #2087, "The National Birth Defects Prevention Study" (Expedited)

TO: Margaret Honein, PhD, MPH [MRH7]
NCBDDD

CDC's IRB B has reviewed and approved your request to amend protocol #2087 by adding a genetic testing fact sheet, adding a partial ID to the informed consent documents in the cheek cell collection kits, to add candidate genes to the study, to delete Emory University as a collaborator, and to add Biologics Focus Groups. The action 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 #2087 will still expire on 2/17/2006. 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.

Pam Galusha

cc:
NCBDDD HSR
Rob Merritt