



Memorandum

Date September 5, 2012

From LaShonda Roberson, MPH
LCDR, USPHS
IRB-B Administrator
Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 5717, "Katrina Pilot Registry." (Expedited)

To Jay Sapp
ATSDR/ATSDR

CDC's IRB-B has reviewed and approved your request to amend protocol 5717, "Katrina Pilot Registry". These changes included the following: Deleted all health questions from questionnaire per OMB request. Changed goals/objectives to exclude comparing health questions to NHANES. Added secondary goals to compare data collected on type and location of trailer with FEMA data set and to attempt to create a person time exposure variable using the data collected currently in questionnaire. Added questions on type and location of trailer. Changed sample size from 5,000 to 3,000 due to power calculations to account for change in goals. Changed sampling plan due to new sample size. Outreach material and website contents changed to delete some references to health questions. Changes are noted in protocol and appendices submitted.

The action was reviewed in accordance with the expedited review process outlined in [45 CFR 46.110(b)(1), Category 7 or 46.111(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized].

Reminder: IRB approval of protocol #5717 will still expire on 6/25/2013.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB 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 (404) 639-7570 or e-mail: huma@cdc.gov.

cc:
NCEH/ATSDR Human Subjects