



Memorandum

Date October 21, 2011

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: Updated outreach material added: Appendix A updated letter of introduction; Appendix B new radio advertisement, web materail and frequently asked questions added. Updated introduction, screening and proxy scripts in Appendix C. Deleted some health questions in main questionnaire in Appendix D per OMB request. Sampling plan added as Appendix E per OMB request. All changes are noted in the marked 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 6/25/2012.

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) 639-4721 or e-mail: huma@cdc.gov.

cc:
NCEH/ATSDR Human Subjects