ATTACHMENT E

IRB Approval Notices

ATTACHMENT E1

RTI IRB Approval

RTI INTERNATIONAL

IRB ID Number: 12743

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Children's Health after the Storm
RTI Project Number: 0212734 **RTI Proposal Number** (if no Project Number)
Project Leader: Lisa Thalji
Project Team Member Contact (if different from Project Leader): Marjorie Hinsdale
Source of Funding for this Study: CDC
Date Submitted to IRB: March 17, 2011 (revised)
Level of Review *(check one)*:
Full ☒, IRB Meeting Date: 1/18/2011
Expedited ☐, category: None

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☒ Pretest/Pilot Test
- ☐ Full Implementation:
- ☐ Amendment, describe:
- ☐ Add study site(s):
- ☐ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☒ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: 02-16-2012
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caldell
Signature - IRB Member or Chair

03-23-2011
Date of IRB Approval

Juesta Caddell, PhD
Name - IRB Member or Chair (print or type)

- ☐ Copy sent to project leader on:
- ☐ Entered into MIS

Office of Research Protection, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA

RTI INTERNATIONAL

IRB ID Number: 12743

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Children's Health after the Storm
RTI Project Number: 0212734 **RTI Proposal Number** (if no Project Number)
Project Leader: Lisa Thalji
Project Team Member Contact (if different from Project Leader): Marjorie Hinsdale
Source of Funding for this Study: CDC
Date Submitted to IRB: March 24, 2011
Level of Review *(check one)*:
Full ☐, IRB Meeting Date:
Expedited ☒, category: M: Minor changes in approved research

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test
- ☐ Full Implementation:
- ☒ Amendment, describe: revised authorizations, consents/assents and scripts, website FAQs, letters, and brochure
- ☐ Add study site(s):
- ☐ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☐ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
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- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: 02-16-2012
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell

Signature - IRB Member or Chair

04-08-11
Date of IRB Approval

Juesta Caddell, PhD
Name - IRB Member or Chair (print or type)

- ☐ Copy sent to project leader on:
- ☐ Entered into MIS

Office of Research Protection, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org

ATTACHMENT E2

CDC IRB Approval - Site Restriction

Memorandum

Date July 29, 2011

From Betty Wong, MPH, CHES
IRB C Administrator, Human Research Protection Office

Subje Site Restricted: CDC IRB Approval of New Protocol #6115, "The Children's Health after the Storms (CHATS)" (Expedited)

To Fuyuen Yip, PhD, MPH
NCEH/EHHE

CDC's IRB C has reviewed the request for approval of new protocol #6115, "The Children's Health after the Storms (CHATS)," and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on 07/28/2012. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 2-5 and 7. The IRB determined that the study poses no greater than minimal risk to subjects.

Collaborator Site Restriction: Study activities may not begin with the following collaborator/site until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office (HRPO) and the PI has been notified by HRPO that this restriction has been lifted:

Louisiana State University Health Sciences Center

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 along with available IRB approvals from all collaborators. 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 along with all completed supporting documentation at least six weeks before the protocol's expiration date of 07/28/2012.**

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
Betsey Dunaway
Marlena Wald

ATTACHMENT E3

LSU IRB Approval

EXPEDITED APPROVAL
LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER
(Assurance Number FWA00002762)
IRB Registration Number 00000177 expires March 03, 2014

FROM: LSUHSC-NO Institutional Review Board

TO: Joseph Moerschbaecher, Ph.D.
Vice Chancellor for Academic Affairs

RE: IRB Application By: **James H. Diaz, MD, DrPH**
Department of Environmental and Occupational Health Sciences

Entitled: IRB #7749: Children's Health after the Storms (CHATS) Study

This is to document review and approval of the above-referenced research protocol. In the judgment of this Board, the procedures delineated in said application conform to the pertinent DHHS and FDA rules and regulations regarding use of human subjects. This procedure is authorized by 45CFR46.110 and 21CFR56.110 as published in the Federal Register November 9, 1998. Records regarding action of the Board, referable to said project, are on file in the Office of the Chairman. This study is expedited under 46.110 category **#2, 3, 5, 6 & 7** of 45CFR Part 46, and under 45CFR46 Subpart D Sec. 46.404, and 21CFR50 Sec. 50.51.

THE INVESTIGATOR agrees to report to the Committee any emergent problems, serious adverse reactions, or procedural changes that may affect the status of the investigation, and that no such change will be made without Board Approval, except where necessary to eliminate apparent immediate hazards. The investigator also agrees to periodic review of this project by the Board at intervals appropriate to the degree of risk to assure that the new project is being conducted in compliance with the Board's understanding and recommendation, and this interval will not exceed one year.

PLEASE NOTE:

1. Any advertisement to recruit subjects for this study must be approved by the IRB prior to posting, publication and/or distribution.
2. Other institutional approvals may be required before the study can be initiated.
3. Written notification (at the time this study is completed/ canceled) must be sent to the Office of the Chairman.
4. Note that in addition to the Informed Consent Form, HIPAA Authorization is required from each subject.

Approval Period: 22 August 2011 to 21 August 2012

James H. Diaz MD, DrPH — DATE: 08/22/2011
Principal Investigator

Kenneth E. Kratz — DATE: 8/22/11
Kenneth E. Kratz, Ph.D., Chairman

ATTACHMENT E4

CDC IRB Approval Site Restriction Lifted

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date January 5, 2012

From Betty Wong, MPH, CHES
IRB C Administrator, Human Research Protection Office

Subject CDC IRB Approval of New Protocol #6115, "The Children's Health after the Storms (CHATS)" (Expedited)

To Fuyuen Yip, PhD, MPH
NCEH/EHHE

CDC's IRB C has reviewed the request for approval of new protocol #6115, "The Children's Health after the Storms (CHATS)," and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on 07/28/2012. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 2-5 and 7. The IRB determined that the study poses no greater than minimal risk to subjects.

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 along with available IRB approvals from all collaborators. 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 along with all completed supporting documentation at least six weeks before the protocol's expiration date of 07/28/2012.

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 Office of Scientific Integrity (404) 639-7570 or e-mail: huma@cdc.gov.

cc:
NCEH/ATSDR Human Subjects
Betsey Dunaway
Marlena Wald

ATTACHMENT E5

RTI IRB Approval of Amendment Addressing CDC IRB Changes

RTI INTERNATIONAL

IRB ID Number: 12743

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Children's Health after the Storm
RTI Project Number: 0212734 **RTI Proposal Number** (if no Project Number)
Project Leader: Diane Wagener
Project Team Member Contact (if different from Project Leader): Lisa Thalji
Source of Funding for this Study: CDC
Date Submitted to IRB: August 2, 2011
Level of Review *(check one)*:
Full ☐, IRB Meeting Date:
Expedited ☒, category: M: Minor changes in approved research

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test
- ☐ Full Implementation:
- ☒ Amendment, describe: revised RFARP, consent/assent forms and scripts, questionnaires, study brochure, website text
- ☐ Add study site(s):
- ☐ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☐ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
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- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: 02-16-2012
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell

Signature - IRB Member or Chair

August 11, 2011
Date of IRB Approval

Juesta M. Caddell, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: August 11, 2011
☐ Entered into MIS

Office of Research Protection, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org

ATTACHMENT E6

RTI IRB Continuing Notice Approval

RTI INTERNATIONAL

IRB ID Number: 12743

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Children's Health after the Storm Cognitive Testing of Instrument
RTI Project Number: 0212734 **RTI Proposal Number** (if no Project Number)
Project Leader: Lisa Thalji
Project Team Member Contact (if different from Project Leader): Marjorie Hinsdale
Source of Funding for this Study: Genentech
Date Submitted to IRB: January 13, 2012
Level of Review *(check one)*:
Full ☐, IRB Meeting Date:
Expedited ☒, category: 9: Cont. Rev. minimal risk research

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test
- ☐ Full Implementation:
- ☐ Amendment, describe:
- ☐ Add study site(s):
- ☒ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☐ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
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- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: 02-16-2013
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell
Signature - IRB Member or Chair

1/17/2012
Date of IRB Approval

Juesta Caddell, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader
☒ Entered into MIS

Office of Research Protection, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org