Attachment 10

IRB Approval Letters

INSTITUTIONAL REVIEW BOARD NOTICE – FULL APPROVAL WITH CONDITIONS

Principal Investigator/Project Manager : April Greek

Proposal/Project Title : Case Investigation of Cervical Cancer (CICC) Study

Client/Funding Agency : HHS Centers for Disease Control and Prevention

IRB No. : IRB 0617-100069348 Rev 0.0 **Date of Submission to IRB :** 1 June 2016

Proposal No. : OPP200998/ CON00023780 **Project No. :** 100069348

Subcontract to Battelle from N/A (if applicable)

Subcontract from Battelle to N/A (if applicable)

Level of Review

☒ Expedited Approval. Minimal Risk to Human Subjects per 45 CFR 46.110 (b)(1):

- Category 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
- Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Subject to HIPAA regulations at 45 CFR 164. Participants will voluntarily provide their AUTHORIZATION to contact participants' healthcare provider(s). Under HIPAA authorization, healthcare providers will send applicable PHI to designated State Cancer Registries. Each State Cancer Registry will prepare and provide a Limited Use Dataset to Battelle under the terms of a Data Use Agreement. Battelle will not be in possession of participants' Protected Health Information (PHI) at any point in this research.

Type of Approval – IRB FULL APPROVAL with CONDITIONS

All phases of research may proceed subject to the following Condition:

The Principal Investigator may NOT receive any human subject data FROM a participating State Cancer Registry WITHOUT the Battelle IRB's verification/acknowledgement that a fully executed Data Use Agreement has been established.

Upon the Battelle IRB's verification/acknowledgement of same, the research study may proceed without restriction.

See IRB Requirements and Restrictions (Page 2 of 3).

This study continues approval to 3 March 2017.

Signature
Co-Chair, Battelle Institutional Review Board

6/1/2016
Date

Print or Type Name

Battelle

Requirements and Restrictions

IRB Requirements:

- The IRB shall possess an appropriate Translation Certificate for each study document translated into a language other than English.
- Per 45 CFR 46.109(e), the IRB has the authority to observe or to have a third party observe the consent process and the research.
- Per 45 CFR 46.113, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Continuing Review/Approval. Federal regulations require that human subjects research protocols maintain IRB approval for the entire duration of the research study, including data analysis and report writing. If this project will continue beyond 3 March 2017, the final day of approval, apply for continuing approval of IRB 0617-100069348 Rev 0.0.

Approval for Amendments. Seek the IRB's approval for any proposed amendments/ revisions to the protocol, including changes to study documents and recruiting materials. Federal regulations require that the IRB re-review and re-approve human subjects research prior to implementing any proposed amendments or revisions. Complete and submit an application for amendment to the IRB manager.

Reporting. The following events must always be reported to the IRB:

- Unforeseen events (within four (4) hours of discovery). See definition of "unforeseen event" on page 3 of 3.
- Protocol violations that
  - Placed a human subject at risk, or
  - Were caused by the action or inaction of a researcher
- New or changed risks to human subjects, including new findings
- Failure to follow regulations or IRB requirements
- Unresolved complaint by a human subject
- Audit, inspection, or inquiry by a federal agency
- Breach of confidentiality
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a human subject
- Incarceration of a human subject.

Documentation Control Requirements. Study documents and records, e.g., informed consent documents and data collection instruments, must be maintained in accordance with established confidentiality measures. Federal regulations require that all documents and records be retained for at least three (3) years after a study is formally closed. Battelle policy or client requirements may require a longer retention.

Definitions

Expedited Review – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal regulations at 45 CFR 46.110 permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Only the IRB can determine if a proposed research activity meets the requirements for expedited review.

Adverse Event - An event or incident not previously known or not anticipated to result from:

- The interactions or interventions used in the research;
- The collection of privately identifiable information under the research;
- An underlying disease, disorder or condition of a human subject, and/or,
- Other circumstances unrelated to the research or any underlying disease, disorder or condition of the subject.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Depending upon applicable regulations, "minimal risk" may be defined differently for minors and other vulnerable populations.

Nonconformance - A determination that some aspect of a research study has not been performed in accordance with applicable laws and regulations, ethical standards, Battelle policies, IRB requirements, or contractual obligations.

Unforeseen Event - - A Battelle-coined term that has no regulatory equivalent, but that may summarize one or more of the following terms: (1) adverse event; (2) unanticipated problem involving subjects or others; or (3) non-conformance. Unforeseen Events must be reported to an IRB via an established reporting process.

Unanticipated Problem Involving Subjects or Others - An event in a human research study that is not expected given the nature of the research procedures and the subject population being studied, and suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

EXPEDITED APPROVAL
LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER
(Assurance Number FWA00002762) September 10, 2018
IRB Registration Number 00000177 expires August 4, 2019

FROM: LSUHSC-NO Institutional Review Board
TO: Joseph Moerschbaecher, Ph.D.
Vice Chancellor for Academic Affairs
RE: IRB Application By: **Mei-Chin Hsieh, Ph.D., MSPH**
Department of Epidemiology

Entitled: IRB # 9387: Case investigation of cervical cancer 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 **# 5, 7** of 45CFR Part 46.

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 changes will be made without Board approval, except where necessary to eliminate apparent immediate hazards to the subject. 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 Chair.
4. Note that in addition to the Informed Consent Form, HIPAA Authorization is required from each subject

Approval Period: 9/20/16 - 9/19/17

Mei-Chin Hsieh, Ph.D., MSPH, Principal Investigator — DATE: 9/19/2016

Kenneth E. Kratz, Ph.D., Chairman
Barry Potter, Ph.D., Vice Chairman — DATE: 9/20/2016

Michigan Department of Health and Human Services
Institutional Review Board for the Protection of Human Research Subjects
South Grand Building, 5th Floor, 333 S. Grand Ave., P.O. Box 30195, Lansing, MI 48909
E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

DETERMINATION NOTICE

To:	**Glenn Copeland**	Responsible Department Employee
From:	**Ian A. Horste**	Institutional Review Board Chair
CC:	**Sarah Lyon-Callo**	Authorizing Bureau/Office Director

MDHHS IRB Log #: 201612-07-EA **Date Received: 12/20/2016**

Study Title: Case Investigation of Cervical Cancer Study (CICC Study)

Primary Investigator(s): Vicki Benard, PhD

Funding Source(s): CDC

Committee Action/Determination Type:

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☒ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☐ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

Comments: This minimal risk research is eligible for expedited review under categories 5 and 7. For the survey component of this research, the IRB approves a waiver of the requirement to document informed consent with a signature under 46.117(c)(2). The information sheet associated with the survey must be made available to each subject. For the medical records abstraction component of the research, the IRB requires (as is proposed in the IRB application) that written authorization be obtained before medical records are recorded for research purposes. Any changes to approved study documents should receive approval from the IRB prior to implementation.

Chair Signature: Ian A Horste **Determination Date: 01/25/2017**

Expiration Date*: 01/25/2018

**Human subjects' research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

The MDHHS IRB must approve any change to this study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unexpected problem or adverse event in the research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

Michigan Department of Health and Human Services
Institutional Review Board for the Protection of Human Research Subjects
South Grand Building, 5th Floor, 333 S. Grand Ave., P.O. Box 30195, Lansing, MI 48909
E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

Institutional Review Board - New Brunswick
335 George Street
Suite 3100, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-9806

Institutional Review Board - Newark
65 Bergen Street
Suite 511, 5th Floor
Newark, NJ 07107
Phone:973-972-3608

DHHS Federal Wide Assurance Identifier: FWA00003913
IRB Chair Person: Nancy Fiedler
IRB Director: Donna Hoagland
Effective Date: 12/20/2016
Approval Date: 12/20/2016
Expiration Date: 12/19/2017

eIRB Notice of Approval for Initial Submission # Pro20160000981

STUDY PROFILE

Study ID:	Pro20160000981		
Title:	Case Investigation of Cervical Cancer		
Principal Investigator:	Antoinette Stroup	**Study Coordinator:**	Natalia Herman
Co-Investigator(s):	Lisa Paddock	**Other Study Staff:**	Nahrin Ahmed Adrian Botchway Susan German Sara Ghauri Natalia Herman Karen Jackson Jie Li Kevin Masterson

Manisha
Narang
Cynthia Nunez
Neeru Suri
Sequoia Young

Sponsor:	Centers for Disease Control and Prevention	**Approval Cycle:**	Not Applicable
Risk Determination:	Minimal Risk	**Device Determination:**	Not Applicable

Review Type:	Expedited	**Expedited Category:**	7	**Exempt Category:**	n/a
Subjects:	544	**Specimens:**	0	**Records:**	

CURRENT SUBMISSION STATUS

Submission Type:	Research Protocol/Study	**Submission Status:**	Approval
Approval Date:	12/20/2016	**Expiration Date:**	12/19/2017

Pregnancy Code:	No Pregnant Women as Subjects	**Pediatric Code:**	No Children As Subjects	**Prisoner Code:**	No Prisoners As Subjects

Protocol:	9/28/16	**Consent:**	n/a	**Other Materials:**

Appendix 1. Physician Letter
Appendix 1_MD letter_v10.25.16.pdf

Appendix 1a. Physician Information Sheet Appendix 1a_NJSCR Physician form_v10.25.16.pdf

Appendix 2. Patient Letter- English
Patient letter_v11.17.16_clean.docx

Appendix 2a. Patient Research Information Sheet- English CICC Research participant information sheet_English_5 10 16 with letterhead version 11.17.16 clean.docx

Appendix 3. Patient HIPAA/Medical Record Release Form- English CICC HIPAA and Medical release form_English_v5 10 16 (002) with letterhead.docx

Appendix 4. Patient Healthcare Source Form- English Appendix4_Healthcare Source Form_8.9.16.pdf

Appendix 5. Survey- English Appendix5_Survey English_8.9.16.pdf

Appendix 6. Phone Script for Follow-up- English Appendix6_Phonescript_8.9.16.pdf

Appendix 7. Thank You Letter- English Appendix7_ThankYou letter_8.9.16.pdf

Appendix 8. Facility Letter Appendix8_Facility Letter MRA_8.9.16.pdf

Appendix 9. Medical Record Chart Abstraction Form Appendix9_Chart Abstraction Form_8.9.16.pdf

Appendix 10. Patient Letter- Spanish SPA_patient letter_11.22.16_clean.docx

Appendix 11. Patient Information Sheet- Spanish SPA_patient research info_5 10 16 with letterhead version 11.17.16 clean.docx

Appendix 12. Patient HIPAA/Medical Record Release Form- Spanish SPA_HIPAA Med Rec Release_5 10 16 with letterhead version 11.16.16 track.docx

Appendix 13. Patient Healthcare Source Form- Spanish Appendix13_SPA healthcare source_8.9.16.pdf

Appendix 14. Survey- Spanish Appendix14_SPA survey_8.9.16.pdf

Appendix 15. Phone Script for Follow-up- Spanish Appendix15_SPA phone script_8.9.16.pdf

Appendix 16. Spanish Translation Certificate Appendix16_Affidavit_O-011222_8.9.16.pdf

Appendix 17. FAQ Brochures (English only) Appendix17_FAQ brochures_8.9.16.pdf

English Patient Letter v.11.17.16

Spanish Patient Letter v. 11.22.16

*** Study Performance Sites:**

There are no items to display
Other 120 Albany Street, Tower 2, 8th Floor, New Brunswick, NJ 08903

There are no items to display
New Jersey State Cancer Registry 135 East State Street Trenton, NJ 08608

ALL APPROVED INVESTIGATOR(S) MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.

3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue. (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.**

4. **Amendments/Modifications/Revisions** : If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.

5. **Unanticipated Problems**: Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

6. **Protocol Deviations and Violations** : Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://orra.rutgers.edu/hspp

7. **Consent/Assent**: The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

8. **Completion of Study:** Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

10. Letter Comments: *There are no additional comments.*