Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmirb@jhmi.edu

Date: August 15, 2011

NEW APPLICATION APPROVAL

Review Type:	Expedited
PI Name:	Rebecca Landa
Study #:	NA_00046473
Study Name:	NCS Formative Research Project #8 • Development and Validation of Autism Case Confirmation Approaches for Use in the National Children•s Study
Committee Chair:	David Cornblath
Committee:	JHM-IRB 2

Date of review: July 28, 2011

Date of approval: July 28, 2011

Date of expiration: July 27, 2012

The JHM IRB approved the above-referenced New Application.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of one parent is required.

Date of Approval and Expiration Date: The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with treatment interventions.

Changes in Research: All proposed changes to the research must be submitted using an eIRB Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review: Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: You must inform the IRB of any unanticipated problems involving risks to participants or others.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

Study documents:

Written Consent:

Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by subjects enrolled in the study should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of protocol records, and consent documentation is part of such monitoring.
FINAL_Landa_NA00046473_CF_072811_NoLogo.doc

Recruitment Materials:
FINAL_Landa_NA00046473_TelephoneScreeningNonClinic_072811_NoLogo.doc
FINAL_Landa_NA00046473_TelephoneScreeningClinic_072811_NoLogo.doc
FINAL_Landa_NA00046473_Flyer_072811_NoLogo.doc
FINAL_Landa_NA00046473_WebsitePosting_072811_NoLogo.doc

HIPAA Form 3:
FINAL_Landa_NA00046473_HIPAAForm3_072811_NoLogo.doc

HIPAA Form 4:

FINAL_Landa_NA00046473_HIPAAForm4_072811_NoLogo.doc

Additional Supplemental Study Documents:
Final_Landa_NA00046473_Parent Self Report Instrument Measure_041811
FINAL_Landa_NA00046473_ADI R Part 1_041811
FINAL_Landa_NA_00046473_Visit letter to families
FINAL_Landa_NA00046473_Parent Interview Measure_PreschoolASI_041811
FINAL_Landa_NA00046473_ADI R Part 2_041811
Final_Landa_NA00046473_NCS assessment summary sheet
FINAL_Landa_NA00046473_Direct Observation Measure_STAT-NCS_041811

eFormA:
FINAL_Landa_NA00046473_eform A_070811

Study Team Members:
Kerry Buechler, Joel Rothwell, Sarah Warnet, Stephanie Merwin, Saime Tek, Cara Griego, Sarah Mccruden, Elizabeth Utter, Sadaf Siddiqi, Umar Khan, Eliezer Sollins, Deborah Crawford, Patricia Rao, Shannon Dillon, Klaus Libertus, Jennifer Wainman, Jessica Holman, Katie Lewis, Ashley Faherty, Kellie Ileto, Justine Stanmyer, Dasal Jashar, Melissa Folsom, Jessica Jacques, Alicia Ritgert, Katelyn Boswell, Rondalyn Whitney, Lindsey Graham, Megan White, Jennifer Sharpless, Rebecca Zimmerman, Jessie Sue Smith, Tracy Singer, Amy Schrembs, Dana Herman, Katelyn Vertucci, Anne Inge, Emily Freilich, Stephanie Kreis, Marguerite Adams, Emily Watkins, Christine Hess, Jessica Decker, Elizabeth Eiler, Jessica Smolarz

UNIVERSITY
OF MIAMI

University of Miami
Human Subjects Research Office (M809)
PO Box 016960, Miami, Florida 33101
1500 NW 12 Avenue, Suite 1002, Miami, F

Ph: 305-243-3
Fax: 305-243-
www.hsro.mia

EXPEDITED – APPROVAL

May 13, 2011

Daniel Messinger, Ph.D.
University of Miami
Department of Psychology
Coral Gables Campus
Coral Gables, FL 33124

HSRO STUDY NUMBER:	**20110311**
STUDY TITLE:	**NCS Formative Research Project #8 – Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study**
IRB ACTION DATE:	**5/13/2011**
STUDY APPROVAL EXPIRES:	**5/12/2012**
SPONSOR NAME:	NIH
FWA:	**FWA00002247**

On May 13, 2011, an IRB Designee approved the following items under the expedited review process. This study has been approved for the inclusion of minors pursuant to 45 CFR 46.404. This review confirms that the grant application is consistent with the goals of the research proposed.

APPROVAL INCLUDES:

New Research Protocol

Research Materials (English Versions Only)

- Informed Consent Form - Main
- Informed Consent Form - Supplemental
- Recruitment Flyer (2)
- Clinician to Subject Letter
- Colleague to Colleague Letter
- ASI
- STAT-NCS
- Recruitment Script
- Parent Self Report

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and it may be officially suspended or terminated.

Sincerely,

[This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature]

Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives

/dsp

cc: IRB File

Brittany Lambert

UNIVERSITY
OF MIAMI

University of Miami
Human Subjects Research Office (M809)
PO Box 016960, Miami, Florida 33101
1500 NW 12 Avenue, Suite 1002, Miami, Fl

Ph: 305-243-3
Fax: 305-243-3
www.hsro.miar

EXPEDITED – APPROVAL

February 16, 2012

Daniel Messinger, Ph.D.
University of Miami
Department of Psychology
Coral Gables Campus
Coral Gables, FL 33124

HSRO STUDY NUMBER:	**20110311**
STUDY TITLE:	**NCS Formative Research Project #8 – Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study**
IRB ACTION DATE:	**2/15/2012**
STUDY APPROVAL EXPIRES:	**2/14/2013**
Continuing Report #:	**CRR013683**
SPONSOR NAME:	NIH
FWA #:	FWA00002247

On February 15, 2012, an IRB Designee approved the following items under the expedited review process.

APPROVAL INCLUDES:

Continuing Report (CRR013683)
Research Materials (English Versions Only)

- Informed Consent Form - Main
- Informed Consent Form - Supplemental

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and it may be officially suspended or terminated.

Sincerely,

[This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature]

Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives

/dsp

cc: IRB File
Brittany Lambert

Mount Sinai
MOUNT SINAI SCHOOL OF MEDICINE

Program for the Protection of Human Subjects
Mount Sinai School of Medicine and Mount Sinai Hospital
One Gustave L. Levy Place, Box 1075
3 East 101st Street, First Floor
New York, NY 10029-6530
Phone: (212) 824-8200
Fax: (212) 876-6789

APPROVAL OF RESEARCH

Date: July 19, 2011

To: **Philip Landrigan, MD (philip.landrigan@mountsinai.org)**

On **7/18/2011**, an Institutional Review Board of the Mount Sinai School of Medicine, in accordance with Mount Sinai's Federal Wide Assurances (FWA#00005656, FWA#00005651) to the Department of Health and Human Services approved the following human subject research from **7/18/2011** until **7/17/2012** inclusive:

Type of Review:	**Initial**
Project Title:	**NCS FORMATIVE RESEARCH PROJECT #8 - DEVELOPMENT AND VALIDATION OF AUTISM CASE CONFIRMATION APPROACHES FOR USE IN THE NATIONAL CHILDREN'S STUDY [MAIN AND SUPPLEMENT] HHSN275201100002C**
Investigator:	**Philip Landrigan, MD**
MSSM Project #:	**HS#: 11-00527, GCO#: 10-1639(0001)(01) ME**
Funding Agency:	**National Institute Of Child Health And Human Development/NIH/DHHS**
IND or IDE (if any):	**No INDs; No IDEs**
Submission Details (if any):	**None**

Before **6/3/2012** or within 30 days prior to study close, whichever is earlier, you are to submit a completed FORM HRP-212: Continuing/Final Review Progress Report and required attachments, in order to request continuing IRB approval or study closure. If IRB continuing review approval is not granted before the expiration date of **7/17/2012**, IRB approval of this research expires on that date.

The IRB has determined that this research involves no greater than MINIMAL RISK. Minimal risk means that 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 (45CFR.46.102; 21CFR50.3k). The IRB approved this research under **expedited review procedure category(ies) #4, 6 & 7.**

In conducting this research you are required to follow the requirements listed in the **Investigator Manual.** If stamped approved consent forms are attached, use copies of these forms to document consent. IRB approval does not constitute or imply institutional support for the conduct of this research.

Sincerely yours,

Jeffrey H. Silverstein, MD

Jeffrey H. Silverstein, M.D.
Chair, Institutional Review Board
Program Director, Program for the Protection of Human Subjects
Associate Dean, Research

cc: Study Contact: Elise Barrow/Zara St. Croix, elise.barrow@mssm.edu/zara.st.croix@mssm.edu

May 06, 2011

KIMBERLEY DAWN LAKES
PEDIATRICS ADMINISTRATION

RE: UCI IRB HS# 2010-7944 *Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study*

The above-referenced human-subjects research project has been approved by the University of California, Irvine Institutional Review Board (UCI IRB). This approval is limited to the activities described in the approved Protocol Narrative, and extends to the performance of these activities at each respective site identified in the Application for IRB Review. In accordance with this approval, the specific conditions for the conduct of this research are listed below, and informed consent from subjects must be obtained as indicated. Additional conditions for the general conduct of human-subjects research are detailed on the attached sheet.

NOTE: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other institutional clearances and approvals may be required (e.g., EH&S, Radiation Safety, School Dean, other institutional IRBs). Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity. Such agreements must be executed by an institutional official in Sponsored Projects, a division in the UCI Office of Research. The University is not obligated to legally defend or indemnify an employee who individually enters into these agreements and investigators are personally liable for contracts they sign. Accordingly, the project should not begin until all required approvals have been obtained.

Questions concerning the approval of this research project may be directed to the Office of Research, 5171 California Avenue, Suite 150, Irvine, CA 92697-7600; 949-824-6068 or 949-824-2125 (biomedical committee) or 949-824-6662 (social-behavioral committee).

Expedited Review: Categories 5, 6, and 7

Kenneth G. Linden, M.D., Ph.D.
Chair, Institutional Review Board

Approval Issued: 05/06/2011
Expiration Date: 05/05/2012
UCI (FWA) 00004071, Approved: January 31, 2003

IRB Determinations as Conditions of Approval:
Child Risk Category I: Minimal Risk: One Parent / Guardian Signature is Required.[1]

Informed Consent Determinations:
1. Signed Informed Consent Required
2. Assent Not Required –Children Under the Age of 7
3. Signed UC HIPAA Research Authorization
4. Partial Waiver of HIPAA Research Authorization Granted (Recruitment Purposes Only)

cc: Department Chair

[1] *Because the study involves procedures that are no greater than minimal risk, the IRB determined that the study should be classified as child risk category I under Subpart D (45 CFR 46.404). The IRB agreed that the permission of one parent is sufficient.*

APPROVAL CONDITIONS FOR ALL UCI HUMAN RESEARCH PROTOCOLS

UCI RESEARCH POLICIES:
All individuals engaged in human subjects research are responsible for compliance with all applicable UCI Research Policies (http://www.research.uci.edu/researchpolicies.htm). The Lead Researcher of the study is ultimately responsible for assuring all study team members review and adhere to applicable policies for the conduct of human subjects research.

LEAD RESEARCHER RECORDKEEPING RESPONSIBILITIES:
Lead Researchers are responsible for keeping protocol and study records. The following web pages should be reviewed for more information about the Lead Researcher's recordkeeping responsibilities, and preparation and maintenance of research files. See http://www.research.uci.edu/ora/hrpp/leadresearcherrecordkeeping.htm and http://www.research.uci.edu/ora/hrpp/researchauditfile.htm.

PROTOCOL EXPIRATION:
The UCI IRB approval expiration date is listed below. As a courtesy, approximately 60 to 90 days prior to expiration of this approval, the Office of Research Administration will send an e-mail reminding you to apply for continuing review. **It is your responsibility to apply for continuing review and receive continuing approval for the duration of the study.** Lapses in approval should be avoided to protect the safety and welfare of enrolled subjects.

MODIFICATIONS & AMENDMENTS:
No changes are to be made to the approved protocol or the approved, stamped consent form without the prior review and approval of the UCI IRB. All changes (e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented.

APPROVED VERSIONS OF CONSENT DOCUMENTS, INCLUDING STUDY INFORMATION SHEETS:
Unless a waiver of informed consent is granted by the IRB, the enclosed consent documents (consent form; study information sheet) with the UCI IRB approval stamp must be used for consenting all human subjects entered into this study. Only the current approved version of the consent documents may be used to consent subjects. **Approved consent documents are not to be used beyond their expiration date.**

ADVERSE EVENT & UNANTICIPATED PROBLEMS REPORTING:
All unanticipated problems or adverse events must be reported to the UCI IRB (via Institutional Review Board Administration) in accordance with Federal regulations and UCI policy. See http://www.research.uci.edu/ora/hrpp/adverseexperiences.htm for complete details.

CHANGES IN FINANCIAL INTEREST:
Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of Interest Oversight Committee (COIOC). If these changes affect the conduct of the study or result in a change in the required wording of the approved informed consent document, then these changes must also be reported to the UCI IRB via a modification request.

CLOSING REPORT:
An electronic closing report must be filed with the UCI IRB when the research concludes. See http://www.research.uci.edu/ora/hrpp/closingaprotocol.htm for complete details.

CLINICAL INVESTIGATIONS
If the study involves biomedical interventions and may use UCIMC facilities or resources (including the Plaza and satellite clinics), financial review by the Office of Clinical Research Finance Assessment (CRFA) is required prior to initiation of your clinical investigation. For information about CRFA submission requirements, please consult http://www.research.uci.edu/ora/hrpp/clinicalresearchfinance.htm or go directly to the CRFA website at https://intranet.hs.uci.edu/CRFA/research01.htm.

11000 Kinross Avenue, Suite 102
Los Angeles, CA 90095-1694

http://ohrpp.research.ucla.edu
GC-IRB: (310) 825-7122
M-IRB: (310) 825-5344

APPROVAL NOTICE
New Study

DATE:	8/15/2011
TO:	ALICE KUO PEDIATRICS-ADMINISTRATION
FROM:	NANCY LEVINE Chair, NGIRB
RE:	IRB#11-002613 NCS Autism Case Confirmation Formative Research Project

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. The UCLA IRB's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642 (IRB00000174).

Submission and Review Information

Type of Review	Full Board Review
Approval Date	8/7/2011
Expiration Date of the Study	4/20/2012
Funding Source(s)	1) NIH/NATIONAL INST OF CHILD HEALTH AND HUMAN DEVELOPMENT *Grant Title*: National Children's Study *Grant Number*: Contract HHSN267200700017C

Regulatory Determinations

-- **Children as Subjects** - The UCLA IRB determined that the research meets the requirements of 45 CFR 46.404 for research involving children as subjects.

Documents Reviewed included, but were not limited to:

Document Name	Document

	Version #
NCS_LOI_8_Formative_Research_Consent_Sup_UCLA.doc.pdf	0.01
NCS_LOI_8_Formative_Research_Consent_Main_UCLA.doc.pdf	0.01
NCS LOI 8 Site Intro Script1.docx.pdf	0.01
NCS LOI 8 Site Intro Script1.docx.pdf	0.01
recruitment_flyer.pdf	0.01

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval
As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.

University of Washington Correspondence
INTERDEPARTMENTAL
Office of Research
Human Subjects Division Box 359470

DATE: October 25, 2011

Researcher Name:	Dr. Thomas Burbacher
Department/Division:	Environmental Health and Occupational Sciences
Box Number:	357234

Re:

Application number:	40796-J
Application title:	National Children's Study - Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study
IRB Review date:	September 27, 2011
Application type:	NEW APPLICATION
Approval type:	Conditional Approval
Approval period:	9/27/2011-9/26/2012

Dear Human Subjects Division,

Human Subjects IRB J reviewed the application cited above at its regular meeting on September 27, 2011.

Your application has received CONDITIONAL APPROVAL. This means that you may hire and train study staff, and develop or refine questionnaires, surveys, tests, and/or other similar study materials, but **you may NOT start your research at this time.** The IRB has minor conditions or requests for clarification described on the following pages of this letter, which must be met before you may begin your research.

Please submit your response to this letter on the *Conditional Approval Response Form,* which is found at our forms page at http://www.washington.edu/research/hsd/forms/. Please follow the submission directions on the form and remember to:

- *Embed your answers,* **preferably in a different font**, *within the original requests detailed in this letter to create a question/answer style response.*
- *Use the "track changes" feature in Word to indicate changes to all revised documents and include a copy of this document with your materials.*
- *Create three identical review packets which contain your response, any new or requested materials and clean and tracked changes copies of revised documents.*
- *Do not include a revised application form in your response unless specifically requested.*

Your *Conditional Approval Response Form* must be received by the Human Subjects Division Office sixty days (60) from the date of this letter. **The IRB will close your new application if your response is not received within sixty (60) days.** Once we have received your *Conditional Approval Response Form* it may be reviewed by a member of the subcommittee.

Should you have any questions, please contact Mr. Richard Brzustowicz at 206-543-4464 or brz@u.washington.edu. Thank you for your prompt response.

Sincerely,

Karen A. Thomas, PhD
Chair, IRB J

KT/rb

Response Form **Conditional Approval**

Version 2.8

UNIVERSITY of WASHINGTON
Human Subjects Division, Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

For HSD Office Use Only

[ ] Master Copy	[✓] Approved
[ ] IRB Working Copy	[ ] Conditional Approval
[ ] Researcher Copy	[ ] Approval in Principle
[ ] Full IRB Review Required	[ ] Disapproved/Denied
[✓] Expedited Review	[ ] Withdrawn

Date Received:
RECEIVED
Human Subjects Division
OCT 26 2011
UW

DORA MOD # 1

Date of IRB action: OCT 28 2011

Printed name: Emily Guthrie

IRB Chair or Designee Signature: Emily Guthrie

Notes:

Research Study Information					
IRB Application Number: *(This is five digits "12345")*	40796	**IRB Committee:**	]		
IRB Application Title:	National Children's Study - Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study				
IRB Application Type:	[X] New Application [ ] Modification [ ] Status Report [ ] Other:				
IRB Review Date:	09/27/2011				
Study Contact Name:	Wendy Stone, Ph.D.				
Lead Researcher Name:	Thomas Burbacher, Ph.D.				
Name of Person Completing This Form:	Kimberly Grant, Ph.D.	**Email:**	ksg@uw.edu	**Phone:**	685-1862

***Purpose**: Use this form to respond to an IRB review letter when your application has received **Conditional Approval**.*

***Instructions**:*

1. *Complete the first page of this form.*
2. *Please mark responses below in between the brackets [ ] / [X], as appropriate.*
3. ***Open the IRB review letter in an electronic format, and then write your answers to IRB questions directly under each question. Please make clear that this letter is from you, to the IRB, by changing the recipient and date.***
4. ***Print out the IRB review letter with your answers.***
5. ***Attach those pages to this form.***
6. *Complete supplemental form(s), if applicable to your research.*
7. *Complete the index of attachments. If you are submitting changes to the consent and/or recruitment materials at the IRB's request, please include copies in "tracked changes."*
8. *When preparing double-sided copies, please make sure that each item (e.g., application, consent form, study instruments, etc.) begins on the front of a new piece of paper.*
9. *Collate all attachments so that you have three complete "application packets."*
10. *Use clips, not staples, on at least one submission, so that the IRB staff may easily distribute your materials to additional IRB reviewers, as needed.*
11. *Submit the original and two copies.*

REC'D Human Subjects Division

UNIVERSITY OF WASHINGTON

Human Subjects Division MAY 09 2011
Box 359470

HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION UW

BOX FOR COMMITTEE USE ONLY
MASTER ☐ COMM. ☐ INVESTIGATOR ☐

APPLICATION NO. 40796 EJ

Send three one-sided copies of this form (including one copy with original inked signatures - *for acceptable methods of original signature delivery please see the Signatures on IRB Forms Policy*) and three one-sided copies of all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to the Human Subjects Division, Box 359470. Do not leave blanks. Attach one one-sided copy of each research proposal, grant or contract, and/or one one-sided copy of the protocol and investigator's brochure for clinical trials. Students should attach one one-sided copy of thesis or dissertation proposals. For information and assistance, visit our web site at http://www.washington.edu/research/hsd/index.php or call (206) 543-0098. We will not accept handwritten forms, incomplete forms, or forms printed on both sides of the paper. Use 10 point type or larger throughout application. The contents of this application and attachments will be kept confidential within the limits of the law.

☐ **Check this box if your project falls into one or more of the minimal risk ("expedited") categories of research (see web site for listing of categories) and send us only two copies of all your materials.**

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Correspondence will be directed to this person. You may designate a contact person other than yourself in section II., below.

Name Thomas Burbacher, Ph.D. Title Professor Positio Co-Director, PNWNCS
Department Environmental and Occupational Health Sciences Division Toxicology
Mail box or address Box 357234
Telephone (206) 685-1862 Fax _____ e-mail tmb@uw.edu

II. CONTACT PERSON (Provide all the information requested. This person does NOT have signatory authority with regard to this application.)

Name Lisa V. Ibanez, Ph.D. Title Post-Doctoral Associate Position Associate of Lead Local Investigator (Dr. Wendy Stone)
Mail box or address BOX 357920
Telephone 206-616-7358 Fax 598-7815 e-mail Libanez1@uw.edu

III. TITLE OF PROJECT: National Children's Study – Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study

IV. SIGNATURES: The undersigned acknowledge that: 1. this application is an accurate and complete description of the proposed research; 2. the research will be conducted in compliance with the recommendations of and only after approval has been received from the Human Subjects Review Committee (HSRC). The lead research is responsible for all aspects of this research, including: reporting any serious adverse events or problems to the HSRC, requesting prior HSRC approval for modifications, and requesting continuing review and approval.

A. Investigator: Thomas M. Burbacher — 5/5/11
TYPED NAME PLUS SIGNATURE — DATE

B. Faculty sponsor (for student): _____
TYPED NAME PLUS SIGNATURE — DATE

C. The Chair, Dean, or Director acknowledges the researcher is qualified to do the research, sufficient resources will be available, and (if no external funding review occurred) there was an internal review of scientific merit.

Michael Morgan for David Kalman, Chair — Michael Morgan — 5/9/2011
TYPED NAME PLUS SIGNATURE — DATE

Karen Thomas — SEP 27 2011 — APPROVE ☒ DISAPPROVE ☐
HUMAN SUBJECTS REVIEW COMMITTEE SIGNATURE — DATE

Subject to the following conditions: See conditional letter at back

Battelle Memorial Institute
100 Capitola Drive, Suite 200
Durham, NC 27713
Federalwide Assurance FWA00004696
Battelle Institutional Review Board: CPHRE Line of Review No.IRB00000284

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

Principal Investigator/Project Manager : Diane Burkom

Proposal/Project Title : NCS Formative Research Project #8: Development & Validation of Autism Case Confirmation Approaches for Use in the NCS

Client/Funding Agency : NIH/NICHD

IRB No. : N/A **Date of Submission to IRB :** 6/1/2011

Proposal No. : N/A **Project No. :** 000073905-ACCTMGMT

(including Task Order and/or Delivery Order)

Subcontract to Battelle from Drexel University (if applicable)

Subcontract from Battelle to N/A (if applicable)

Level of Review

☒ ___Expedited 6/8/2011_____ *(Category/Reason)*

Approved as submitted. Minimal risk.

Type of Approval – See Page 2 of 3 for Requirements and Restrictions

☒ Full Study Implementation

Margaret Pennybacker

_____ __6/8/2011_____

Signature Date

Official, Battelle Institutional Review Board, CPHRE Line of Review

__Margaret R. Pennybacker, PhD_____

Print or Type Name

Requirements and Restrictions

IRB Requirements: _____.

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. Apply for continuing approval of 000073905 prior to_**6/7/2012**_____, the final day of approval.

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 one (1) hour of discovery). If, during the course of the research study, there are any unforeseen events (see definition of unforeseen event on page 3), notify the IRB manager within one (1) hour of discovery, then follow IRB instructions
- 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.

☒ Copy of approved informed consent document(s) on file.

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 - An event that was unforeseen or unexpected, was related to the research, and had the potential to adversely impact a human subject or the conduct of a human subjects study. Unforeseen event(s) are reported to an IRB via an established reporting process and may include incidents that could be categorized as: (1) adverse events; (2) unanticipated problems; or (3) non-conformances.

Unanticipated Problem - 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.

DREXEL UNIVERSITY
COLLEGE OF MEDICINE

Office of Regulatory Research Compliance

APPROVAL NOTICE WITHOUT CONSENT

TO: Craig Newschaffer , PhD
School of Public Health / SPH-Epidemiology & Biostatistics
Mailstop: 1033

FROM:

John Medendorp , MS, BSN, CIP
Institutional Review Board (IRB #1)
Drexel University College of Medicine
1601 Cherry St, 3 Parkway Bldg, Suite 10444, Philadelphia, PA 19102
Tel: 215-255-7857 Fax: 215-255-7874

SUBJECT: Development and Validation of an Autism Case Confirmation Approach for Use in the National Children's Study (Formative Research 8)

SPONSOR: Johns Hopkins University

PROJECT No: 11012386, PROTOCOL No: 19871 , ACTION No: 58161 Type: New Period: 1 Seq: 1 , DETAIL No: 276499

CURRENT APPROVAL PERIOD: 07/25/2011, EXPIRES: 07/24/2012

RE: 07/25/2011 - According to 45 CFR 46.110 this study has been Approved Expedited Category 5, 6, 7. Approval Includes: Recruitment of 685 Parent-Child Dyads to take part in a Multi-Site Study (No Recruitment at DU) to Assess the Criterion Validity of New Autism Spectrum Disorder Case Confirmation Instruments (Three Instruments).

Date: 07/25/2011

On behalf of the Committee, I am pleased to inform you that the subject protocol has been reviewed and approved for the period indicated above. We operate under many Government requirements. As a result, this approval is granted with the following understandings:

1. If this is a sponsored project, then the study may not be activated until the Contract is fully executed by the Clinical Research Group. If this is not a sponsored study (designated "internal"), the costs of the project must be identified and a cost center designated. Please call 215-255-7857 if you have any questions regarding these procedures.
2. You must advise the IRB of the activation date. "Activation" for the purposes of this notice is the enrollment of the first human subject or the performance of the first experimental procedure on or after the above approval date. Please use the ACTIVATION NOTICE for this purpose.
3. Any change to the protocol must be submitted in writing and approved by the IRB in advance.
4. Any adverse reaction must be reported to the IRB as soon as it occurs.
5. Should the IRB decide to monitor your project directly, please cooperate fully. Failure to do so may result in withdrawal of this approval and notification to the sponsor and/or Federal agencies. Specific information regarding monitoring appears in **GUIDELINES FOR BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS**, and **GUIDELINES FOR NON-MEDICAL** obtainable through this office or the website http://research.drexel.edu.
6. Whether or not this protocol is activated, the IRB will conduct Continuing Review at least annually. Should you fail to respond to this Federally-required continuing review and progress report, the project may become ineligible for re-approval and the IRB may choose not to consider other projects for approval.
7. A final progress report must be submitted to the IRB in format similar to that of a periodic report.

The IRB welcomes your research project into the list of approved protocols. Your compliance with the above conditions will help to protect the continuation of all research activity at the University. With your project and others like it, we look forward to additions to knowledge of human health and benefits to science, our patients, and society.

cc: IRB Chair, Dept Chair, Tenet, Drexel

MEMORANDUM
Institutional Review Board (IRB #1)
ACTIVATION NOTICE

TO:	Institutional Review Board (IRB #1) 1601 Cherry St, 3-Parkway Bldg, Suite 10444, Philadelphia, PA 19102 Tel: 215-255-7857 Fax: 215-255-7874
FROM:	Craig Newschaffer , PhD School of Public Health / SPH-Epidemiology & Biostatistics
SUBJECT:	ACTIVATION OF HUMAN RESEARCH PROTOCOL ENTITLED: Development and Validation of an Autism Case Confirmation Approach for Use in the National Children's Study (Formative Research 8) PROJECT No: 11012386, PROTOCOL No: 19871, ACTION No: 58161 Type: New Period: 1 Seq: 1 , DETAIL No: 276499 DATE OF APPROVAL: 07/25/2011, EXPIRES: 07/24/2012
Date:	07/25/2011

This is to inform the IRB that the subject protocol was activated* on __/__/____. I understand that a Periodic Report for Continuing Review or Final Summary is due on or before the above Expiration Date.

[ ] Yes
[ ] No I have a copy of the University's Human Subjects Guidelines and Federal Wide Assurance (FWA) to the OHRP, as required in 45 CFR Part 46.

NOTE:
The University Guidelines for Biomedical and Behavioral Research for the protection of human subjects have been posted on the Office of Research website.
There are two sets of Guidelines - one each for Medical and Non-Medical Research.
You must have a hard copy and read these Guidelines to make sure that these Guidlines are met.
To download a copy of the University Guidlines, follow the below instructions:

1. Go to http://research.drexel.edu
2. Click "Medical IRB" or "Non-Medical IRB" in Quick Links
3. Under "Go to", click "Medical IRB" or "Non-Medical IRB Guidelines"
4. Please keep a copy of the University Guidelines in your office.

(Signed) Newschaffer, Craig

* "Activated" means that the first new human subject was accrued, or an experimental procedure was performed, or records were reviewed under this protocol on or after the date of last approval: 07/25/2011.
Accordingly, this notice must be sent to the IRB ONLY for the FIRST such accrual since that date.