RTI INTERNATIONAL

IRB ID Number: 13987

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

Title of Study: Positive Health Check Evaluation Trial
RTI Project Number: 0214934 **RTI Proposal Number** (if no Project Number):
Project Leader: Megan Lewis
Project Team Member Contact (if different from Project Leader): Kate Ferriola-Bruckenstein
Source of Funding for this Study: CDC
Date Submitted to IRB: August 15, 2016 (revised)
Level of Review *(check one)*:
Full ☒, IRB Meeting Date: July 27, 2016
Expedited ☐, category: **None**

Type of Review *(check one)*:
☐ Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.**)
☐ Amendment, describe:
☐ Add study site(s): _____
☐ Pretest/Pilot Test:
☒ Full Implementation
☐ Renewal
☐ Study Closure

IRB Approval of Special Conditions *(check all that apply to this review)*:
☒ Waiver of Signed Informed Consent/Parental Permission
☒ Waiver of elements of Informed Consent or requirement for 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 required)
☐ Participation of Minors (**Worksheet D** submitted by project team)
☐ IRB Agreement of Nonsignificant Risk Device Study Determination
☒ HIPAA Waiver of Authorization

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: **July 27, 2017**
(No human subjects research can occur after this date without continuing review and approval.)

Jamia Bachrach

Signature - IRB Member or Chair

August 18, 2016
Date of IRB Approval

Jamia Bachrach, JD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: August 18, 2016
☐ Entered into MIS
☐ OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on:_____

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

RTI INTERNATIONAL

IRB ID Number: 13987

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

Title of Study: Positive Health Check Evaluation Trial
RTI Project Number: 0214934 **RTI Proposal Number** (if no Project Number):
Project Leader: Megan Lewis
Project Team Member Contact (if different from Project Leader): Catherine Slota Gupta
Source of Funding for this Study: CDC
Date Submitted to IRB: November 30, 2016
Level of Review *(check one)*:
Full ☐, IRB Meeting Date:
Expedited ☒, category: **M: Minor changes in approved research**

Type of Review *(check one)*:
☐ Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.**)
☒ Amendment, describe: revision to staff consent forms
☐ Add study site(s): _____
☐ Pretest/Pilot Test:
☐ Full Implementation
☐ Renewal
☐ Study Closure

IRB Approval of Special Conditions *(check all that apply to this review)*:
☐ Waiver of Signed Informed Consent/Parental Permission
☐ Waiver of elements of Informed Consent or requirement for Informed Consent/Parental Permission
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☐ HIPAA Waiver of Authorization

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: **July 27, 2017**
(No human subjects research can occur after this date without continuing review and approval.)

Jam I Bachrach

Signature - IRB Member or Chair

November 30, 2016
Date of IRB Approval

Jamia Bachrach, JD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: December 1, 2016
☐ Entered into MIS
☐ OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on:_____

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

Unaffiliated Institution or Site Agreement for RTI IRB

Name of Institution with the Federal Wide Assurance (FWA): Research Triangle Institute (RTI)

Applicable FWA #: 3331

Unaffiliated Institution/Site Name: Crescent Care

Unaffiliated Institution/Site Lead Investigator Name: Seema Gai

Specify Research Covered by this Agreement: Positive Health Check Evaluation Trial

RTI Project Director Name: Megan Lewis

RTI Project Number: 0214934 **RTI IRB ID Number: 13987**

(1) The above-named Lead Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; and 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46.

(2) The Lead Investigator understands and hereby accepts the responsibility to comply – and to insure that the entire research team working under the direction of the Lead Investigator complies - with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Lead Investigator and the research team under the direction of the Lead Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Lead Investigator and the research team under the direction of the Lead Investigator will abide by all determinations of the RTI Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the RTI IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Lead Investigator and the research team under the direction of the Lead Investigator will complete any educational training required by the Institution and/or the RTI IRB prior to initiating research covered under this Agreement.

(6) The Lead Investigator will report promptly to the RTI IRB any proposed changes in the research conducted under this Agreement. The Lead Investigator will not initiate changes in the research without prior RTI IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Lead Investigator will report immediately to the RTI IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Lead Investigator and the research team under the direction of the Lead Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the RTI IRB.

(9) The Lead Investigator and the research team under the direction of the Lead Investigator acknowledge and agree to cooperate in the RTI IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Lead Investigator and the research team under the direction of the Lead Investigator will provide all information requested by the RTI IRB in a timely fashion.

(10) The Lead Investigator and the research team under the direction of the Lead Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the RTI IRB.

(11) Emergency medical care may be delivered without RTI IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Lead Investigator or any members of the research team under the direction of the Lead Investigator from taking part in research not covered by this Agreement.

(13) The Lead Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Lead Investigator Signature: _____ Date 11/17/2016

Name: Gal (Last) Serena (First) _____ (Middle Initial) Degree(s): M.BBS (MD) MPH

Address: 2601 Tulane Ave. Ste 500 phone #: 504-821-2601 x249

New Orleans (City) LA (State/Province) 70119 (Zip/Country)

Signature of RTI IRB Official:

_____ **Date:** 02/13/2017

Designee for Institutional Official: Juesta Caddell, Ph. D.
IRB Chair and Director, Office of Research Protection
Research Triangle Institute (RTI International)
3040 Cornwallis Road, PO Box 12194
Research Triangle Park, NC 27709-2194
Telephone: 919-541-6523

February 9, 2017

To: Charurut Somboonwit, MD
Protocol Title: Positive Health Check Evaluation Trial
Protocol #: 170004HD

Submission Type: Initial Review
Review Type: Expedited Procedures

Approval Date: February 9, 2017
Expiration Date: February 8, 2018

The Department of Health Institutional Review Board has reviewed and approved your application, including the following documents:

- Program and local site support dated 12/27/16
- A01 Patient Tailoring Questions dated 1/11/17
- A03 Patient Handout dated 1/11/17
- A04 Tips Library dated 1/11/17
- A05 Questions Library dated 1/11/17
- A12 CWA PHC Data Dictionary dated 1/11/17
- A13 EMR Data Dictionary dated 1/11/17
- A14 PHC Outreach Scripts dated 1/11/17
- A15 PHC Outreach Questionnaire dated 1/11/17
- B2 Online Clinic Survey dated 1/11/17
- B3 Clinic Interview Guide dated 1/11/17
- C0 Cost Questionnaire Instructions 1/11/17
- C1 Non-Research Labor Cost Questionnaires dated 1/11/17
- C2 PHC Outreach Labor Cost Questionnaires dated 1/11/17
- C3 Non-Labor Cost Questionnaire dated 1/11/17
- D1 Standard of Care Data Collection Instrument dated 1/11/17
- Data Reviewed for Recruitment dated 1/11/17
- Participant ICF dated 12/06/16
- Protocol v.2 dated 12/06/16
- Research Award Notice dated 07/15/16
- Somboonwit Recruitment Letter dated 1/11/17
- Staff ICF v.2 12/06/16
- Staff Online 12/06/16
- USF Initial Approval Letter 01/10/17

Please keep in mind:

- Apply for continuing review at least 60 days prior to expiration, even if your study is closing.
- Report all problems listed below as soon as possible, but no later than five working days.
- If you need to make changes to your study, complete the modification application.
- If you have to make a change to eliminate hazard to human subjects and there is not time to submit a modification, notify the IRB as soon as possible but no later than five working days.

If you have questions, want to offer suggestions, or talk with someone about this or other projects, please contact Rotanya Bryan or Bonnie Gaughan-Bailey at the Department of Health IRB at (850) 245-4585 or toll-free in Florida (866) 433-2775.

Thank you for your cooperation with the IRB.

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Sincerely,

Bonnie Gaughan-Bailey, MPA
Administrator
Biomedical Research Section
Public Health Research

Federal Wide Assurance#: 00004682

Reportable Events

Report the following problems to IRB Staff, as soon as possible, but within five business days:

- Adverse events and adverse outcomes which in the opinion of the principal investigator are both unexpected and related and suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.
- Any interim analysis or safety monitoring report indicating the frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
- Any breach of confidentiality.
- Any change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Any incarceration of a participant in a protocol not approved to enroll prisoners.
- Any event that requires prompt reporting to the sponsor.
- Any sponsor imposed suspension for risk.
- Any protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm or has the potential to recur.
- Any unanticipated adverse device effect.
- Any non-compliance identified by Department of Health audit or monitoring.
- Any investigation by FDA or OHRP or other federal agency of research (not just including this study) by any researcher on the study.
- Any loss of license or hospital privileges by any researcher on the study.

Contact IRB staff to obtain answers to questions, express concerns, and convey suggestions regarding the HRPP by emailing irb@flhealth.gov or calling 850-245-4585.

UNIVERSITY OF SOUTH FLORIDA

RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX(813)974-7091

1/10/2017

Charurut Somboonwit, M.D.
Internal Medicine
1 Tampa General Circle, G318
Tampa, FL 33606

RE: **Expedited Approval for Initial Review**
IRB#: Pro00028388
Title: Positive Health Check Evaluation Trial

Study Approval Period: 1/9/2017 to 1/9/2018

Dear Dr. Somboonwit:

On 1/9/2017, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within, including those outlined below.

Approved Item(s):
Protocol Document(s):
Protocol Document_Version #2

Consent/Assent Document(s)*: **online/verbal consent forms are unstamped
Participants Consent 12.6.2016 v2.pdf
Staff ICF_v2 - 12.6.2016
Staff Online 12.6.2016_v2

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s). **online/verbal consent forms are unstamped**

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110. The research proposed in this study is categorized under the following expedited review 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).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(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.

Your study qualifies for a waiver of the requirements for the informed consent process as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. [Medical Records]

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117(c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. [Verbal & Online Consent]

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45CFR164.512(i) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

A partial waiver of HIPAA Authorization is granted for recruitment/screening purposes only for Aim 1; written Authorization will be obtained as part of the informed consent process. Pursuant to this partial waiver, the study team is allowed to obtain PHI from the Florida Department of Health - Hillsborough Specialty Care Clinic medical record (HMS) of patients aged 18 years or older with a diagnosis of HIV to determine whether they meet inclusion criteria specified in the protocol.

HIPAA Authorization is not required for Aims 2-4 of this study. Although the PI is part of a covered entity, information collected for Aims 2-4 does not include PHI. Thus, Authorization is not required.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John A Schinka, Ph.D.

John Schinka, Ph.D., Chairperson
USF Institutional Review Board

RUTGERS THE STATE UNIVERSITY OF NEW JERSEY eIRB ELECTRONIC INSTITUTIONAL REVIEW BOARD

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: Cheryl Kennedy
IRB Director: Carlotta Rodriguez
Effective Date: 2/7/2017
Approval Date: 1/16/2017
Expiration Date: 1/15/2018

eIRB Notice of Approval for Initial Submission # Pro20160001405

STUDY PROFILE

Study ID: Pro20160001405
Title: Positive Health Check Evaluation Trial

Principal Investigator:	Shobha Swaminathan	**Study Coordinator:**	Baljinder Singh
Co-Investigator(s):	Gilda Bontempo Debra Chew Michelle Dalla Piazza	**Other Study Staff:**	Shazia Chatha Christie Costanza Marta Paez-Quinde Jeanne Prevost-Fernandez Susana Rivera Baljinder Singh
Sponsor:	CDC Foundation	**Approval Cycle:**	Twelve Months
Risk Determination:	Minimal Risk		

Review Type:	Expedited	**Expedited Category:**	(5) (6) (7)	**Subjects:**	250

Specimens: 350

CURRENT SUBMISSION STATUS

Submission Type:	Research Protocol/Study	**Submission Status:**	Approved

Approval Date:	1/16/2017	**Expiration Date:**	1/15/2018		
Pregnancy Code:	No Pregnant Women as Subjects	**Pediatric Code:**	No Children As Subjects	**Prisoner Code:**	No Prisoners As Subjects

Protocol:	Protocol Positive Health Check Evaluation V1.0 15 Dec2016.docx	**Consent:**	A10 ConsentForm_10 28 2016.doc.pdf B1 Staff Consent Form_final.docx.pdf B2 Online Clinic Survey_final.docx.pdf B4 Online Clinic Survey Consent_final.docx.pdf Positive Health Check Evaluation Staff Consent Form V1.0 28Nov2016.docx Positive Health Check English ICF V1 0 15Dec2016.DOC Positive health Check Evaluation Online Clinic Survey Consent V1.0 27Jan2017 .docx	**Other Materials:**	A14 PHC Outreach Scripts_final.docx A09 Recruitment Scripts_final.docx A01 Patient Tailoring Questions_final.docx.pdf A03 Patient_Handout_final.pdf A04 Tips Library_final.docx.pdf A05 Questions Library_final.docx.pdf A12 CWA PHC Data Dictionary_final.docx.pdf A13 EMR Data Dictionary_final.docx.pdf A15 PHC Outreach Questionnaire_REVISED.docx.pdf B3 Clinic Interview Guide_final.docx.pdf C0 Cost Questionnaire Instructions_final.docx.pdf C1 Non-Research Labor Cost Questionnaire_final.docx.pdf C2 PHC Outreach Labor Cost Questionnaire_final.docx.pdf C3 Non-Labor Cost Questionnaire_final.docx.pdf D1 Standard of Care Data Collection Instrument_final.docx.pdf

*** Study Performance Sites:**

The University Hospital	UH Infectious Disease Practice Ambulatory Care Center D-Level 140 Bergen Street, NJ 07103

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.

CONFIDENTIALITY NOTICE: This email communication may contain private, confidential, or legally privileged information intended for the sole use of the designated and/or duly authorized recipients(s). If you are not the intended recipient or have received this email in error, please notify the sender immediately by email and permanently delete all copies of this email including all attachments without reading them. If you are the intended recipient, secure the contents in a manner that conforms to all applicable state and/or federal requirements related to privacy and confidentiality of such information.

EMORY UNIVERSITY | Institutional Review Board

TO: **Vincent Marconi, MD**
Principal Investigator
SOM: Medicine: Infectious Dis

DATE: **26 January 2017**

RE: **Expedited Approval**
IRB00093861: Positive Health Check Evaluation Trial

This is a VA *STUDY* requiring Atlanta VAMC Research and Development, and ACOS/R *APPROVAL* of the study prior to initiation of the study at the AVAMC.

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits the **regulatory categories of expeditable research #7** as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on **24 January 2017** and granted **approval effective from 1-24-2017 through 1-23-2018.** Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this approval:

- **Positive Health Check Evaluation Trial PROTOCOL version 4 of 12-22-2016.**
- **AVAMC PHC Patient informed consent version 1-19-2017.**
- **AVAMC PHC Staff informed consent version 12-22-2016.**
- **AVAMC PHC Patient HIPAA authorization version 1-19-2017.**
- **AVAMC PHC Patient HIPAA revocation form version SEPT 2015.**
- **PHC Aim 2 interview guide**
- **PHC Aim 2 online clinic survey**
- **PHC Aim 2 online survey disclaimer**
- **PHC Aim 3 cost instructions**
- **PHC Aim 3 non-labor cost**
- **PHC Aim 3 non-research labor cost**
- **PHC Aim 3 outreach labor cost**
- **PHC Aim 4 SOC data collection**
- **PHC CWA Data Dictionary**
- **PHC EMR Data Dictionary**
- **PHC Outreach Questionnaire**
- **PHC Outreach Scripts**
- **PHC Patient Tailoring Questions**
- **PHC Questions Library**
- **PHC Scripts**
- **PHC Tips Library**

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, study design, you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you

Daniel Roysden, PhD
Atlanta VAMC/Emory University IRB Liaison
This letter has been digitally signed.
Please tell us how we're doing! Respond to a quick satisfaction survey: https://www.surveymonkey.com/s/PY2KYLR.
OHRP/FDA Emory Biomedical IRB00000569
OHRP Atlanta VAMC FWA00002551

??CC:	Clark Stuart	Theron	SOM: Medicine: Infectious Dis
	Rai	Ramona	SPH: Career Services

Emory University
1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322
Tel: 404.712.0720 - Fax: 404.727.1358 - Email: irb@emory.edu - Web: http://www.irb.emory.edu/
An equal opportunity, affirmative action university