Appendix 13

IRB Approval Letters From the Six Participating Sites

Baylor College of Medicine

Human Approval Letter
July 23, 2013

THOMAS PETER GIORDANO
BAYLOR COLLEGE OF MEDICINE
MEDICINE: INFECTIOUS DISEASE

BCM Saylor College of Medicine

Baylor College of Medicine
Office of Research
One Baylor Plaza, 6000
Houston, Texas 77030
Phone: (713) 798-6970
Fax: (713)798-6990
Email: irb@bcm.tmc.edu

H·32781 • COMPREHENSIVE HIV CLINIC·BASED INTERVENTION TO IMPROVE PATIENTS' HEALTH AND REDUCE TRANSMISSION RISK

APPROVAL VALID FROM *7/23/2013* TO *6/25/2014*

Dear Dr. GIORDANO

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was approved. The study may not continue after the approval period without additionallRB review and approval for continuation.

You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and Significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as thoseof hospitals and institutions affiliated with the College.

Sincerely yours,
VERNON R SUTTON, M.D., B.S.

Boston University Medical Center

SCHOOL OF MEDICINE * SCHOOL OF PUBLIC HEALTH * GOLDMAN SCHOOL OF DENTAL MEDICINE * BOSTON MEDICAL CENTER

Boston University Medical Center

BOSTON MEDICAL CENTER

Office of the Institutional Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts
02118-2526
Tel: 617-638-7207
Fax: 617-638-7234

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Boston Medical Center

Title of Study: Comprehensive HIV Clinic-Based Intervention to Promote Patients' Health and Reduce Transmission Risk
Protocol Number: H-32301

RE: New Protocol
Review Type: Full Board
Action: Approved

Date of Action: 05/23/2013
Date Revisions Were Accepted: July 26, 2013
Date of Expiration: 05/22/2014

Funding Source: Center for Disease Control and Prevention (CDC), NIH/National Institute of Mental Health (NIMH)
Award #: 6003158,

Protocol Version #: 1.2
Consent Form(s): PwP Informed Consent Version 1.3

Dear Dr. Mari-Lynn Drainoni, PhD:

At the 05/23/2013th Panel Blue Institutional Review Board (IRB) meeting, chaired by James Feldman, the above referenced protocol was reviewed. It has been determined that this study meets the requirements set forth by the IRB and is hereby approved. This protocol is valid through the expiration date indicated above.

This approval corresponds with the versions of the protocol and consent form(s) indicated above.

Protocol Specific Determinations and Findings

- The board made pregnancy findings in accordance with 45 CFR 46.204.
- The board approved a Waiver of Consent (45 CFR 116 (d)) and HIPAA Waiver.
- The board determined the study is minimal risk and can be expedited in the future

Requirements

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms, validated with current approval dates generated by the INSPIR system, may be used when informed consent is required.

Any changes to the approved protocol or informed consent documents must be reviewed and approved prior to implementation unless the change is necessary for the safety of subjects.

You must report to the IRB unanticipated problems involving risk to subjects or others according to the process posted on the IRB website (www.bumc.bu.edu/irb). The IRB must also be informed of any new or significant information that might impact a research participant's safety or willingness to continue in your study.

Investigators are required to ensure that all HIPAA requirements have been met prior to initiating this study. Once approved, validated HIPAA forms may be found within INSPIR under Study Documents.
It is the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any research activities.

Sincerely yours,

Signature applied by Jamie Merrill on 07/26/2013 04:12:18 PM EDT

Senior IRB Analyst, Panel Blue

University of California at San Diego

130733

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Edward Cachay Mailcode: 8681

RE: Project #130733
Comprehensive HIV clinic-based interventions to promote patients' health and reduce transmission risk

Dear Dr. Cachay:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval.

The IRB determined that waiver of informed consent may be granted for the Behavioral Screener, CBI assessment, Quarterly exit survey and provider survey in this project as it meets the requirements outlined in 45 CFR 46.116(d). The research is minimal risk; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration. Full documented consent will be obtained for the Health Coach counseling session.

In addition, a waiver of individual authorization for use of Protected Health Information (PHI) was granted by the IRB as stipulated by the HIPAA Privacy Rule, 45 CFR 164 Section 512(I). The IRB determined that the proposed research satisfies following criteria:

1. The use or disclosure of PHI involves no more than minimal risk.
2. Granting of waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.
3. The project could not practicably be conducted without a waiver.
4. The project could not practicably be conducted without use of PHI.
5. The privacy risks are reasonable relative to the anticipated benefits of research.
6. An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal.
7. An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.
8. The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.

It was determined that this project presents no more than minimal risk to human subjects in 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.

Date of IRB review and approval: **6/6/2013**

On behalf of the Institutional Review Board,

/lg

Michael Caligiuri, Ph.D.
Director, Human Research Protections Program
(858) 657-5100

Note: IRB approval does not constitute funding **or other institutional required approvals.** Should your studies involve other review committees such as Office of Clinical Trials Administration (OCTA), Office of Coverage Analysis Administration (OCAA), Conflict of Interest (COI), Protocol Review Monitoring Committee (PRMC), and committees under Environmental Health & Safety (EH&S) such as Institutional Biosafety Committee (IBC), Human Exposure Committee (HERC), and RSSC (Radiation Safety and Surveillance Committee), it is the researchers responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens.

Approval release date: 8/13/2013

University of Miami

UNIVERSITY
OF MIAMI

University of Miami
Human Subjects Research Office (M809)
PO Box 016960, Miami, Florida 33101
1500 NW 12 Avenue, Suite 1002, Miami, Florida 33136

Ph: 305-243-3195
Fax: 305-243-3328
www.hsro.miami.edu

FULL BOARD – APPROVED AS MODIFIED

August 13, 2013

Allan Rodriguez, M.D.
University of Miami
Department of Medicine, Division of Infectious Diseases
Medical Campus
Miami, FL 33136

HSRO STUDY NUMBER:	**20120619**
STUDY TITLE:	**Comprehensive HIV Clinic-Based Intervention to Promote Patient's Health and Reduce Transmission Risk.**
IRB MEETING DATE:	**8/12/2013**
STUDY APPROVAL EXPIRES:	**8/11/2014**
SOURCE(S) OF FUNDING/SUPPORT:	**Centers for Disease Control and Prevention and National Institute of Mental Health (NIMH)**
FWA #:	**FWA00002247**

On 8/12/2013, the Medical Sciences IRB A determined that the above referenced study is **approved as modified**, with a partial waiver of HIPAA. This review confirms that the grant application is consistent with the goals of the research proposed.

APPROVAL INCLUDES:

New Research Protocol

Sponsor's Protocol, Version 6, dated 02/28/2013

HIPAA Form B - Revision Date 12/10/10 (*English & Spanish*)

Research Materials *(English)*

- Informed Consent Form
- APTcare CBI
- Contact-Locator Information Form
- Counseling Approach & assessment forM
- Draft Scripts of videos
- Patient exit survey

- Primary Care Provider Survey

MODIFICATIONS INCLUDE: (Please see enclosed document with tracked changes)

- Research Materials *(English)*
  - Informed Consent Form

This study must be conducted in accordance with IRB approval and you must use the documents as modified by the IRB. If you do not accept the changes made by the IRB, the study must not be initiated. If the changes are not acceptable, you may withdraw the study or appeal to the IRB.

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.

You must prepare and submit to the Office of HIPAA Privacy & Security a record of disclosure for each disclosure of patient information under a waiver of authorization by using the HIPAA Accounting for Disclosures form (HIPAA Attachment 45) located on the HSRO HIPAA page.

You must send a copy of each signed authorization form to the Office of HIPAA Privacy & Security, PAC 409, Locator M-879, telephone: 305-243-5000.

Your study indicates JHS as a performance site. As the PI, you must ensure that you have been granted permission by the JHS Clinical Research Review Committee prior to commencing study activities at JHS. **If you have any questions regarding this process, please contact the JHS Clinical Trials Office at 305-585-7596.**

This protocol is required to comply with UM's patient enrollment and tracking policy. You must notify UM's Clinical Research Revenue Cycle (CRRC) office of a consented subject no later than 48 hours after obtaining a signed consent and upon patient disenrollment. Notification can be submitted to CRRC automatically via Velos or manually via the CRIS website. For more information, contact crrc@med.miami.edu.

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.

Should you have any questions, please contact Adriana Robledo , *IRB Regulatory Analyst* (phone: 305-243-3195 ; email: arobledo@med.miami.edu).

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

/AR

cc:

OMB No. 0990-0263
Approved for use through 3/31/2015

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[X] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[X] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:	

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other
Implementation and Evaluation of a Comprehensive Prevention with Positives Intervention at HIV Clinics	MUGAVERO, MICHAEL J

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00005960, the expiration date 01/24/2017 IRB Registration No. IRB00000726

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____ *(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [X] Expedited Review on (date) 8-13-13
[ ] If less than one year approval, provide expiration date _____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments
Protocol subject to Annual continuing review.

Title X130715003
Implementation and Evaluation of a Comprehensive Prevention with Positives Intervention at HIV Clinics

Partial HIPAA Waiver Approved?: Yes

IRB Approval Issued: 8-13-13

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* (205) 934-3789 12. Fax No. *(with area code)* (205) 934-1301 13. Email: irb@uab.edu	University of Alabama at Birmingham 701 20th Street South Birmingham, AL 35294
14. Name of Official Marilyn Doss, M.A.	15. Title Vice Chair, IRB
16. Signature Marilyn Doss	17. Date 8-13-13

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UNIVERSITY of WASHINGTON

HUMAN SUBJECTS DIVISION

Date: September 10th, 2013

PI: Shireesha Dhanireddy, MD
Allergy & Infectious Disease/Department of Medicine

RE: Human Subjects Application #45249, "Comprehensive HIV clinic-based intervention to promote patients' health and reduce transmission risk"

Dear Dr. Dhanireddy,

Human Subjects application #45249 "Comprehensive HIV clinic-based intervention to promote patients' health and reduce transmission risk" and the related Conditional Approval response have been approved by IRB J at the University of Washington. The application was conditionally approved on August 27th, 2013 and the research team's response to the conditions of approval was verified and approved on September 10th, 2013. The approval is valid from August 27th, 2013 through August 26th, 2014.

Please note that subject number is part of your IRB-approved protocol. Over-enrollment is considered non-compliance with your IRB approval. Any revisions which need to be made to the IRB-approved protocol, including an increase to subject numbers, must be reviewed and approved by the IRB before they are implemented. This review can be requested by submitting a Modification form, which can be found on the HSD website. Non adherence to the IRB-approved protocol may be considered non-compliance and must be reported to the IRB as soon as it is discovered.

If at anytime during your study an adverse event occurs, contact HSD immediately.

Note that HSD policy requires that you use copies of the stamped approved consent materials with subjects. You will find the stamped forms in your approval packet. If use of stamped copies is not applicable to your study because you have been approved to obtain oral or electronic consent, you must use the exact form that has been approved.

Please use the IRB application number listed above on any forms submitted which relate to this research, or on any correspondence with the HSD office.

If we can be of further assistance, please contact us at (206) 543-0098 or via email at hsdinfo@uw.edu. Thank you for your cooperation, and good luck in your research.

Sincerely,

Blair Maman
Administrator for IRB J
Human Subjects Division
(206) 543-0919
uwvibro@uw.edu