DATE: 14 August 2014

TO: Patrick Clay, PharmD
UNT System College of Pharmacy

FROM: Christopher Cooper, PA-C, MPAS
Chair, UNTHSC Institutional Review Board

CC: Brian A. Gladue, PhD, CIP
Executive Director, Office of Research Compliance

PROTOCOL: **2014-104**
Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-Centered HIV Care

CDC Grant Number: PS-13-1315

NOTICE OF DETERMINATION / APPROVAL

The Office of Research Compliance, on behalf of the Institutional Review Board (IRB) of the University of North Texas Health Science Center (UNTHSC) has reviewed your protocol and has determined this protocol to meet criteria for **EXEMPT** status (as specified in Federal Regulations 45 CFR 46 101(b) in the following categories below:

CC (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

CC (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs...

This determination concurs with the determination made by CDC NCHHSTP ADS/ADLS Office Project determination Letter dated March 18, 2013 stating that the project activity is not human subject research, in that the primary intent is public health program activities.

As principal investigator, we remind you that you are responsible for complying with all UNTHSC policies, decisions, conditions and requirements regarding projects involving human participants. You are responsible for insuring that the activity is implemented as specified in the protocol. In addition, you are required to use ONLY the reviewed and approved documents, materials and/or procedures designated for this protocol that were acknowledged by the Office of Research Compliance.

You must report to the Office of Research Compliance any changes affecting the protocol upon which this certification is based. **No changes may be made without prior approval by the Office of Research Compliance** or the IRB except those necessary to eliminate immediate hazards.

If you have any questions, please contact the Office of Research Compliance at (817) 735-0409.

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University of North Texas Health Science Center
Office for the Protection of Human Subjects (OPHS) / Institutional Review Board (IRB)

Request for Review of EXEMPT Category Research Project

IRB # 2014-104

ALL research involving human subjects requires review and consideration by the UNTHSC Office for the Protection of Human Subjects (OPHS) and the Institutional Review Board (IRB). Some research projects may be "exempt" from Full Board Review and thus qualify as "Exempt Category" research. To determine if your research project is in this category, provide information using the following form. Note that proof or declaration of Human Subjects Research Training for all study personnel must accompany this form. Also, incomplete applications and supporting documentation will delay OPHS-IRB review and approval of this project. If it is determined that your research project is NOT Exempt category research, you will need to re-submit a full protocol and a completed Expedited IRB Application Form. Attach page if more space is needed for any of the below. Go to website for guidance on what is NOT Exempt.

PROJECT INFORMATION

Faculty Research ☒ **Student Research:** ☐ **Masters** ☐ **Doctoral**

Title of Research Activity:
Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-centered HIV Care

Name of Principal Investigator (Faculty Member): Patrick Clay

Contact Information- Telephone: x2798 *Email Address:* Patrick.Clay@unthsc.edu

APPROVED AS EXEMPT
AUG 14 2014
UNTHSC Research Compliance

RECEIVED
JUL 21 2014
UNTHSC Research Compliance

Name of Student Investigator: N/A

Contact Information- Telephone: N/A *Email Address:* N/A

Department/Program: Pharmacotherapy / College of Pharmacy

Name(s) of each Co-Investigator (Study Personnel): UNTHSC (Shara Elrod, Katura Bullock, Sumihiro Suzuki); HealthHIV: Michael Shankle, Brian Hudjich; Northwestern U (Kristin Darin); University of Nebraska Medical Center (Kimberly Scarsi); University of Minnesota (Jon Schommer); APhA (Ben Bluml); University of Kentucky (Roberto Carderelli)

Project Description: Briefly state the objective(s) and procedures associated with this project. *Recall that incomplete or unclear information will delay OPHS-IRB review and approval* (**attach page if needed**):

The project's long-term outcomes are to monitor de-identified data received from clinics and pharmacies for three primary outcomes: retention in HIV care, adherence to HIV medication therapy, HIV viral load suppression. Secondary measures include adherence to non-HIV medications, costs associated with conducting the project. Exploratory measures are detailed in protocol.

Educational Practices and Strategies: Yes ☐ **No** ☒ (If Yes, please answer **all** questions below)

Will research involve normal educational practices such as (check appropriate box)?

☐ Regular instructional strategies including those commonly used in a classroom
☐ Special education instructional strategies such as the use of a device for performing skill sets or exercise
☐ Effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
☐ Other: _____
☐ The study does not involve research in educational practices and strategies

Will research be conducted in an established or commonly accepted educational setting (university or teaching hospital)?

Yes ☒ **No** ☒ **[If yes, please answer the question below]**

Where will it be conducted? Some of the data provided will be generated by commonly accepted educational settings such as university or teaching hospitals, but that is not by design (not an inclusion criteria) for the project.

Is the educational activity itself part of your research or will the educational activity occur regardless of research?

☐ **Yes, it is part of research**
☒ **No, the practices are normal educational practices that will occur regardless of this research project**

Survey or Interview Study: Yes ☐ **No** ☒ (If Yes, please answer **all** questions AND attach copy of survey instruments and procedures)

Source of subject population: _____

Age Range of subjects to be included in the survey or interview: _____

Where will the survey/interview occur? (Location of activity): _____

Date(s) survey/interview to be conducted? (Include month and year) From_____ To _____

Will subjects be identified? **Yes** ☐ **No** ☐ Will subject responses be audio, video or digitally recorded? **Yes** ☐ **No** ☐

Will your subjects include children (under age 18)? **Yes** ☐ **No** ☐ **[If Yes, STOP. Project does not qualify as EXEMPT]**

Retrospective Record or Chart Review: Yes ☒ **No** ☒ (If "Yes", Please check all that apply)

☒ Retrospective review of medical records: Name of hospital or institution from which records will be obtained: We are asking clinics to provide up to 2 years historical de-identified data for those participants they identify if it exists. If not, they are only providing prospective data. We have not yet secured all sites and therefore cannot provide names of healthcare institutions that will be providing records. This can be provided on a real-time basis or annually if desired by the board.

☐ Employment records ☐ Student records ☐ Other records: _____

Name of institution or agency from which records will be obtained:

If a non-UNTHSC unit will provide records, attach letter from that agency/clinic.

The data were collected during Time Period (month and year): From 08/2014 To 06/2016

Will the investigators have access to subject identifiers? **Yes** ☐ **No** ☒

Will a "master list" of subject identifiers for this data set be kept? **Yes** ☐ **No** ☒ If yes, for how long? The sites will have a way to connect the de-identified data to the actual patient information at their respective sites. Walgreens Corporate will have a mechanism to connect project identifiers with PHI. Neither site nor Walgreens Corporate will provide this to non-site level personnel authorized to receive this information. Sites will be asked to maintain this in order to resolve any issues that occur with data submitted. Sites will be asked to maintain this (along with other project materials) for 3 years beyond project completion date.

If your protocol calls for a "master list" of identifiers then this may NOT qualify for Exempt. Contact OPHS staff for assistance

Use of existing biological specimens: Yes ☐ **No** ☒ If "Yes", Source of specimens (contact name, entity name and address) and attach description of specimens and origin:

Secondary Data Set Study: Yes ☐ **No** ☒ If "Yes", Answer all questions.

Source of data:

Were the data originally collected for research purposes: **Yes** ☐ **No** ☐ If yes, by UNTHSC researchers? **Yes** ☐ **No** ☐

Is the Source "publicly available"? **Yes** ☐ **No** ☐

Note that "Publicly available" means that the general public can obtain the data. Sources are not considered "publicly available" if access is limited ONLY to researchers. ***NOTE: You must attach a copy of the catalog page/ website page indicating where the dataset can be obtained or located.***

Does the secondary dataset contain personal identifiers? Yes ☐ **No** ☐

Type of identifier (i.e., name, SSN, address, medical record number, etc.):

Public Benefit or Services Programs

Is the study conducted or subject to approval by the federal department or agency head? ☒ **Yes** ☐ **No**

Is the aim to study, evaluate, or otherwise examine one or more of the following [check appropriate box(es)]?

☒ Public Benefit or Service Programs (i.e. Social Security Services, Medicaid, welfare)
☐ Procedures for obtaining benefits or services under those programs
☐ Possible changes in or alternatives to those programs or procedures
☐ Possible changes in methods or levels of payment for benefits or services under those programs

Taste and Food Evaluation

Will this study involve taste evaluation and/or food quality assessment? ☐ **Yes** ☒ **No**

Is the food approved by the Food and Drug Administration (FDA)? ☐ **Yes** ☐ **No [if No, STOP. This does NOT qualify as Exempt]**

Will wholesome (no additives) food be consumed? ☐ **Yes** ☐ **No**

Are the food ingredients at or below the level found to be safe by the FDA? ☐ **Yes** ☐ **No**

Do you ever intend to publish or present (oral, poster or written) the results of this project? **Yes ☒ No ☐**

Is an informed consent needed for this research? Yes ☐ No ☒

If yes, this project may NOT be Exempt from Full Board or Expedited IRB review and consideration. Please attach a complete protocol form and synopsis along with this application for further review (see OPHS website for Protocol Form and Summary Format guidelines).

ATTACH TO THIS FORM:

- *Certificate of Human Subjects Training* for **all** study personnel. If such documentation is already on file for *all* key personnel, initial here: PC [Note that inaccurately claiming that such documentation is on file will significantly delay Review]

(If applicable)

- *Copy of Secondary Data documentation* (examples include: website address or reference information for public use data files; letters of agreement from owners of the dataset, etc.)
- *Copy of Survey or Interview questions* and any research statement or cover letters to be used (if applicable)
- Any other documentation that will assist in a timely review of your project.

SIGNATURES AND ASSURANCE Signature certifies that the Principal Investigator understands and accepts responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform to the OPHS-IRB approved protocol, OPHS-IRB requirements/policies and procedures, and all applicable federal regulations.

Patrick P. Clay, PharmD	PATRICK CLAY	2/3/2014
PRINCIPAL INVESTIGATOR Signature	Print Name	Date

NOTE: If this is a "Student Project", the Principal Investigator signing above agrees to be fully responsible for all aspects of this project. Ordinarily this person will also serve as the Faculty Advisor for the Student on this project. The Faculty Sponsor / Advisor may designate an alternate Faculty Sponsor / Advisor who will assume responsibilities on a temporary basis, and will notify the OPHS-IRB of any change in the Faculty Sponsor / Advisor for this project.

Student Investigator's Assurance: By my signature as student investigator, I certify the above applicable assurances and that I will meet with my Faculty Sponsor / Advisor on a regular basis to monitor study progress. If my Faculty Sponsor / Advisor is unavailable, I will meet with his/her designated alternate Faculty Sponsor / Advisor who will assume his/her responsibilities. I also agree to notify the OPHS-IRB of any change in Faculty Sponsor / Advisor

N/A		
STUDENT INVESTIGATOR Signature	Print Name	Date

Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-centered HIV Care

Principal Investigator: Patrick Clay, PharmD

Project Director: Michael Shankle, MPH

UNTHSC IRB #: 2014 - 104

CDC Protocol Number: (not applicable)

CDC Grant Number: PS-13-1315

CDC Program Official: Kathy Byrd, MD

Version Number: 2013.10

Date Finalized: 13 Aug 2014

STATEMENT OF COMPLIANCE

To the extent applicable for demonstration projects, the project will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Participants (45 CFR Part 46), and the CDC Clinical Terms of Award. All UNTHSC/HealthHIV team personnel involved in the conduct of this project have completed human participants' protection training. This project has been listed at www.clinicaltrials.gov.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this project will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and as applicable for federal regulations.

Clinical Site Authorized Designee:

Signed: _____ Date: _____

Name:

Title:

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GLOSSARY / LIST OF ABBREVIATIONS

CDC	Center for Disease Control and Prevention
CMR	Comprehensive Medication Review
DCC	Data Coordinating Center located at UNTHSC under the direction of Dr. Sumihiro Suzuki
GCP	Good Clinical Practice
HIV	Human immunodeficiency virus
IRB	Institutional Review Board
MAP	Medication-related action plan
MTM	Medication Therapy Management
N	Number
ORION	Walgreens proprietary MTM documentation system: ORION is used to provide PHI-containing Initial and Interim MTM reports (CMR, TMR, MAP) to medical providers. Once entered by WAG SNP at local site, Walgreens Corporate is able to access and provide project team de-identified datasets.
PHI	Protected Health Information
PID	(Project's) Participant Identification Number
PMR	Personal Medication Record / Active Medication List

Project team	Refers to the UNTHSC, HealthHIV, Walgreens and CDC personnel who are not privy to PHI and will be reviewing de-identified data submitted by project clinics and WAG SNP.
RPh	Protocol designation for state-licensed pharmacist in good standing with board of pharmacy regardless of terminal degree designation (BSPharm, PharmD, PhD or PD)
SOC	Standard of care / Usual and customary practice of medical provider (defined as a project clinic's established pattern of HIV care provision for their patients)
TMR	Targeted Medication Review
WAG SNP	Walgreens Specialty Network Pharmacy (specifically, a licensed pharmacist in good standing provides all MTM services noted in this protocol). Some forms may be completed by pharmacy technicians acting under direct supervision of pharmacist as allowable by state law.
UNTHSC	University of North Texas Health Science Center

PROTOCOL SUMMARY

Title:	Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-centered HIV Care
Précis:	The primary goal of the overall project is to develop and implement a patient-centered HIV care model that incorporates community pharmacists with primary medical providers to improve retention in HIV care, adherence to HIV medication therapy and HIV viral load suppression. The project will be conducted at 10 sites throughout and country and will largely target minority populations. Each project site will consist of at least one medical clinic and one partnered Walgreens pharmacy. Project clinics will recruit patients who have established care with the clinic and are HIV-positive into the patient-centered HIV care model program. Clinics will refer patients to Walgreens to fill their prescriptions and to receive Medication Therapy Management (MTM) services. The clinic will provide the partner pharmacy with patient data necessary to more effectively provide patient-centered HIV care services - including clinical procedure and laboratory test results and medical problem lists. All laboratory tests / procedures done by the clinic to the patient are solely at the discretion of the patient's medical provider and individualized based upon the patient's medical diagnoses and standards of care for those diagnoses. As data is obtained through the course of care for the patient over the project's duration, it is sent to the partnered pharmacy every 90 days to facilitate delivering MTM services. These data (collected via project data forms but with personal identifiers removed) will also be provided to project team. The project clinics will closely communicate with partner pharmacists and collaboratively develop action plans for identified medication-related problems. The project pharmacies will provide MTM to participants including individualized adherence support, actively monitor prescription refills to assess adherence to treatment, and work directly with the clinical sites to routinely communicate the project participants' progress, to address and to suggest solutions for identified problems. These MTM visits will occur every 90 days. De-identified versions of the communication to the clinics will be provided to project team. Therefore, every 90 days, the project team will receive de-identified, retrospectively collected medical and prescription data from both the clinics and pharmacy sites. The de-identified project data will be analyzed and routinely reported to project sites throughout the course of the project period. Data will be analyzed to determine if project outcomes were achieved. Project sites will provide input on barriers encountered to deliver the model. Data analysis and project sites' feedback will also be used to adjust the program model as needed.

Objectives:	The project's long-term outcomes are to monitor de-identified data received from clinics and pharmacies for three primary outcomes: retention in HIV care, adherence to HIV medication therapy, HIV viral load suppression. Secondary measures include adherence to non-HIV medications, costs associated with conducting the project. Exploratory measures are detailed in protocol.
Population:	1,000 HIV + male and female age 18+
# Sites:	10
Project Duration:	24 months
Participant Participation Duration:	18 months – 24 months
Estimated Enrollment Period:	6 months

Schematic of Project Design: