THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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To: Christine Oramasionwu
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From: Biomedical IRB

Approval Date: 6/08/2015
Expiration Date of Approval: 6/07/2016
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Renewal
Expedited Category: 5.Existing or non-research data
Study #: 12-1777

Study Title: Evaluating therapies and barriers to therapy in a cohort of HIV patients

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose:

This IRB approval will cover patient medical record reviews that are designed to evaluated racial/ethnic differences in barriers to therapy for HIV and other associated infections.

Participants:

This IRB approval is to conduct observational, retrospective studies HIV patients from the UNC Center for AIDS Research (CFAR) HIV/AIDS Research and Clinical Cohort. Established in January 2000, this is a prospective cohort of ~3,000 HIV-infected patients aged 18 years or older receiving care at the UNC HIV clinic. Ongoing enrollment is available for patients who provide written informed consent to participate in the cohort.

Procedures (methods):

Corresponding Author:
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Data for each patient are recorded electronically and include clinically obtained demographic characteristics, laboratory values, medication histories, comorbid conditions, new diagnoses, and clinic visit information. We anticipate running analyses along several dimensions, for example: for patients coinfected with HIV/hepatitis C virus (HCV), we will determine racial/ethnic differences in barriers to HCV therapy.

Regulatory and other findings:

This research meets criteria for waiver of informed consent for research [45 CFR 46.116(d)] and waiver of HIPAA authorization [45 CFR 164.512(i)(2)(ii)].

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=12-1777.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40CFR 26 (EPA), where applicable.