Attachment 6c
ChiCAS IRB UNC Agreement

Institutional Review Board Authorization Agreement for an Individual Protocol

Title of Research Study:	**HIV Prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention**
Principal Investigator:	**Scott Rhodes, PhD**
Co-Investigator:	**Amanda Tanner, PhD**
Sponsor or Funding Agency:	**CDC**
Institution Providing IRB Review:	**Wake Forest University Health Sciences**
Federalwide Assurance (FWA) Number:	**FWA00001435**
IRB Registration Number:	**IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, IRB00008495**
Institution Relying on the Review of the Above Designated IRB:	**University of North Carolina Greensboro**
Federalwide Assurance (FWA) Number:	**FWA00000216**

The purpose of this Agreement between **Reviewing Institution** and **Relying Institution** is to establish a written understanding defining the scope of responsibility of the respective institutions for the above named research study in which both institutions are involved. This agreement is limited to the above titled research study.

The Officials signing below agree that **Relying Institution** may rely on the designated IRB for review, approval and continuing oversight of the above titled research study.

The **Reviewing Institution** IRB is guided by the ethical principles regarding research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research" or other internationally recognized equivalent.

The review, approval and continuing oversight performed by **Reviewing Institution** IRB satisfy the requirements of the HHS regulations for the protection of human subjects at 45 CFR 46, as well as the requirements of federal, state and local laws. For research involving FDA regulated products, the **Reviewing Institution** IRB is in compliance with the requirements defined in 21 CFR Parts 50, 56, 312 and 812 and ICH (International Conference on Harmonization) guidance related to GCPs (Good Clinical Practices).

For this research study, the **Reviewing Institution** IRB will arrange for prompt reporting to appropriate officials at Wake Forest University Health Sciences, the Office of Human Subject Protections (OHRP) and to all other appropriate agencies of:

1. Any unanticipated injuries or problems involving risks to subjects or others.
2. Any serious or continuing non-compliance with the provisions of the Assurance or the determinations of the IRB, and
3. Any suspension or termination of IRB approval

Relevant minutes of IRB meetings and any other documents related to the conduct or approval of this research study shall be made available to **Relying Instiution** upon request. **Relying Institution** remains responsible for ensuring compliance in terms of its Assurance and with the determinations of **Reviewing Institution** IRB regarding this research study. This Agreement remains in effect until **Reviewing Institution** IRB approval for this research study is closed or until written notification of the closure of this agreement is provided by either institution.

This document must be kept on file at both institutions and must be provided to OHRP upon request.

Wake Forest University Health Sciences

Signature _____ Date 10/14/16

Joseph Andrews, PhD, CIP
Director, IRB
Wake Forest University Health Sciences
Medical Center Blvd.
Winston-Salem, NC 27157
336-716-4542

University of North Carolina Greensboro

Signature: _____ Date 10/13/16

Cristy McGoff, MA, CIP
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