Attachment 6a
ChiCAS IRB Approval

Office of Research
INSTITUTIONAL REVIEW BOARD.

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS-Social Sciences

From: Brian Moore, Chair,
Institutional Review Board

Date: 6/15/2018

Subject: Human Protocol: IRB00040441
HIV Prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention

Study Documents:
Protocol Version: Protocol CDC 04 18 2018 Clean.docx; Informed Consent Version: ChiCAS Consent ENGLISH.docx (approved), ChiCAS Consent SPANISH.docx (approved); Advertisements: 17-01869 Latina Transgender Women and Hiv Prevention_English_PRINT.pdf, 17-01869 Latina Transgender Women and Hiv Prevention_Spanish_PRINT.pdf; Other Documents: Appointment Card ENGLISH.docx, Appointment Card SPANISH.docx, Assessment ENGLISH.docx, Assessment SPANISH.docx, CDC Data sharing plan, ChiCAS Attendance Log.doc, ChiCAS curriculum.docx, ChiCAS interview guide ENGLISH.doc, ChiCAS interview guide SPANISH.doc, ChiCAS Observer's Guide.doc, In person screening English 03 30 18.docx, In person screening SPANISH 03 30 18.doc, Medical Chart Review Form.docx, signed agreement UNCG-Wake Forest, Stay in Touch Card ChiCAS coordinator ENGLISH docx.docx, Stay in Touch Card ChiCAS coordinator SPANISH docx.docx, Trent_COI Trans.pdf, Trent_FWA_Trans.pdf, Trent_Resume 2017.docx

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 6/15/2018 and will expire on 6/14/2019. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

This submission has met the requirements of the 2018 Common Rule.

Upon review of the research, the IRB finds that this study is classified as Expedited Category 5.

Upon review of the research, the IRB finds that this study is classified as Expedited Category 6.

Upon review of the research, the IRB finds that this study is classified as Expedited Category 7.

This research meets criteria for a waiver of written (signed) consent according to 45 CFR 46.117(c)(2).

This application indicates that advertising materials will be used for research purposes. Please consult with Creative Communications to ensure the appropriate visual identity is put forth.

A waiver for the requirements of signed consent and HIPAA authorization have been granted by the IRB for preliminary screening purposes.

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Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.

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