WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS-Department of Social Sciences and Health Policy

From: Brian Moore, Chair, Institutional Review Board

Date: 2/14/2020

Subject: Human Protocol: IRB00040441
HIV Prevention among Latina transgender women who have sex with men: Evaluation of a locally developed intervention
Amendment 29 for IRB Study #IRB00040441

Study Documents:
Protocol Version: ChiCAS Protocol (08 22 19).docx; Informed Consent Version: Appendix C1_English Consent Form.doc.docx (approved), Appendix C2_Spanish Consent Form.docx (approved); Advertisements: Appendix H1_English Informational Flyers.pdf, Appendix H2_Spanish Informational Flyers.pdf; Other Documents: Appendix B1_English Participant Screening Form.docx, Appendix B2_Spanish Participant Screening Form.docx, Appendix D1_English Questionnaire FOLLOW UP.docx, Appendix D1_English Questionnaire.docx, Appendix D2_Spanish Questionnaire FOLLOW UP.docx, Appendix D2_Spanish Questionnaire.docx, Appendix E_Spanish-language ChiCAS Curriculum Manual.docx, Appendix F_Implementation Observer's Guide.docx, Appendix G_Participant Attendance Log.docx, Appendix I_Medical Chart Abstraction Form.docx, Appendix J_Data Sharing and Use Agreement.docx, Appendix K1_English Qualitative In-Depth Interview.docx, Appendix K2_Spanish Qualitative In-Depth Interview.doc, Appendix L1_English Stay In Touch Cards.docx, Appendix L2_Spanish Stay In touch Cards.docx, Appendix M1_English Appointment Card.docx, Appendix M2_Spanish Appointment Card.docx, Appendix N_Individual Investigator (Trent) IRB Agreement.pdf, Appendix O_UNC Greensboro IRB Agreement.pdf, Appendix P1_English script for DVD1 (HIV impacts).docx, Appendix P2_Spanish script for DVD1 (HIV impacts).docx, Appendix Q1_English outline for DVD2 (PrEP etc.).docx, Appendix Q2_Spanish script for DVD2 (PrEP etc.).docx, Appendix R_Hormone Therapy PPT curriculum (Sp).pptx, Appendix S_HIV and STDs PPT curriculum (Sp).pdf, Appendix T_PrEP PPT curriculum (Sp).pptx

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

6-month follow-up assessments added.

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

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHRP/FDA; our IRB registration numbers are IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, and IRB00008495.
WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.