

Office of Research  
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

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

From: Gregory Hawkins, Ph.D., Chair, Institutional Review Board

Date: 11/23/2020

Subject: Human Protocol: IRB00040441  
HIV Prevention among Latina transgender women who have sex with men: Evaluation of  
a locally developed intervention  
Amendment 32 for IRB Study #IRB00040441

Study Documents:

Protocol Version: ChiCAS Protocol revised 07 30 20 11 19 20.docx; Informed Consent Version: Appendix C1\_English Consent Form 07 30 20.docx (approved), Consent ChiCAS SPANISH.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:

Catchment area is expanded to: in and around NC.

**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.

