

**Miami VA Healthcare System Human  
Studies Subcommittee APPROVAL**

DATE: August 27, 2019  
FROM: Leonardo Tamariz, M.D. <sup>5</sup>  
Miami VA Healthcare System Human Studies Subcommittee  
To: Joslyn Wiley, MD  
PROJECT TITLE: Factors Predicting High Risk Sex Practices and Incidences of STIs among  
Female Veterans  
REFERENCE #: 1382739-1  
SUBMISSION TYPE: New Project  
REVIEW TYPE: Expedited Review  
ACTION: APPROVED

The following items were reviewed and approved through Expedited Review:

- Conflict of Interest - Other - COI\_Fray (UPDATED: 08/26/2019)
- Consent Waiver - IRB Request for Waiver of Documentaion of IC\_Rev.01.2019.pdf (UPDATED: 07/10/2019)
- HIPAA Waiver - IRB Request for Waiver of Authorization and IC\_Rev.01.2019.pdf (UPDATED: 07/10/2019)
- Letter - Fray Informational Letter Department of Veterans Affairs - Updated July 8, 2019; Rev. March 29, 2019.docx (UPDATED: 07/8/2019)
- Letter - MEMORANDUM to Address Questions Posed May 24, 2019.docx (UPDATED: 06/8/2019)
- Miami VA - Initial IRB Application - Miami VA - Initial IRB Application (UPDATED: 07/8/2019)
- Miami VA - Privacy and Data Security Form - Miami VA - Privacy and Data Security Form (UPDATED: 07/8/2019)
- Other - Report of Staff (UPDATED: 07/10/2019)
- Other - FIU Approved PROTOCOL NO.107085.pdf (UPDATED: 07/8/2019)
- Other - IRB Request for IRB Exemption Review (UPDATED: 03/16/2019)
- Protocol - Research Protocol (UPDATED: 07/11/2019)
- Questionnaire/Survey - APPENDIX B - Revised Updated Demographic Questionnaire July 11, 2019.pdf (UPDATED: 07/11/2019)
- Questionnaire/Survey - APPENDIX F - Abuse Assessment Tool Short Form - modified with scoring.pdf (UPDATED: 07/8/2019)
- Questionnaire/Survey - APPENDIX D - SDO Scale July.pdf (UPDATED: 07/8/2019)
- Questionnaire/Survey - APPENDIX E - STD Knowledge Questionnaire -Short Form with scoring.pdf (UPDATED: 07/8/2019)
- Questionnaire/Survey - APPENDIX A - Study Participant Screening Form.pdf (UPDATED: 07/8/2019)

- Questionnaire/Survey - APPENDIX C - Safer Sex Behavior Questionnaire with scoring for IRB.pdf (UPDATED: 07/8/2019)
- VA - R&D Request to Review Research Proposal - VA - R&D Request to Review Research Proposal (UPDATED: 07/8/2019)

**Expedited under Federal Regulation: 45 CFR 46.110(2a)/VA Regulation: 38 CFR 16.110(2a) was granted on 07/18/2019. This Expedited review will be reported to the fully convened HumanStudies Subcommittee meeting on 09/05/2019.**

**Based on the Revised Common Rule, your study meets the criteria for not requiring continuing review (minimal risk); however, please be aware that local policy still requires the PI to annually inform the IRB of the project status. Also, please be reminded that investigators remain responsible for updating the IRB about adverse events and other unanticipated problems, seeking IRB approval for changes to personnel, protocol amendments, recruitment materials, etc., and informing the IRB when the research is complete.**

Please note that any revision to previously approved materials must be approved by this committee prior to initiation.

All apparent NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

If you have any questions, please contact Raul Rojas at (305) 575-7000 ext 7241 or raul.rojas54@va.gov. Please include your project title and reference number in all correspondence with this committee.

**Research may not begin until the R&D Committee has approved the initiation of the study and you have received FINAL WRITTEN APPROVAL that the study may commence from the Associate Chief of Staff for Research and Development.**

This letter has been issued in accordance with all applicable regulations, and a copy is retained within Miami VA Healthcare System Human Studies Subcommittee's records.