

# Department of Veterans Affairs

# Memorandum

**Date:** September 16, 2019

**From:** Associate Chief of Staff for Research (151)

**Subj:** Approval of Research Protocol titled "Factors Predicting High Risk Sex Practices and Incidences of STIs among Female Veterans" (*Protocol Version July 2019*)

**To:** Joslyn Wiley, M.D.

1. At its meeting of August 27, 2019, the Medical Center Research and Development Committee approved the research protocol cited above, for which you are listed as Principal Investigator. Permission to carry out this study is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects. You are approved for the participation of veteran subjects. Please be reminded that research activities conducted on VA time should only occur at VA sites, unless otherwise authorized. This project has been assigned number #9406.01 for identification and reporting purposes.

This study was reviewed and approved by the Human Studies Subcommittee (IRB) on 7/18/2019.

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. Your next report is due on 7/17/2020.

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.

2. The Research Office has reviewed the list of individuals who will participate in carrying out this study as provided by you on the "Report of Research Staff Members." The records in our Office for each of the following individuals are complete in that documentation of educational and training background, human studies education and appropriate certification of "Scope of Practice" meet the current Office of Research and Development (ORD) standards (Research 'Stand Down' Memorandum of March 6, 2003) and accordingly they have approval to participate in carrying out this study:

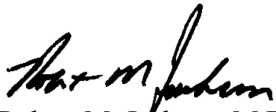
**J. Wiley, B. Fray**

If there are any changes in the educational and training background, human studies education certification or "Scope of Practice" for any of the individuals currently listed or to be added to your "Report of Research Staff Members," or if you have any questions concerning this matter, please contact the IRB Office at (305) 575-4278.

3. Since your study involves the participation of human subjects at this medical center, you must be aware of and comply with the requirements for approval by the Human Studies Subcommittee (as well as by the Research and Development Committee) of the initial protocol and of any modifications.

You should already be aware of these requirements; if you have any questions concerning them, please consult the Research Service Office staff. A copy of VA Form 10-1223, Report of the Subcommittee on Human Studies is enclosed for your files. While the original of this document is available in the Research Service Office, you may be asked by various groups with oversight responsibilities to provide copies and so you should have a copy in your own files.

4. Please note that you are required to submit an annual report to the IRB informing the IRB of the project status. You will be reminded of these requirements by the Research Office staff and must complete the required forms by the indicated deadline. Upon completion or termination of the project, a Final Progress Report must be filed.
5. Due to recent events relating to data handling, you are being reminded that you are not authorized to remove any sensitive research-related data from the premises of this Medical Center without first obtaining the required approvals AND complying with all information that pertain to protecting confidentiality of data and patient privacy. For more information you may contact the Information System Security Officer (ISSO) at ext. 3461 or the Privacy Officer at ext. 6464.
6. If you have any questions concerning any of these requirements, please feel free to consult the Research Office staff.



Robert M. Jackson, M.D.

Attachments