# MIAMI VAHCS IRB
# Waiver of Documentation of Informed Consent

Name of Study:

Principal Investigator:

VA regulations permit an IRB to waive the requirement to obtain written documentation of informed consent. (**Note:** This provision can be used only for the waiver of documentation of consent, not for waiver or alteration of consent itself.) To approve such a waiver, the IRB must find and document **either** of the following conditions listed below. Please determine the reason for the waiver (#1 or #2) and provide justification in the space provide.

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject shall be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (The waiver provision is not applicable to FDA-regulated research)

   *Provide justification using description of study and procedures you will follow to comply with this Requirement:*

Or

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the principal investigator to provide subjects with a written statement regarding the research. This policy is also applicable to FDA-regulated research.

   *Provide justification documenting why this study does not pose more than minimal harm and procedures or activities that do not require written consent:*

3. Attach a "Letter of Introduction" that provides a written description of the research to potential participants. This letter is to be reviewed and approved by the IRB in a manner similar to a consent document that is on a VA form 10-1086.