**Single IRB Plan - Section 3.2**

1. **Study Information**

 Title: [Title of the Research Grant]

 PI: [ Name of the Lead PI]

 NIH Grant Number: [ #]

1. **Statement of Compliance**

We plan to comply with the NIH sIRB policy pursuant to NOT-OD-16-094 by designating a single IRB of record to conduct ethical review required for the protection of human subjects.

1. **Single IRB of Record**

**<Choose appropriate language>**

University of Miami will use [Name of the sIRB] to serve as the single IRB of record for the project for all sites.

<Or>

Although a single IRB of Record has not yet been chosen for this study, the lead institution is dedicated to identifying a single IRB of Record for all sites in this study. The following participating sites have expressed their willingness to rely upon the review of a single IRB of Record for this study: [List Relying Institutions]. <Or>

We are requesting an exception to the single IRB requirement for [Name of the sIRB]. [Describe in detail the reasons why you are requesting the exception. You must provide a compelling justification. See [NIH’s guidance](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html) on requesting this type of exception.]

1. **Agreement of the Participating Sites**

Currently identified sites, [List the names of the identifies sites], agreed to rely on [Name of the IRB]. All participating institutions/sites identified in the future must agree to use [Name of the IRB] as a condition of their participation, unless they meet the NIH criteria for exemption from using a single IRB.

1. **Communication Plan**

Please see the attached Communication Plan which shall be implemented by all participating sites. <Use the attached (Communication Plan and collaborate with the chosen sIRB to ensure agreement.>

1. **IRB Authorization Agreements**

University of Miami will maintain an IRB Authorization Agreement with [Name of the sIRB] that describes roles and responsibilities of the reviewing IRB and the institution. Prior to the engaging in human subject research, all institutions for future sites added to this study will also sign a reliance agreement.

If SMART IRB Master Reliance Agreement is used, documentation of the reliance will be recorded in the portal.

**IF APPLICABLE**: [Name of the participating site] maintains an agreement with [Name of the sIRB] that allows [Name of the participating site] to rely on the review performed by [Name of the sIRB].

1. **Recordkeeping**

[name of the sIRB] and each institution will maintain records related to the fully executed IAAs. [Name of the sIRB] and the overall PI will be responsible for maintaining records related to the communication plan. [Name of the sIRB], overall PI, and the site PIs will maintain records related to the human subject research.