Single IRB Plan

1. Study Information

 **Title:[Study Title]**

**PI: [Name of Lead PI]**

1. Compliance

We plan to comply with the single IRB requirements for this study by designating a single IRB of record.

1. Single IRB of Record

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].

1. Presently-Identified Participating Sites

All presently-identified participating sites, as listed above, have agreed to rely on a single IRB of record for the above study/studies. Any potential participating sites included after the submission of this application shall be required to rely on the chosen single IRB of record for the above-named study/studies as a condition of their participation, unless they meet the any applicable criteria for exemption or exception from using a single IRB.

1. Communication Plan

Please see the attached Communication Plan which shall be implemented by all participating sites.

1. Individual Authorization Agreement

All presently-identified participating sites shall enter into and sign an individual authorization agreement (IAA) prior to the initiation of the study, or shall use the SMART IRB reliance agreement. Said IAA shall include, but not be limited to, the division of responsibilities in Section E.

1. Recordkeeping

Specifically, lead institution shall be responsible for maintaining records related to the fully executed IAA. Lead institution shall be responsible for maintaining records related to the Communication Plan.