Document Title: Multi-site Research (MSR): Overall Principal Investigator Responsibilities

A. Introduction

This document provides an overview of the Principal Investigator (PI) responsibilities associated with a multisite study where an University of Michigan IRB has single IRB (sIRB) oversight. As a PI on a multisite - sIRB study you should be aware of your additional responsibilities. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

B. Responsibilities

- ☐ Have adequate and qualified study team members (i.e. study coordinators or research staff) to conduct and manage the study.
- ☐ Work in collaboration with the IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
- ☐ Obtain documentation of each relying site's approval to cede review
- ☐ Promptly respond to questions or requests for information from study teams and IRB personnel at the relying site.
- ☐ Provide the relying site with the applicable IRB policies. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.
- ☐ Prepare participating site IRB applications on behalf of all relying sites. This will involve creating friend accounts for the relying site Principal Investigators.
    - The participating site application provides a mechanism to:
        - provide relying sites with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
        - obtain and collate information from the relying site, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
        - ensure that consent documents follow the IRB approved templates and include the required local-context language from each relying site.
- ☐ As the overall PI, you must be aware of all the reportable events, amendments and continuing review data that is

being reported by the relying sites via their participating site application.

- ☐ As the overall PI, you must submit study-wide amendments, reportable events or continuing review reports that affect the overall study.
- ☐ When agreed upon in coordination with the IRB, promptly report to the relying site of any unanticipated problems involving risks to subjects or other research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research at the Relying Institution.
- ☐ Provide access, upon request, to study records for audit by IRB, and other regulatory or monitoring entities.

NOTE: This document is adapted from the SMART IRB PI/Lead study team Guidance and Checklist.