

**Re: NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research**

The Program for the Protection of Human subjects (PPHS) at the Icahn School of Medicine at Mount Sinai (ISMMS) understands that the new NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies, involving non-exempt human subjects research and funded by the National Institutes of Health (NIH), will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects.

When ISMMS will be a relying site (regardless of whether ISMMS is the prime awardee), the ISMMS IRB agrees to cooperate with the Single IRB plan when the Reviewing IRB is one of the following:

* accredited and utilizing the SmartIRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SmartIRB Agreement), or
* a non-accredited CTSA hub with no OHRP/FDA warning letters utilizing the SmartIRB Agreement)
* an external IRB with which ISMMS already has an existing master agreement.