

Ratified September 2014

PEDSnet Single Institutional Review Board (IRB) Policy

Purpose of Policy: To establish a single Institutional Review Board (IRB) framework for multi-institutional research studies.

Definition

- **Single Institutional Review Board (IRB):** An Institutional Review Board framework that provides a vehicle for investigators proposing multicenter studies to request "ceded review" - that is, to request that the IRBs on a multicenter study rely on the review of one IRB, and for the IRBs at the participating institutions to elect to do so on a protocol-by-protocol basis.

§1. Participation in the PEDSnet Single IRB Framework

All PEDSnet institutional members are required to endorse the PEDSnet single IRB policy by becoming a participating institution of the Master Common Reciprocal Institutional Review Board Reliance Authorization Agreement (also referred to as the Master Reliance Agreement).

§2. Voluntariness

Participation in the Master Reliance Agreement allows an institution to choose on a case-by-case protocol basis whether to participate in a ceded review, as a relying or reviewing institution, or perform its own IRB review.

§3. Development of the Master Reliance Agreement

- 3.1 The PEDSnet Executive Committee will charge the PEDSnet Regulatory workgroup to develop a Master Reliance Agreement.
- 3.2 The purpose of Master Reliance Agreement is to allow institutions that sign this Agreement to cede IRB review (Relying IRB(s)) to another signatory (reviewing IRB). This Agreement will set forth the respective authorities, roles, and responsibilities of each party when a ceded review arrangement is determined to be acceptable.