Georgetown University  Institutional Review Board  
Policy for Facilitated Review (IRB of Record)  

Institution Providing IRB Review (Institution A or “Designated IRB”)  

Institution Relying on the Designated IRB (Institution B or “Designating IRB”)  

This policy establishes procedures relating to the designation of Institutional Review Board (“IRB”) review of collaborative research involving human subjects to be performed by Institution A. The designation of review to one institution’s IRB (Institution A or “Designated IRB”) avoids multiple institutional reviews of the same protocol by the IRBs of the other institution (Institution B or “Designating Institution”). Designation of review will be determined by the institution affiliation of the lead Principal Investigator unless the research will be conducted physically elsewhere. In that latter case, the Designated IRB will be the IRB located at the institution where the research will be conducted. If research will be performed at more than one institution, a Principal Investigator may select the Designated IRB, with the consent of that IRB’s Chair.

Upon request of the Human Subjects Protection Officer of the Designating Institution,
(a) a representative from the Designating Institution(s) may attend that portion of the meeting of the Designated IRB at which a collaborative protocol will be considered; and

(b) the Designated IRB will provide requested documents, including excerpts of the approved minutes reflecting the Designated IRB’s discussion of the protocol, the approved protocol and consent form, a list of adverse events and annual progress reports.

The Designated IRB shall provide to the Designating IRB without request from the Designating IRB, (a) Notice of study suspensions and/or terminations, and (b) Notice of continuing review approvals or denials.

It shall be the responsibility of the Principal Investigator to notify the Designating IRB of
  (a) serious adverse events, and (b) amendments/modifications affecting risks to subjects.

Institution B (the Designating IRB) remains responsible for ensuring compliance with the IRB’s determinations and with the terms of its OHRP-approved FWA. This document must be kept on file by both parties.