Managing inter-institutional reliance agreements*: the process

STEP 1: Request is initiated: inquiry
- May initiate inquiry, consult with RC as to viability of reliance
- Consults with PI and/or IRB Administrator regarding request; engagement determined when Harvard relies
- When Harvard is proposed to Review for External sites: determines engagement, refers PI to RC for consultation

STEP 2: Request is formalized: submission of materials
- External IRB/pSite (Harvard relies) or initial application/modification in ESTR (Harvard reviews); SmartIRB request; supporting documents.
  - Provides instructions to PI for submission
  - Receives External submissions and pSites for review; receives notice of SmartIRB submissions
  - Receives notifications of SmartIRB requests

STEP 3: Routing of requests
- Provides clarifications to RC or External IRB staff, uploads additional supporting documents
- Evaluates request for completeness, viability \(^1\), presence of FWA, corresponds with PI, CUHS staff, external IRB POC
- Provides information obtained from IRB review that pertains to request for reliance
- Harvard relies: determine local requirements; ancillary reviews; informs relying IRB OR CUHS admin
- Incorporates local context considerations in overall IRB review process (Harvard reviews)
- Discusses request with RC, determines additional clarifications needed for RC follow-up

STEP 4: Evaluation of reliance request
- Harvard relies: determine local requirements; ancillary reviews; informs relying IRB OR CUHS admin
- Incorporates local context considerations in overall IRB review process (Harvard reviews)

STEP 5: Local context review
- Provides clarifications to RC or External IRB staff, uploads additional supporting documents
- Evaluates request for completeness, viability \(^1\), presence of FWA, corresponds with PI, CUHS staff, external IRB POC
- Provides information obtained from IRB review that pertains to request for reliance
- Harvard relies: determine local requirements; ancillary reviews; informs relying IRB OR CUHS admin
- Incorporates local context considerations in overall IRB review process (Harvard reviews)
- Discusses request with RC, determines additional clarifications needed for RC follow-up

STEP 6: Presentation to IRB Director - recommendation
- Harvard relies: determine local requirements; ancillary reviews; informs relying IRB OR CUHS admin
- Provides information obtained from IRB review that pertains to request for reliance
- Harvard reviews: obtains local context info from relying IRB
- Incorporates local context considerations in overall IRB review process (Harvard reviews)
- May provide preliminary indication of agreement, stipulations; if IRB is not responsive, request may be discarded at Harvard IRB discretion after 60 days.

*Reliance agreement: agreement between IRBs in which one IRB cedes and the other extends oversight for collaborative research. See investigator manual: “Ceding review allows one institution to serve as Reviewing Institution/IRB (‘single IRB’ or ‘sIRB’), while the others serve as the Relying institution/IRB (‘participating sites’).” The agreement is formalized through an IAA document or through SmartIRB platform. Terminology: cede request, reliance request, IAA (IRB Authorization Agreement), reliance agreement, External IRB, participating site.
1. For types of research that this IRB will not review, and for which it will rely on another IRB, see HRP-101; refer to HRP-101 and HRP-103 for additional conditions that pertain to consideration of cede requests.
2. Refer to HRP-103 for the detailed investigator responsibilities when 1) Harvard IRB provides oversight to non-Harvard collaborators and 2) when relying on an external IRB.
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