

Using IREx to fulfill SMART IRB Documentation and Notification Requirements.



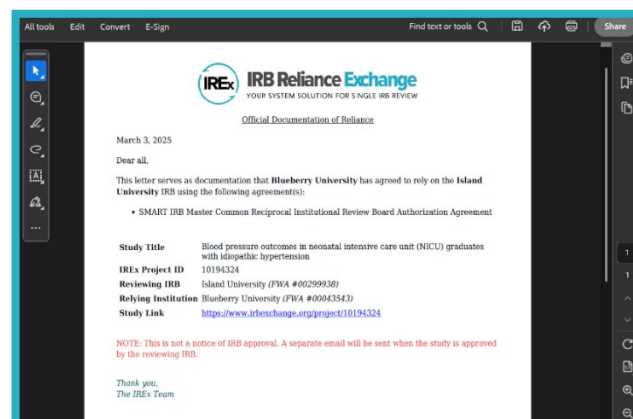
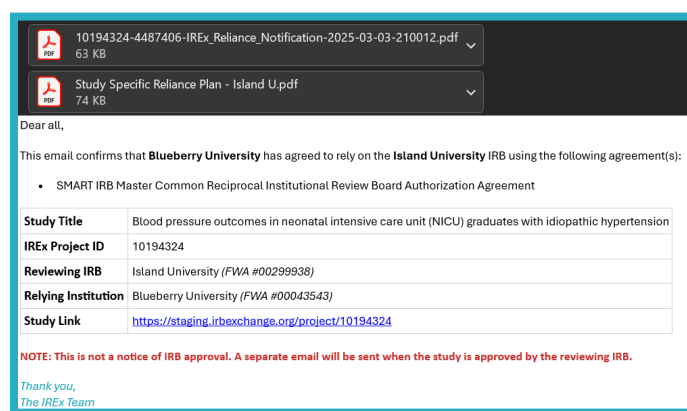
The IREx platform supports operationalization of the SMART IRB Agreement (all versions). Outlined below are the critical SMART IRB Agreement requirements and the IREx features Reviewing IRBs and Relying HRPPs can use to operationalize them.

RELIANCE DOCUMENTATION REQUIREMENT: Section 3.2.3 of the SMART IRB Agreement requires that sites be notified of the acceptance or declination of a Reliance Request.

SMART IRB Agreement 3.2.3 Notification of Acceptance or Declination of a Reliance Request and of the Reviewing IRB/Reviewing IRB Institution. *Unless otherwise agreed, the Reviewing IRB/Reviewing IRB Institution should generally be the one to notify the Overall PI and the Site Investigator(s) and the applicable Participating Institutions (i) whether the Reliance Request for Ceded Review with respect to an instance of Research has been accepted or declined under this Agreement; and (ii) if accepted, which Party shall be the Reviewing IRB/Reviewing IRB Institution.*

IREx Feature: In compliance with Section 3.2.3, IREx can be used to indicate cede decisions and reliance arrangements. First, a Participating Institution agrees to serve as the Reviewing IRB for a study by (1) creating the study in IREx and (2) completing the study-specific reliance plan (SSRP), which documents how the flexible elements of the SMART IRB Agreement will be implemented as part of the Ceded Review.

Next, Participating Institutions can access the study in IREx and review and accept the SSRP. Acceptance of the SSRP finalizes the cede decision and produces documentation for the Reviewing IRB and Relying Institution. Below are screenshots of the email and attached Documentation of Reliance (PDF) that is sent to the Reviewing IRB's and Relying Institution's HRPP/IRB point of contacts, Overall PI, and Site Investigator. The SSRP can also be viewed within IREx at any time.

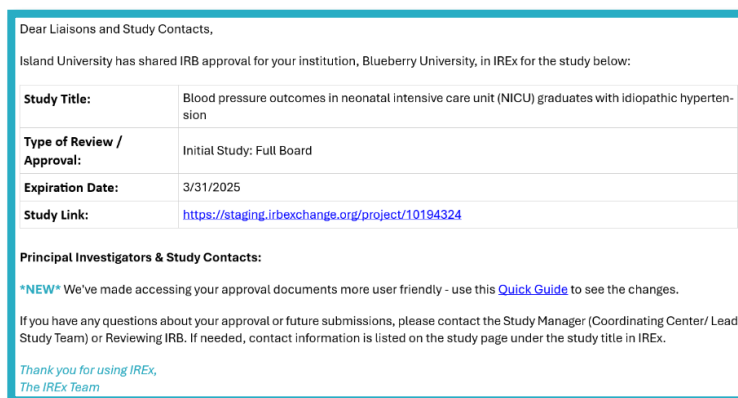


NOTIFICATION REQUIREMENT: Section 5.8 requires the Reviewing IRB notify the Site Investigators and Relying Institutions of any review decisions.

SMART IRB Agreement 5.8 Notification of IRB Decisions, Changes, and Lapses in Approval. *A Reviewing IRB/Reviewing IRB Institution will promptly notify the Overall PI, Site Investigator(s), and the Relying Institution(s) of its determinations (e.g., exemption) or review decisions regarding Research (e.g., approval, disapproval, required modifications); of changes in the Research that are reviewed and approved by the Reviewing IRB after initial approval; and of lapses in IRB approval of the Research and any applicable corrective action plans. Such notifications may be made through the Reviewing IRB/Reviewing IRB Institution's designee, if agreed by the relevant Relying Institution(s) in connection with the instance of Research.*

IREx Features: IREx can be used to fulfill the requirements of section 5.8, to notify participating sites of the Reviewing IRB's determinations (e.g., at the time of initial approval, continuing review, for site-specific

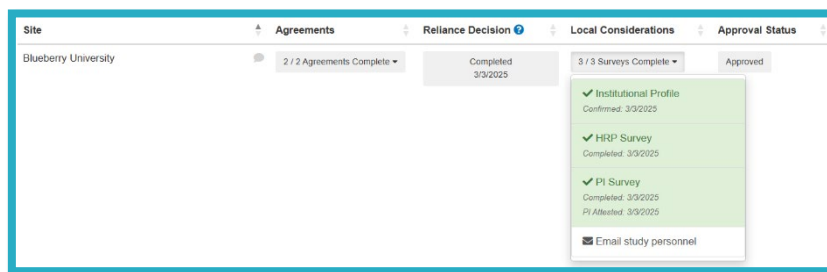
amendments or changes and for study-wide modifications or changes). Below is a screenshot of the email that is sent to the Relying Institution HRPP/IRB point of contact, Overall PI, and Site Investigator when the Reviewing IRB or a designee (e.g., coordinating center) shares an approval for a site in IREx.



LOCAL REVIEW COMMUNICATION REQUIREMENT: Section 6.6 of the SMART IRB Agreement requires each Relying Institution communicate Local Considerations to the Reviewing IRB.

SMART IRB Agreement 6.6 Local and Other Considerations. *A Relying Institution will identify and communicate to the Reviewing IRB/Reviewing IRB Institution (i) the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews (“Local Considerations”); and (ii) the requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that are not readily apparent from the IRB submission for the Research or that are specific to the Relying Institution (“Other Considerations”) that would affect the conduct by or approval of the Research or the grant of an Exemption Determination on behalf of the Relying Institution. Such communication may be made through the Reviewing IRB’s/Reviewing IRB Institution’s designee, if agreed by the relevant Relying Institution(s) in connection with the instance of Research. Notwithstanding anything else in this Section 6.6, for purposes of this Agreement, HIPAA and its requirements are not considered Other Considerations and are addressed separately in Section 4.4 hereof.*

IREx Features: IREx can be used to fulfill Section 6.6 of the SMART IRB Agreement when single IRBs choose to collect Local Considerations in IREx. When the Reviewing IRB utilizes this function, IREx prompts Relying Institutions (HRPPs and study teams) to complete three different Local Considerations surveys within IREx – the Institutional Profile, the HRP Survey, and the PI Survey. The Lead Study Team or Coordinating Center submits completed surveys to the Reviewing IRB for their review.



Additionally, IREx functionality supports single IRB review for Exemption from Informed Consent (EFIC) studies through facilitating dissemination and retrieval of required documents outside of Local Considerations Surveys (e.g., Community Consultation Plan, Summary of Results).