Using IREx to fulfill SMART IRB Documentation and Notification Requirements.

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Notifications and communications are one of the required, but flexible elements of the SMART IRB Agreement. That is, it requires specific notifications and communications, but the SMART IRB Agreement does not prescribe one system or method for fulfilling these requirements.

Section 3.4 of the SMART IRB Agreement requires that sites be notified of the acceptance or declination of Ceded Review.

> *3.4 Notification of Acceptance or Declination of Ceded Review. Unless otherwise agreed, the Reviewing IRB(s) (or designee(s)) shall generally be the one(s) to notify the Overall PI and the Site Investigator(s) and the applicable Participating Institutions (i) whether the request for Ceded Review of the Research has been accepted or declined under this Agreement; and (ii) if accepted, which IRB(s) shall be the Reviewing IRB(s).*

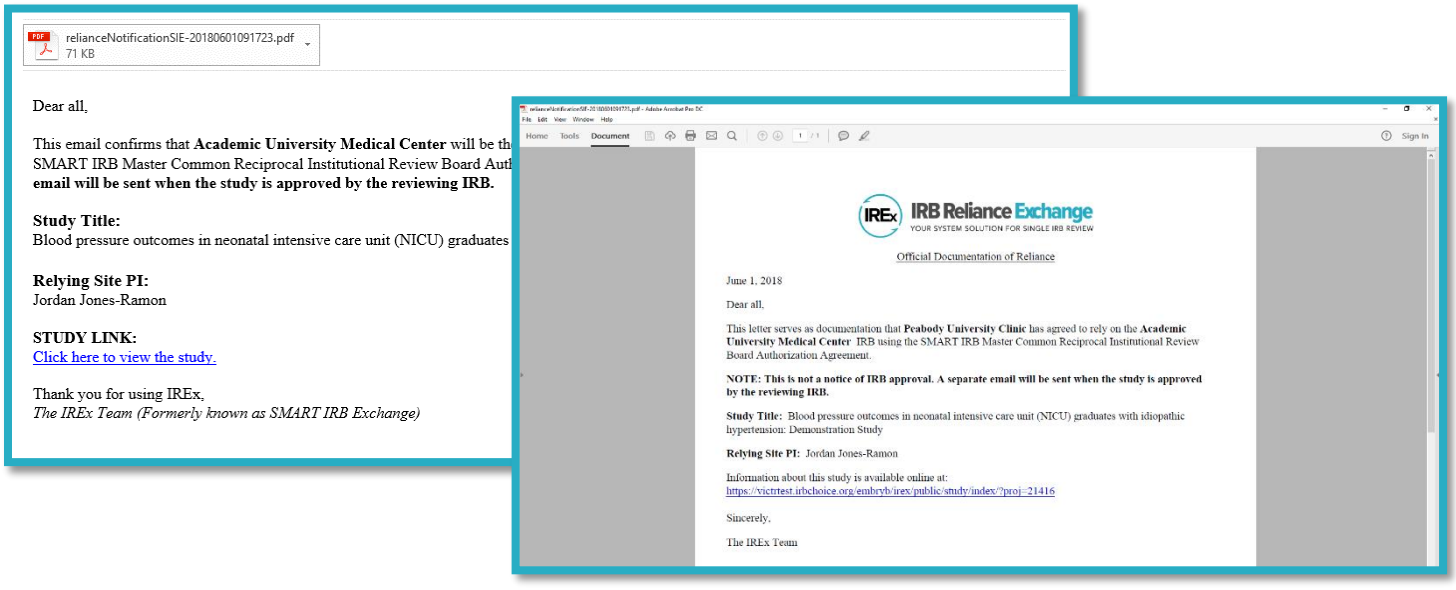
Additionally, Section 5.9 requires the Reviewing IRB notify the Site Investigators and Relying Institutions of any review decisions.

> *5.9 Notification of IRB Decisions, Changes, Lapses in Approval. Promptly notify the Overall PI, Site Investigator(s), and the Relying Institution(s) of its determinations (e.g., exemption) or review decisions regarding the Research (e.g., approval, disapproval, required modifications); of changes in the Research reviewed and approved by the Reviewing IRB after initial approval; and of lapses in IRB approval and any applicable corrective action plans. Such notification may be made through the Reviewing IRB's designee, as determined by the Participating Institutions in connection with the specific Research.*

The IRB Reliance Exchange (IREx) can be used to fulfill both of these requirements.

In compliance with Section 3.4, 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.



IREx can also be used to fulfill the requirements of section 5.9, to notify participating sites of the Reviewing IRB's determinations. 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.

Dear All,

The Academic University Medical Center has shared IRB approval for your institution, Peabody University Clinic, for the following study:

Blood pressure outcomes in neonatal intensive care unit (NICU) graduates with idiopathic hypertension: Demonstration Study

This was an Initial Approval: Full Board approval by the Reviewing IRB. The expiration date is **04/03/2019**.

Principal Investigators & Study Contacts:
Your approval documents are available in IREx. If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

Access the study at: https://www.irbexchange.org/study/index/?proj=9

Thank you,
The IREx Team

IREx can be used to communicate approvals at the time of initial approval, continuing reivew, for site-specific amendments or changes and for study-wide modifications or changes.