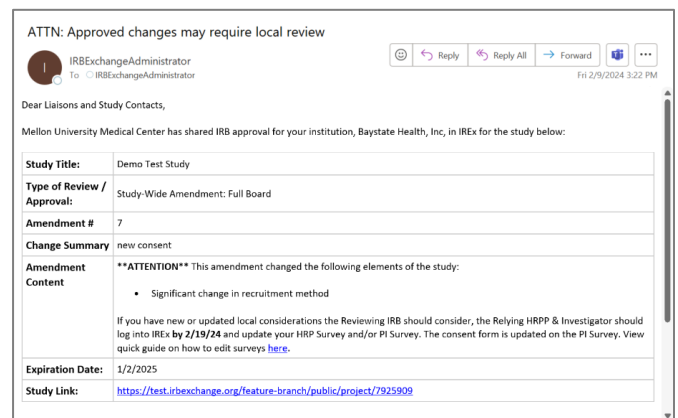


# UPDATING LOCAL CONSIDERATIONS THROUGHOUT THE LIFE OF A STUDY

## WHEN WILL MY SITE BE REQUESTED TO UPDATE LOCAL CONSIDERATIONS IN IREx?

After initial approval, changes in a study (amendments, modifications) can trigger the need for a relying institution to reassess their local considerations (e.g., a study initially approved to include adults could be modified to include minors).

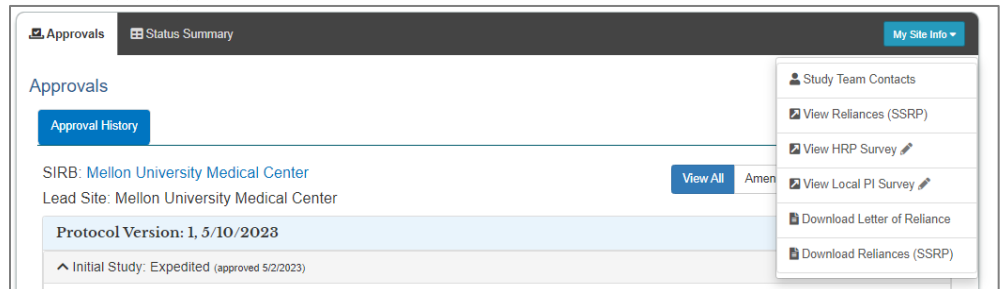
If the sIRB prefers for relying sites to document changes to local considerations in IREx, the Relying HRPPs and Study Teams will receive an IREx notification with the subject line **ATTN: Approved changes may require local review**. An **Amendment Content** section in the email will outline the type of changes. If these changes impact local considerations, Relying HRPPs and/or Study Teams should log into IREx and update the HRP and/or PI surveys, respectively.



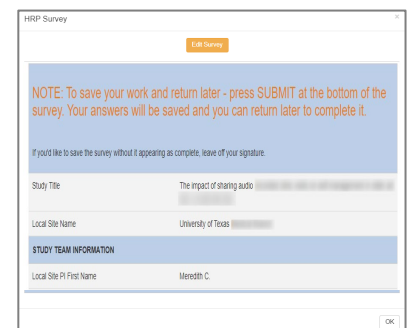
## HOW DO I UPDATE MY SITE'S LOCAL CONSIDERATIONS IN IREx?

- Log into IREx and navigate to the study. From **My Site Info**, click the pencil icon for the survey that needs to be edited – the HRP and/or the Local PI Survey.

**IREx Tip:** Multisite Liaisons can access the **My Site Info** button from the **Your Sites** tab.



- Click **Edit Survey**, make the necessary edits, and click **Submit**. This will send an IREx notification to the IREx Study Manager, who will submit the updated Local Considerations to the sIRB.
- If anyone besides the Local PI edits/updates the PI Survey, the PI will need to log into IREx and re-attest to the survey. PIs will receive an IREx notification that their attestation is required, and the **Complete/Attest to PI Survey** will reappear on their IREx Checklist.



**IREx Tip:** The Study Manager will submit the update local considerations to the sIRB for review. If a site amendment is issued, the Study Manager will upload it to IREx and an IREx notification will be sent to the relying site HRPP and study team.

## CAN RELYING SITES ONLY MAKE UPDATES WHEN THE SIRB REQUESTS IT?

No, Relying Site HRPP or study personnel can make edits to their local considerations at any time! Whether changes are requested by the sIRB or, for example, due to local policy changes, the process looks the same; simply follow the steps above. Examples of when relying site personnel could update their local considerations in IREx include (but are not limited to) to reflect a local site PI change or to note new or revised institutional policies that impact the conduct of the study.