

eIRB: The Upgrade

IMPORTANT
NEWS YOU NEED
TO KNOW!

THE LATEST ON OUR SYSTEM UPGRADE



Known issue with the New eIRB's "Devices" section

Instead of the intended options, you will see a list of device names in Question 2 of the "Devices" section. This is an issue for New Studies and for Modifications to studies using devices. (See screenshot at the end of this message.)

Even if you select a device from the list, the error prevents you from moving forward.

The vendor is working on a solution. We will update you as soon as we know the repair timeline.

In the meantime, **please do the following if modifying or submitting a study using a Device:**

- Make sure you have copies of all of your device information
- Say **"No"** to the Device question in "Scope of Research," so the Device section does **not** appear
- Under **"Local Site Documents,"** attach device information in a document, along with other device attachments.
 - Include, as applicable: name of Sponsor, IDE number, [justification for IDE exemption](#), [justification for non-significant-risk device](#), and/or device instructions.
- Please **log a comment** to your analyst alerting them that you experienced this error and followed the above guidance. Thank you!

The screenshot shows the eIRB interface for editing a study (STUDY00000). On the left, a sidebar lists various sections with green checkmarks, indicating they are complete. The 'Devices' section is highlighted in orange and shows a red error icon. The main content area displays the 'Devices' section with a message: 'Could not update the IRB Submission due to one or more errors. Validation Failed. Please review the page and correct any errors...'. Below this, there are two questions: '1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:' and '2. * Device exemptions applicable to this study:'. Question 1 has a table with columns for Device, Humanitarian Use Device, and Attachment Name. Question 2 has a list of device exemptions with radio buttons for selection. At the bottom right, there are buttons for 'Exit', 'Save', and 'Continue'.