## eIRB: The Upgrade



IMPORTANT

TO KNOW!

NEWS YOU NEED

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, <u>justification for IDE exemption</u>, <u>justification for non-significant-risk device</u>, 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!

E 🕄 Validate 🎒 Compare	**	You Are Here: 📦 Study	
Error/Warning Messages (1)	2 Refresh	Editing: STUDY00000	• @Help
Basic Study Information	~	Could not update the IRB Submission due to one or more errors: Validation Failed. Please review the page and correct any errors	
Study Funding Sources	*		
Local Study Team Members	~	1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:	
Study Scope	~	+ Add	
Local Research Locations	~	Device Humanitarian Use Attachment Name Device	
Devices	•	C Update	
<ul> <li>Device Type This is a required field; therefore, y information</li> </ul>	ou must provide the required	2. * Device exemptions applicable to this study:	
Local Site Documents	~	ID00000744 2/26/2020 Valiant Navion™ Thoracic Stent Graft System     ID00000734 2/13/2020 Lariat-0125 Rev C IFU	
Waiver Requests and Ancilary Considerations	~	ID0000001 2/8/2020 "Emery Anesthesiologist" Application for Android     ID00000002 9/10/2019 "MY ED"     ID00000003 2/8/2020 3D Imaging and Navigation for Prostate Biopsy, Attemis	
		ID00000004 28/2020 3D printer, Pruse i3 MK2 3D Printer kit with LCD     D00000005 28/2020 3D series Circulare Series	
		ID0000006 2/8/2020 3T MRI Scanner, Nuclear Magnetic Resonance, MAGNETOM Trio a Tim System     ID00000007 2/8/2020 4D Flow, WIP 785	
		ID0000008 2/8/2020 5Fr compatible, single-use RF probe, Symplicity Catheter     ID00000009 2/8/2020 5MAX ACE	
		O ID00000010 2/8/2020 6 Degrees of Freedom IMU Digital Combo Board - ITG3200/ADXL345	ntinue ℈