Single IRB Stakeholder Feedback: Evaluating the Use of the IRB Reliance Exchange

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BACKGROUND

In 2018, the NIH Single IRB (sIRB) Policy went into effect, requiring NIH-funded multi-site research to utilize a single IRB of record. The Institutional Review Board (IRB) Reliance Exchange (IREx) is a freely available, NIH-supported web-based platform supporting sIRBs, lead study teams (LST), and relying sites (HRPPs and study teams) through the complex sIRB process for the life of the study.

- Over **40** different sIRBs using IREx
- Over **650** studies
- **500+** sites
- **3700+** reliance decisions
- **29,000+** site approvals documented

METHODS

Users were asked to complete satisfaction surveys in Q2 of 2023

WHO to survey

- **sIRB:** Primary Contact listed on the study
- **Relying HRPP:** Relying HRPP contact who signed the HRP Survey
- **LST/Study Manager (SM):** most active member-based a) email interactions or b) the person listed most frequently in the log
- We did not contact potential respondents >2 times, even if they were eligible
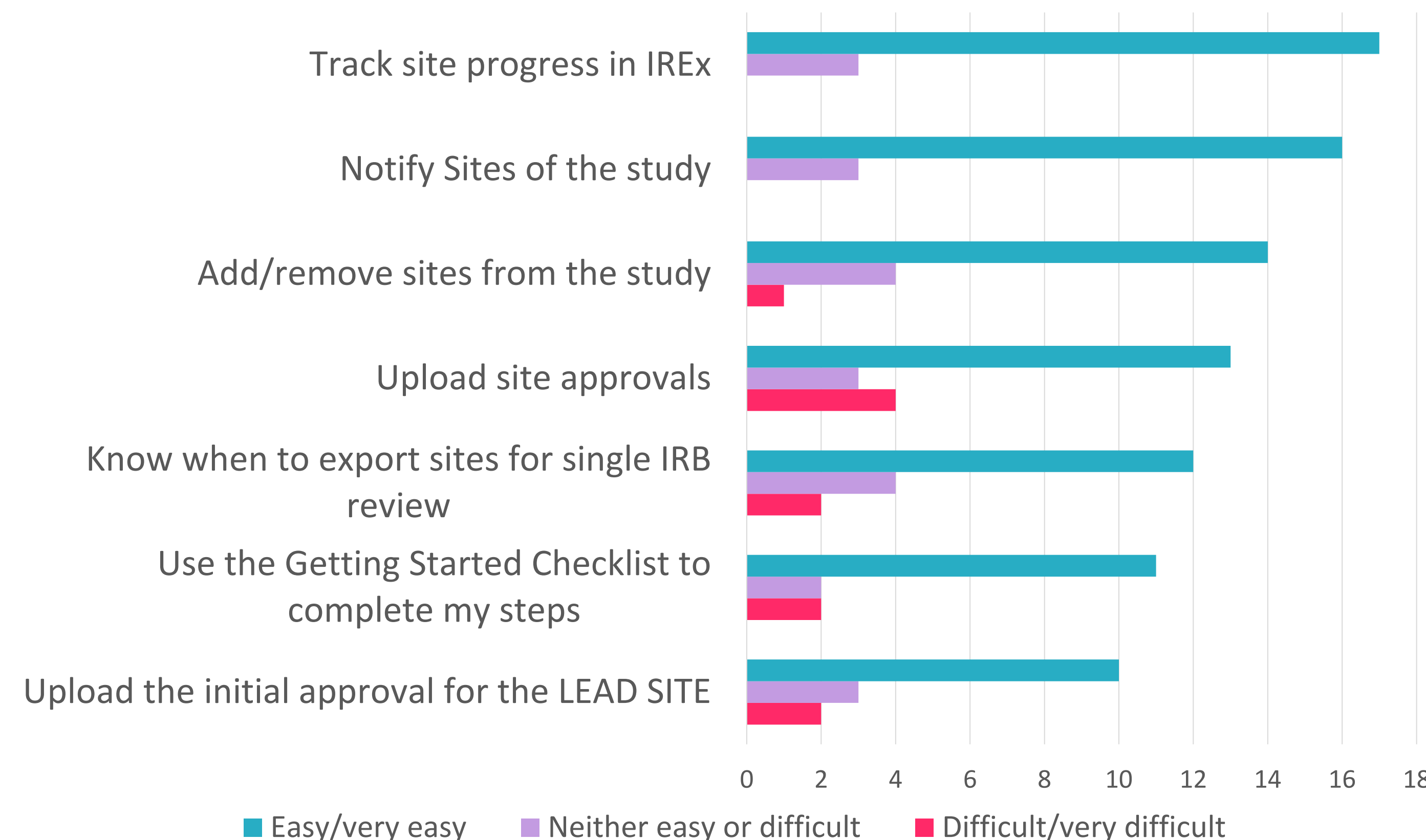
WHEN to survey IREx users

- **sIRBs:** after lead site approval posted to IREx
- **LST/SMs:** after ~25% of their participating sites received initial approval
- **Relying HRPPs:** after receiving initial approval on a study

RESULTS

- **48 total respondents:** sIRB (n=6 completed/15 sent), lead study teams (n=20/40), and relying HRPP users (n=22/55)
- All sIRB respondents would recommend using IREx to coordinate sIRB studies
- Majority of sIRB respondents said **using IREx takes less time** than studies where IREx is not used
- 85% of LST respondents were **satisfied/very satisfied** with using IREx for their studies, reported that IREx made their LST duties easier, and would recommend other LSTs use IREx
- 90% of relying site HRPP respondents found using **IREx made their steps as a relying site easier**
- 5 different feature suggestions have already been addressed and implemented in IREx, demonstrating the program's flexibility and commitment to continually improving the user experience

How easy are tasks for Lead Study Teams?

- Track site progress in IREx
- Notify Sites of the study
- Add/remove sites from the study
- Upload site approvals
- Know when to export sites for single IRB review
- Use the Getting Started Checklist to complete my steps
- Upload the initial approval for the LEAD SITE

■ Easy/very easy   ■ Neither easy or difficult   ■ Difficult/very difficult

DISCUSSION

- IREx **users are highly satisfied** with their experience
- **Utilization continues to grow** annually, both in the number of new sIRBs that use IREx for the first time and number of studies created in the platform each year
- **5/9** feature suggestions from open text fields have already been addressed and others are being worked on
- IREx team is working on incorporating user satisfaction into normal IREx workflow as well as **further quantitative evaluation**

*"We suggest to study teams to use IREx if they have 4 or more sites for their study to alleviate the email back and forth to document reliance and provide study teams with **one location to easily see all of the site information**.*

*We have had a few of our larger study teams and consortiums begin to use IREx within the last year. **They have indicated that they can't imagine having to do the reliance process any more through email like they had in the past**. One consortium has multiple studies that have a minimum of 10 sites for each study." —sIRB user*

LIMITATIONS

- Small sample size for these surveys, especially for sIRB users
- Did not survey relying site study teams, as we worried they would be unable to distinguish between their frustration with the sIRB process and IREx

IRB Reliance Exchange — YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW