

01.17.2025 QUARTERLY CALL AGENDA



Welcome & Announcements



Development Updates:

- Top 10 Items from 2024
- 2025 Planned Enhancements



IREx Metrics:

- Year in Review Metrics
- Demo: How to Run Metrics for your sIRB Studies



Wrap Up & Next Call

Welcome - About the IREx Quarterly Calls



hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!



learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?



share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

2025 Quarterly Calls



April 18, 2025

July 18, 2025

October 17, 2025







Announcements

New / Revised IREx Materials



RESOURCES

We have resources for each role within IREx. Click the link to access each resource page:

 Reviewing IRB Resources	 Participating Site HRPP Resources
 Study Manager Resources	 Study Team Resources

FOR REVIEWING IRBs & STUDY MANAGERS

- [Site Closure Quick Guide](#)
- [Study Closure Quick Guide](#)
- [Document Types Quick Guide](#)
- [Combo Site Quick Guide](#)

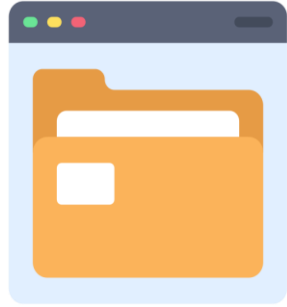


Development Updates

Top 10 Development Items from 2024



SIRBs and SMs can upload additional documents for site onboarding



Onboarding Tab available for all studies to help sites with SIRB process



SIRBs can request sites update their local considerations for the life of study



Amendment content changes can be indicated on amendment uploads



Relying sites can edit HRP and PI Surveys after initial approval



IREx now supports Exception from Informed Consent (EFIC) studies



Institutional Profile (IP) is available for download in CSV format



Enhanced Combo Site Management



SIRBs can connect their eIRB system to IREx



Participating Site Report now separated by review type

SMs = Study managers

Anticipating 2025 Enhancements

Automating **local consideration** surveys

Better info for the sIRB
Less repetition for the HRPP

Allow lead study teams to **import site contacts** when adding sites to a study

Enhance **IREx API** to allow approvals sent from the eIRB to be **modified /confirmed prior to publishing**

Remove file upload fields from the **Institutional Profile**

Allow Reviewing IRBs & SMs to **disable approval notification emails**

Incorporate **user satisfaction** in IREx (sIRB, relying HRPP, lead and relying study teams)

SMs = Study managers



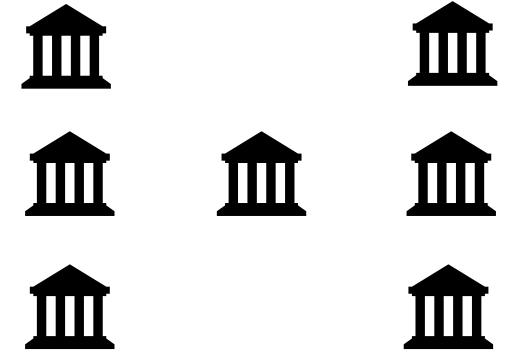
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IREx Metrics

2024 Year in Review

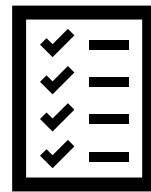
135 studies created 
↑ **9% increase**

32 sites joined 



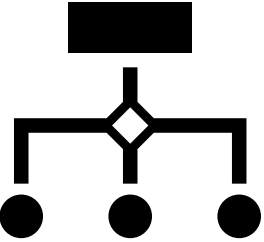
7 average sites per study in IREx

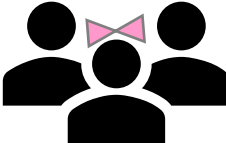
663 new reliances 



580 sites received initial approval
↑ **47% increase**

13 
median days from sIRB submission to approval for relying sites

10 
average studies per relying site
↑ **25% increase**

2549 users added 

 **10** major system enhancements

Single IRB Utilization of IREx



47 single IRBs are using IREx for over 700 studies

- **187** Vanderbilt studies with **1359** reliances
- **104** UCSF studies with **534** reliances
- **98** Utah studies with **740** reliances
- **43** Wake Forest studies with **387** reliances
- **23** Johns Hopkins studies with **423** reliances
- **19** Nationwide Children's studies with **193** reliances
- **13** UT Southwestern studies with **118** reliances
- **13** Duke University studies with **120** reliances

New Institutions using IREx as the Single IRB in 2024

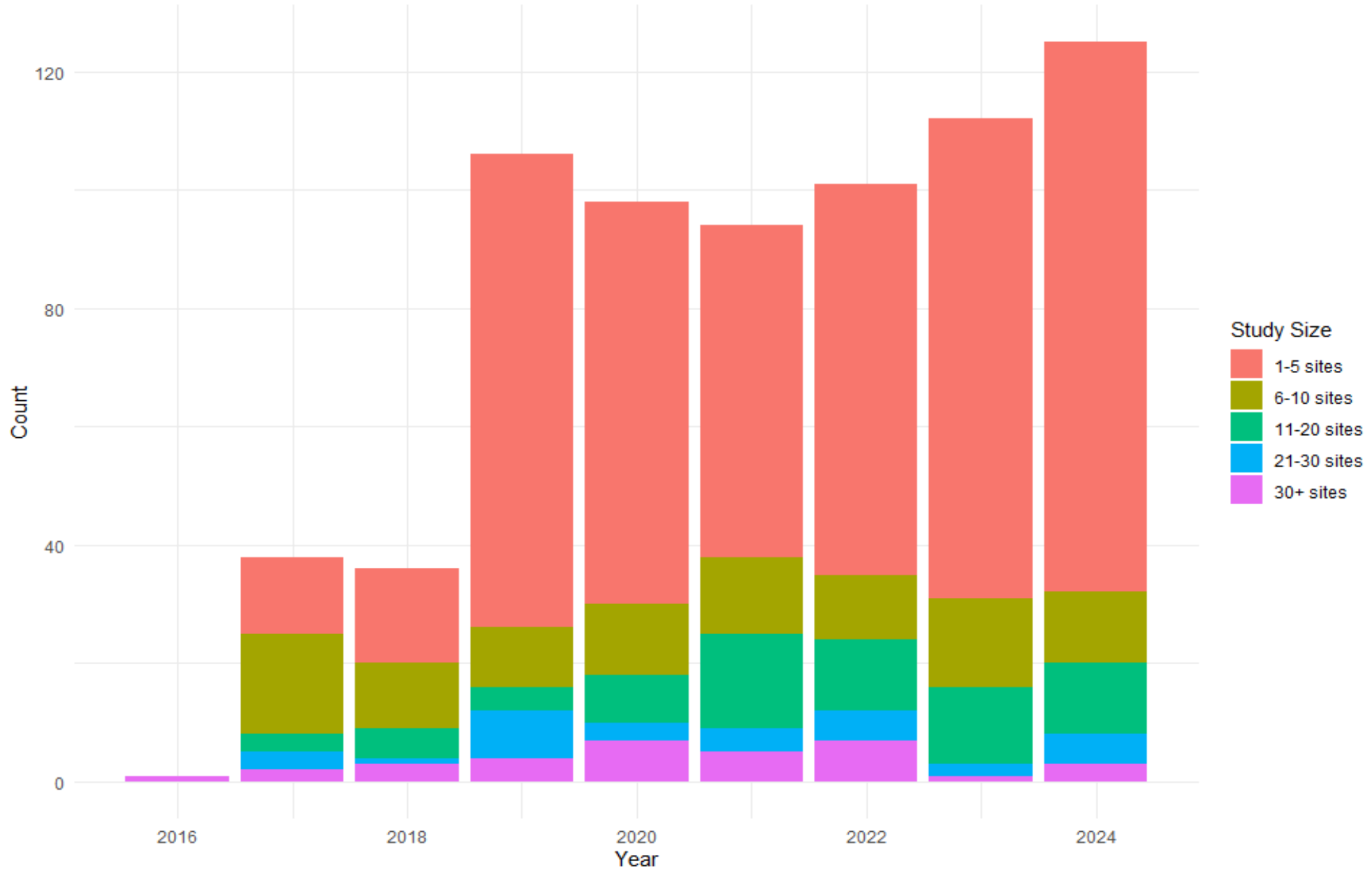
- ❖ **Children's Hospital of Orange County**
- ❖ **University of Oklahoma Health Sciences Center**
- ❖ **University of South Carolina**

2024 Metrics Update

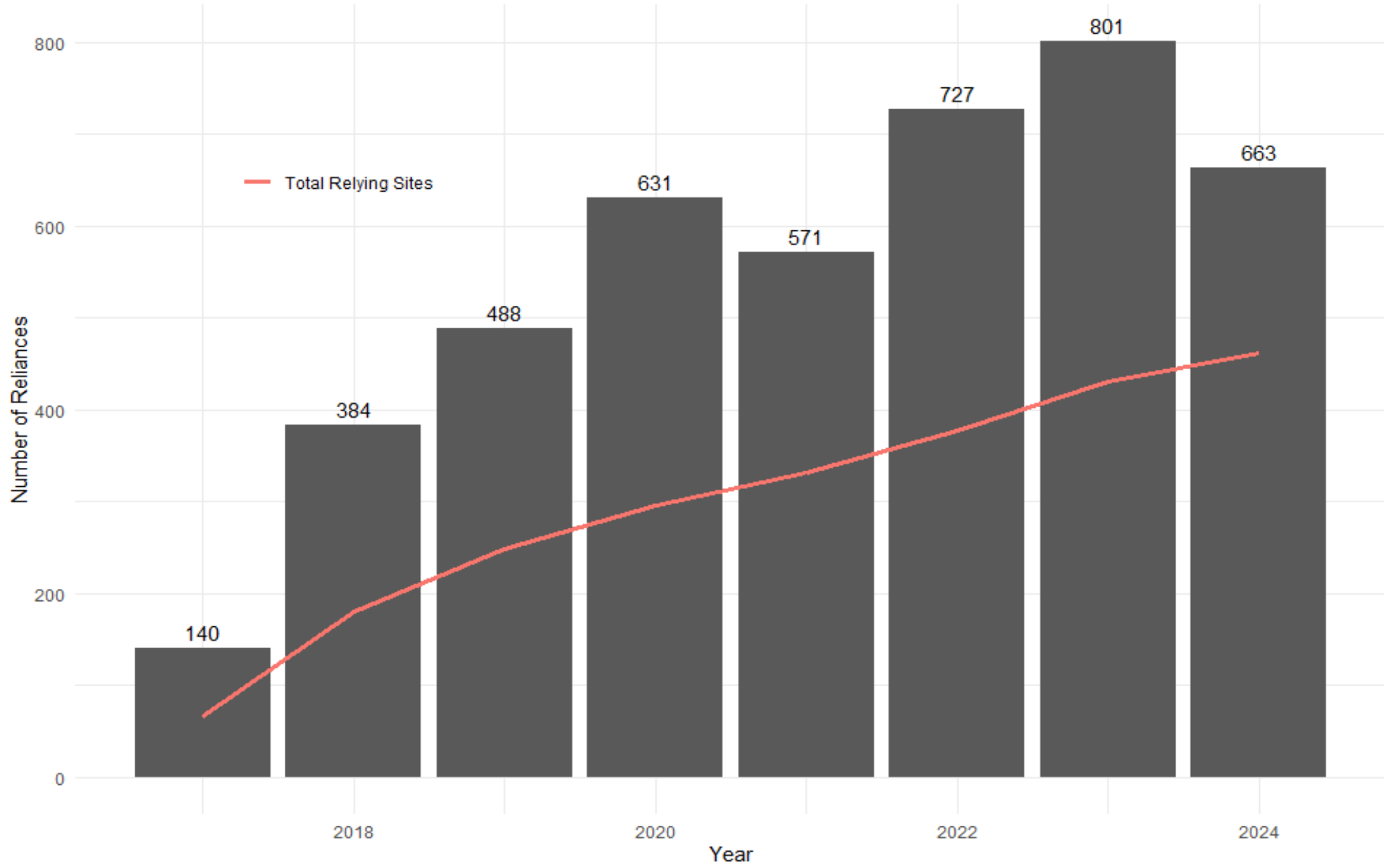


- **92%** of sites in IREx have completed their Institutional Profile
- **88%** of IREx sites used IREx to rely on a sIRB
- **88%** of sites have made it through the sIRB process and received initial approval
- **13** median days from initial sIRB submission to sIRB approval for relying sites (*not including local review time*)

Study Size by Year Study Created



Relying HRPPs Use of IREx

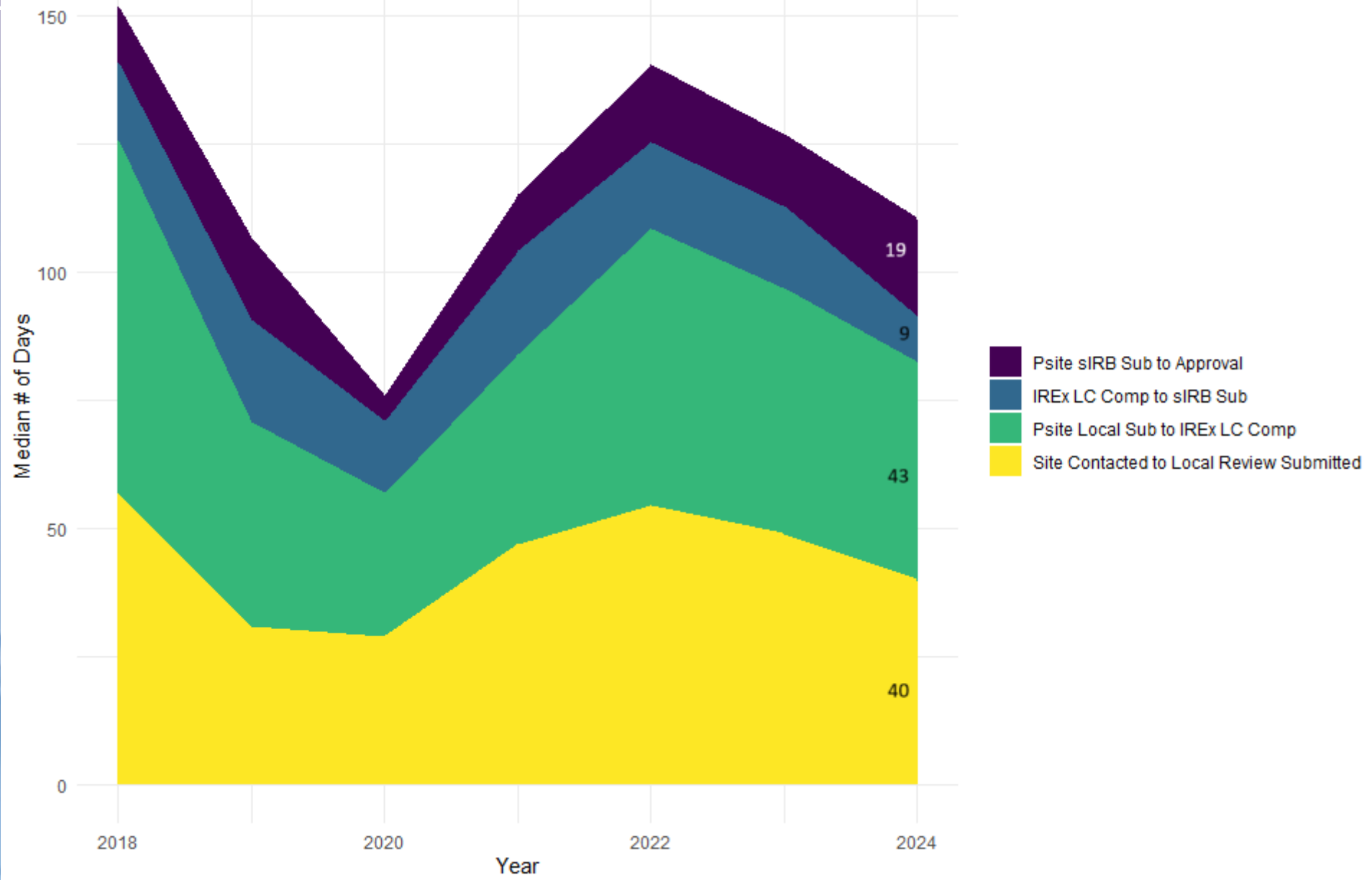


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Time to Approval Stats by Year Study Created





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Using IREx Exports

Where can I find my site's data?



- Only liaisons (sIRB users) have access to their site's data
- Exports are found on the Reviewing Site's Studies page

The screenshot shows the Ance Exchange website interface. At the top left is the logo 'ance Exchange' with the tagline 'SOLUTION FOR SINGLE IRB REVIEW'. To the right of the logo is a navigation menu with links: Home, Your Profile, Resources, Admin, Admin Dash, API, and Logout. Below the navigation is a search bar labeled 'Study search...' with a search icon and the text 'Search'. The main content area is titled 'Reviewing Site's Studies' and features a search bar labeled 'Search:'. Below the search bar is a table with columns for 'IRB #', 'Study Title', and 'Participating Sites'. To the right of the table is an 'Export' button with a dropdown arrow. The dropdown menu is open, showing four options: 'Overall Study Report (CSV)', 'Participating Site Report - Initial and Closure (CSV)', 'Participating Site Report - Continuing Review (CSV)', and 'Participating Site Report - Amendment (CSV)'. The 'Reviewing Site's Studies' title and the export menu are highlighted with red boxes.

Overall Study Report



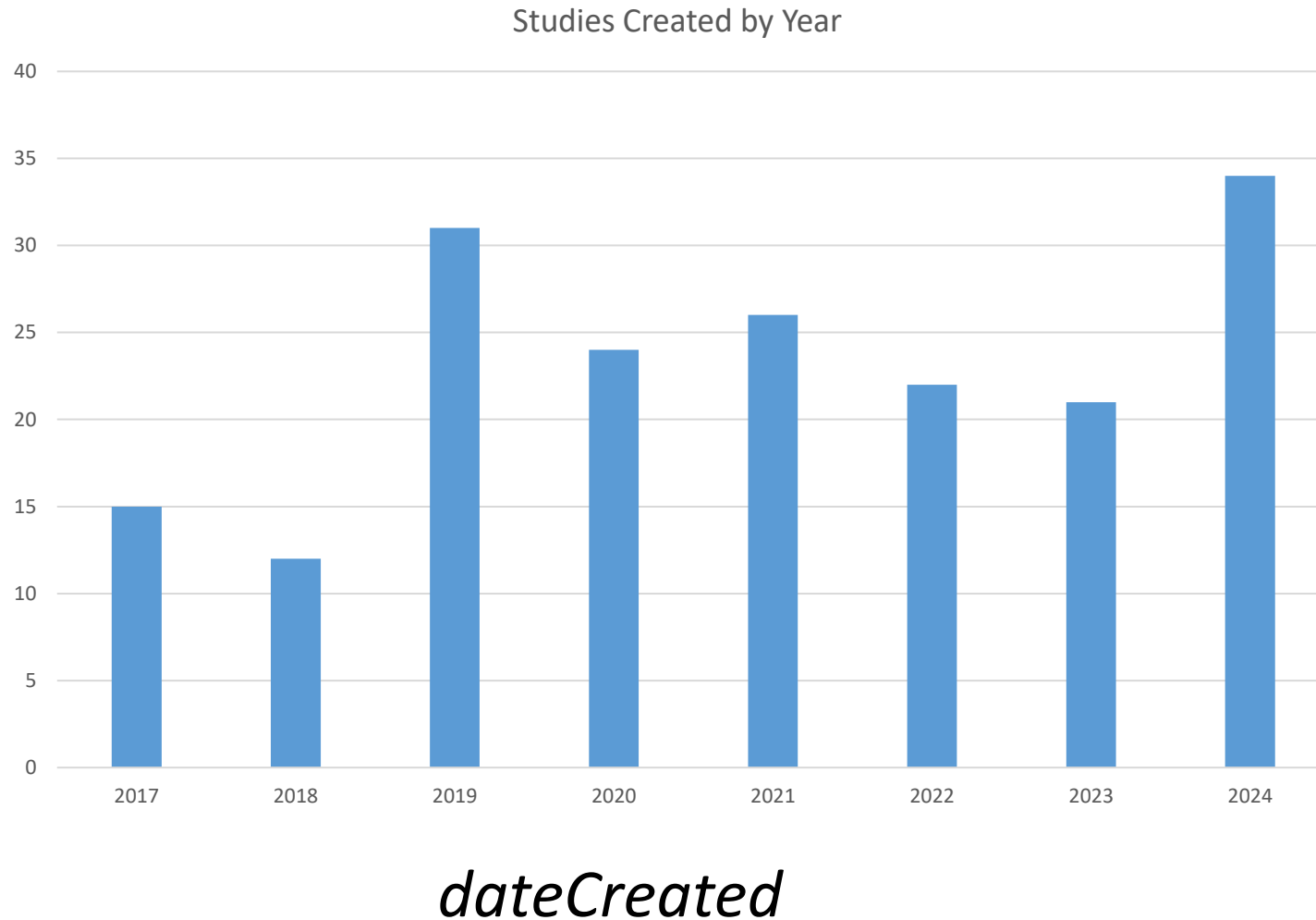
Dataset	Variable Name	Data Type	Data Format	Definition
overall_study_report	projectId	Numeric	Integer	Unique IREx project ID
overall_study_report	shortTitle	Character		Study short title
overall_study_report	longTitle	Character		Full study name
overall_study_report	isProjectActive	Numeric	Yes = 1, No = 0	Is the study active in IREx? (If 0, a study closure been issued in IREx)
overall_study_report	dateCreated	Date	MM/DD/YYYY	Date the study was created in IREx
overall_study_report	isCollectingLocalConCharacter	Numeric	Yes = 1, No = 0	Is the study collecting Local Considerations in IREx? (Note: available for studies created starting in 2018)
overall_study_report	isCapturingLocalConCharacterUpdates	Numeric	Yes = 1, No = 0	Is the study collecting Local Considerations for the life of the study in IREx? (Note: available for studies created starting in 2024)
overall_study_report	isTin	Numeric	Yes = 1, No = 0	Is the study a Trial Innovation Network study?
overall_study_report	riskType	Character	Minimal, greater than minimal risk	Study risk type: greater than minimal risk or minimal risk
overall_study_report	minRiskCategories	Character	(f)(1-7)	Category of research that qualifies study to be reviewed through expedited review procedures (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)
overall_study_report	isReviewingSiteParticipating	Numeric	Yes = 1, No = 0	Is the reviewing IRB also the lead site?
overall_study_report	reviewingIRB	Character		Name of single IRB
overall_study_report	reviewingIRBFwa	Numeric	Integer	FWA of single IRB
overall_study_report	reviewingIRBContact	Character		Name of single IRB primary liaison point of contact
overall_study_report	leadSite	Character		Name of lead site
overall_study_report	leadSiteFwa	Numeric	Integer	FWA of lead site
overall_study_report	leadPi	Character		First and last name of lead site study PI
overall_study_report	studyManager	Character		First and last names of all study managers listed on a study, separated by semicolons
overall_study_report	reviewingIRBNumber	Character	Numeric and character	Study's IRB # in the Reviewing IRB's system
overall_study_report	dateInitialReviewSubmitted	Date	MM/DD/YYYY	Date the lead site/overall study was submitted to the sIRB
overall_study_report	datePreReviewRequests.0	Date	MM/DD/YYYY	Date the pre-review changes were requested, if any
overall_study_report	datePreReviewRequests.1	Date	MM/DD/YYYY	Subsequent date additional pre-review changes were requested
overall_study_report	datePreReviewResponses.0	Date	MM/DD/YYYY	Date the pre-review changes were received
overall_study_report	datePreReviewResponses.1	Date	MM/DD/YYYY	Subsequent date the pre-review changes were received, if applicable
overall_study_report	datePreReviewed	Date	MM/DD/YYYY	Date pre-review of lead site/overall study was completed
overall_study_report	dateInitialReviewReviewed.0	Date	MM/DD/YYYY	Date of initial lead site/overall study review by sIRB

Participating Site Reports



Dataset	Variable Name	Data Type	Data Format	Definition
psite_report	projectId	Numeric	Integer	Unique IREx project ID
psite_report	projectShortTitle	Character		Study short title
psite_report	projectLongTitle	Character		Full study name
psite_report	reviewingIRB	Character		Name of single IRB
psite_report	reviewingIRBFWA	Numeric	Integer	FWA of single IRB
psite_report	isCollectingLocalContext	Numeric	Yes = 1, No = 0	Is the study collecting Local Considerations in IREx? (Note: available for studies created starting in 2018)
psite_report	isCapturingLocalContextUpd	Numeric	Yes = 1, No = 0	Is the study collecting Local Considerations for the life of the study in IREx? (Note: available for studies created starting in 2024)
psite_report	isProjectTin	Numeric	Yes = 1, No = 0	Is the study a Trial Innovation Network study?
psite_report	riskType	Character	Minimal, greater than minimal risk	Study risk type: greater than minimal risk or minimal risk
psite_report	minRiskCategories	Character	(f)(1-7)	Category of research that qualifies study to be reviewed through expedited review procedures (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)
psite_report	siteName	Character		Name of participating site
psite_report	siteFwa	Numeric		FWA of participating site
psite_report	siteSignedIrex	Numeric	Yes = 1, No = 0	Has the participating site joined IREx?
psite_report	siteSignedSmart	Numeric	Yes = 1, No = 0	Has the participating site signed at least one out of SMART V1 or V2?
psite_report	siteSignedSmartV3	Numeric	Yes = 1, No = 0	Has the participating site signed SMART V3? (Note: as of Jan 2025, will be blank)
psite_report	studyRequiresLoi	Numeric	Yes = 1, No = 0	Is the sIRB documenting the requirement for indemnification in IREx?
psite_report	siteRequiresLoi	Numeric	Yes = 1, No = 0	Has the participating site signed the Letter of Indemnification?
psite_report	dateLoiSent	Date	MM/DD/YYYY	Date the Letter Of Indemnification was sent to sIRB
psite_report	dateLoiExecuted	Date	MM/DD/YYYY	Date the Letter Of Indemnification was executed
psite_report	studyPi	Character		Name of site PI
psite_report	studyManager	Character		First and last names of all study managers listed on a study, separated by semicolons
			Numeric and	

What can we do with this data?



What can we do with this data?



dateLeadSiteInitialApproval

What can we do with this data?



- Overall study report
 - Count of studies by PI, Study Manager, sponsor
 - Number of sites per study
- Participating site report
 - How long are relying sites are taking to get through the approval process?
 - How has this changed over time?
 - How does this change depending on study type? Risk type?
 - Breakdown by each step in the process

What can we do with this data?



Date that all local considerations were complete (*dateLCcomplete*) = taking the maximum value (latest date) out of the following variables

- dateSsrpUpdateAccepted
- dateSsrpUpdateCompleted
- dateSiteProfileValidated
- dateLcHrppSurveyUpdated
- dateSsrpAccepted
- dateSsrpReset
- dateSsrpUpdateAccepted
- datePiSurveyCompleted
- datePiSurveyUpdated.0 – datePiSurveyUpdated.9
- datePiSurveyAttested.0 – datePiSurveyAttested.9

**Note: studies prior to 2018 did not allow for LCs to be collected in IREx, so exclude these studies and those where isCollectingLocalContext = 0*

What can we do with this data?



- Time it took from contacting a site for their local review to be submitted = $dateLocalReviewSubmitted - dateSiteContacted$
- Time it took from the site submitting the local review to their Local Considerations to be completed = $dateLCcomplete - dateLocalReviewSubmitted$
- Time it took for the site to be submitted to the sIRB after completing their Local Considerations = $dateSubmitted - dateLCcomplete$
- Time it took for site to be approved after submitted to sIRB = $dateSubmitted - dateApproved$

Considerations



- Sample size
- Metrics used (median vs. mean)
- *dateSiteContacted* variable as a proxy for when the site was added
- IREx history (e.g. local considerations in 2018)
- How your site uses IREx (e.g. if your site does not upload relying site approvals)



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Next Call: April 18, 2025!