

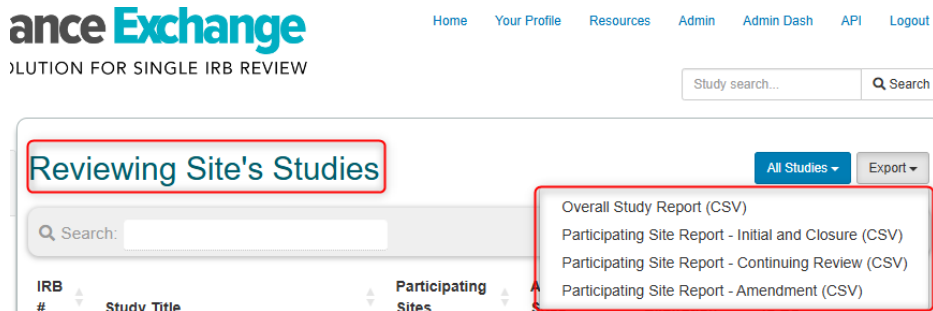
IREx Data Dictionary Overview/FAQs

Who has access to exports?

sIRB users (liaisons) are the only users that can access their site data exports.

Where do I find my exports?

Exports can be found on the reviewing sIRB studies page, by clicking the Export dropdown.



What is the difference between the exports?

The Overall Study Report will download a report of all the studies where your site is the reviewing IRB. One row will correspond to one study.

The 3 participating site reports all contain the same variables but are divided by approval types: initial approval and site closures, continuing reviews, and amendments. One row corresponds to one type of approval per participating site. Depending on how many studies a reviewing IRB has and how many sites per study, the participating site reports are typically much larger than the overall study reports.

How up to date is the data from the exports?

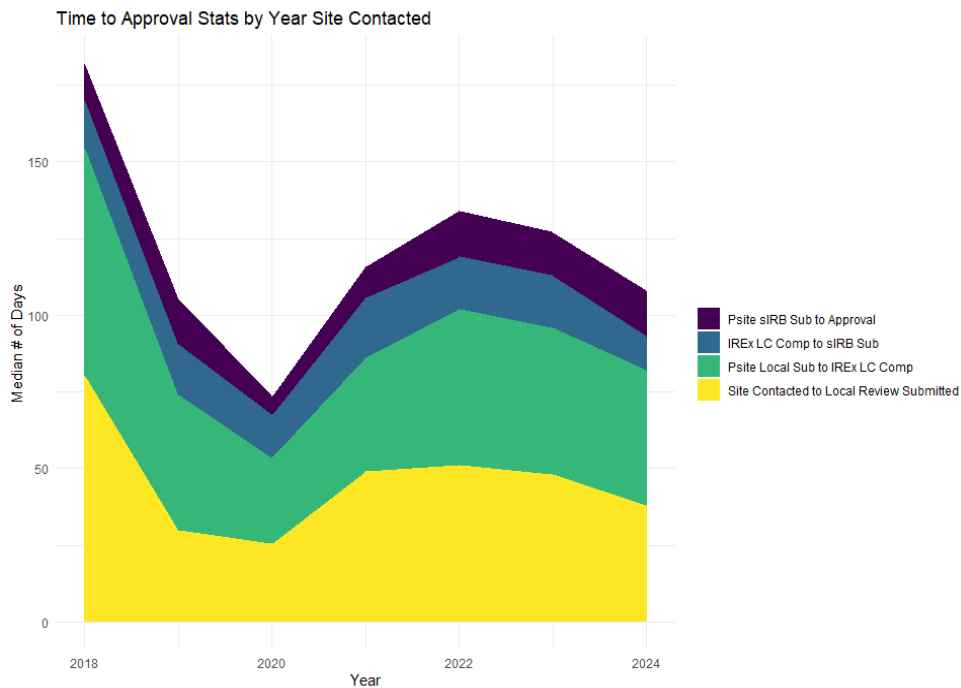
The datasets are updated until the time of export and include all historical data.

What are some important variables to know?

- The *dateLeadSiteInitialApproval* variable is in both the overall study dataset and the participating site report and represents the date that the overall study/lead site was approved by the sIRB
- The *dateSsrpAccepted* variable in the participating site report will be the most accurate indicator of the date reliance occurred. If there is no date, this means the site has not yet indicated reliance

What are some other variables you may be interested in and want to calculate?

- 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*
- We often look at time to approval over time (graph below) using the following variables



- 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 = $\text{dateSubmitted} - \text{dateLCcomplete}$
- Time it took for site to be approved after submitted to sIRB = $\text{dateSubmitted} - \text{dateApproved}$