

Reliance Metrics, Processes and Initiatives

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THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Reliance Team



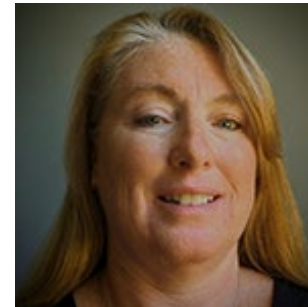
Kristen Katopol
Assoc. Director, Reg. Affairs & Compliance



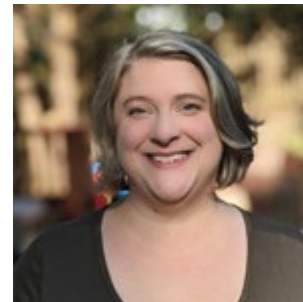
Ariana Peden
Compliance Manager



Barbara Griese
Contract Specialist



Ivy Bergquist
Reliance Analyst



Christine Brown
Reliance Analyst

Reliance Team Workload



1. When UNC-CH will rely on another external IRB

- Institutional IRB
- Commercial IRB (WCG, Advarra, Sterling)
- NCI IRB

2. When UNC-CH will serve as IRB of Record for other sites/collaborators

- Institutional IRB
 - Review sites being requested
 - Execute Reliance Agreement
 - Local Context Review
 - Onboard sites
- Independent Investigator



Reliance Team Workload



Submission types

1. When UNC-CH relies on another external IRB

- Initial (study start-up)
- Modifications
- Personnel modifications (for UNC personnel)
- Renewal
- Closure



2. When UNC-CH serves as IRB of Record for external sites/collaborators

- Modification to onboard sites and/or independent investigators
- PI changes for external sites
- Modification to update external site materials
- Modification to close external sites

Criteria for Reliance



Reliance agreements are only executed for *non-exempt human subjects research*. Regardless which IRB is the IRB of record, at least one of these building blocks for engagement must be met:

1. Primary recipient of federal funding where there is HSR,
2. Directly interacting with human subjects for research purposes,
or
3. Receiving/using/analyzing identifiable data and/or specimens of living humans

Criteria for Reliance



- Is single IRB (sIRB) review required per the federal regulations;
 - Federally Funded Research
 - The research is non-exempt human subjects research
 - UNC is the prime recipient on the federal award, regardless of role in the study
- Is the study industry sponsored;
- UNC-Chapel Hill's role in the research;
- The risk level of the research;
- Where the research interventions will be performed, and by whom;
- Qualifications and experience of the researchers performing more than minimal risk interventions or procedures;
- Whether the proposed Reviewing IRB is AAHRPP-accredited; and
- How many sites for which we're being asked to provide IRB oversight.

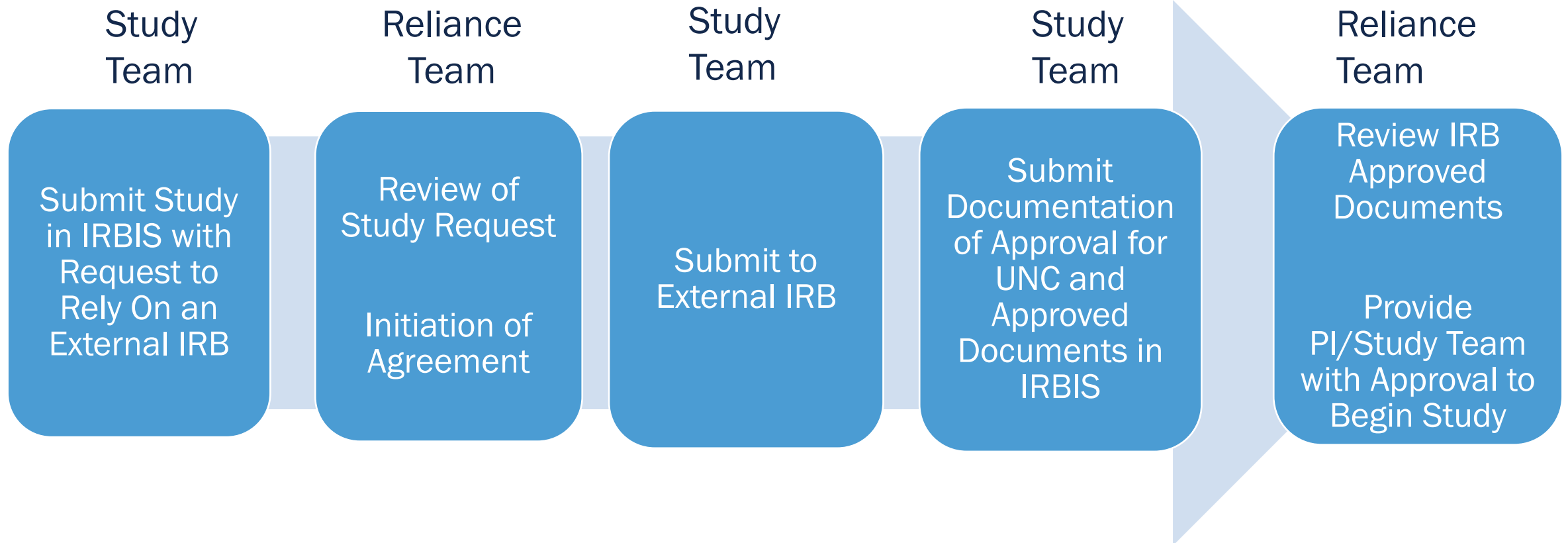
Note: The IRB, not the investigators, will make the decision whether UNC will enter into a reliance agreement with another institution.

Types of Agreements

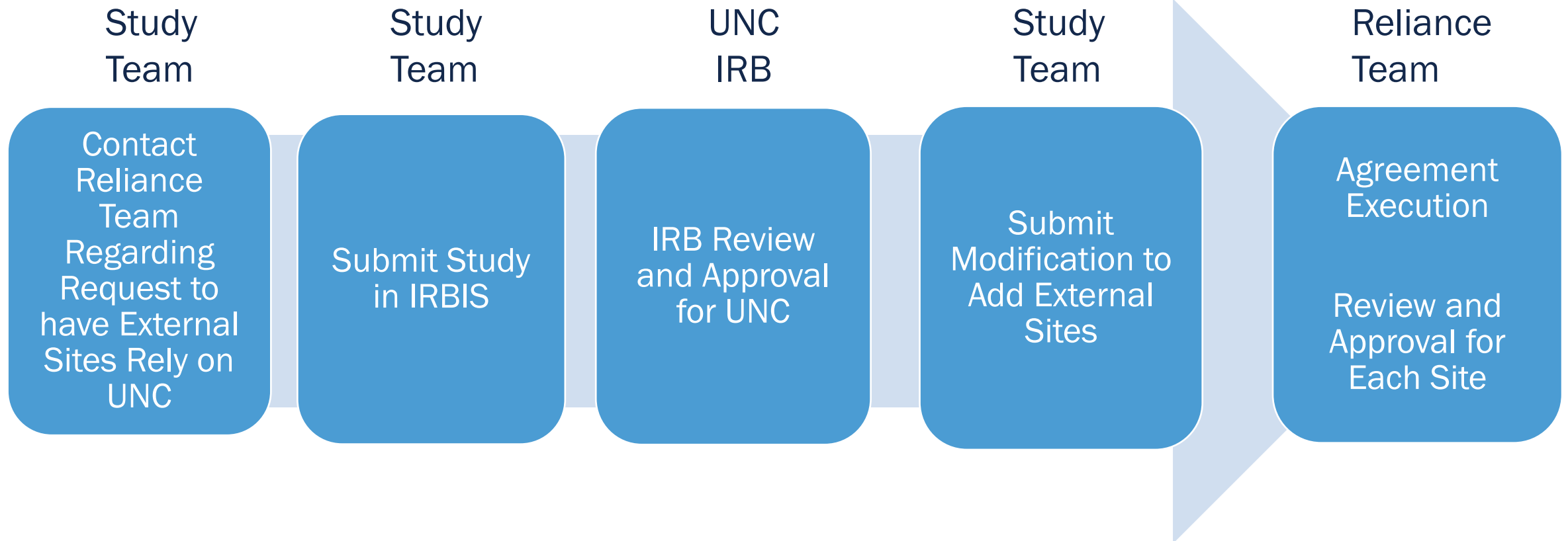


- **Master or Broad Agreement**
 - An agreement with an Institution or Commercial IRB to cover multiple studies
 - This can cover UNC relying on another IRB as the IRB of record, or for another Institution to rely on the UNC IRB as the IRB of Record
- **Institutional Authorization Agreement**
 - An agreement with an Institution or Commercial IRB to cover one study
 - This can cover UNC relying on another IRB as the IRB of record, or for another Institution to rely on the UNC IRB as the IRB of Record
- **Individual Investigator Agreement**
 - An agreement for the UNC IRB to cover an individual's engagement in a study being conducted by UNC
 - The individual is not affiliated with an institution that has a Federalwide Assurance (FWA) and/or an IRB of Record (i.e., an independent contractor)

Process for Relying on an External IRB



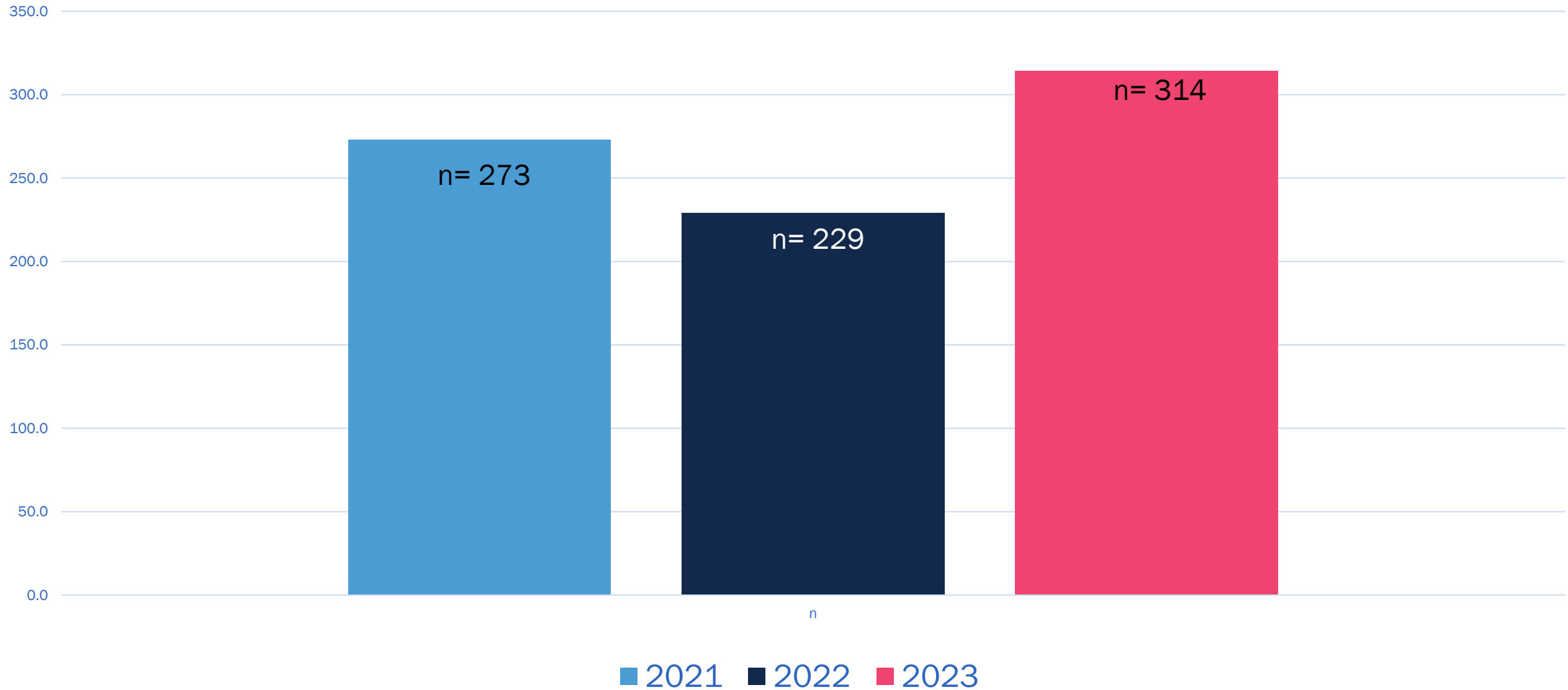
Process for External Sites to Rely on UNC



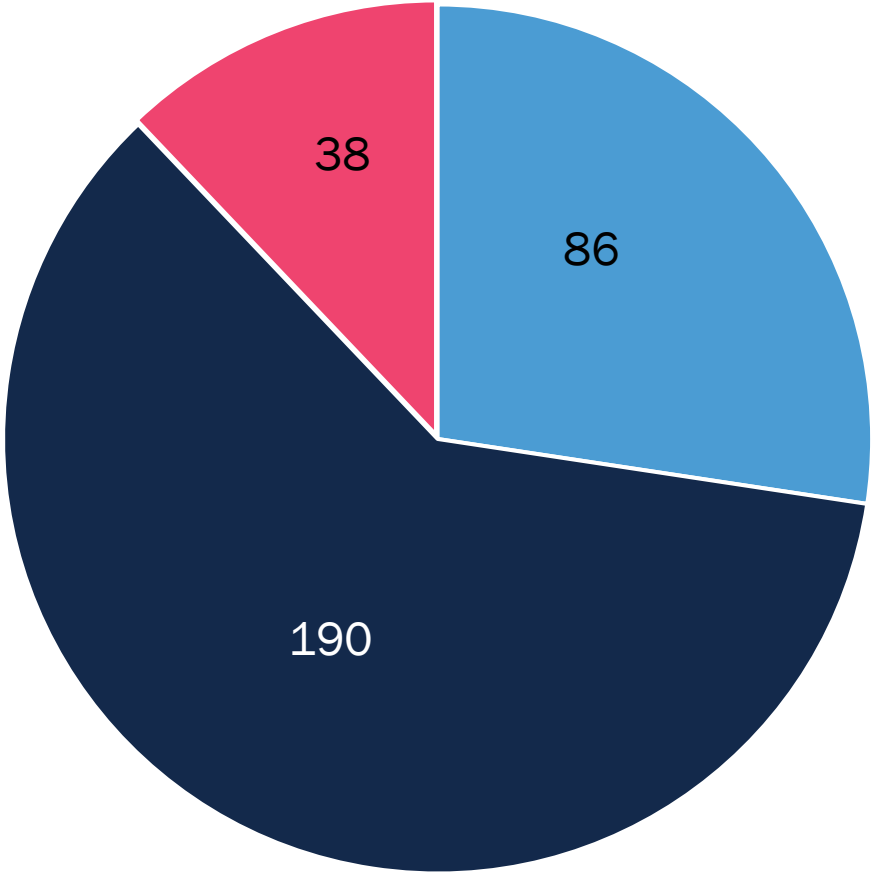


Metrics

Number of Initial Rely On Submissions Received (submissions requesting UNC rely on external IRB)

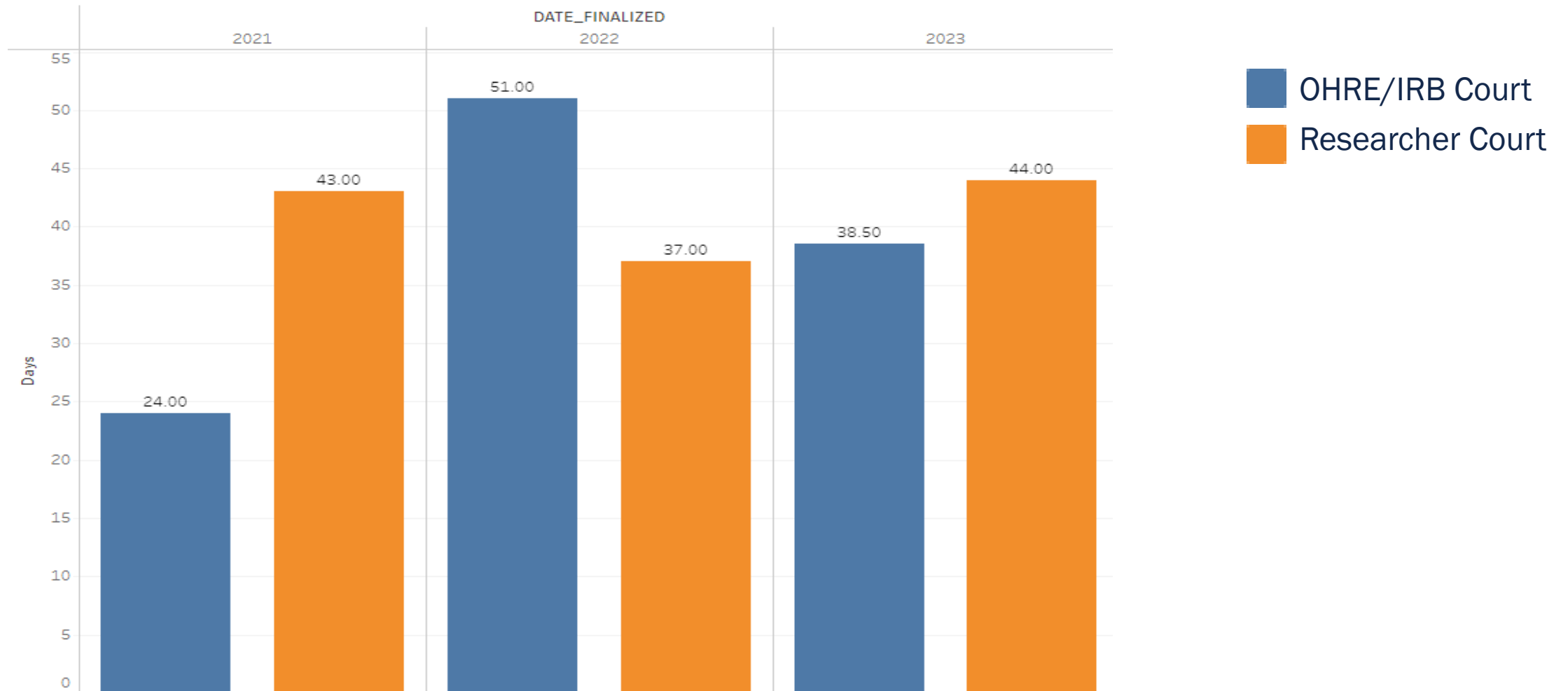


Break down of Initial Rely On Submissions Received (submissions requesting UNC rely on external IRB)

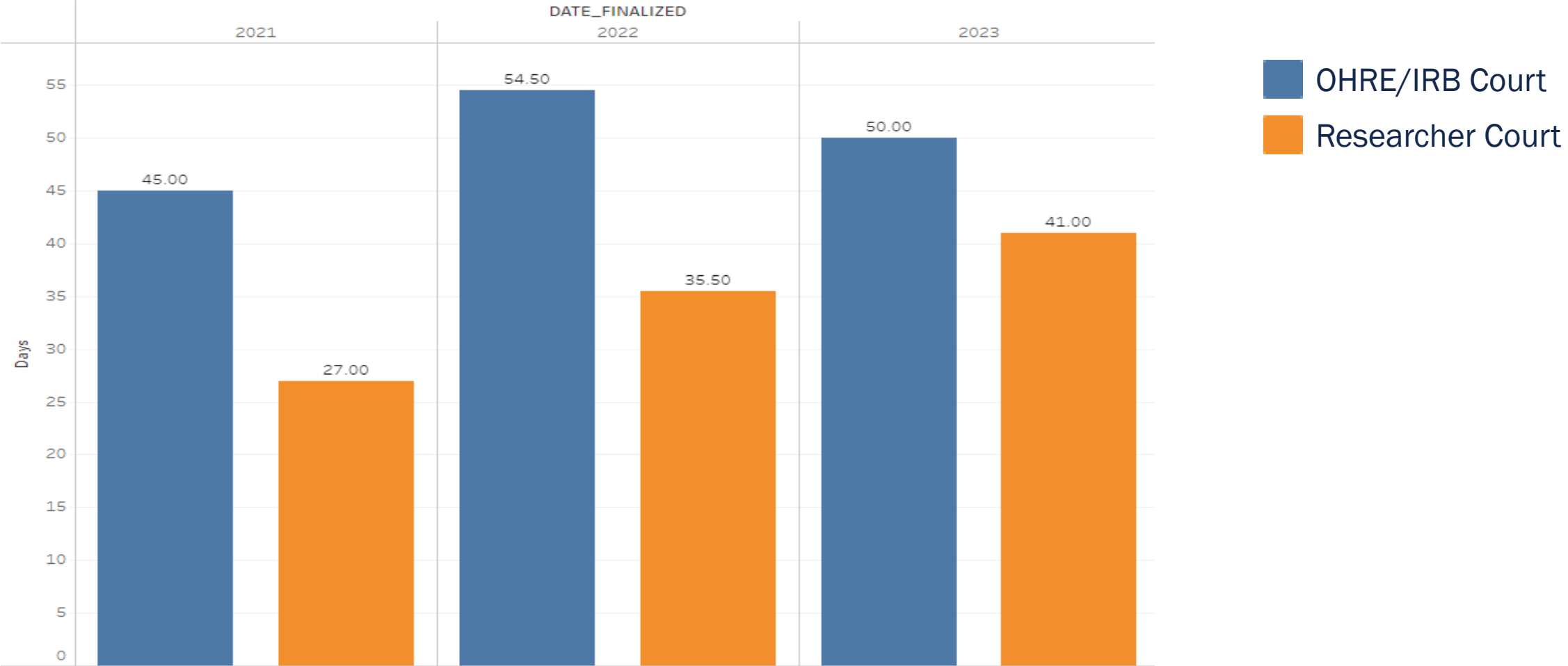


■ Institutional ■ Commercial ■ NCI

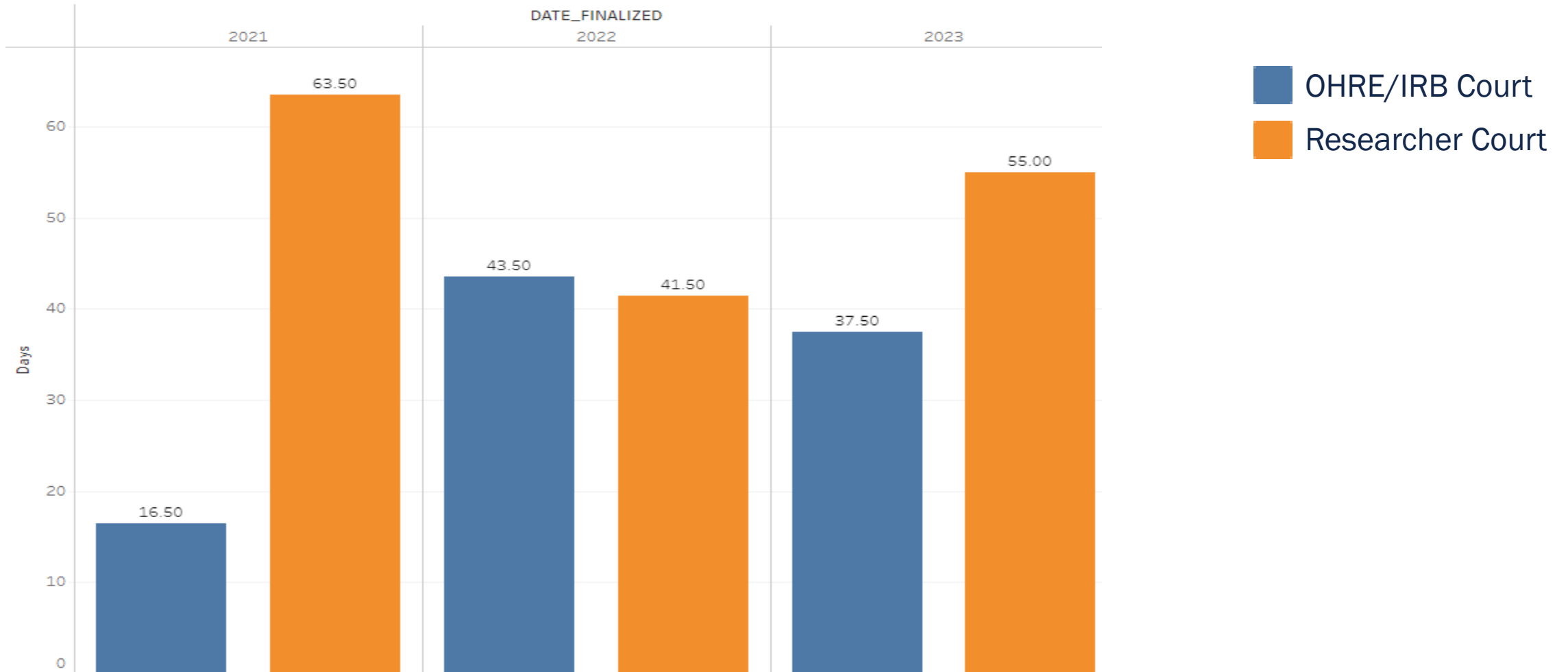
Initial Submissions, All Rely On Median Days



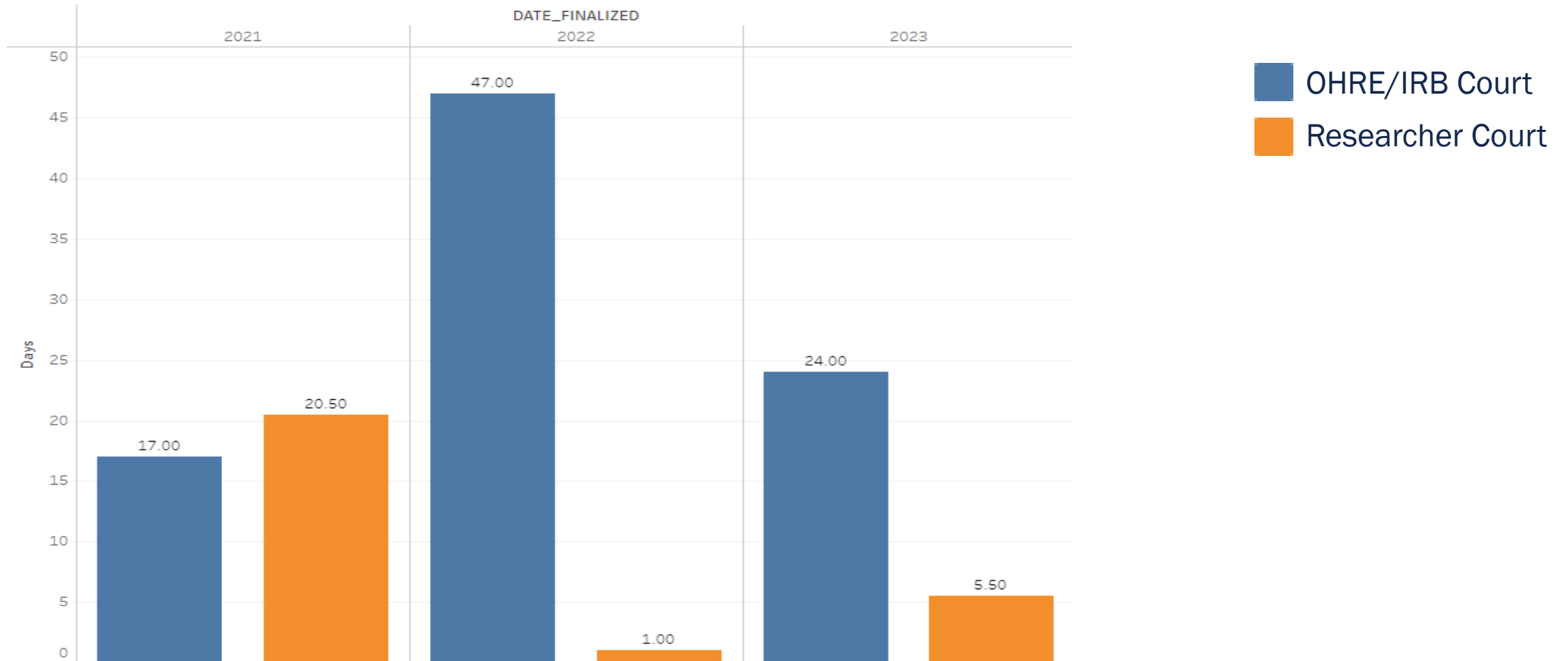
Initial Submissions, Institutional Rely On Median Days



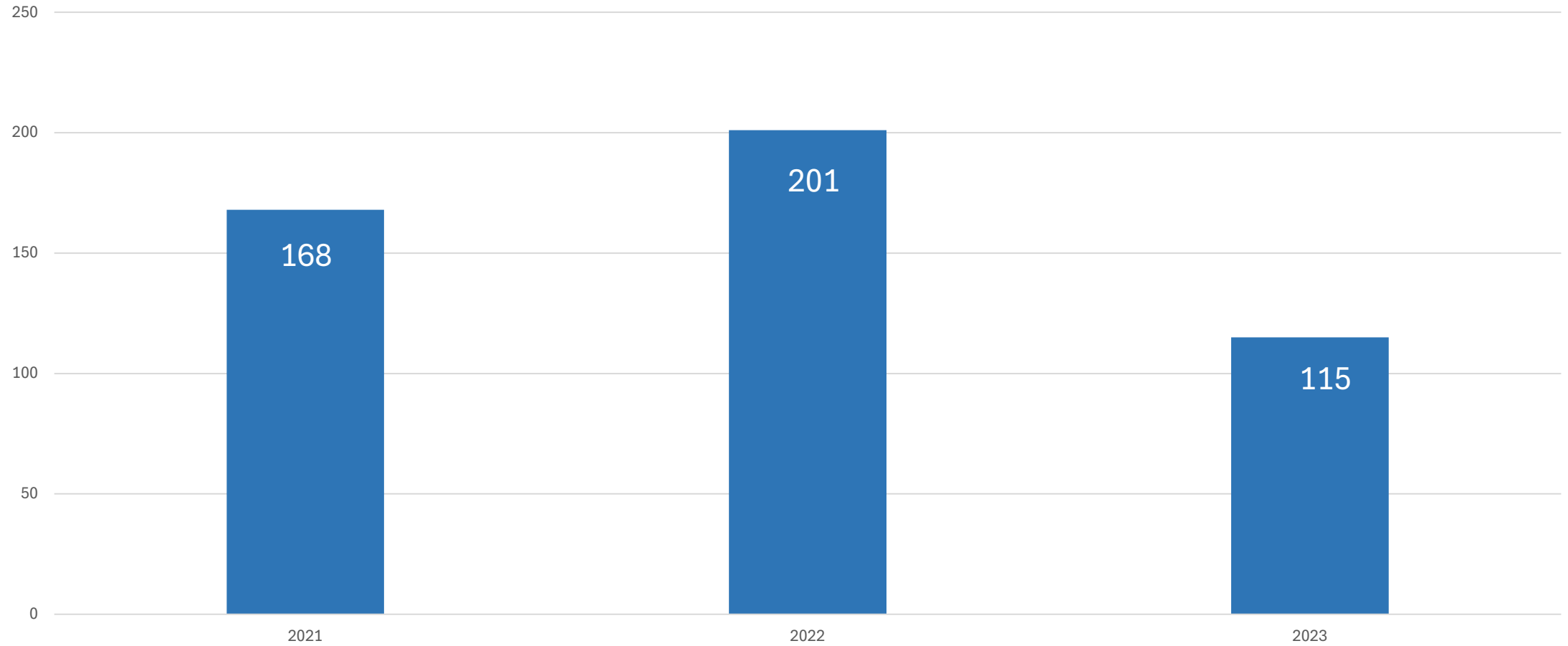
Initial Submissions, Commercial Rely On Median Days



Initial Submissions, NCI Rely On Median Days



UNC-CH as the IRB of Record for Other Sites



Reliance Initiatives



- Reducing Turnaround times
 - Fully staffed - ongoing training of newer staff
 - Implementation of “flex” analyst to help streamline review when higher reliance volume and when UNC-CH is IRB of Record for other sites
- IRBIS Updates
 - More intuitive and streamlined workflow
 - Separate modifications to add external sites and external investigators
 - Help guidance for navigation of the reliance submission process
 - Intake Form for requesting UNC serve as IRB of Record for external sites
- Educational guidance updates

Contact Us!



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Questions?