OHSRP Education Series

October 6, 2020

Transition to a new eIRB System:

Where we are now, and where we are going

Agenda

Agenda Topic	Lead(s)	Allotted Time
• Introductions	Jonathan and Meredith	5 minutes
• General Project Overview	Jonathan	15 minutes
• iRIS by iMedris	Jonathan	
• iRIS Customer Satisfaction Survey	Jonathan	
• eIRB System Replacement Steering Committee	Meredith	15 minutes
• Steering Committee Overview	Meredith	
• High Level eIRB Project Phases	Meredith	5 minutes
• eIRB System Requirements Survey	Meredith	10 minutes
• Axle Informatics	Meredith	5 minutes
• eIRB System Vendors	Jonathan	5 minutes
• Closing Remarks	Jonathan	5 minutes

Introduction

- Dr. Jonathan Green, MD MBA
  - Director, Office of Human Subjects Research Protections (OHSRP)
- Meredith Mullan, MPA
  - Program Manager, OHSRP
  - Former Administrative Officer in NHLBI
  - Former Healthcare IT Consultant for 5 years implementing Electronic Medical Record (EMR) systems at various medical centers in the US

General Project Overview

- Over the past year, in response to NIH's former decentralized IRB structure, OHSRP put in place a single, centralized IRB system.
- The objective was to:
  - Create a single, centralized IRB review structure.
  - Allow for a consistent, compliant review process across the intramural program.
  - Create the necessary separation for a truly independent review process.

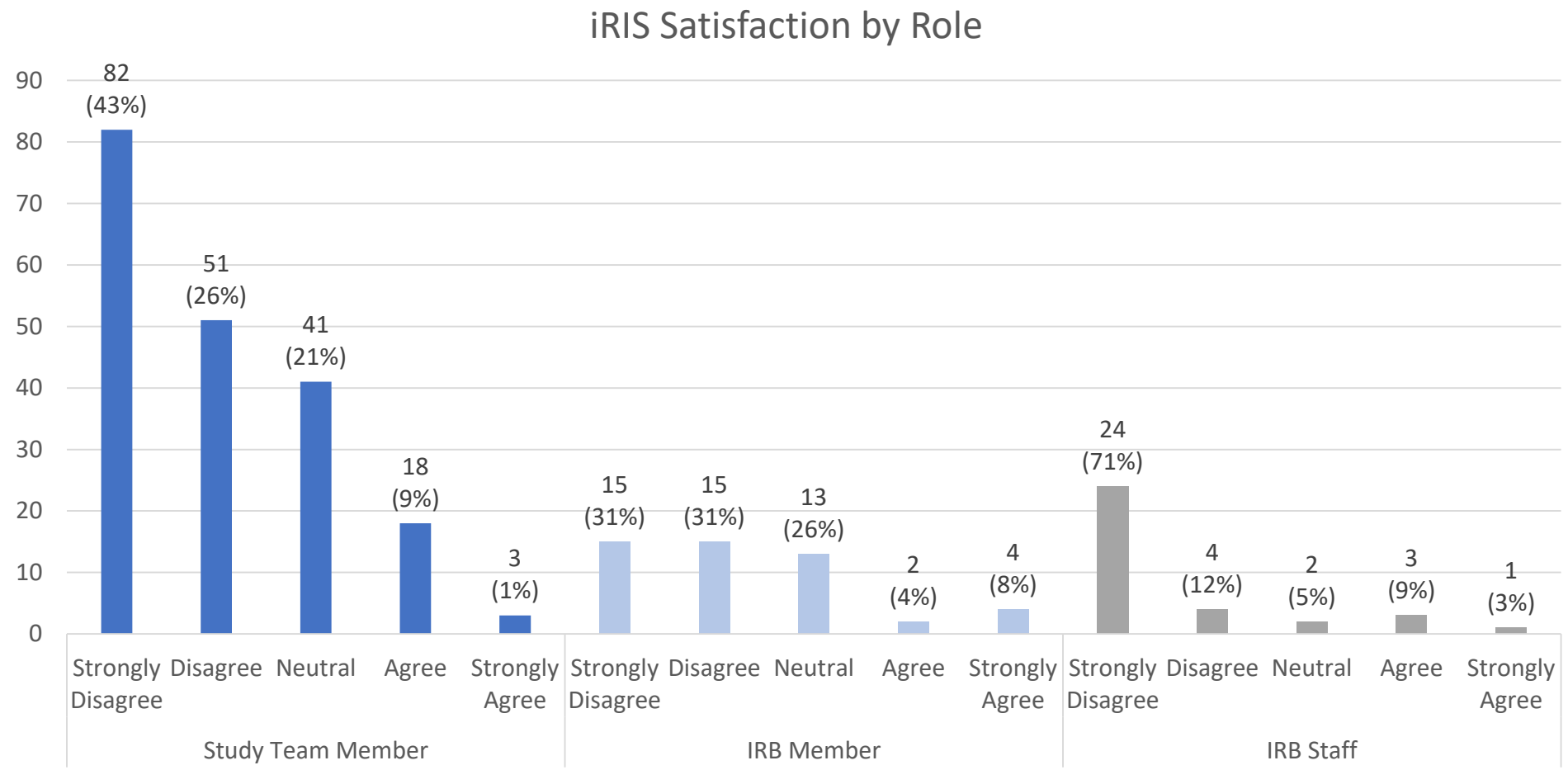
General Project Overview

- The centralized IRB system is almost fully operational. OHSRP currently has 37 staff members onboard (this includes Compliance & Training, and Policy teams).
- Prior to OHSRP reorganization, 3 electronic submission systems were in use.
  - NCI iRIS
  - NIAID iRIS
  - PTMS
- Consolidated to one instance of iRIS.

Is iRIS the right system?

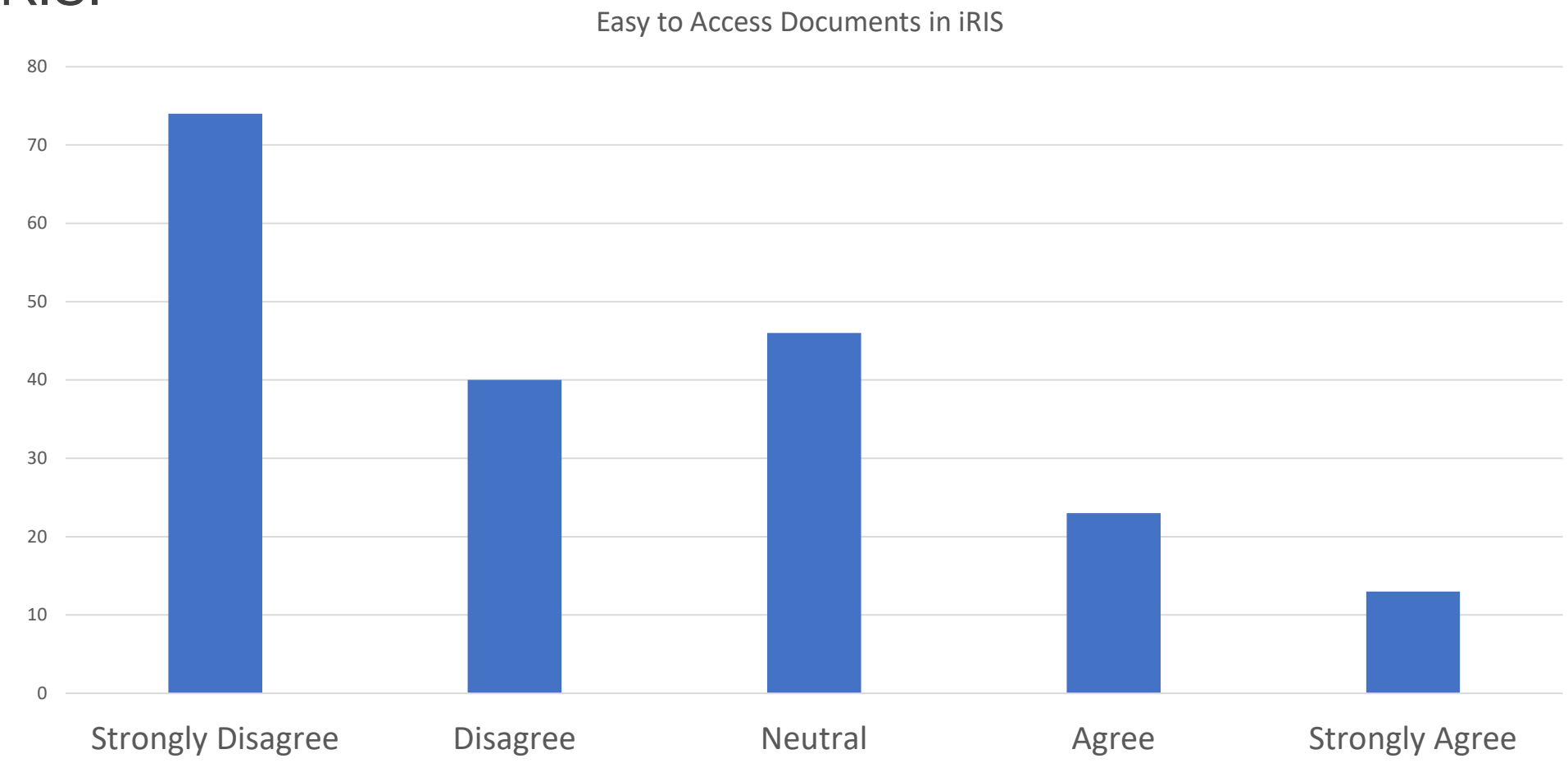
iRIS Customer Satisfaction Survey

- "Overall, as a _____, I am very satisfied with iRIS."



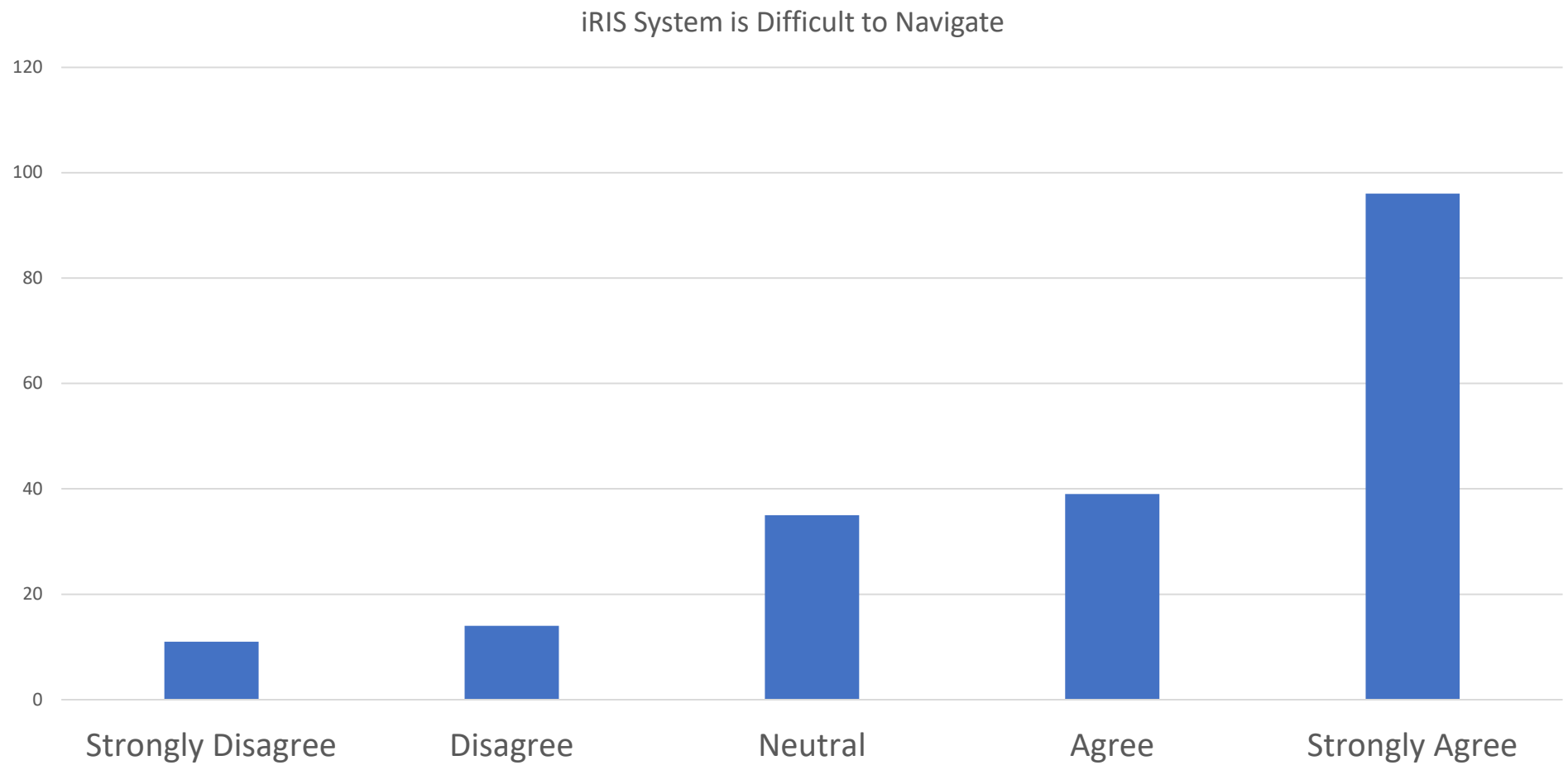
iRIS Customer Satisfaction Survey- Study Teams

- It is easy for me to access the documents I need during the study in iRIS.



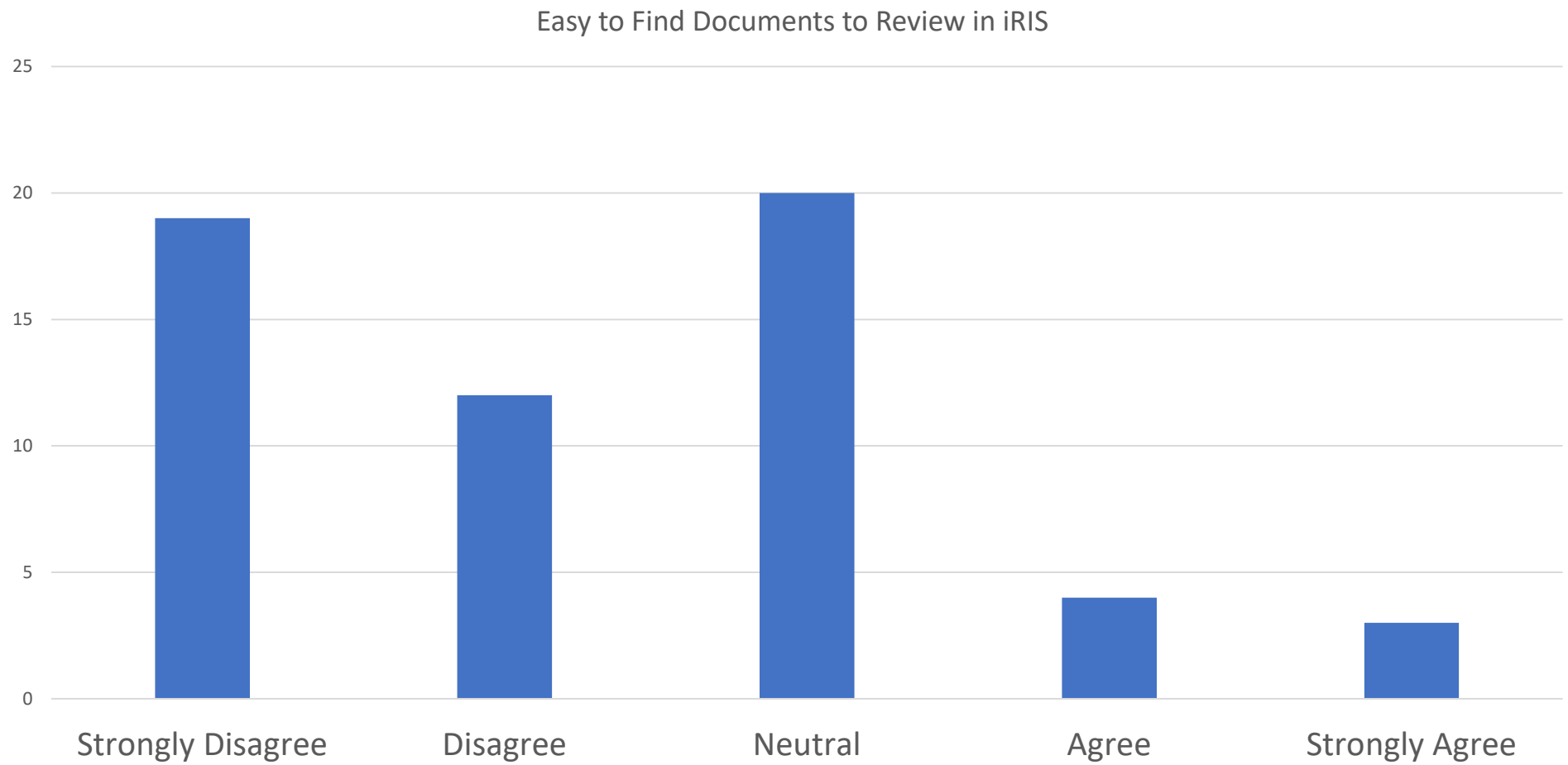
iRIS Customer Satisfaction Survey- Study Teams

- I find the iRIS system difficult to navigate.



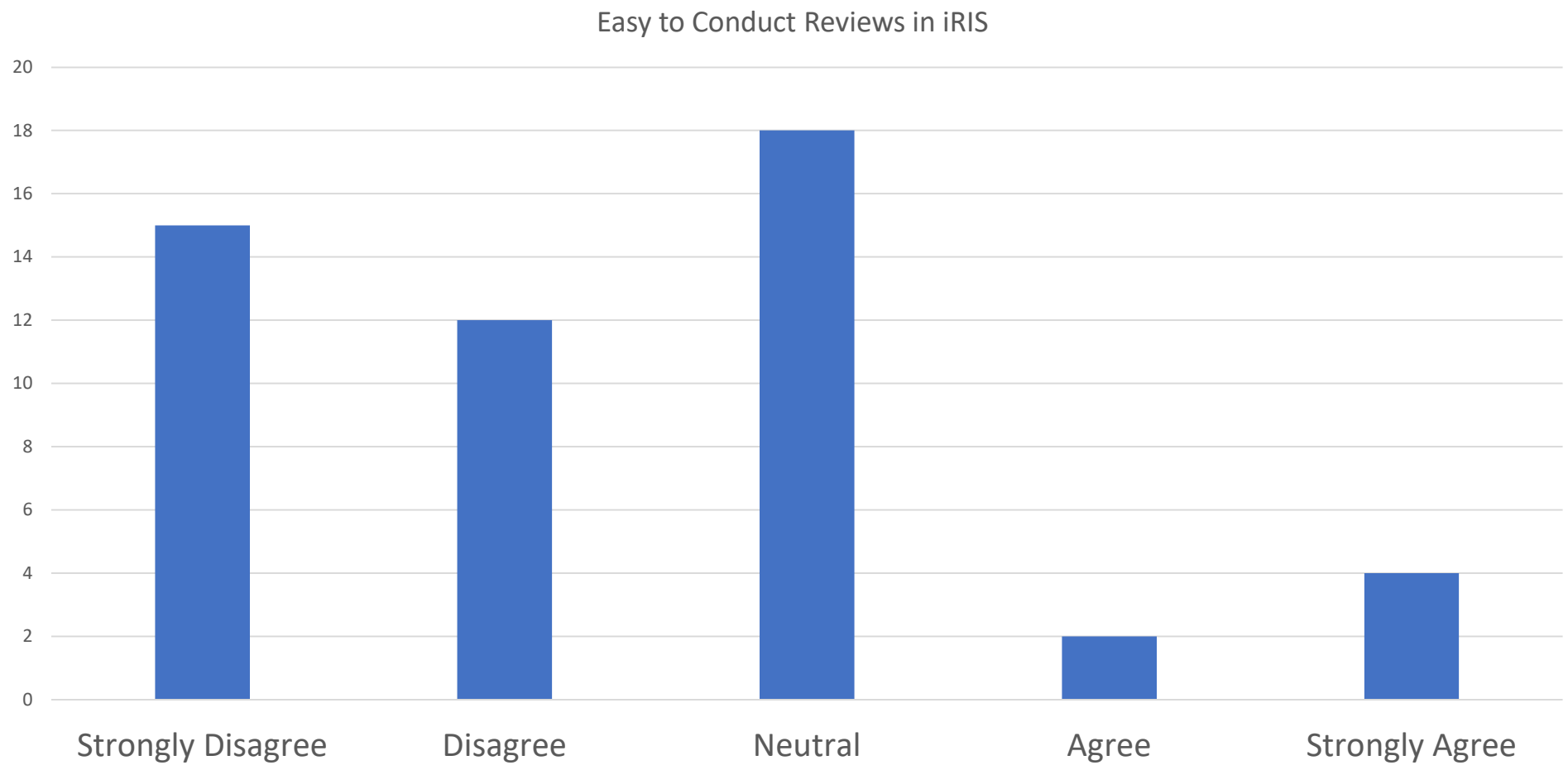
iRIS Customer Satisfaction Survey- IRB Members

- It is easy for me to find the documents I need to review in iRIS to prepare for an IRB meeting.



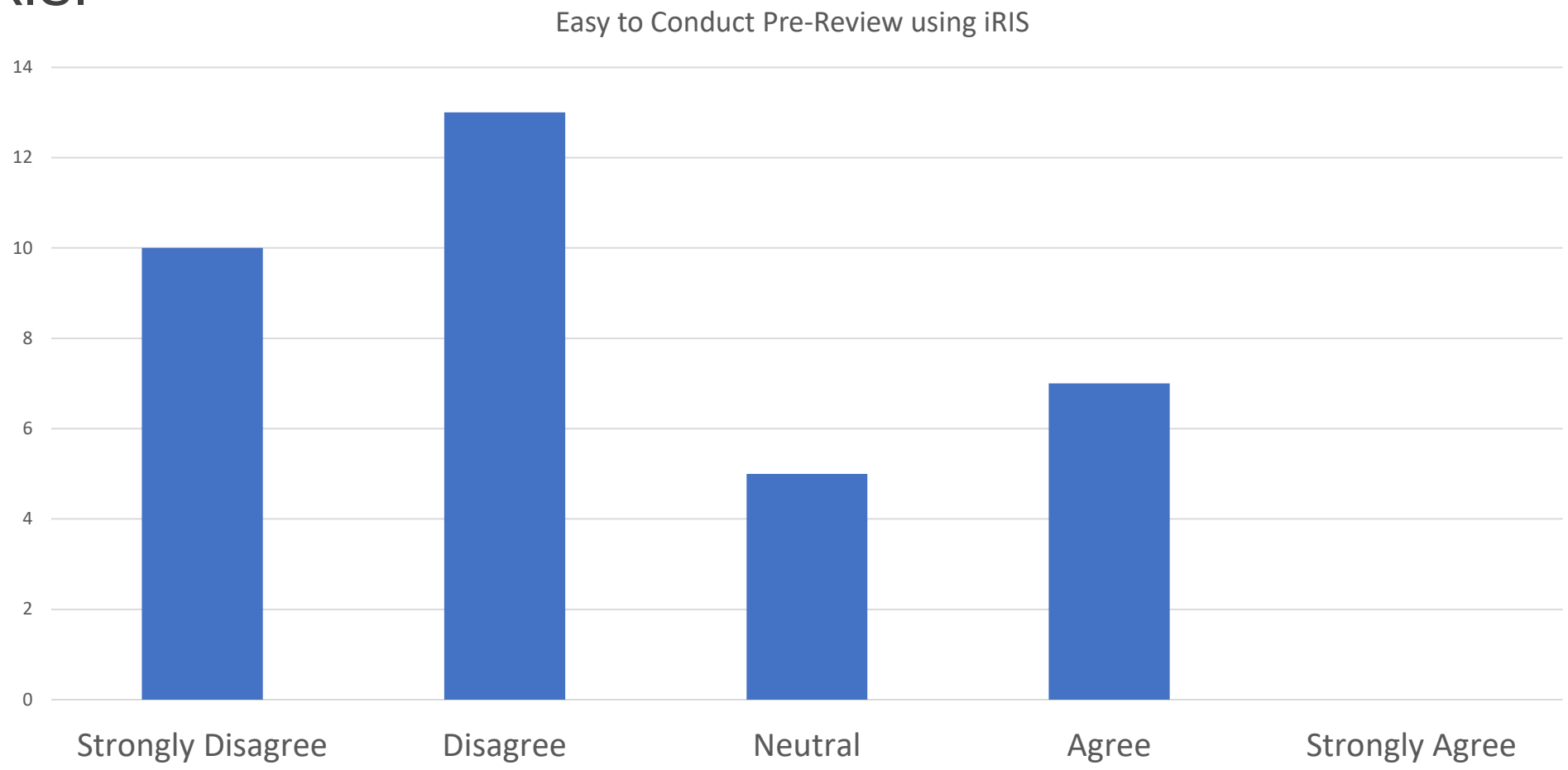
iRIS Customer Satisfaction Survey- IRB Members

- It is easy for me to conduct my review using iRIS.



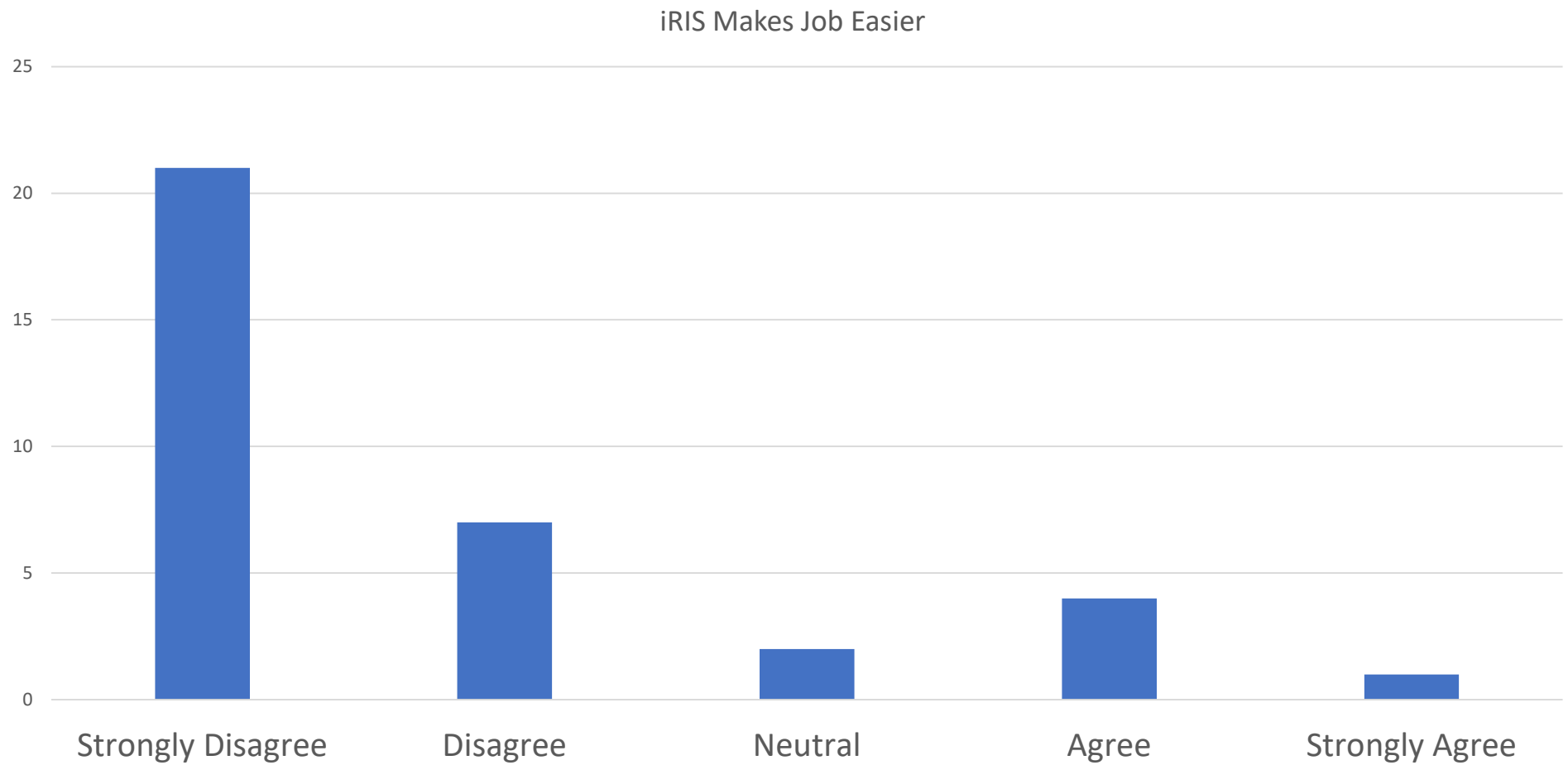
iRIS Customer Satisfaction Survey- IRB Staff

- It is easy for me to conduct my pre-review of IRB submissions using iRIS.



iRIS Customer Satisfaction Survey- IRB Staff

- As an IRB staff member, iRIS makes my job easier.



Is iRIS the right system?

- Optimize iRIS
- Explore other options

General Project Overview- Purpose and Mission

- The purpose of the project is to initiate the process of potentially replacing the electronic Institutional Review Board (eIRB) protocol management system at the National Institutes of Health (NIH).
- The mission of the project is to streamline the submission and review of human subjects research protocols across the NIH Intramural Research Program (IRP) and facilitate the documentation of regulatory compliance.
- To potentially make this change, we have started planning, and have created a steering committee to gain insight from the research community, evaluate solutions and to help guide the project.

eIRB System Replacement Steering Committee

- Steering committee members:
  - Bradley Alvarez
  - Bibi Bielekova, M.D.
  - Melissa Bryant
  - Marcelo Fontinha
  - Nancy Fryzek
  - Tiffany Gommel
  - Nicole Grant
  - Jonathan Green, M.D.
  - Ramesh Karuppiah
  - Jason Levine, M.D.
  - Jon McKeeby, DSc
  - Tracey Miller
  - Meredith Mullan
  - Sue Tindall
- Steering committee members were selected through:
  - Medical Executive Committee (MEC): 3 members
  - Assembly of Scientists (AOS): 1 members
  - Subject Matter Experts: 2 members

Purpose

- Stay informed of key project activities and milestones.
- Discuss, provide recommendations, and make key decisions for system selection and implementation.

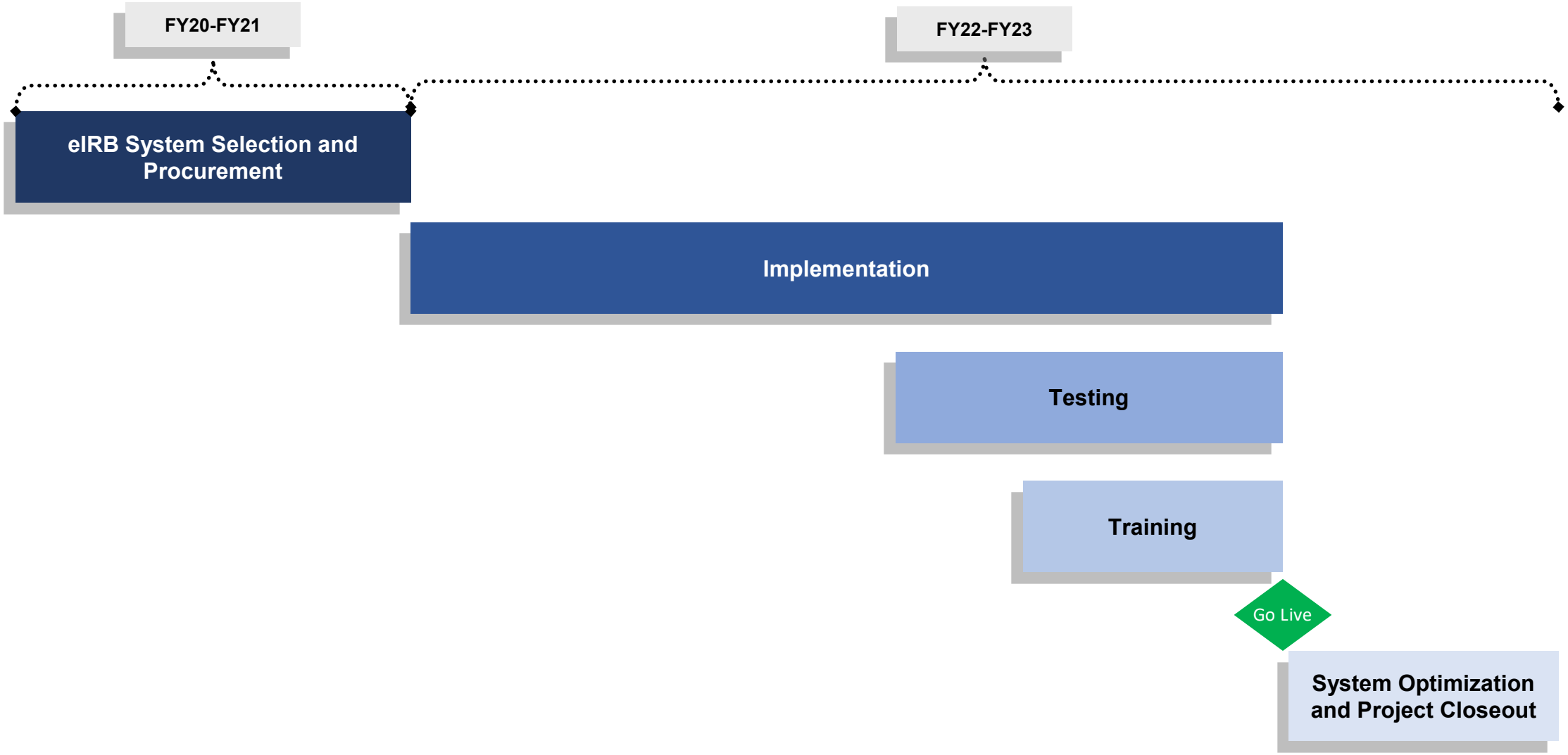
Key Roles and Responsibilities

- Provides and shapes vision for the project
    - Must Haves
    - Wants
- Decision making body.

Meeting Cadence

- Monthly. Meeting cadence will be reevaluated to fully support project.

High Level eIRB Project Phases (proposed)



eIRB System Requirements Survey

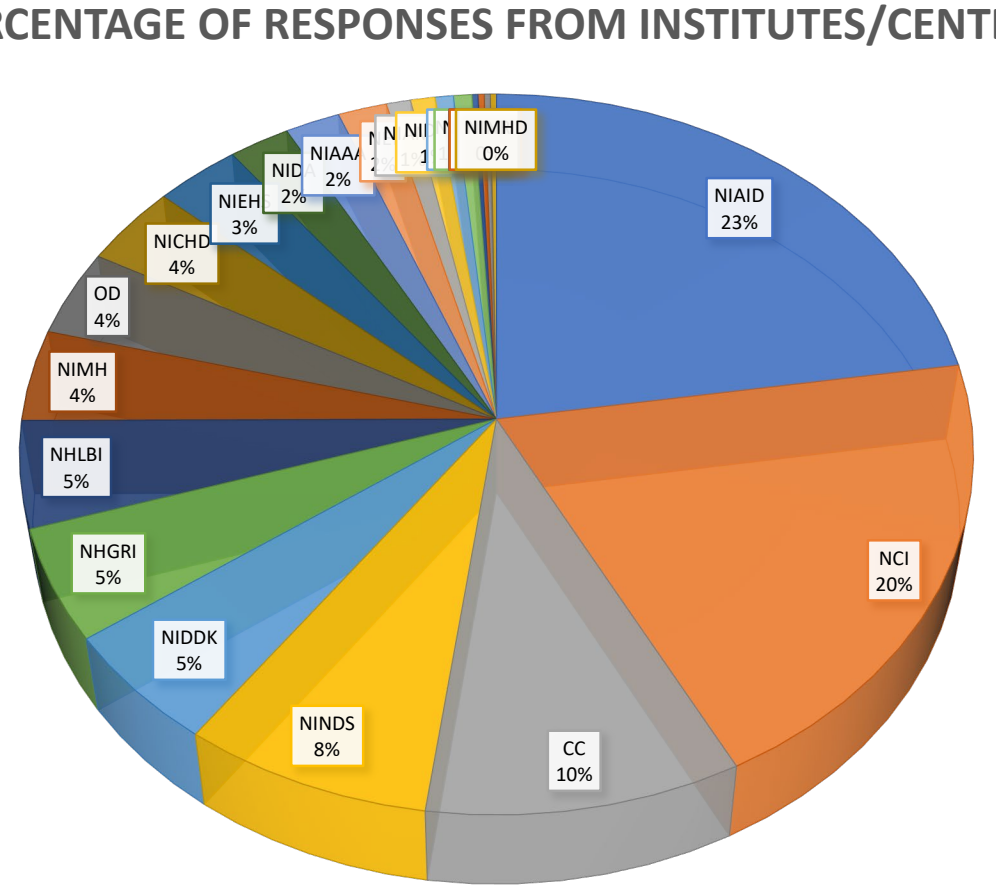
- In order to better understand what the NIH research community would want in a new system, we sent out a survey to capture these requirements.
- Creating the survey
  - Steering committee provided their “must haves and nice to haves” in a system.
  - This information was categorized, as there were many overlapping suggestions.
  - Looked at high-level categories and converted them into a question format.

eIRB System Requirements Survey

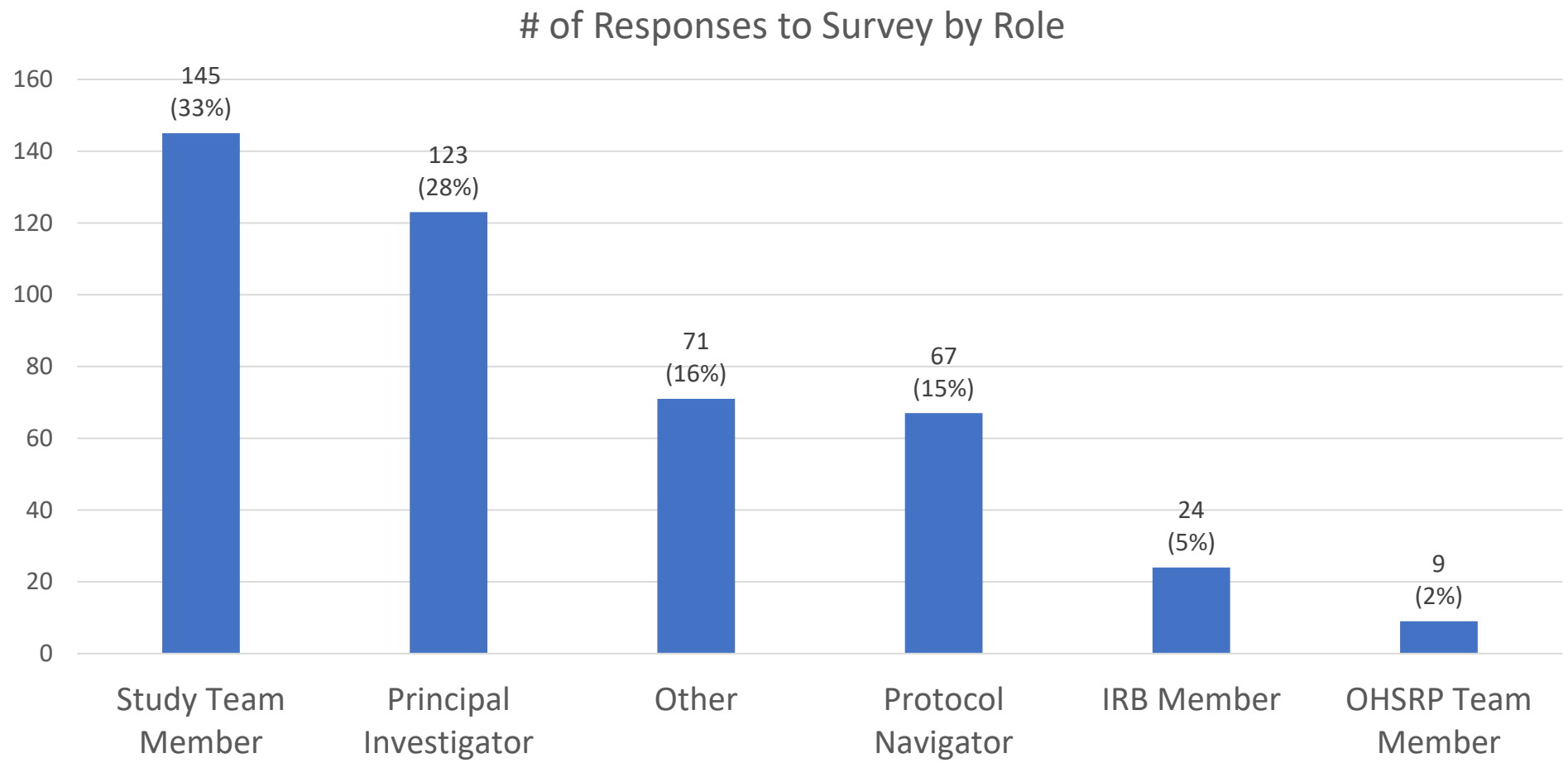
- Next, the results of the survey will be reviewed.
- This data will be used to help us evaluate various vendors.
    - Vendors may not be able to provide every single piece of functionality we want, so understanding the priorities of the research community is very helpful.

eIRB System Requirements Survey

- We received 439 responses to the survey.
- Below, the percentage break down of responses by IC is shown in a pie chart:



- Of the 439 responses, we received most responses from Study Team Members. The full breakdown is listed below:



- Top 10 highest rated requirements:

Question	Rating
Provide easy access to and identification of the currently approved study documents (ie, most recent approved consent, protocol etc).	2.95
Ability to enable electronic notification of study team when protocol approval is due for renewal at the defined points in time and when a study lapses.	2.90
Ability to verify that required fields are completed prior to finalizing submission and prevent submission of an incomplete application. Contain validations that will alert if submission contains inconsistencies.	2.85
System should provide easy access to most currently approved consent document.	2.83
Ability to manage documents taking into account the following: PDF creation for approved forms and attachments, manage approved study documents for study teams/IRB office review, ability to generate letters without active X, system generated pre set naming conventions for documents, version control and tracking of documents, easy comparison of different selections of application.	2.81

- Top 10 highest rated requirements:

Question	Rating
Ability to track the date the submission is received.	2.78
Ability to track who completed the IRB documents and who to contact if there are questions.	2.78
Ability for system to document and track regulatory determinations, and the ability to incorporate determinations into outcomes. Ability to select and document more than one pediatric risk category to support component analysis.	2.75
Ability to submit non-compliance and unanticipated problems in the system.	2.74
System should provide dashboard/easy visualization of ongoing and upcoming tasks, events, submissions (all work-in-progress, queues, etc. for IRBO).	2.74

- 10 requirements that received the lowest rating:

Question	Rating
System should allow in-line editing of all documents (protocols, consent forms, etc.) so that document is uploaded a single time at submission and then tracked within the application itself.	2.32
Ability to allow and track two way communication within the system between end users; privately and through public comments, and the ability to send emails to specific user groups/end users from the system.	2.31
Provide reporting capabilities that are pre-built, customizable (AAHRPP, regulatory, workflow, role and rule based etc), and able to be exported.	2.28
Ability for system to track conflicts of interest for protocols by Investigators/Research Personnel/IRB members (by protocol).	2.28
Ability to create, revise and distribute agendas within system.	2.27

- 10 requirements that received the lowest rating:

Question	Rating
System should contain integrated reviewer sheets for all submissions reviewed by the IRB.	2.25
System should provide integrated scheduling tool that allows scheduling of more than one meeting per day, and meetings that can be created as needed.	2.16
Ability for system to auto assign of IRB number.	2.08
Ability for IRB members to sign up for IRB meetings in the system, and the ability for the IRB office to manage IRB membership within the system, and attendance.	2.05
Ability to create validations that will block a new protocol from being created (i.e. an expired study has not been closed) based on PI/AI training records that develops protocol application.	1.93

eIRB System Requirements Survey- Free Text Comments

- Over 300 free text comments.
- Major themes:
  - Intuitive system
  - User friendly
  - Better document versioning
  - Improved ability to “search”
  - Improved reporting capabilities
  - Welcome page/dashboard to understand where your protocols stand
    - Improved status tracking of protocol
  - Easier access to protocols/documents in system

elRB System Requirements Survey- Free Text Comments

- Improved ability to upload documents in system
- Access to “help” while using the system
- Ability to add comments on forms where appropriate

- THANK YOU!

Axle Informatics

- We have started working with Axle Informatics to help us potentially select a new eIRB vendor.
- Axle Informatics specializes in assessing and implementing research technologies across the NIH community in the following areas:

Biomedical and Clinical Research	Scientific Computing and Informatics
Application Development and Data Science	Programmatic and Enterprise Management

- They will help us with the technology assessment, the application review, and the enterprise management of the project.

- Their assistance will entail:
  - Finalize system requirements
  - Survey of vendors to determine which vendors can meet NIH needs
  - Collect preliminary cost information from candidate vendors
  - Solicit vendors to come for demonstrations of their systems to the NIH research community
  - Evaluate candidates against requirements
  - Collect formal bids from finalists

eIRB System Vendors

- Who are the eIRB vendors in the marketplace?
  - iMedRIS (status quo)
  - Huron
  - InfoEd
  - Ideate Research Administration Suite
  - IRB Manager
  - Kuali Coeus
  - IRBNet
  - Others!
- We will work with Axle to create an exhaustive list to ensure we do a deep dive on the available systems and select the top candidates for a broader review.

Closing Remarks

- As explained above, we are working to determine if it would be in the best interest of the NIH to move to a new eIRB system, considering the NIH research community's thoughts and feedback.
- We recognize that this is a huge undertaking and will be a lift for the research community, however we want to improve the protocol review process here at NIH and feel a new system could aid in doing this.
- Please feel free to reach out to Meredith or myself if you have anything you'd like to share related to this.
- The slides for this presentation will be listed on our website in the next few days.
- Thank you for your time!