



WELCOME!



# GOALS FOR TODAY

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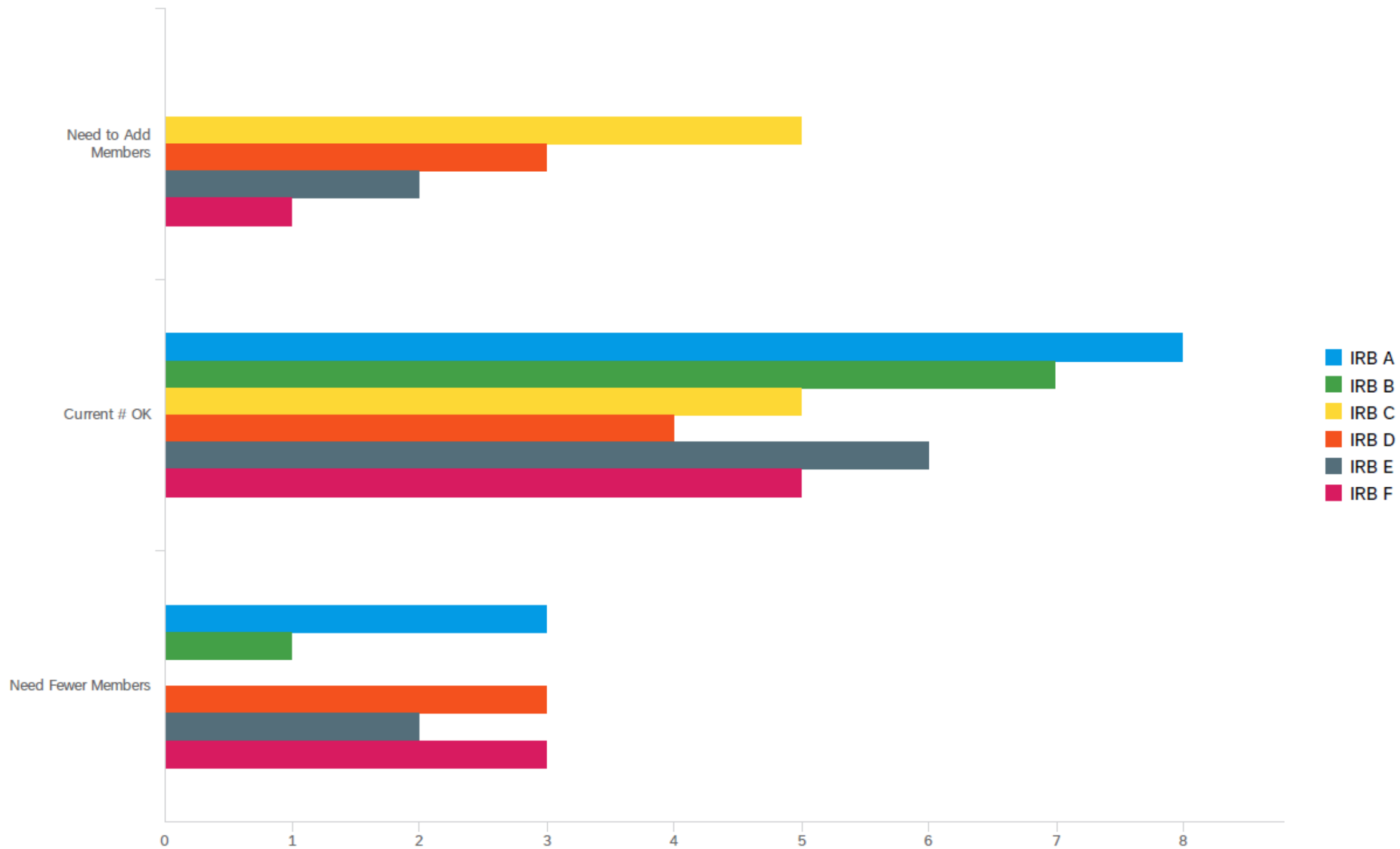
- Improve use the regulatory framework to answer day-to-day questions
- Discuss how to address conflicting regulatory requirements
- Discuss how to improve overall meeting processes
  - Communication
  - Collaboration
  - Consistency

# BOARD MEMBERSHIP

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- All committees have 11 members except A (12) and C (9)
- Majority of responses said committees had enough members
- Need to add more members:
  - Comm C (5 responses)
  - Comm D (3 responses)
  - Comm E (2 responses)
  - Comm F (1 response)
- Members needed are pregnant persons rep (A, C, D, E), prisoner rep, nonscientist members, oncologists, specific expertise (Pharmacology; radiology; neurology; infectious diseases; developmental psychology)

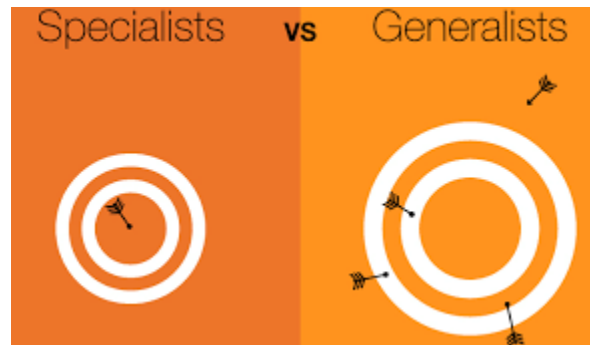




# SPECIALIZED VS GENERAL BOARDS COMMENTS

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- Prefer having the separate PRI committee
- Prefer having Social Behavioral committee
- One comment: Need some degree of specialization but prefer members with broad experience



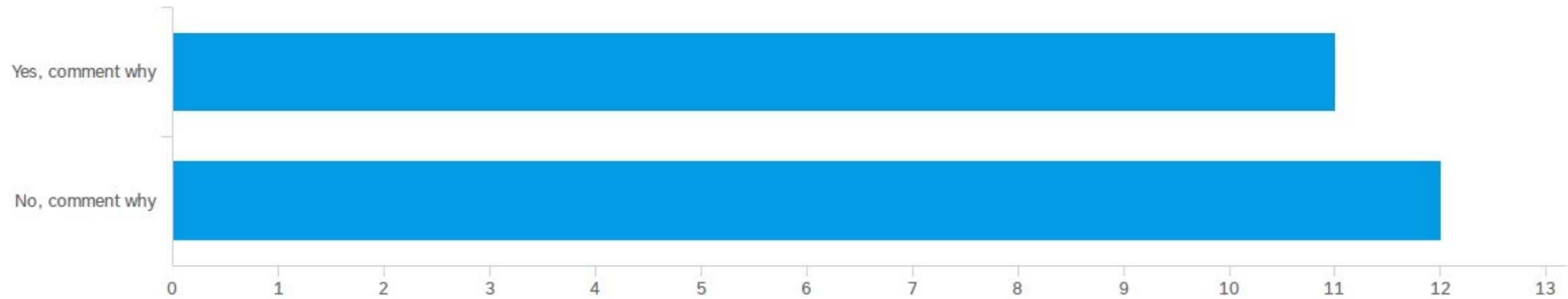


#	Field	Choice Count
1	More general	54.55% 6
2	More specialized	63.64% 7

SPECIALIZED VS GENERAL BOARDS

# SHOULD PI BE "ON-CALL" AT IRB MEETINGS?

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- Because sometimes a Board member brings up a concern that was not one of the reviewers' concerns. Having a study team member would help clarifying extra queries.
  - We used to do this and it proved to be beneficial in avoiding deferrals as it is difficult to know what issues other IRB members might raise during the meeting. Some researchers were very responsive and others were not interested but nice to have the option.
  - It should not be required but recommended.
  - sometimes are simple questions whose answers can be sufficient.
  - only for those studies identified in pre-review as having potential issues
  - Only on a case by case basis for complex or controversial reviews





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- Better to email the PI prior to the meeting if questions.
  - In my experience that often slows down the meeting.
  - Concerns about verbal communication being accurately recalled and crafted into directive stips
  - Would require a person to be present for all studies but only a small number are deferred. However, if deferred, PI should be available when rediscussed.
  - Not as a standing policy/procedure; if something is flagged prior to the meeting by the reviewer and the PI's input is needed, it is better to get it ahead of time; timing of reviews is so variable we potentially could be asking people to put a significant portion of their afternoon on hold

# THOUGHTS ON ZOOM MEETINGS

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- Not noticed any major issues with the Zoom meetings
- Chairs should recognize members who are need encouragement to speak up or assign someone to keep track of this issue and actively draw that/those members into the discussion.
- Perhaps teaming up experienced members with newer members (buddy up) would be helpful, especially right when a new member joins the committee, to empower them to speak up more
- I do miss in-person meetings – Zoom meetings are more challenging in terms of keeping folks engaged.
- We should replace roll-call voting and use the "Raise Hands" function to speed up the voting process.
- Zoom working but prefer in person

# EDUCATIONAL TOPICS NEEDED

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- Assessing risk
- PRI reviews
- Ways to prepare/present reviews that are complete but succinct
- What to consider in reviewing biobank protocols, especially those that may include genetic testing
- Focus on single topic (e.g., INDs, IDEs)
- Review of devices being used as tools (when is worksheet necessary) and wearable devices
- Case discussions are always helpful for me

# GENERAL SUGGESTIONS

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- SOP of the month for members to review
- Reviewers beginning review at time of assignments and drafting steps few days before meeting so any deferrable issues have time to potentially be resolved
- Members contact researchers directly for clarification (when comfortable)
- More in depth discussion of consent forms at meetings
- Compare document feature for all documents within IRBIS
- Pre-review process that includes verification of all necessary documents present
- Only 1 PRI on agenda
- Pls on call when it is anticipated that there is a deferrable issue

# SUGGESTIONS (CONT)

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- Meetings between the chairs can include a "case study" portion where a chair gives an overview of a study that presented their board with a unique issue.
- A list of thorny issues (e.g. waiver of signed consent, genetic testing and return of results, does increasing anesthesia time make something GMR, etc) where staff and chairs/vice chairs can add study numbers and a brief description of the decision as a resource should issues be encountered again
- Having chairs/vice chairs visit other committees occasionally. Have each chair at least once a year lead another committee
- When an issue comes it, it should then be brought to the executive committee to review and make a determination about how it should be handled
- Report form templates ensure the basic information is presented at each board meeting.
- Guidance to members on how to present, what to review, when to alert analyst or PI regarding major issues.
- Recommend assigned ICF reviewer for each Initial

# SHOUT OUTS TO CHAIRS AND VICE CHAIRS

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**detail  
oriented and  
organized**

takes time to  
familiarize  
themselves with  
each application  
on the agenda

excellent at managing  
review process.

While newer is also very  
knowledgeable and responsive

Very  
knowledgeable,  
very inclusive of  
members  
options/comments

Knowledgeable, patient, a good  
listener, makes recommendations  
based on facts and discussion,  
respects other opinions

brings the PI  
perspective into  
the board room;  
reasonable-minded

provide  
valuable  
insights.

# KUDOS TO OHRE STAFF

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All analysts are very good at providing additional support on ad hoc basis during reviews

**Very efficient**

**I always am impressed by their depth of knowledge. They are superb.**

Wonderful

welcoming and organized

**willing to go the extra mile in pre-board work**

**Fantastic**

Analysts do a great job of pre-review.

**Excellent**





# BRUCE GORDON, MD

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- Assistant Vice-Chancellor for Regulatory Affairs, and Professor of Pediatrics in the Division of Pediatric Hematology/Oncology at the University of Nebraska Medical Center (UNMC)
- Member of the UNMC institutional review board since 1992, served as chair since 1996, and as executive chair since 2011.
- First chair of the National Cancer Institute Pediatric Central IRB.
- Co-developed an “IRB Chairs Boot Camp” program for PRIMR
- Serves on the AAHRPP Council on Accreditation, and has been a faculty member at numerous AAHRPP conferences and a frequent AAHRPP site visitor
- Founding member of the Collaborative Institutional Training Initiative (CITI) and served on the Executive Advisory Committee for the program
- Co-editor of the third edition of “IRB: Management and Function.”

# EXTRA BIG THANKS

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- Charlotte
- Laura
- Eric S.