



RCR and REBs, Respective Roles and Responsibilities

The intersection of research ethics and RCR – Exploring challenges, strategies and practical approaches to balancing the dual institutional responsibility

CAREB-ACCER Pre-conference Workshop

April 26, 2018

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Trillium Health Partners, Institute for Better Health

Disclaimer

The views and opinions expressed in this presentation are my own and:

1. do not necessarily represent official policy or position of Trillium Health Partners; and
2. do not represent official policy or position of CAREB-ACCER.

All names and examples used in case studies are fictional, any likeness to actual circumstances or persons, either living or dead, is strictly coincidental.

Workshop Goals and Objectives

Objective: review and discuss the intersection of research ethics and RCR through introduction of a principle-based accountabilities concept and interactive case-based discussion

Goals:

1. Identify and discuss how, why and when research ethics and RCR intersect;
2. Provide strategies to address common challenges faced by REBs and Research Ethics Administrators in the face of RCR compliance issues; and
3. introduce and apply a principle-based research ethics & RCR accountability concept and decision-making framework

Workshop Approach & Participation Options

1. Interactive Dialogue
2. Real time polling – “Kahoot!”
 - Web-based tool
 - anonymous means of gathering attendee opinions and responses in real time to facilitate interactive dialogue
 - **Access Requirements:** Internet connection
 - **Accessible through:** Mobile phone, laptop, tablets
 - **Poll participation** (voluntary):
 - Go to: “kahoot.it”
 - Enter event code
 - Create a screen name
3. Group-based Case Review & Discussion

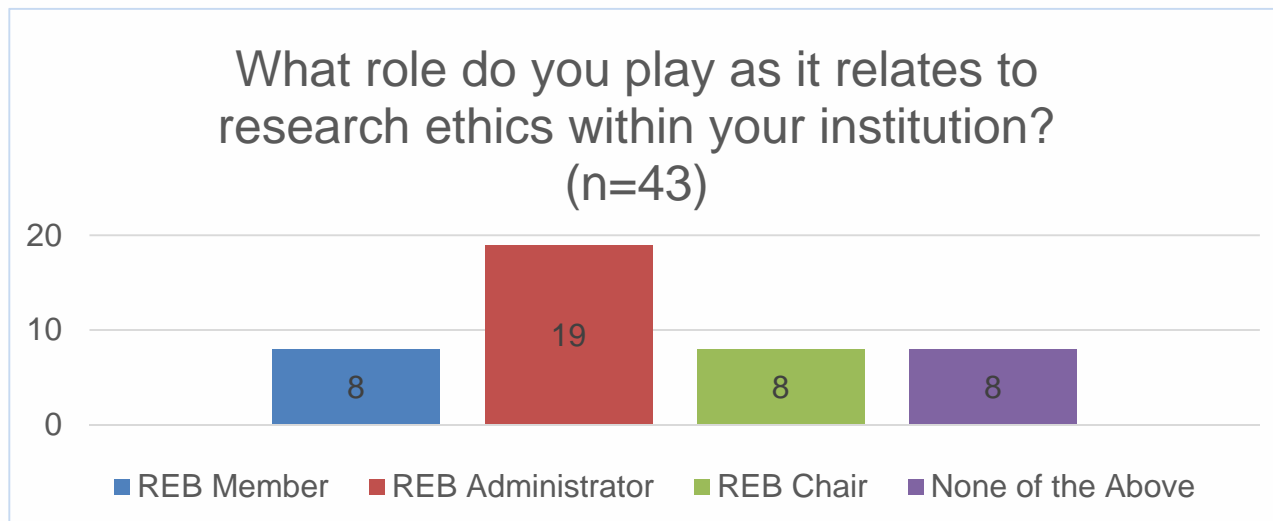
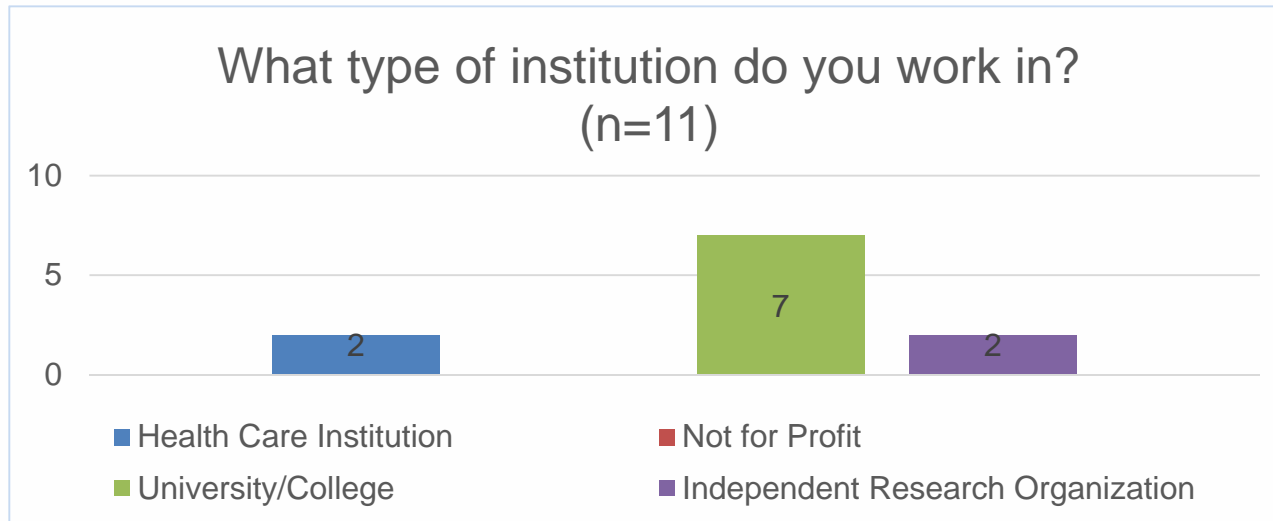


GETTING TO KNOW YOU!

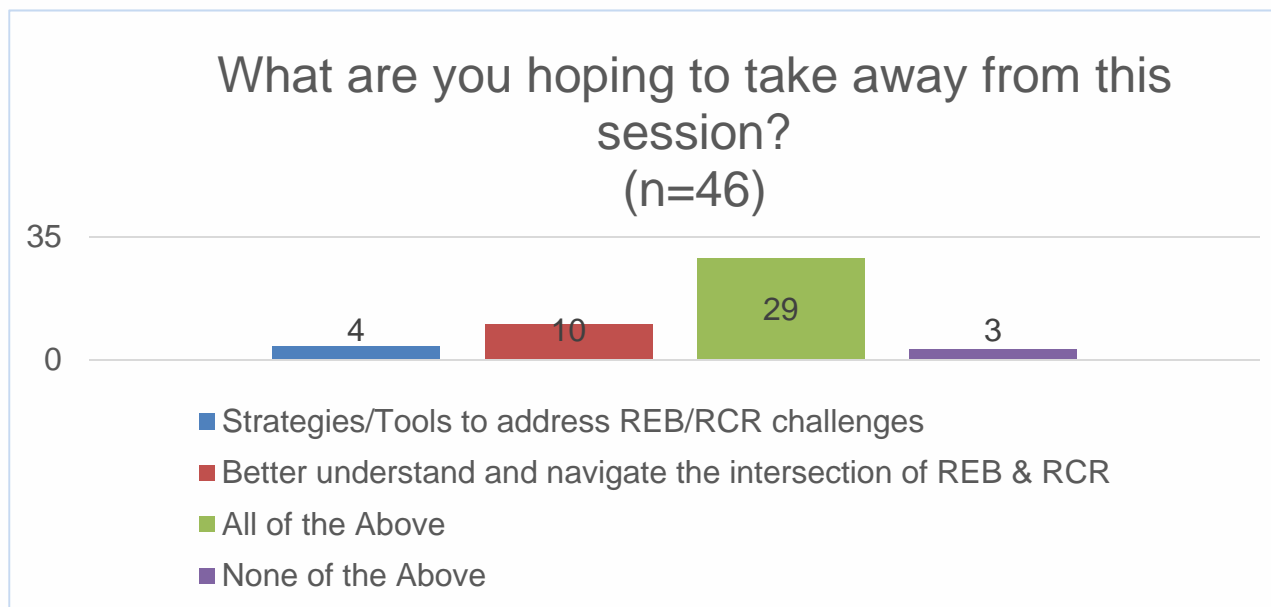
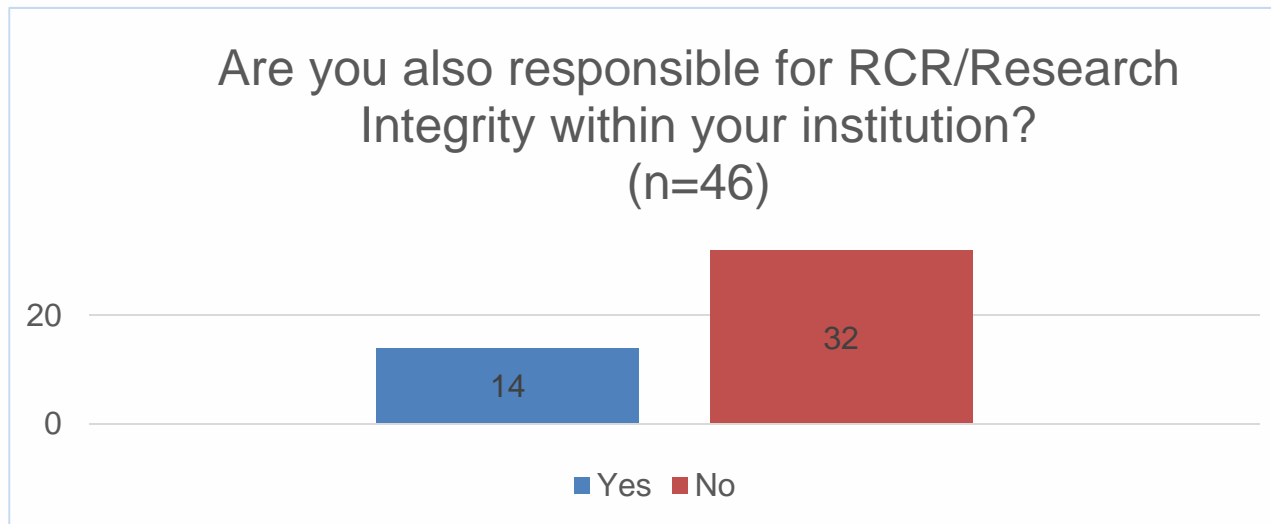
Kahoot! Poll

Go to: [Kahoot.it](https://kahoot.it)

Getting To Know You! Kahoot! Poll Results



Getting To Know You! Kahoot! Poll Results





INTERSECTION OF RESEARCH ETHICS & RCR/RESEARCH INTEGRITY

“How, Why and When”

An Introduction to our Cases

Student “Green”



New Study Submission

- Prospective Chart Review
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Professor “Blue”



Study Closure

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Active Study

- REB has received a complaint from a family member of a deceased study participant
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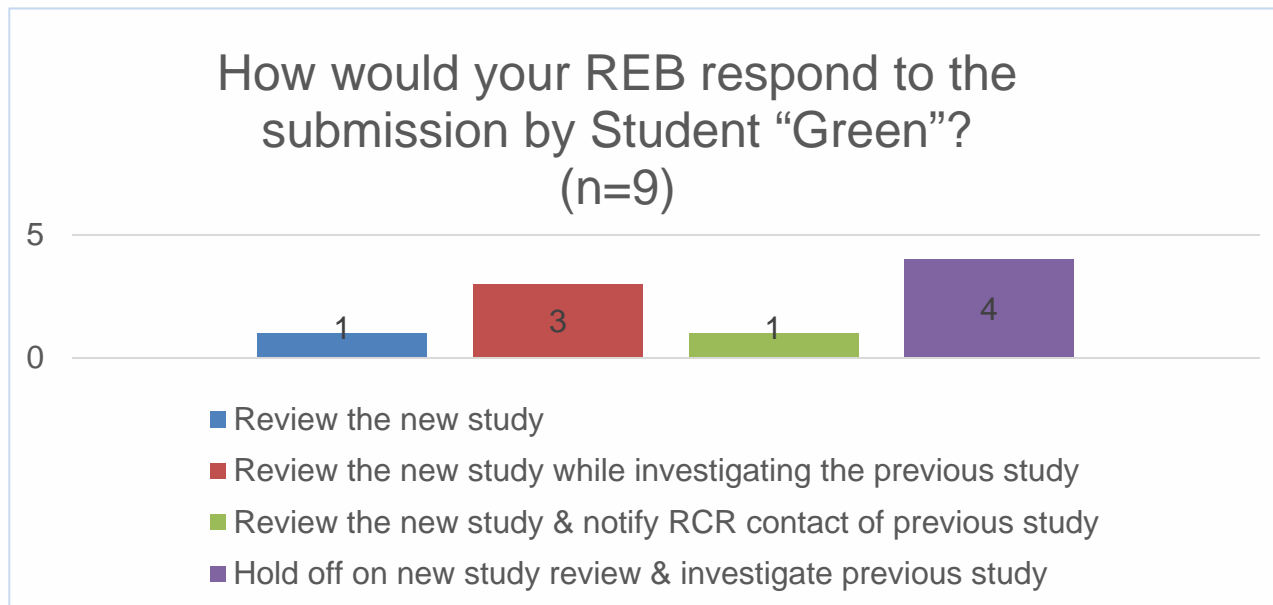
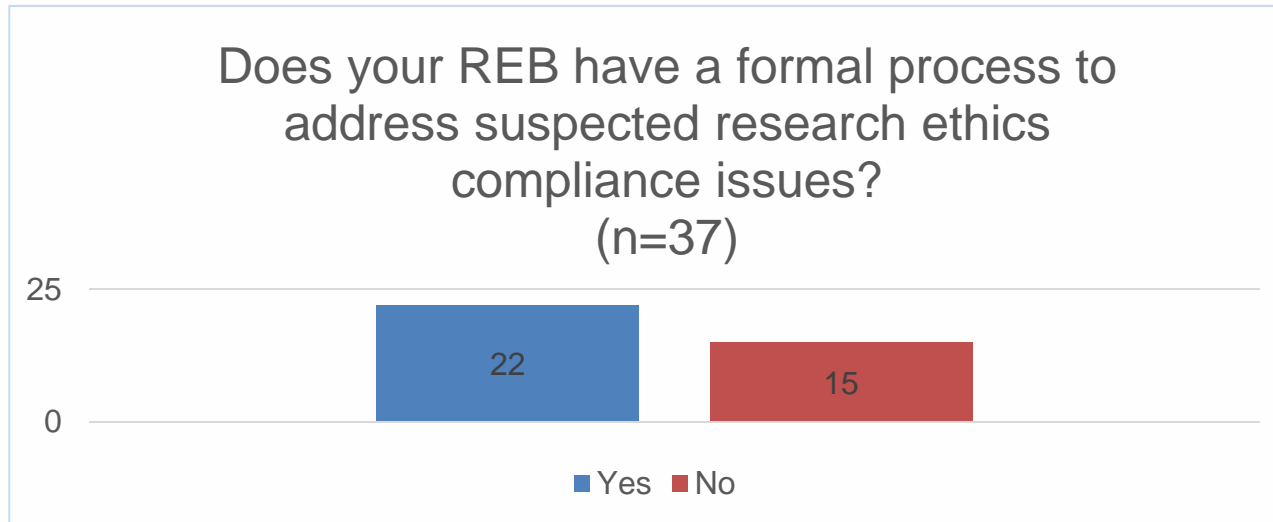


A REVIEW OF THE CASES

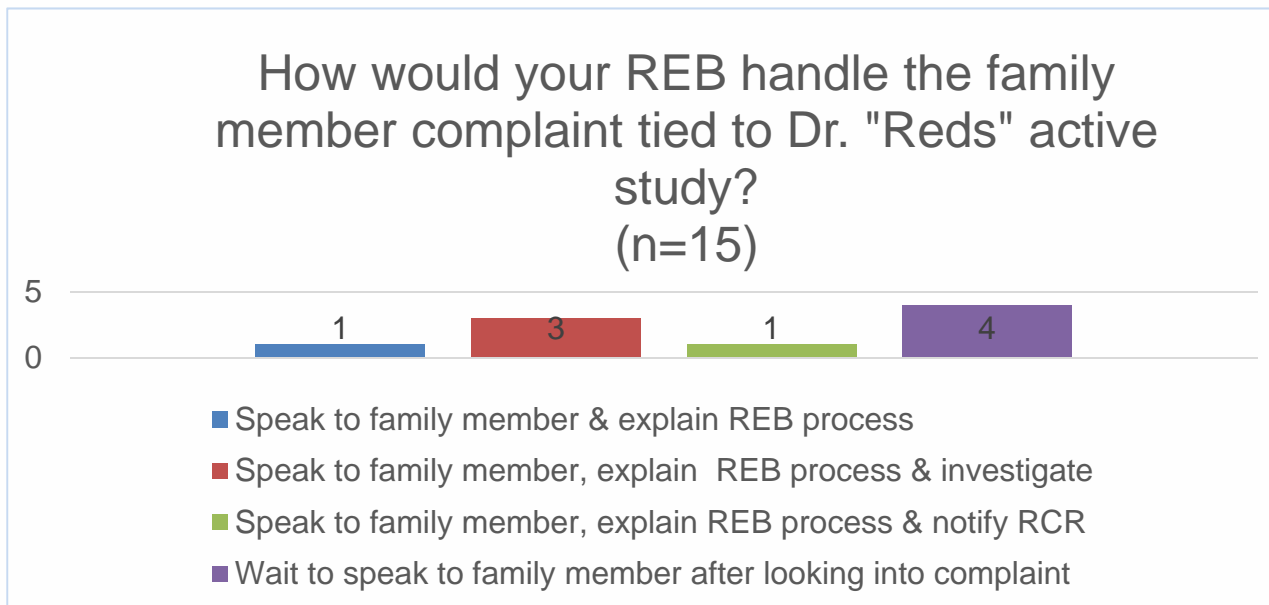
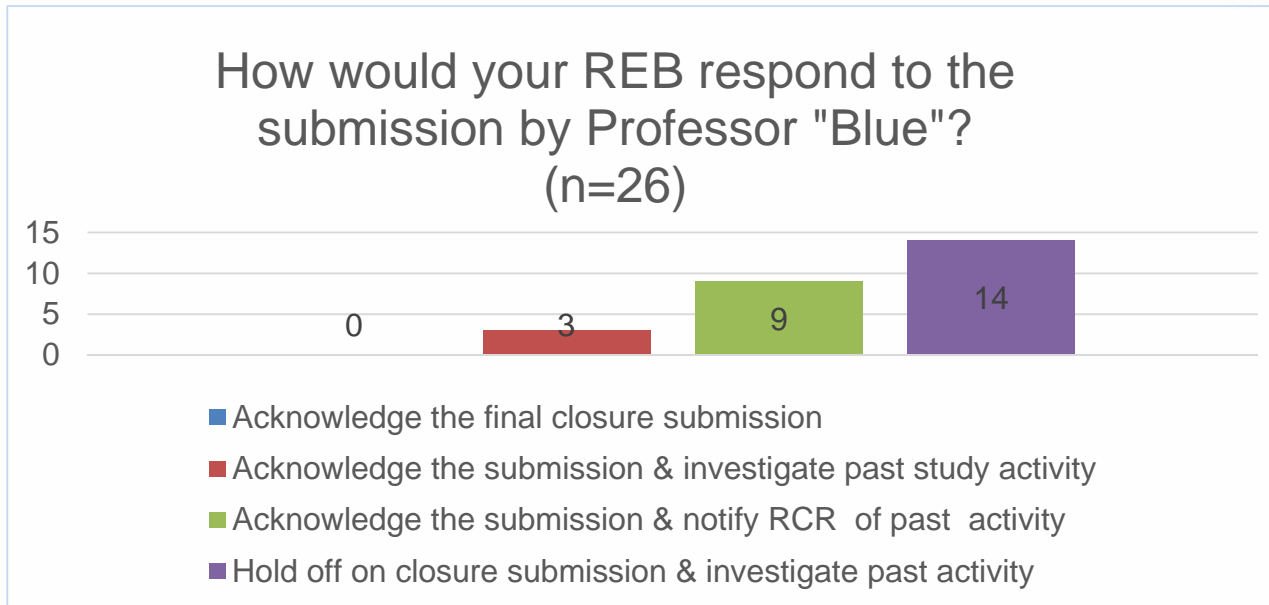
Kahoot! Poll

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A Review of the Cases – Kahoot! Poll Results



A Review of the Cases – Kahoot! Poll Results





INTERSECTION OF RESEARCH ETHICS & RCR/RESEARCH INTEGRITY

“How, Why and When”

INTERSECTION OF RESEARCH ETHICS AND RCR/RESEARCH INTEGRITY

“HOW, WHY & WHEN” – Roles & Associated Responsibilities

REB



Roles

- Ethical conduct of research
- Protection of participants rights, safety and wellbeing

RCR/Research Integrity



- Responsible Conduct of Research
- Compliance with the Tri-Agency Framework



Responsibilities

- Initial review of studies – based on proposed activities
- Ongoing review of studies – based on reported activities and information



- Oversight of Researchers Activities
- Oversight of Institution Practices and responsibilities under the Tri-Agency Framework



Focus

**Conduct of
Human Research Studies**



**Activities of
Individuals & Institutions**

INTERSECTION OF RESEARCH ETHICS AND RCR/RESEARCH INTEGRITY

“HOW, WHY & WHEN” – Joint Accountability

REB



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“HOW, WHY & WHEN” – Joint Accountability

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INTERSECTION OF RESEARCH ETHICS AND RCR/RESEARCH INTEGRITY

“HOW, WHY & WHEN” – Joint Accountability

Conduct of Human Research Studies

REB

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- Ongoing review of studies – based on reported activities and information

RCR/Research Integrity

- Oversight of Researchers Activities

Research Ethics & RCR/Research Integrity Interface

1. Concurrent
2. Ongoing
3. Requires particular attention in the face of:
 - Suspected research ethics compliance matters
 - Confirmed research ethics compliance matters

INTERSECTION OF RESEARCH ETHICS AND RCR/RESEARCH INTEGRITY

“HOW, WHY & WHEN” – Joint Accountability

CORE FOUNDATIONAL FACTORS *(Human Research Ethics & RCR/Research Integrity)*

1. Research Ethics Review and RCR/Research Integrity are **interdependent research oversight functions**
2. **Human research study conduct** is a **core connecting element**
3. **REB** purview = **study** *(review, approval oversight)*
4. **RCR/Research Integrity** purview = **individual**
5. Ethical conduct of research is a joint accountability

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RESEARCHER

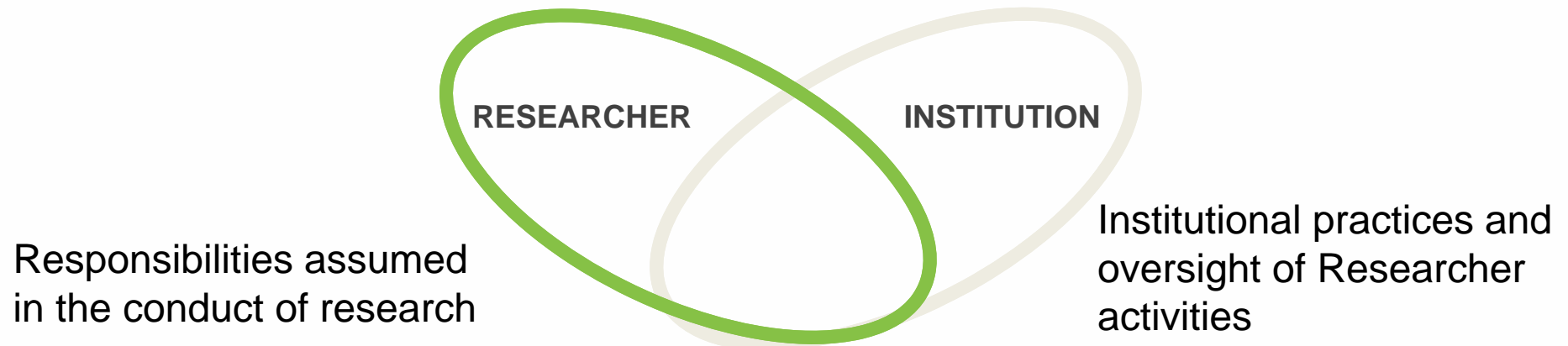
Responsibilities assumed
in the conduct of research

INTERSECTION OF RESEARCH ETHICS AND RCR/RESEARCH INTEGRITY

“HOW, WHY & WHEN” – Joint Accountability

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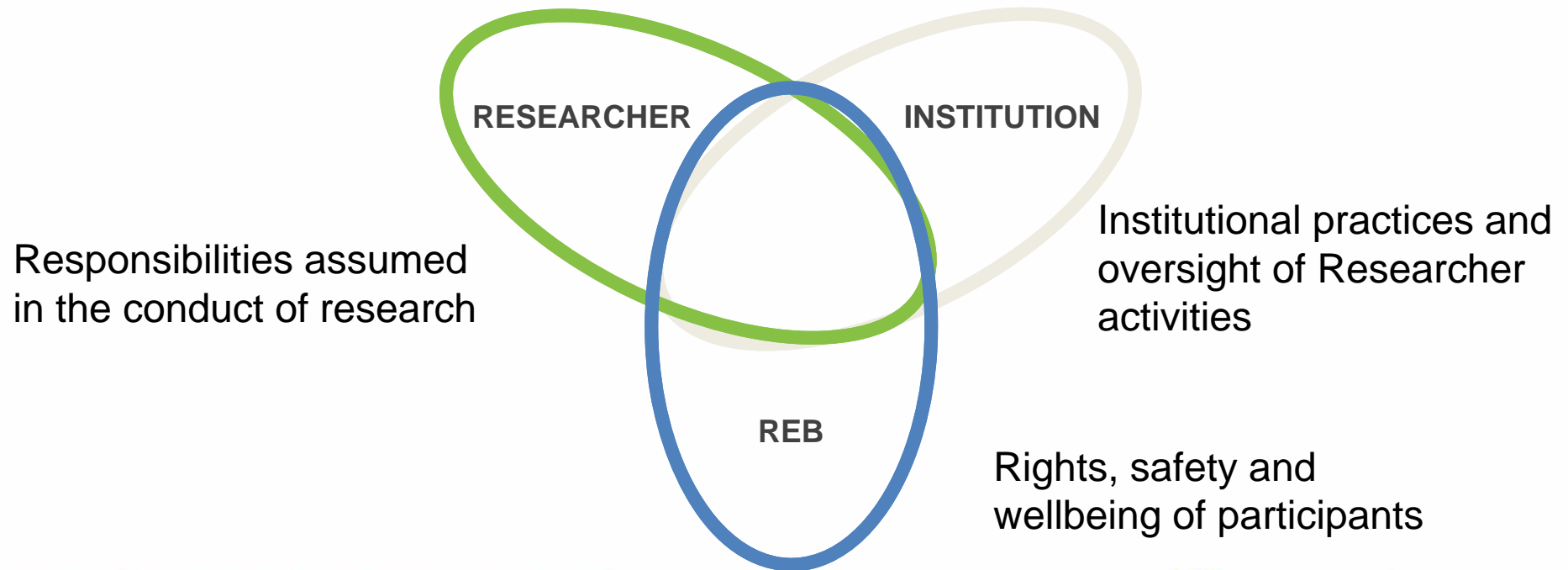


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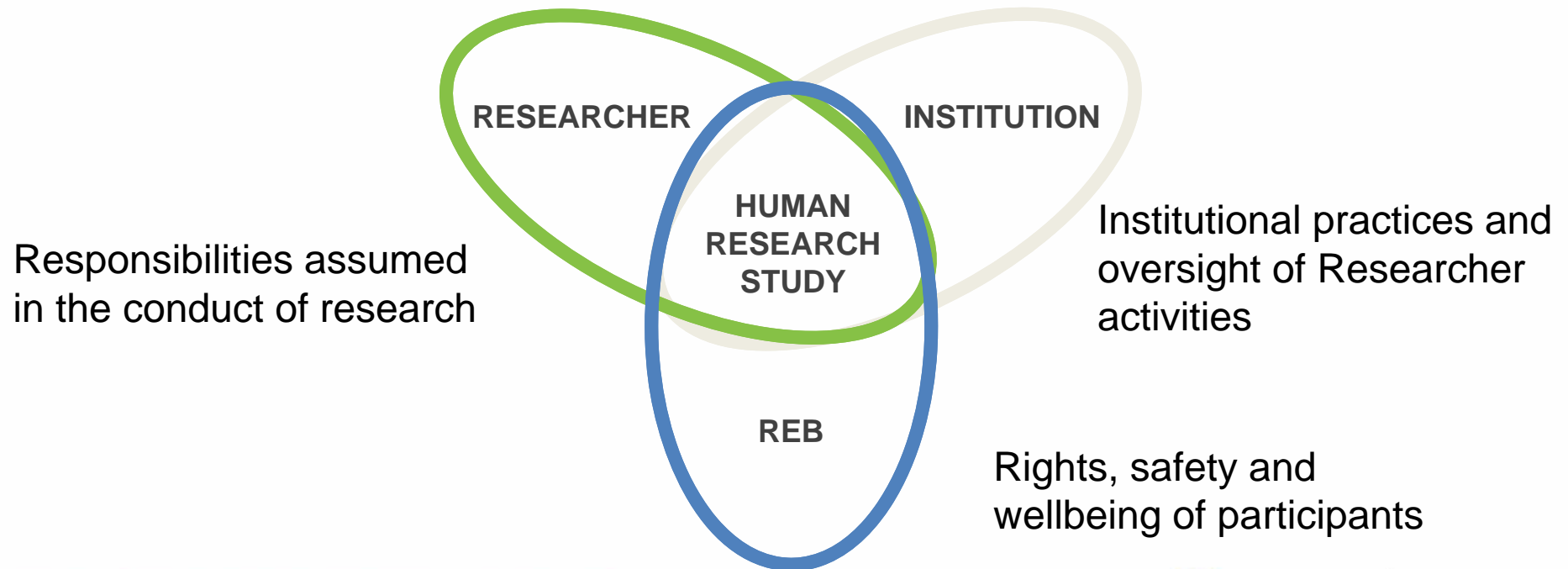


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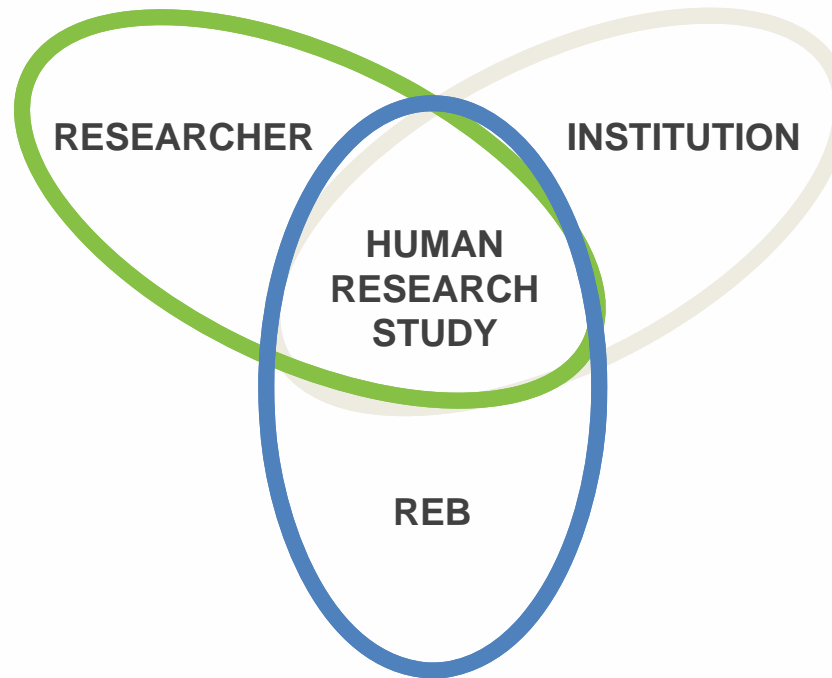
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INTERSECTION OF RESEARCH ETHICS AND RCR/RESEARCH INTEGRITY

“HOW, WHY & WHEN” – Joint Accountability



ROLE CLARITY

- Essential in fostering a culture of research accountability
- Important when facing research ethics compliance matters
- Highlights the importance of continuous reciprocal communication and information sharing



THE “PRINCIPLE-BASED ACCOUNTABILITY CONCEPT”

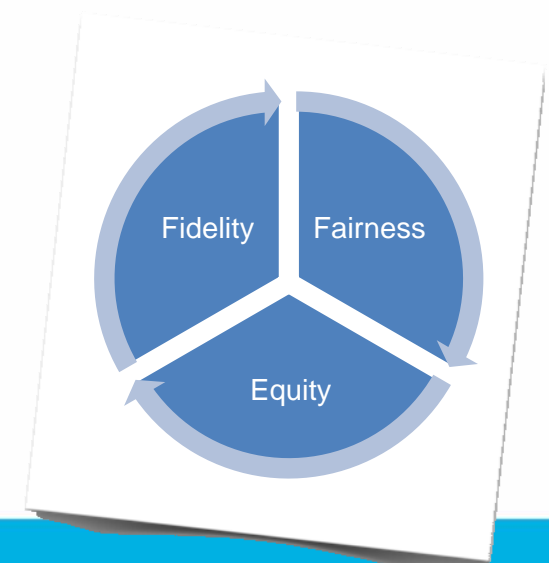
PRINCIPLE-BASED ACCOUNTABILITY CONCEPT

3 Principles Employed:

1. **Fairness**
 - Due process for compliance investigations
 - Not letting allegations/suspected compliance matters impact REB review process

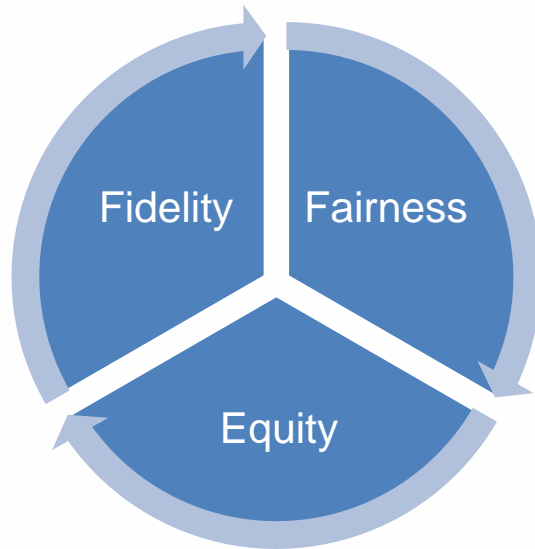
2. **Equity**
 - As it relates to the research ethics review process
 - Ensuring established review processes are followed consistent with the expectation of proportionality in reviews based on study specific risk to participants

3. **Fidelity**
 - Maintaining trust in the REB review system by fulfilling the obligations of the REB



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PRINCIPLE-BASED ACCOUNTABILITY CONCEPT



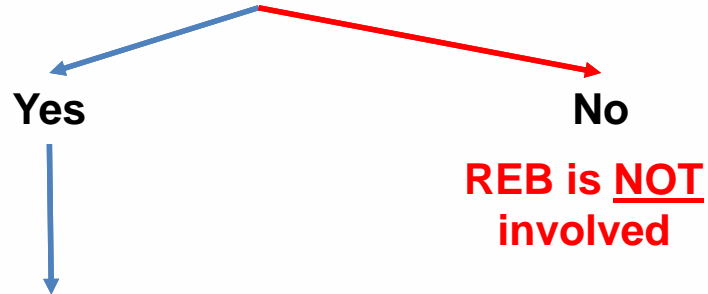
Rationale

1. Prevents/mitigates risk of biased decision-making by the REB
2. Builds and maintains trust in the research ethics and RCR/research integrity functions
3. Recognizes the interdependence and intersectional nature of research ethics and RCR/Research integrity

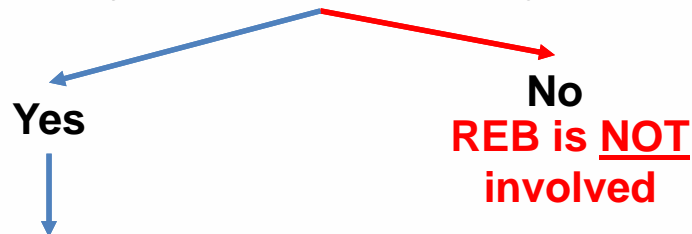
PRINCIPLE-BASED ACCOUNTABILITY CONCEPT

Decision-making framework

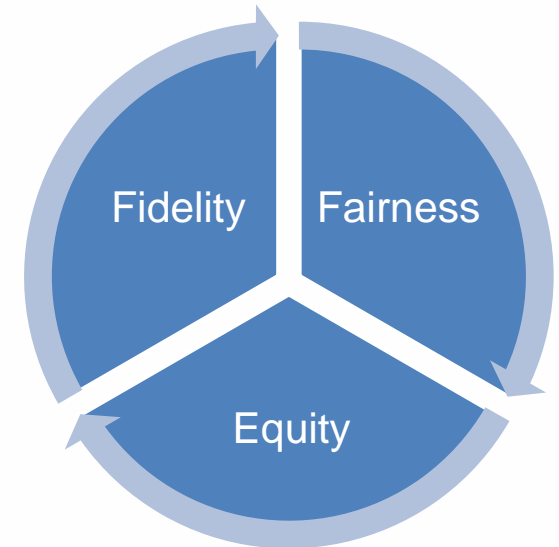
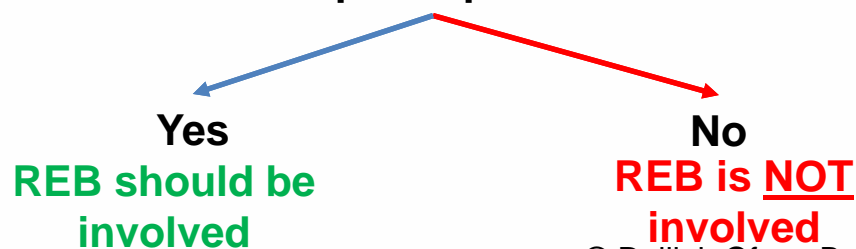
1. Is the issue related to a human research study?



2. Is the study currently under the purview/jurisdiction of the REB?



3. Does the issue have an impact on the rights, safety or wellbeing of study participants?



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Revisiting our Cases

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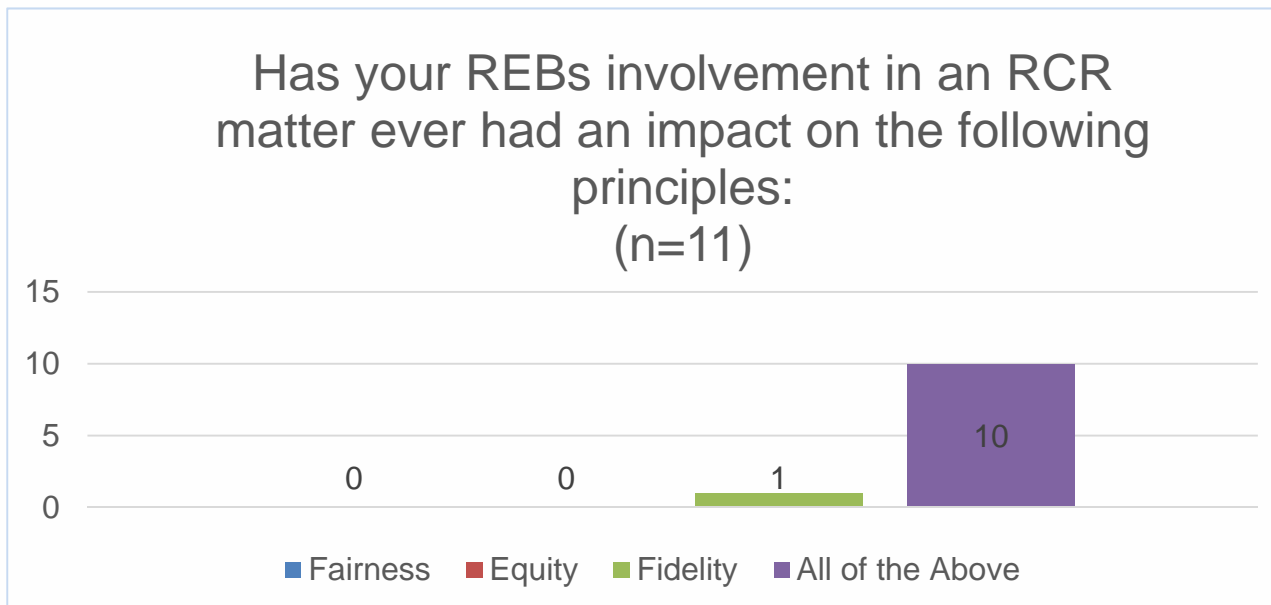
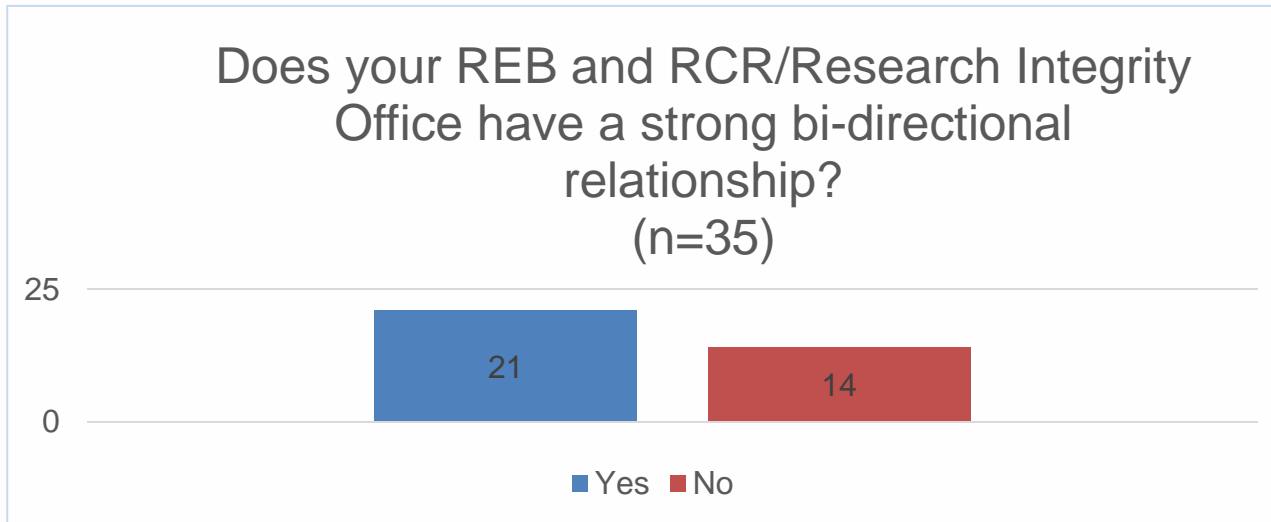


APPLYING THE PRINCIPLES & FRAMEWORK

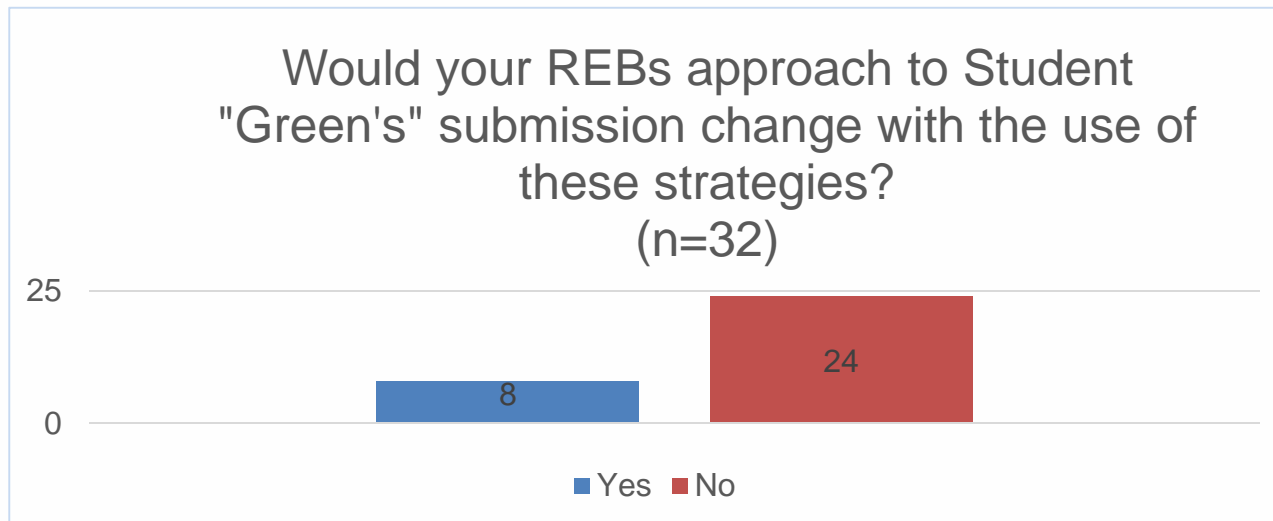
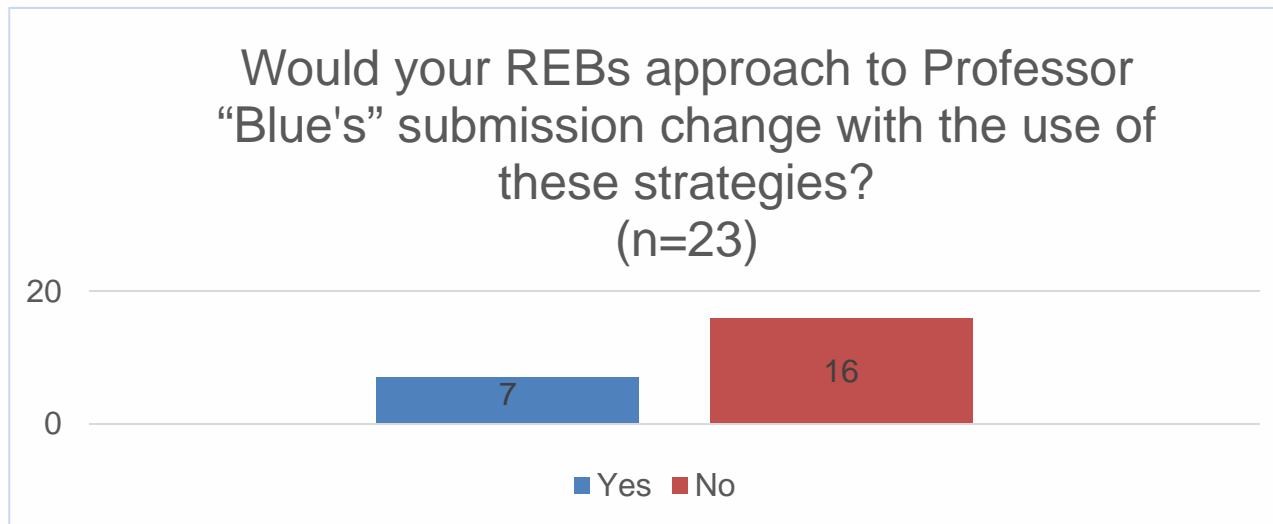
Kahoot! Poll

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Applying the Principles – Kahoot! Poll Results



Applying the Principles – Kahoot! Poll Results





GROUP-BASED CASE STUDY

“CONCEPT APPLICATION”

Group-Based Case Review

Dr. “Red”



Active Study

- REB has received a complaint from a family member of a deceased study participant
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Group Activity

- Group discussion – 10 minutes
- Reporting back/discussion – 10 minutes

Group-Based Case Review

Dr. “Red”



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Decision-making framework

1. Is the issue related to a human research study?
2. Is the study currently under the REB’s purview/jurisdiction?
3. Does the issue impact the rights, safety or wellbeing of study participants?

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Group-based Case Discussion/Review

Considering:




1. the interdependent functions of REBs and RCR/Research Integrity
2. 3 Principles introduced
3. Decision-making Framework

How might you/your REB address this scenario?

Be prepared to share:

- Proposed approach you would take, and
- The rationale for the approach taken

Session Summary

Goal	Workshop Milestone
<ul style="list-style-type: none">Identify and discuss how, why and when research ethics and RCR intersect	
<ul style="list-style-type: none">Provide strategies to address common challenges faced by REBs and Research Ethics Administrators in the face of RCR compliance issues	
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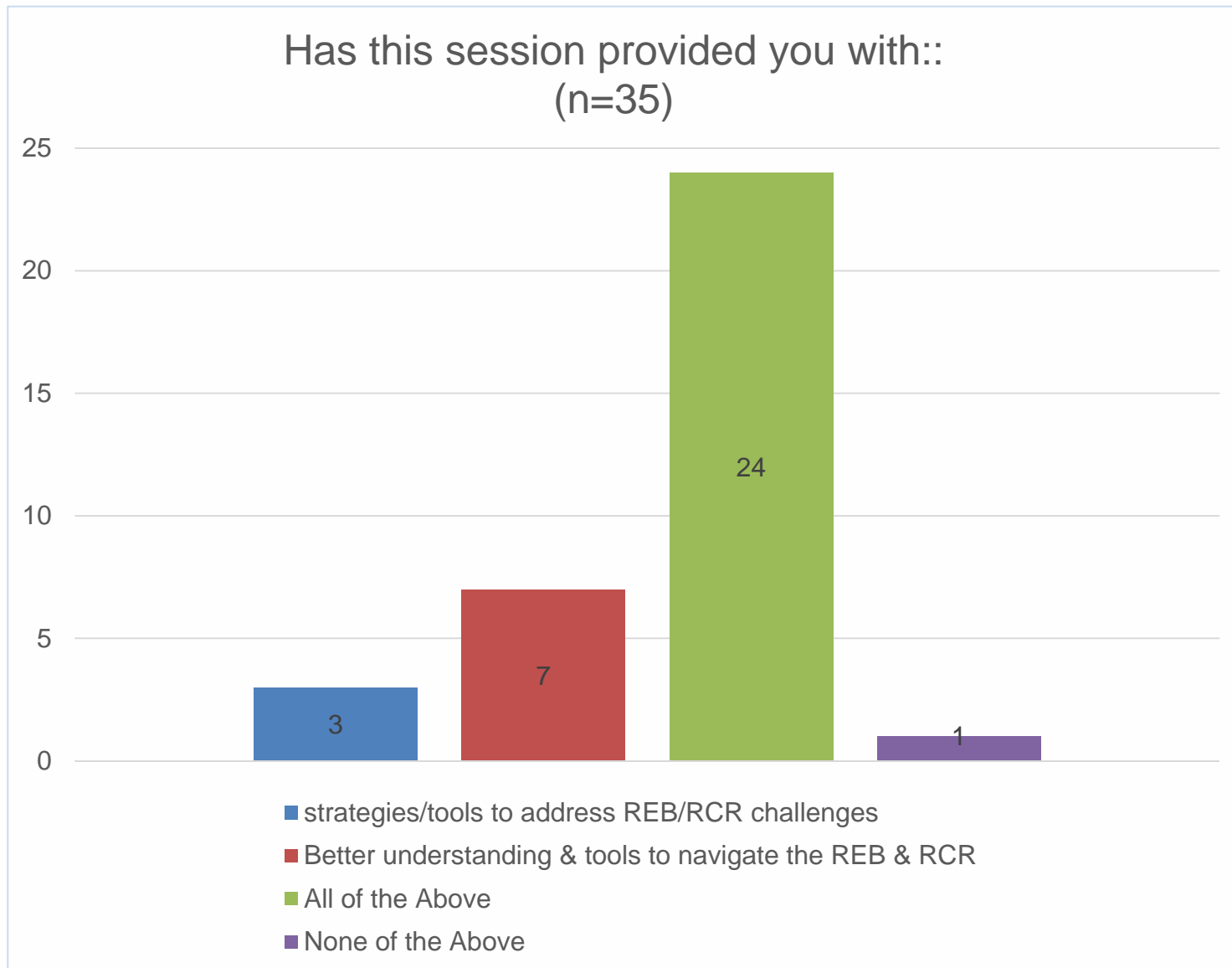


SESSION IMPACT

Kahoot! Poll

Go to: [Kahoot.it](https://kahoot.it)

Session Impact – Kahoot! Poll Results





Thank you for your participation!