Ethics Review During a Pandemic: the experience of REB Offices and their REBs

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Overview

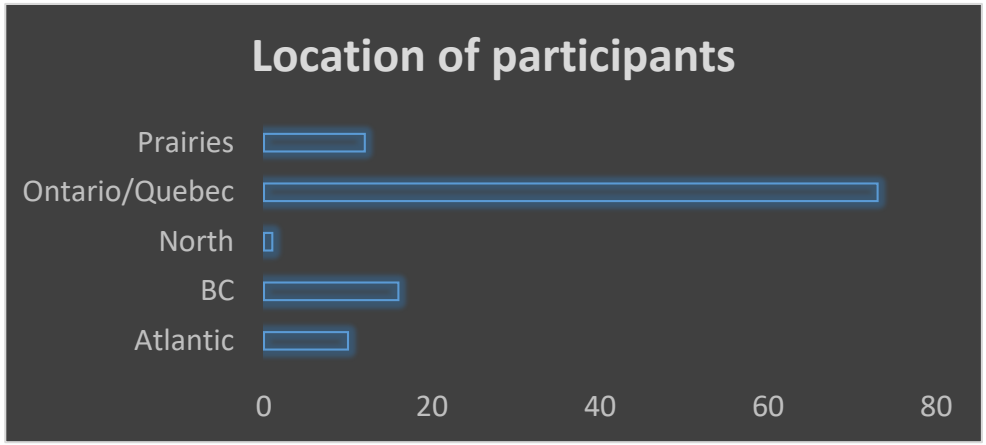
- CAREB-ACCER Initiatives and activities
- Results from June session
- Results from *Survey of Research Ethics Administration and Research Ethics Board Practices for Allowing In-person Research*
- *Highlights*
- *Discussion*

CAREB-ACCER Initiatives related to COVID-19

- Panel session on **Addressing REB Review Challenges for Onsite Research in the Time of COVID-19** in June 2020.
  - How risk is assessed in light of the COVID-19 pandemic
  - REB requirements vs institutional requirements
- **Survey of Research Ethics Administration and Research Ethics Board Practices for Allowing In-person Research**
  - Active from August to November 2020
    - Highest number of responses in mid-to late October and November
  - 24 questions
  - 76 responses
    - 15 from colleges (20%)
  - Typical time spent: 10 minutes
- COVID-19 **Forum** on www.careb-accer.org to discuss and share on various issues; open to non-members
- **Links** to various institutions' COVID-19 webpages posted on our website
- **Monthly engagement sessions** on clinical trial oversight and implementation in Canada, led by Health Canada, with participation from CIHR, CAREB and REBs that frequently review clinical trials in Canada.

Panel session on **Addressing REB Review Challenges for Onsite Research in the Time of COVID-19**

- Reached the maximum of 200 participants
  - 13% College
  - 29% Health care setting
  - 46% University



Speakers shared strategies, best practices and documents on how to re-engage in onsite research in academic and healthcare settings.

- **Eleanor Fitzpatrick**, IWK Health Centre
- **Marie Hirtle**, MUHC
- **Rachel Zand**, University of Toronto
- **Laurel Evans**, UBC

Highlighted issues and questions that needed to be looked into further.

- Led to CAREB-ACCER sending out the survey on COVID-19 practices

Highlights

Effect of the pandemic on REB review of projects (N=109)

69%	REB continued to review, but with modifications (e.g., prioritize COVID-19 projects, no new projects)
28%	continued to review as normal
1%	stopped all operations

Impact of the COVID-19 pandemic on risk levels for research (N=89)

75%	Risk depends
22%	All in-person research activities are now above-minimal risk
2%	Not a risk that goes beyond those experienced by participants in their everyday life

Highlights (cont'd)

Many felt it was important to distinguish between the role of the REB and the role of the

Various approaches in terms of who does the initial assessment of what should be sent for REB review

REB / VPR / Deans / Central

Was REB involved in the plan to restart research at your institute (N=92)

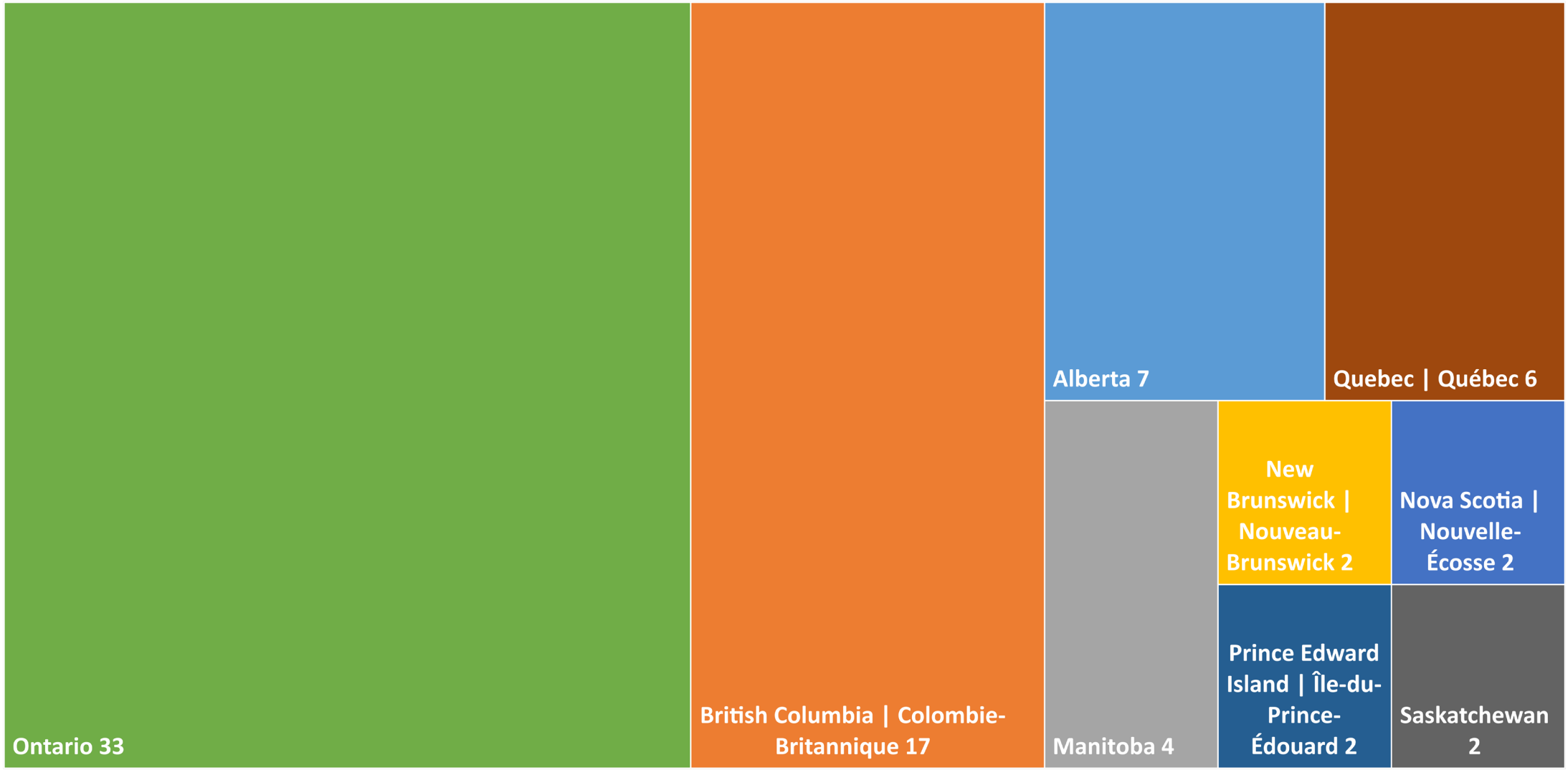
- No 42%
- Yes 58%

9% - only ask the researchers to confirm they will abide by applicable guidelines and regulations

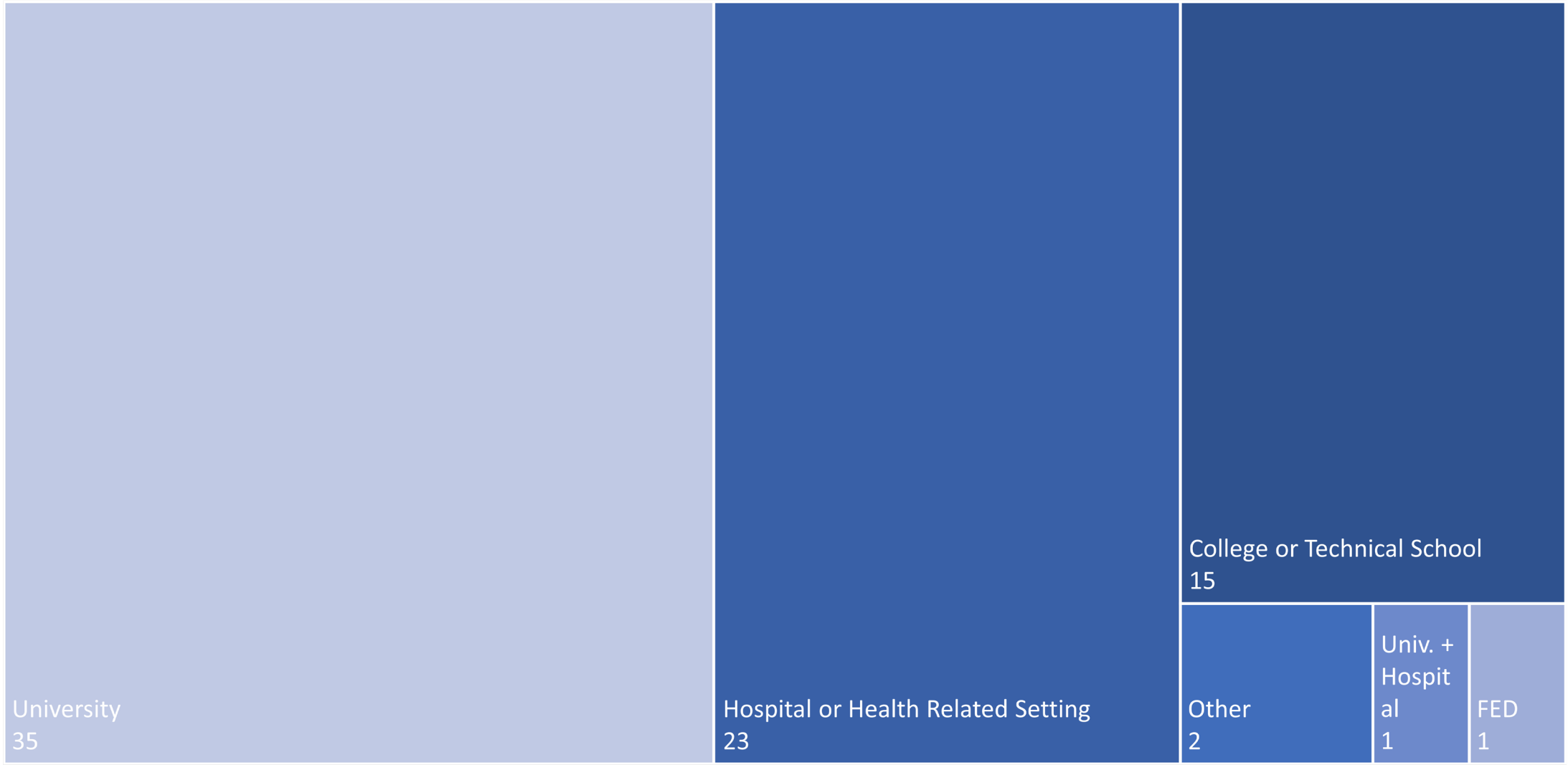
67% - researcher needs to provide detailed information in new protocols describing how COVID-19 will impact in-person research activities

Survey of Research Ethics Administration and Research Ethics Board Practices for Allowing In-person Research

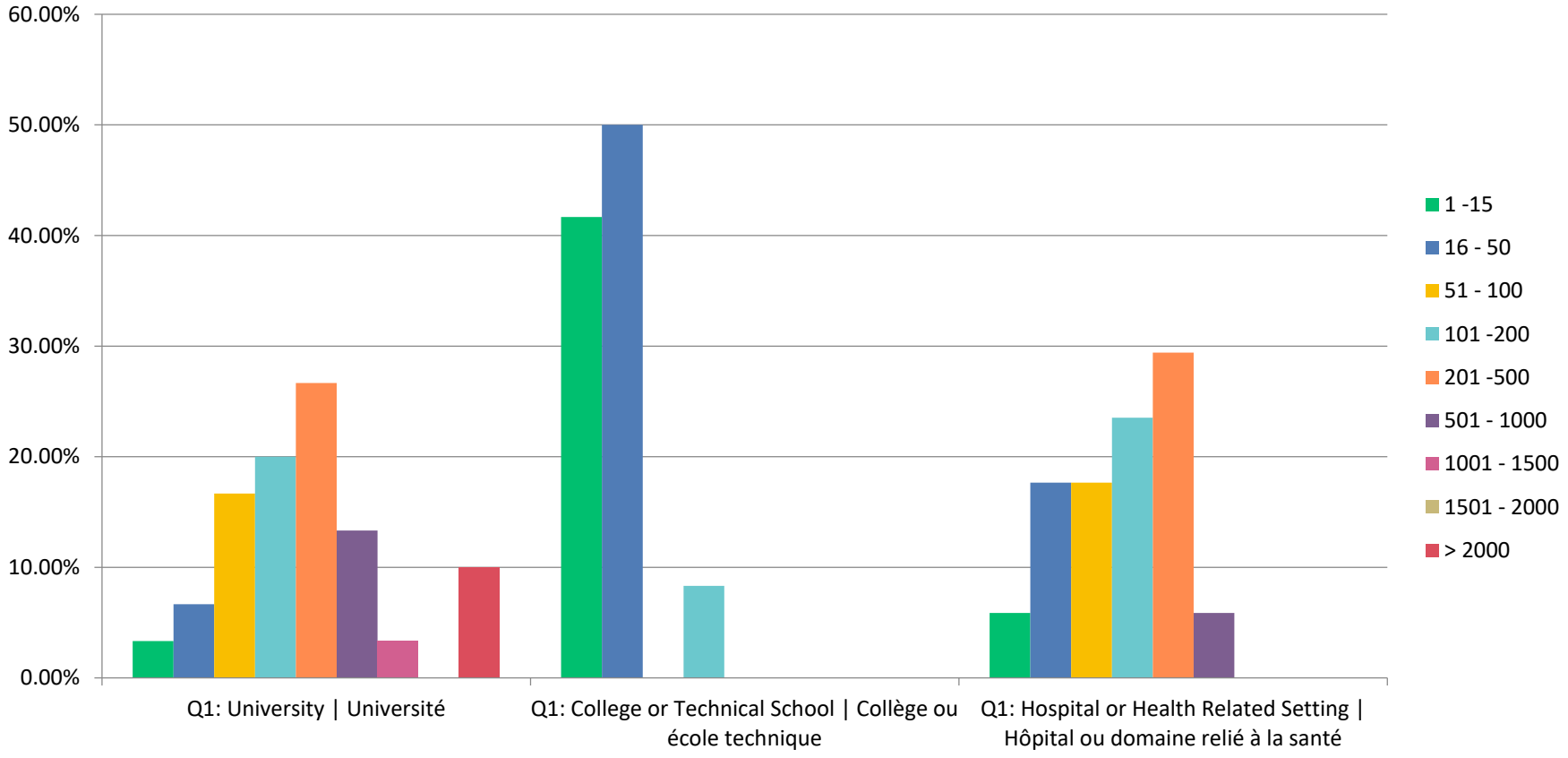
RESPONDENTS BY PROVINCE



RESPONDENTS BY INSTITUTION TYPE



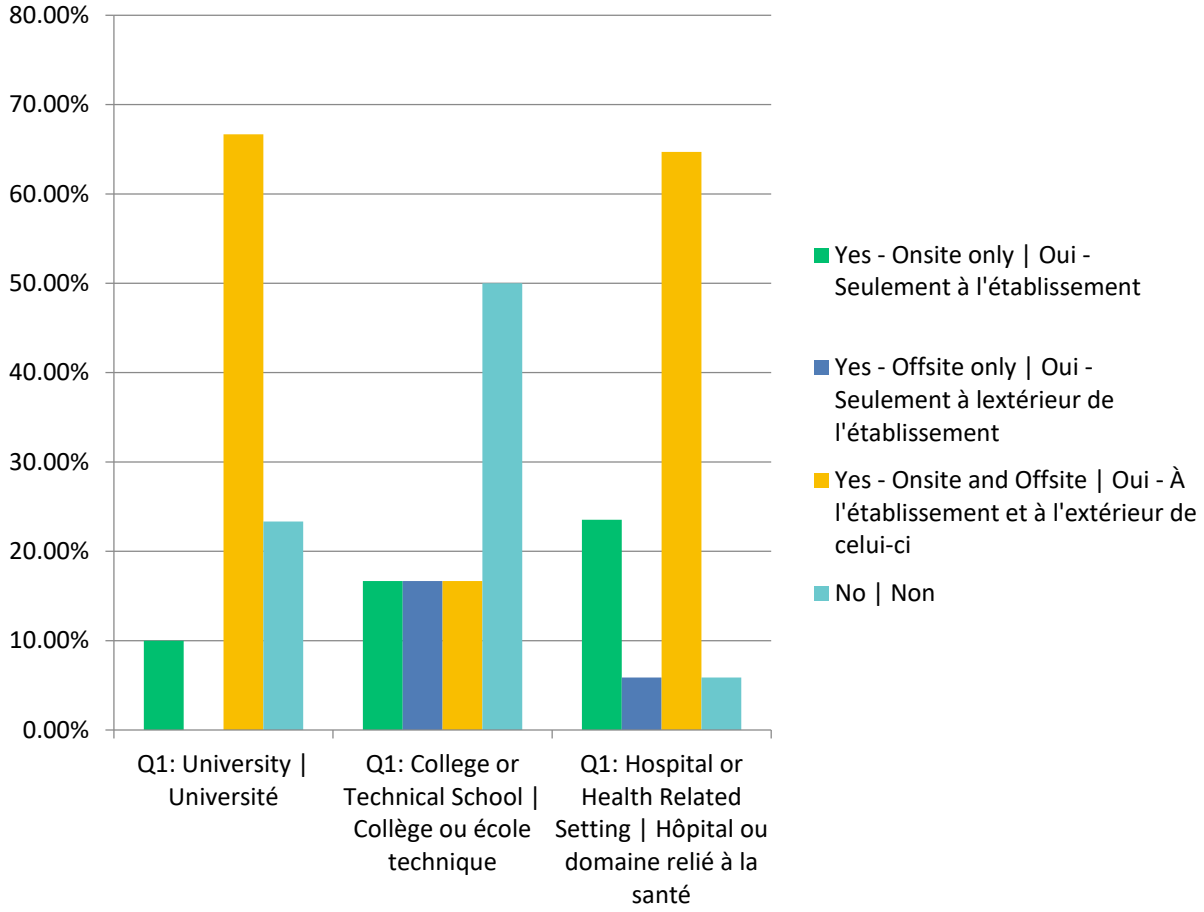
How many new applications (total for all REBs) do you typically review in a 12-month period?



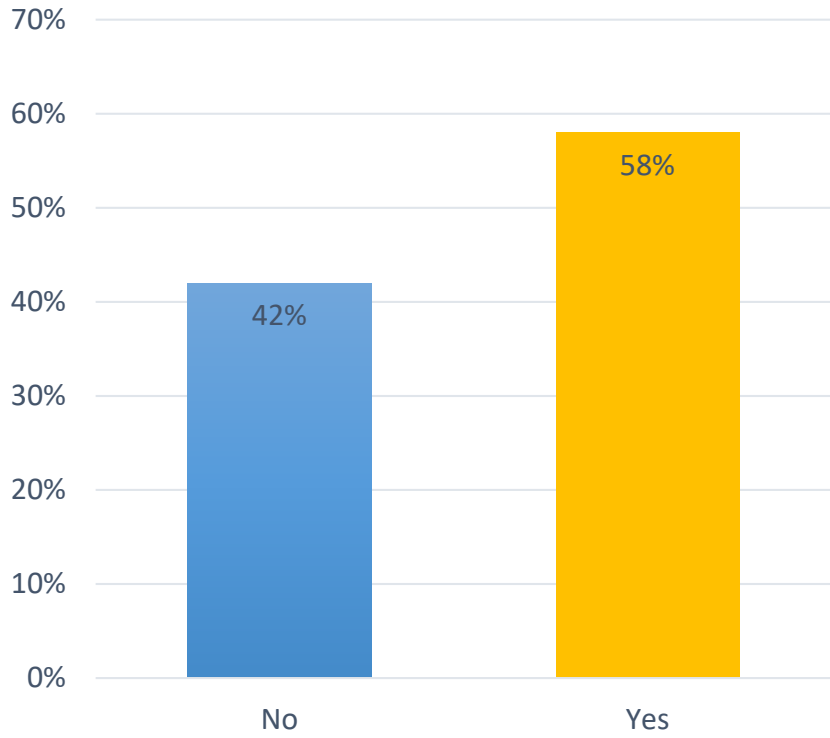
Most colleges reviewed less than 50 protocols annually.

Only one reviewed 101-200/yr.

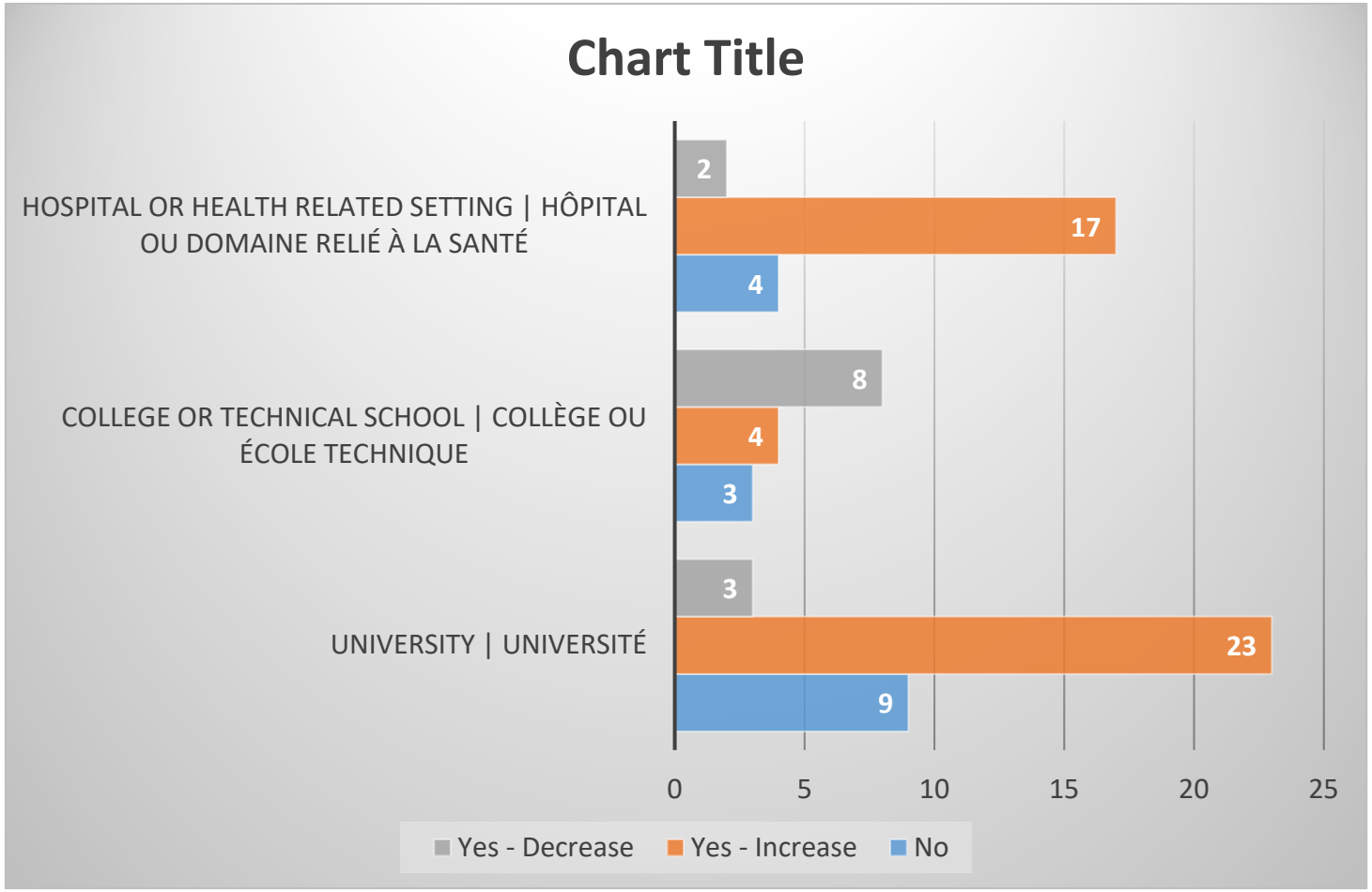
Is your institution currently allowing in-person research to be conducted?Votre établissement permet-il présentement la cherche en présentiel?



June Poll
Was your REB involved in the plan to restart research? (N=92)



Has the workload of your REBs(s) changed since the beginning of the pandemic?



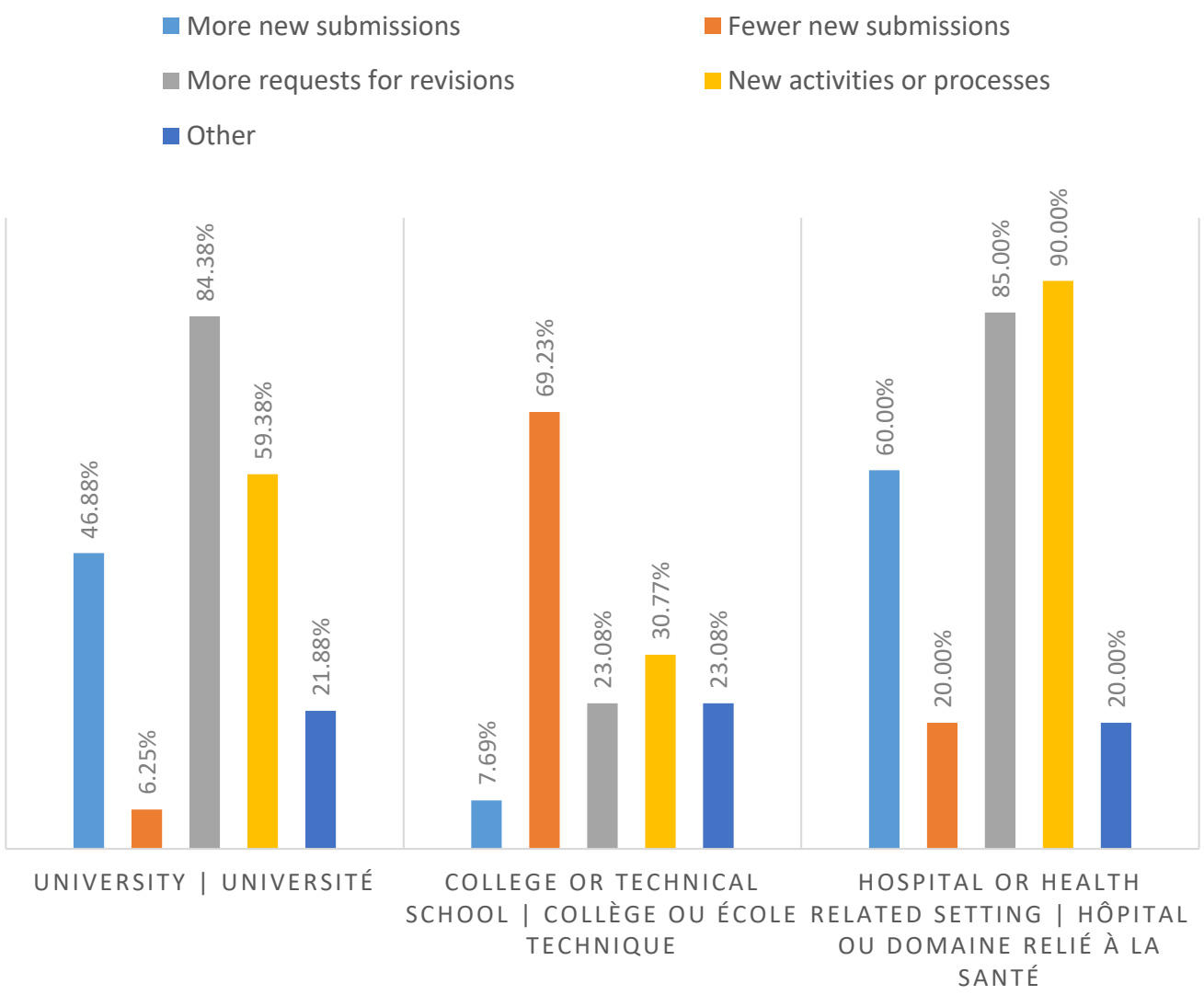
College or Technical School

❑ Most saw a decrease

Comments

- Increased only for August/September when reviewing COVID plans; has decreased now due to fewer new submissions
- Lot more queries, guideline probes to support online research and ethical consideration for PIs

TYPE OF CHANGE IN WORKLOAD



Highlights

- Most colleges saw a **decrease in new submissions**, compared to universities and hospitals who saw an increase. May be due to COVID-specific funding opportunities.
- There was a slight increase in the number of requests for revisions to approved projects
- 30% had to put in place new activities or processes
- Other changes: Data management, storage, disposal and ongoing virtual implications

Do researchers have to submit an amendment request to change their research methods from in-person to virtual for projects that were approved before the pandemic?

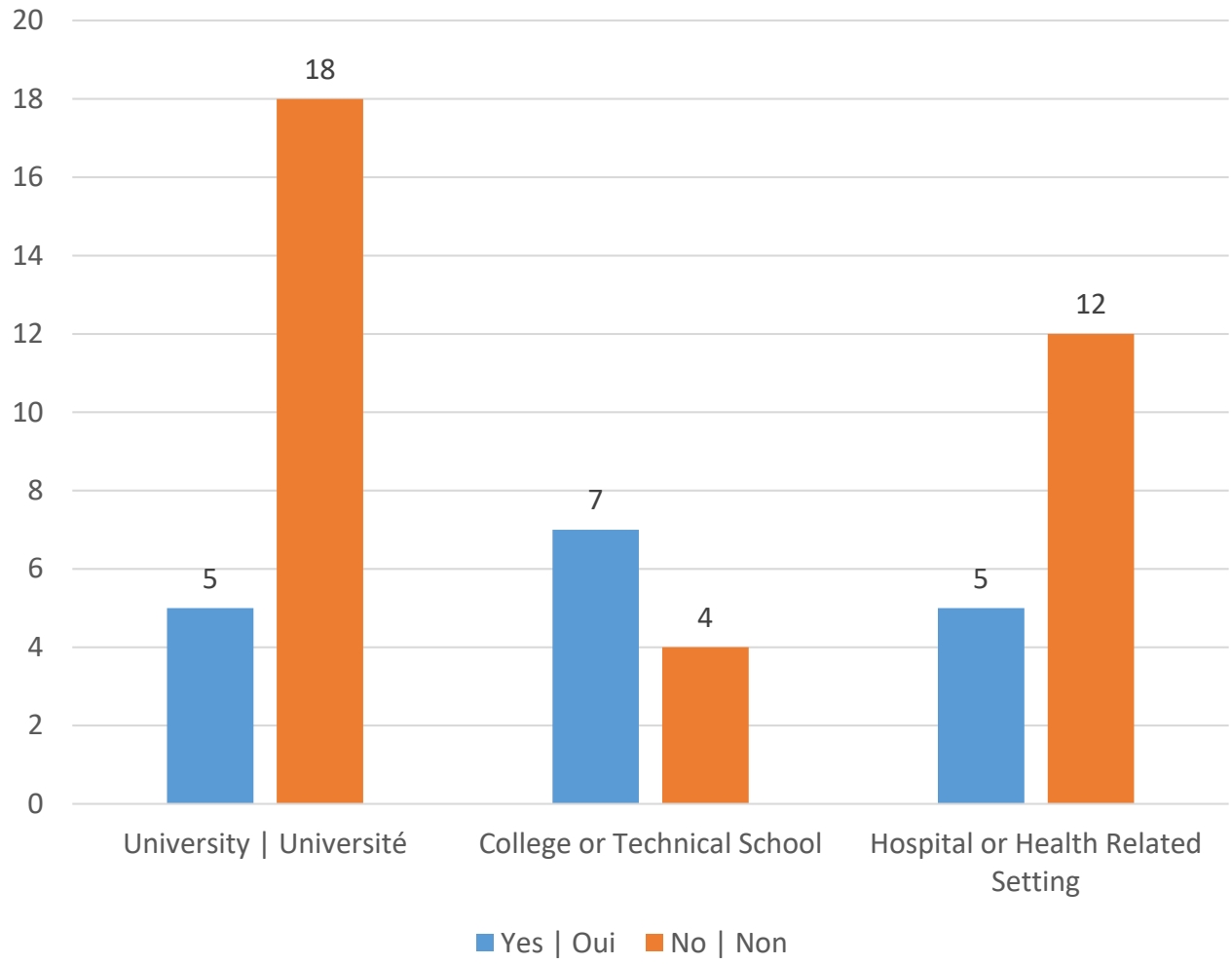
No	16.50%
Yes, but only if there is an increase in risk	25%
Yes, for all changes	58%

Poll from panel session:

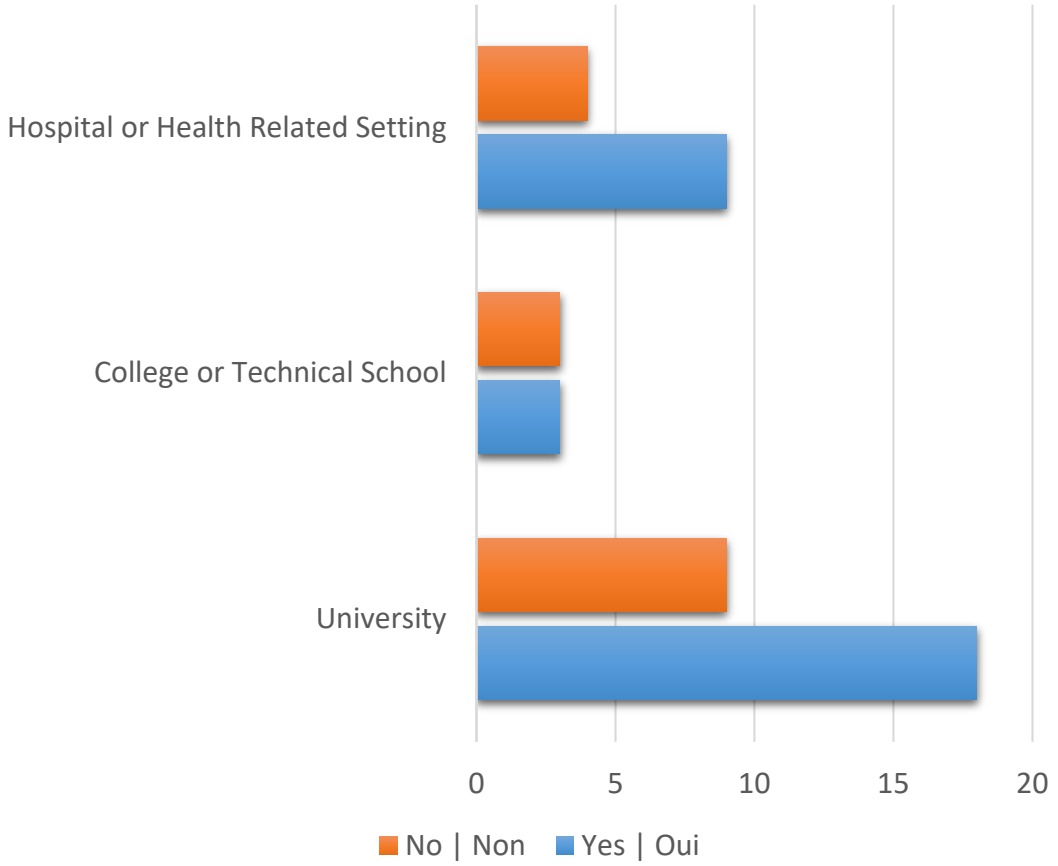
22% indicated they believed the risk for all in-person research activities is now above-minimal risk

Reflected in survey results, but % is higher for Colleges

Is all in-person research at your institution (e.g. amendment requests, new applications) currently considered above minimal risk and being reviewed by the full board?

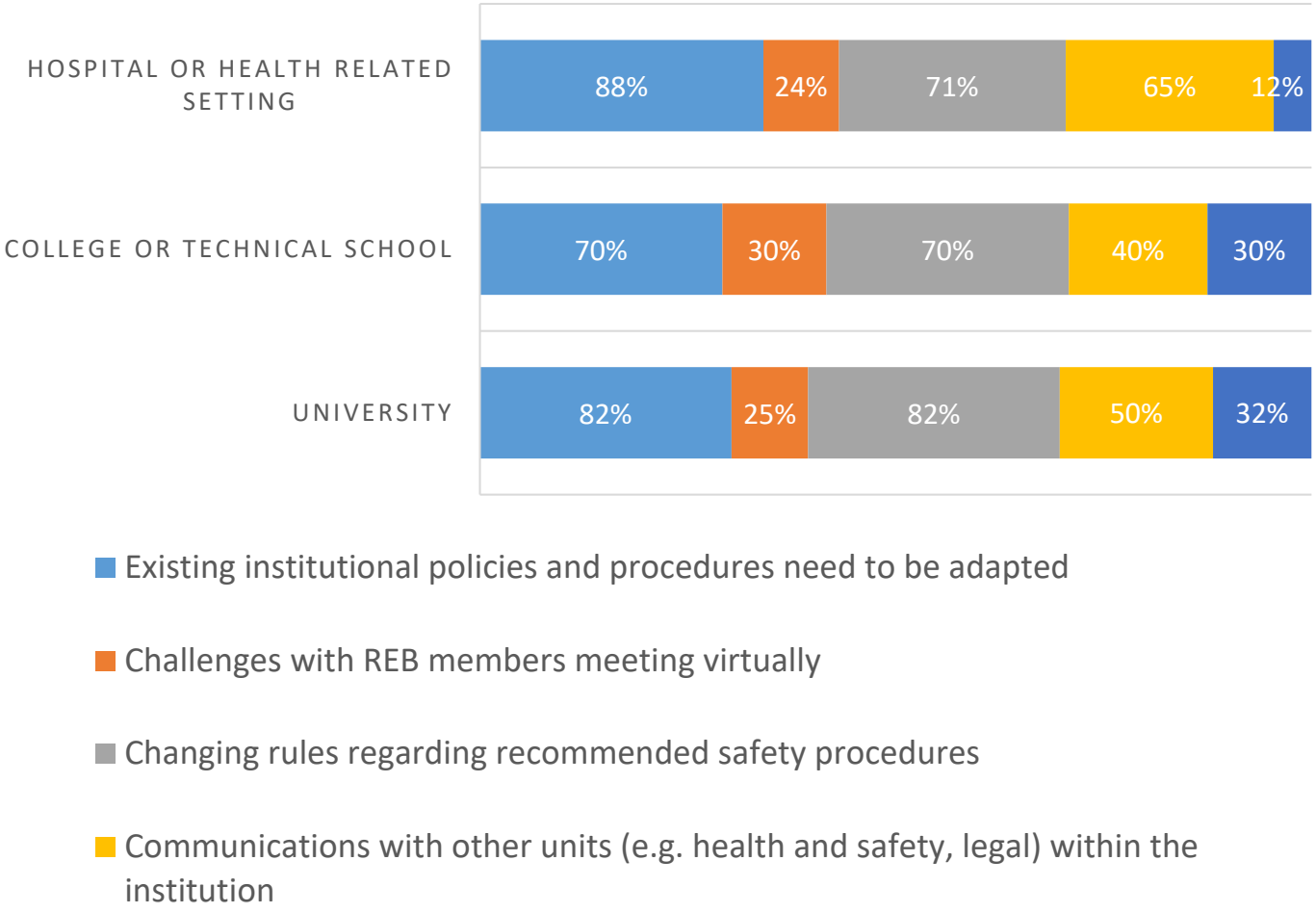


Do you have a staged approach to restarting in-person research?



- Most have 2 or more stages; varies from 2 to 5
- Some are linked to governmental restrictions
- Others differentiate between onsite and offsite activities
- Vulnerability of participants is often considered
- Exceptions are made to restrictions when dealing with COVID-related research

What operational challenges have you faced in terms of review of research in general since the beginning of the pandemic?



Other

- The incredible **complexity** of managing risks associated with face to face research in an **ever-changing** health risk environment
- **Lack of clarity** in guidance to REBs
- Health & safety protocols impose an additional layer of approvals
- **Workload** issues
- **Pressure** from researchers to resume research activities quickly
- Speed at which COVID-related studies were expected to be reviewed
- Training new chairs and members remotely

Strategies and solutions to overcome challenges

Working with institutional counterparts

- IT
- Library
- Research Office
- Health and Safety

REB & REB Office

- Increasing capacity; Hiring contract staff
- Developing new workflows for COVID projects
- Regular team meetings
- Waiver of written consent
- Revised SOP on research during publicly declared emergencies.

Remain up to date on new information coming from local and federal health units

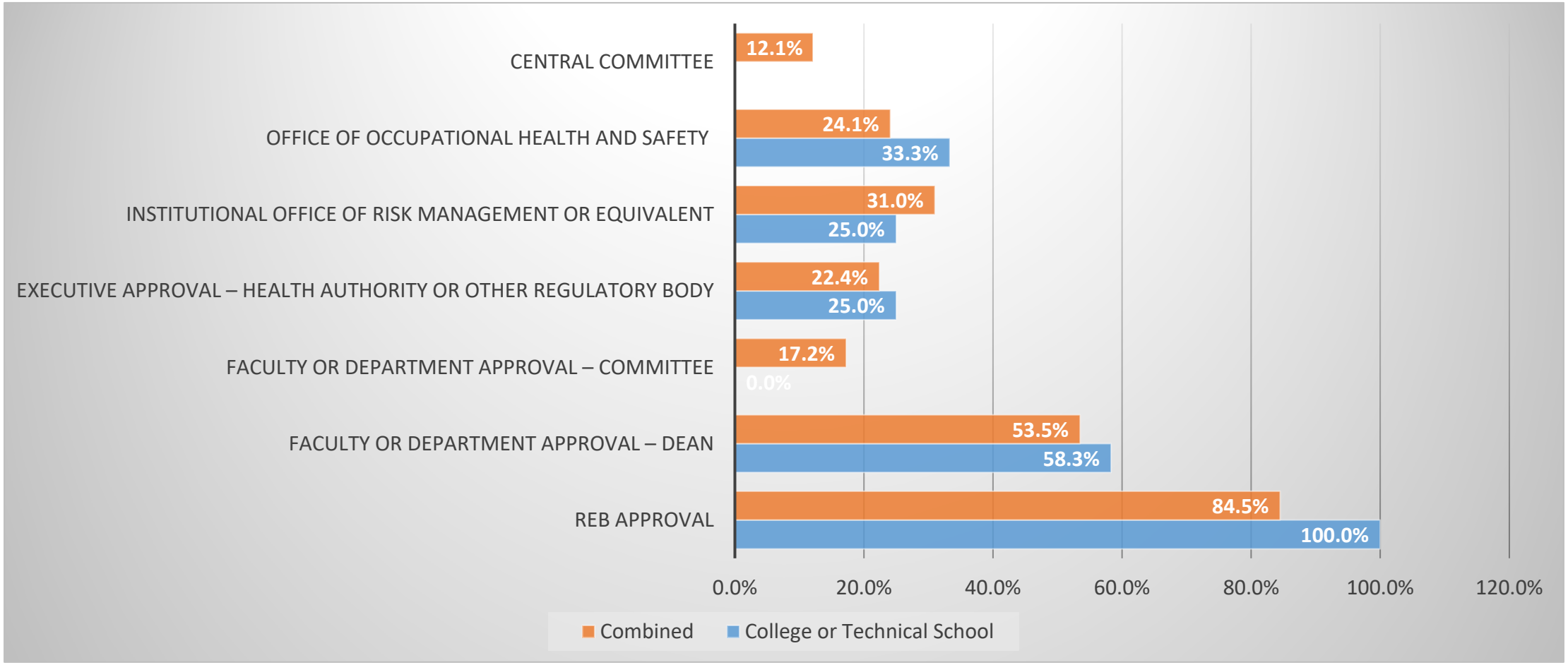
Communication with researchers
From VP research to deans
VP research website
Newsletters

Speak with other REBs locally and nationally

Develop Guidelines for in-person research

- Steps
- Criteria
- Levels or tiers to determine urgency
- REB guidance document with new risks related to conducting research during a pandemic

What approvals must researchers obtain in order to proceed with in-person research?



Do researchers have to develop a safety plan and/or a Standard Operating Procedure (SOP) in order to proceed with in-person research?

All Colleges ask for a Safety plan

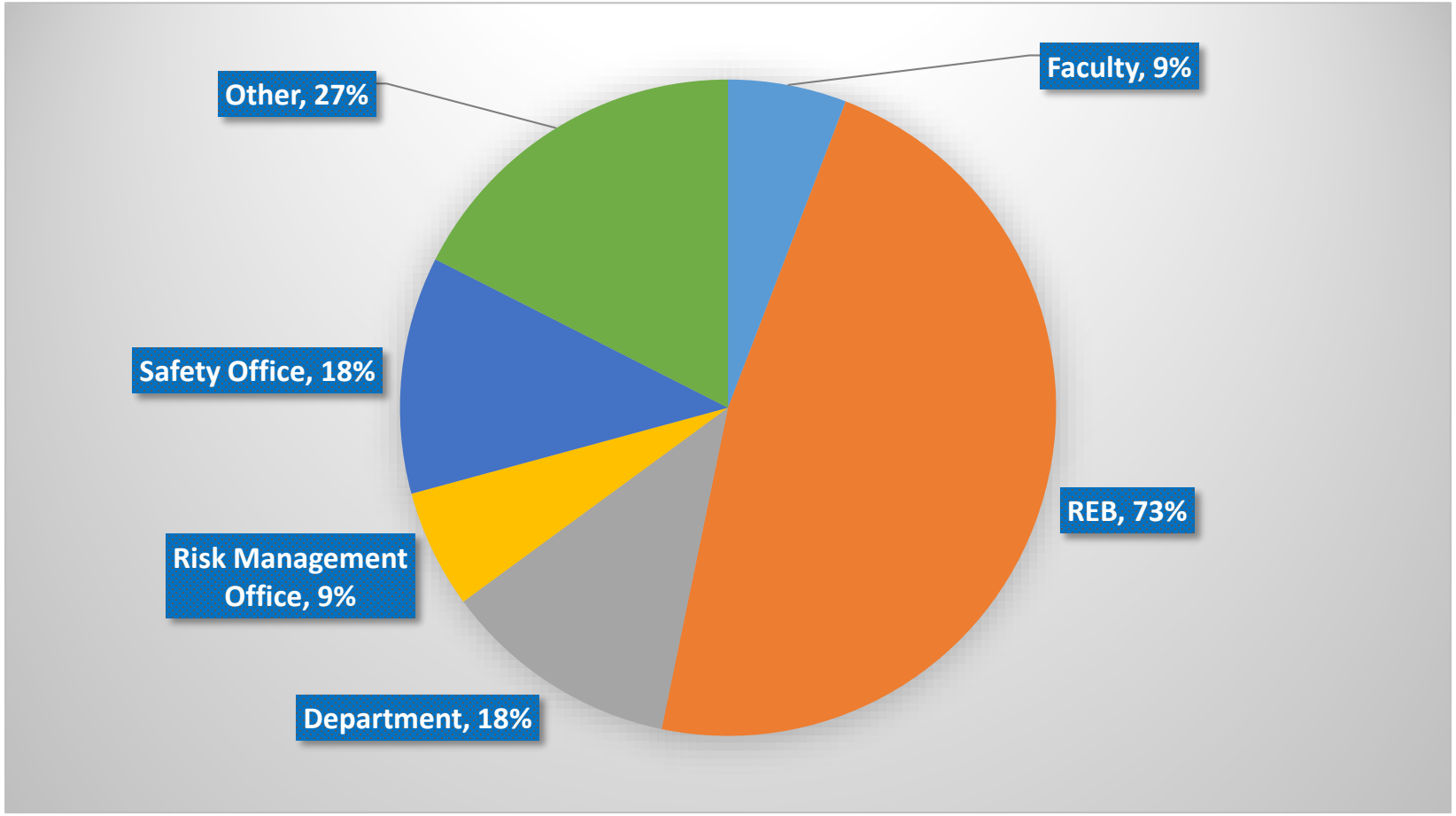
87% of Universities

63% Hospitals & Health Setting

Comments

- Researchers are expected to follow institutional guidelines, whether on site or in the field
- Imposed by the institution and researchers will have to follow the institutional plan
- They must develop one for the institution in order to access campus. The same safety plan must be included in their REB submission. The REB May request adjustments in order for the safety plan to be participant centric.
- Checklist / modification form to articulate the provisions they are enacting
- Administration developed a health & safety plan following the provincial guidelines
- Safety plan is included in the Risk Assessment Form
- Plan is sent to the faculty for sign-off, then sent to the REB
- They must mention that they will follow the governments' public health directives at the time. However, most researchers are opting for virtual/phone consent and data gathering

Who evaluates the plan (Colleges)?



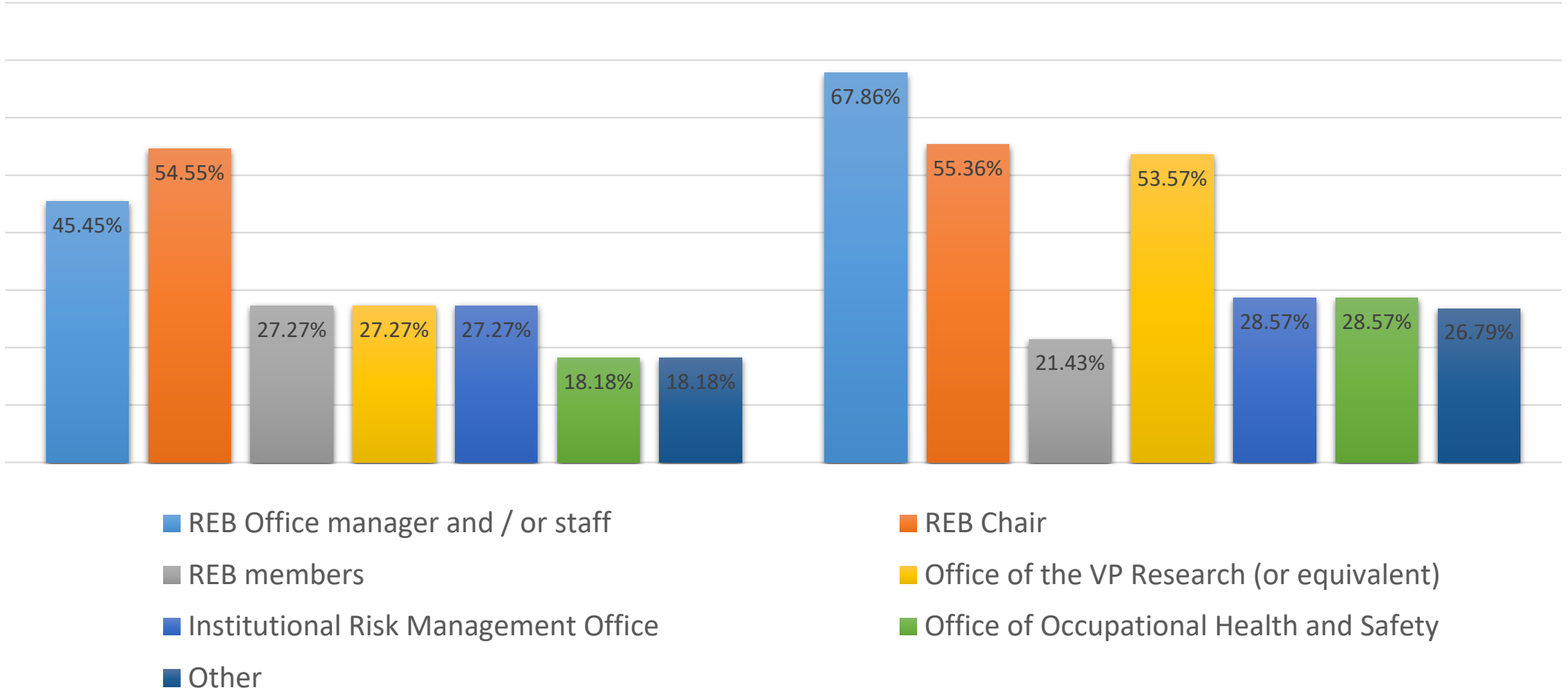
Other

- Direction
- Senior Management

What type of documents has your institution developed to guide researchers?

Documents	%
Guidelines relating to safety plan	27.3%
Checklist to assess risk	36.4%
Guidelines to assess / justify the need for in-person research	36.4%
Guidelines to assess urgency of review of in-person research	9.1%
Information and Consent document language (either as addendum or integrated)	54.5%
Additional form to be submitted to the REB	18.2%
Other: Researchers are following the college policies related to in person activities broadly. These were developed by administration.	9.1%

Who was involved in developing these documents?



Final thoughts

- There still isn't a standardized approach across institutions
- There continues to be a wide variety of approval processes between institutions, e.g.,
  - Central committees
    - sometimes but not always involving the REB
  - Review of safety plans by deans or central (for some but not all)
    - can precede or follow REB review
- Most institutions have taken the position that research with humans falls under the auspices of the institution and not the REB
  - Comfort with risk and exposure varies across sites
  - The institution's perception and comfort with risk to participants and that of the REB aren't always aligned
  - Impact on researchers and students not viewed the same way by REB as by insitution
- The ever-changing status of COVID-19 cases continues to be an issue in managing the ethical review of research involving humans.
- May researchers seem to find it difficult to think outside the box and change their projects to move away from in-person research activities, even when risks exist.

Questions
Discussion