

# Research Ethics Office

## Information Session – Spring 2023

April 27, 2023

# Welcome to our first Information Session!



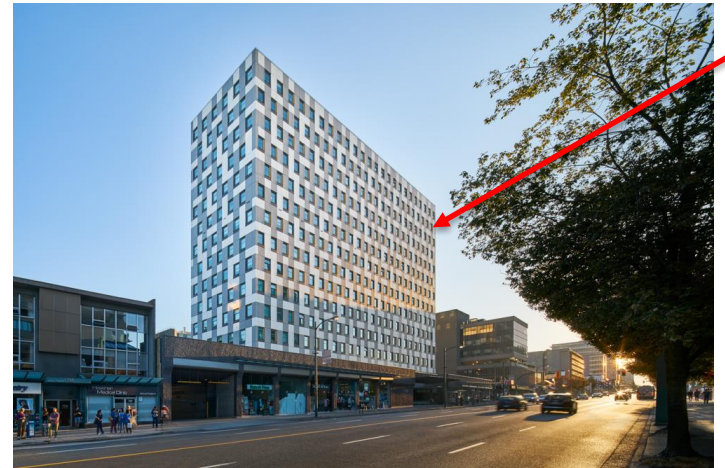
# AGENDA

---

- Introduction – meet our newest member!
- TCPS2 – 2022 updates
- Ethics Education Survey results
- Q & A

# Introduction

- 1 Director, 3 Officers  
NEW Officer: **Melissa Riding**
- Fairmont Medical Building 13<sup>th</sup> floor
- REB Chairs & members
- **Updated [Website](#)** :
  - Newsletter
  - More detailed submission guides
  - Ethics Education Resources
  - This presentation + recording



# TCPS2 Updates 2022

---

1. Broad consent
2. Multi-jurisdictional review
3. Totipotent stem cells/human cell lines
4. Revised & Additional definitions

# 1. Broad & Blanket consent: New uses/restrictions

**NEW! Broad Consent for storage of data and biospecimens:** *New addition* to TCPS to allow for **future unspecified research** with restrictions\*

\*e.g. consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry

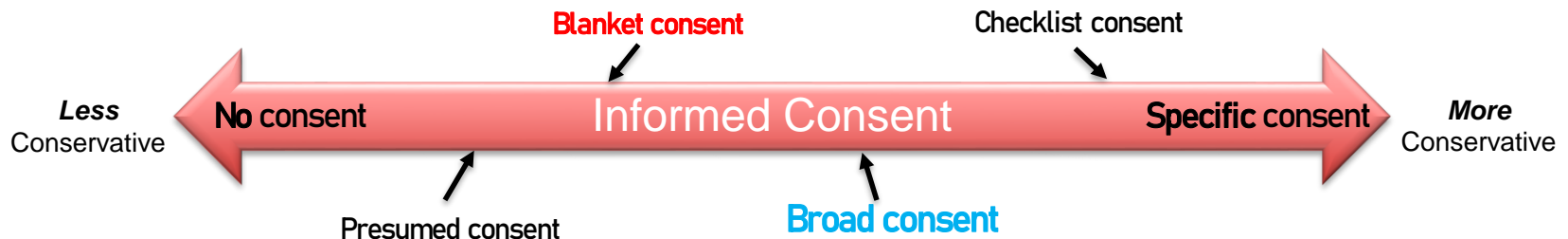
- Allows for future research using data/biospecimen without requiring participant re-contact

*As opposed to*

**Blanket Consent:** unrestricted use of data/biospecimens



**Not permitted** under TCPS2



# 1. Broad Consent: NEW Considerations for Biobanks

\*BC Cancer is already factoring these into our REB review – no further requirements



## REB review of Biobanks/Data Repository

1. Contributing biospecimens requires *additional separate Optional Consent \*in addition to main study consent\**
2. Biobanks require *initial and ongoing REB review*

**Evolving consent capacity** (i.e. developing, partially developed, diminished, fluctuating)

- *Researchers need to develop a mechanism to maintain informed and ongoing consent from donors for biobanks*



## Shared responsibility

- *Researcher, relevant authority of the repository, and future researchers to ensure patient respect*

## 2. Streamlining multi-jurisdictional research ethics review of minimal risk studies

- **NEW!** REB Multi-Jurisdictional Review model:

1. Research Ethics Review Delegated to an External, Specialized or Multi-
2. Reciprocal REB Review



### 3. Single REB Review for Minimal Risk Research:

*Key Message: Streamlined multi-jurisdictional ethics review of minimal risk research is **encouraged** without a requirement for official agreements amongst institutions.*



*Multi-jurisdictional reviews should happen more seamlessly*

4. Independent Ethics Review by More than One REB

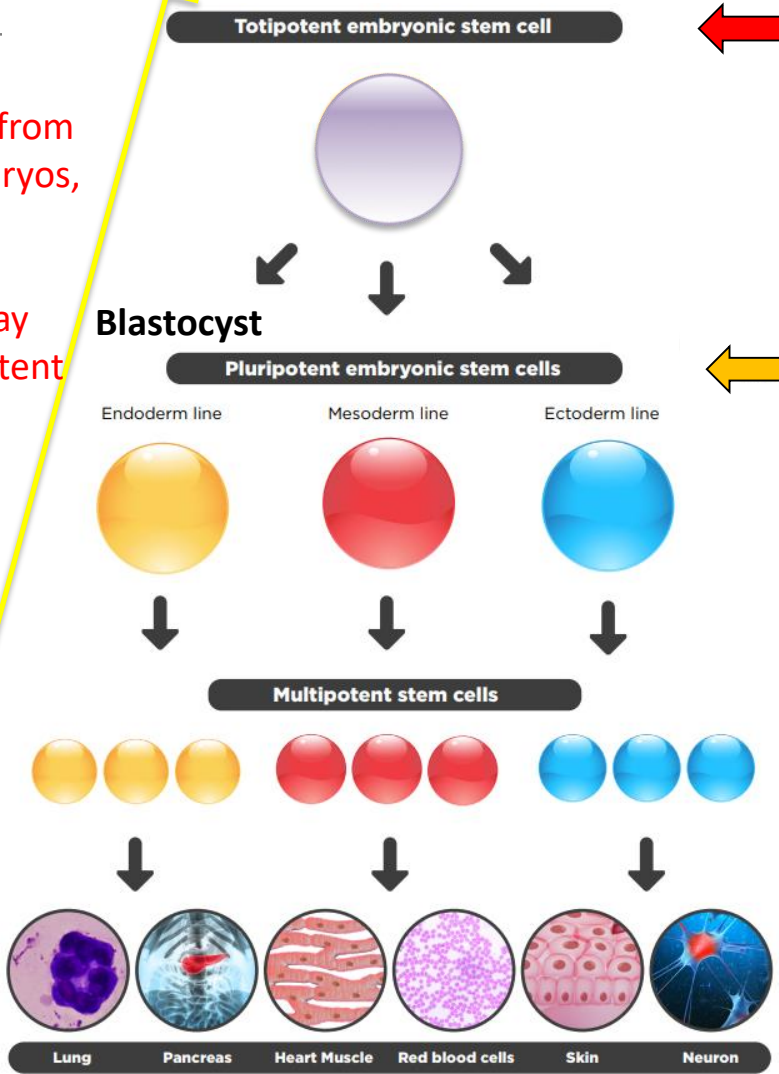
**Note:** Provincial legislation or policies that designate one or more REBs for the review of certain types of research **supersede the review models listed above**



# 3. Research involving human totipotent stem cells - Revised Definitions

## (Human) Embryonic stem cell

An embryonic stem cell derived from a human embryo. A cell derived from early stage human embryos, up to and including the blastocyst stage, that is pluripotent and that may be able to adopt totipotent potential under certain conditions



## Totipotent stem cell

A cell that can become **all the cell types** that are found in an implanted embryo, fetus, or developed organism, **including embryonic components of the trophoblast and placenta**

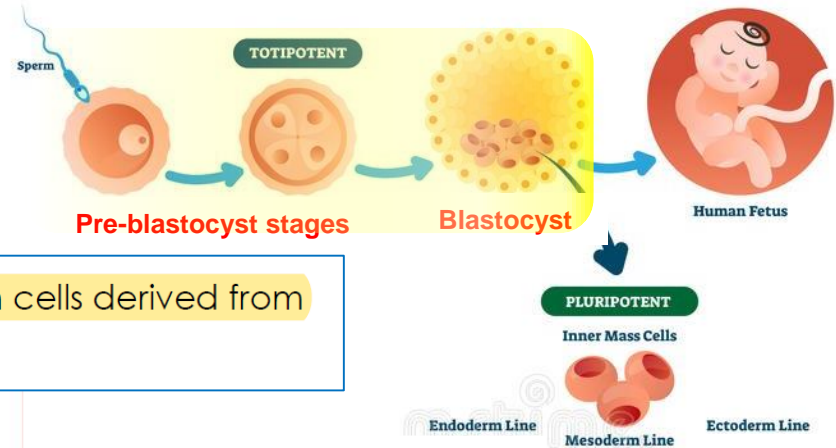
## Pluripotent stem cell

A cell that can become all the cell types that are found in an implanted embryo, fetus or developed organism, **but not embryonic components of the trophoblast cells that form components of the placenta**. Pluripotent stem cells include embryonic stem cells, induced pluripotent stem cells and embryonic germ cells

### 3. TCPS2 has provided further guidance for research involving human **totipotent** or **pluripotent stem cells**

- Stem Cell Oversight Committee (SCOC) **does not permit:**

b. Research involving the creation of blastocysts from cells derived from pre-blastocyst stage human embryos;



#### **Revised Consent for Embryonic Stem Cells Donation:**

- As a way of streamlined approach, initial consent for use of biospecimens can include the option to donate for research purposes (i.e. **broad consent**)
- **Re-consent** is required **from donor** for use in research to derive and study embryonic stem cells **only when substantially deviating** from original consent terms
- Participants have the right to **withdraw** at any time **until ~~an anonymized or coded cell line is created~~ it becomes impossible or impracticable** to do so.

### 3. NEW! Cell Lines **Exempt** from REB review



- **NEW Section G** added on “Cell Line Exemptions”
  - Studies **relying exclusively on secondary use of human somatic cell lines** are exempt from REB review based on the following conditions:

#### Exempt from REB review

Re-use of **de-identified** human somatic cell lines, where:

- Researcher **complies with known consent terms**
- Researcher **does not know or have access to the participant identity**
- Researcher **will not** take any steps to **identify the participant**
- Research is **unlikely to reveal the identity**

Re-use of **identified** human somatic cell lines (e.g. HeLa cell lines), where:

- Cell line is **already available** and identified in **public domain**
- Seeking consent is **impossible or impracticable**
- Researcher **complies with known consent terms**
- Research is **unlikely to harm** the participant



# TCPS 2 – SUMMARY OF DEFINITION CHANGES

## REVISED definitions

<b>Biobank</b>	Better aligns with internationally accepted definitions
* <b>Consent</b>	Addition of authorized third party involvement
<b>Embryonic stem cell (ESC)</b>	Pluripotent and potential for totipotency in certain conditions
<b>Human ESC (hESC)</b>	Same as ESC
<b>Pluripotent stem cell</b>	Potential to become all cell types <u>except</u> placental cells

## NEW definitions

* <b>Blanket consent</b>	Unrestricted use – NOT PERMITTED
* <b>Broad consent</b>	Unspecified future use – PERMITTED with RESTRICTIONS
<b>Repository</b>	Data repository or biobank that must ensure safe storage, preservation and curation of data and biospecimens
<b>Research data repository</b>	Organized data stored for specific or future unspecified research
* <b>Whole-genome sequencing</b>	Sequencing of DNA to generate the genome or exome sequence
* <b>Totipotent stem cell</b>	Cell with potential to become all cell types

# TCPS 2 – SUMMARY OF UPDATES

- i. **Broad consent** to allow for inclusion of data or biospecimens in a **biobank for future unspecified research** and a streamlined approach for **stem cell use** (unless research substantially deviates from original consent terms)
  - ✓ Samples are more accessible for future research projects
- ii. **Single REB review is encouraged** for minimal risk multi-jurisdictional studies
  - ✓ More cohesive minimal risk review process
- iii. **Stem cell research** restrictions clarified on the types of **research that cannot be conducted**
  - ⊘ Restricts the creation of blastocysts from pre-blastocyst stage embryos
- iv. **Addition of “totipotent”** to address studies involving totipotent stem cells
  - ✓ TCPS2 updated to reflect scientific accuracy
- v. **REB Review Exemption** for research that relies exclusively on the re-use of **de-identified human somatic cell lines** and **identified human somatic cell lines in the public domain** (e.g. HeLa cell line)
  - ✓ No ethics application required!



Provincial Health Services Authority

# Survey Results:

## Research Ethics Education

BC  
CAN

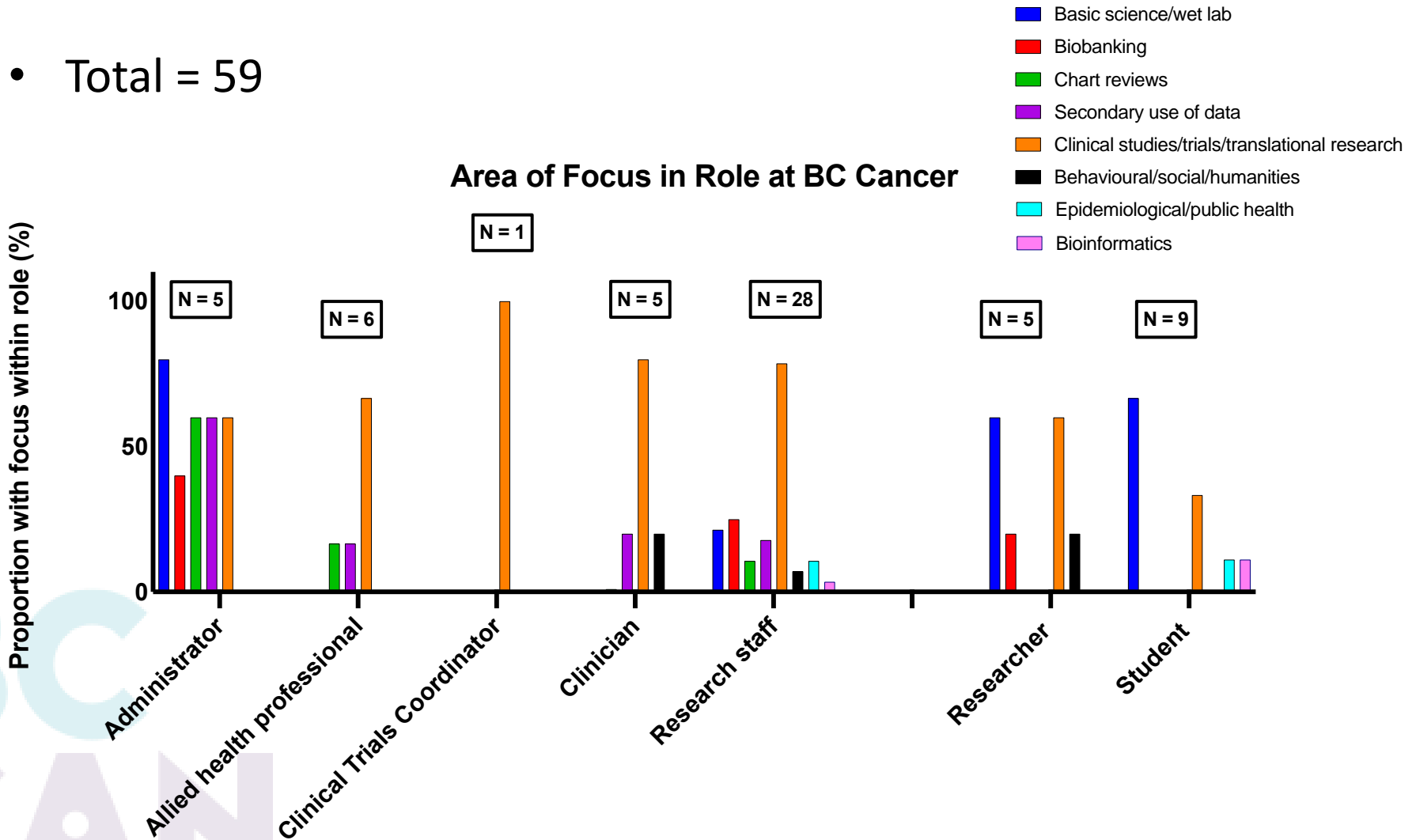
# Survey Overview

---

- Question: **What research ethics education resources are you aware of and what topics would like to learn more about?**
- Goal: **Identify areas of need and provide appropriate resources and support.**
- Gathered information in September-November 2022
- **HERE ARE THE RESULTS!**

# Participant Demographics

- Total = 59





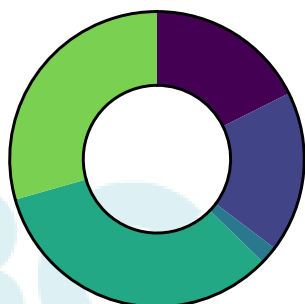
# Familiarity with Legislations and Regulations

## Health Canada Food and Drug Regulations Part C Division 5



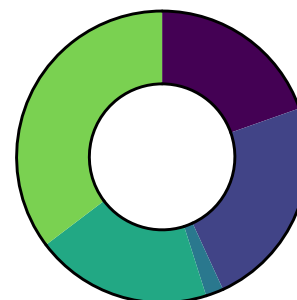
- 9.80% Am aware of and read some parts
- 23.53% Never heard or read
- 11.76% Not applicable to my research
- 23.53% Read it once or more
- 31.37% Understood/Applied it in my work

## “The Common Rule” – Federal Policy for the Protection of Human Subjects



- 17.65% Am aware of and read some parts
- 17.65% Never heard or read
- 1.96% Not applicable to my research
- 33.33% Read it once or more
- 29.41% Understood/Applied it in my work

## Federal/Provincial Privacy Laws: PIPEDA, FOIPPA, PIPA

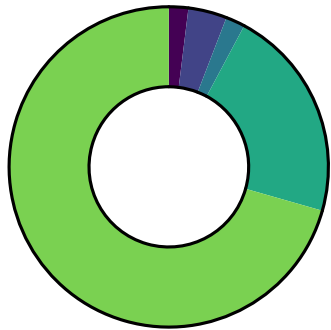


- 19.61% Am aware of and read some parts
- 23.53% Never heard or read
- 1.96% Not applicable to my research
- 19.61% Read it once or more
- 35.29% Understood/Applied it in my work

- ~30% of survey takers understood and applied to work
- Less than 25% never heard or read

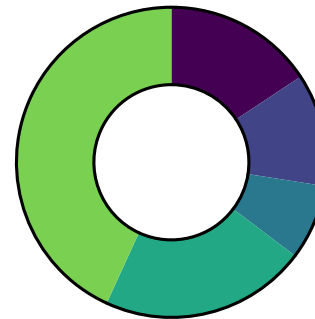
# Familiarity with Policies and Guidelines

## TCPS 2



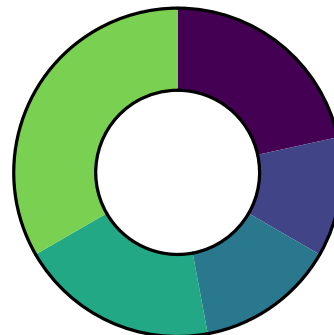
- 1.96% Am aware of and read some parts
- 3.92% Never heard or read
- 1.96% Not applicable to my research
- 21.57% Read it once or more
- 70.59% Understood/Applied it in my work

## ICH-GCP (Good Clinical Practice)



- 15.69% Am aware of and read some parts
- 11.76% Never heard or read
- 7.84% Not applicable to my research
- 21.57% Read it once or more
- 43.14% Understood/Applied it in my work

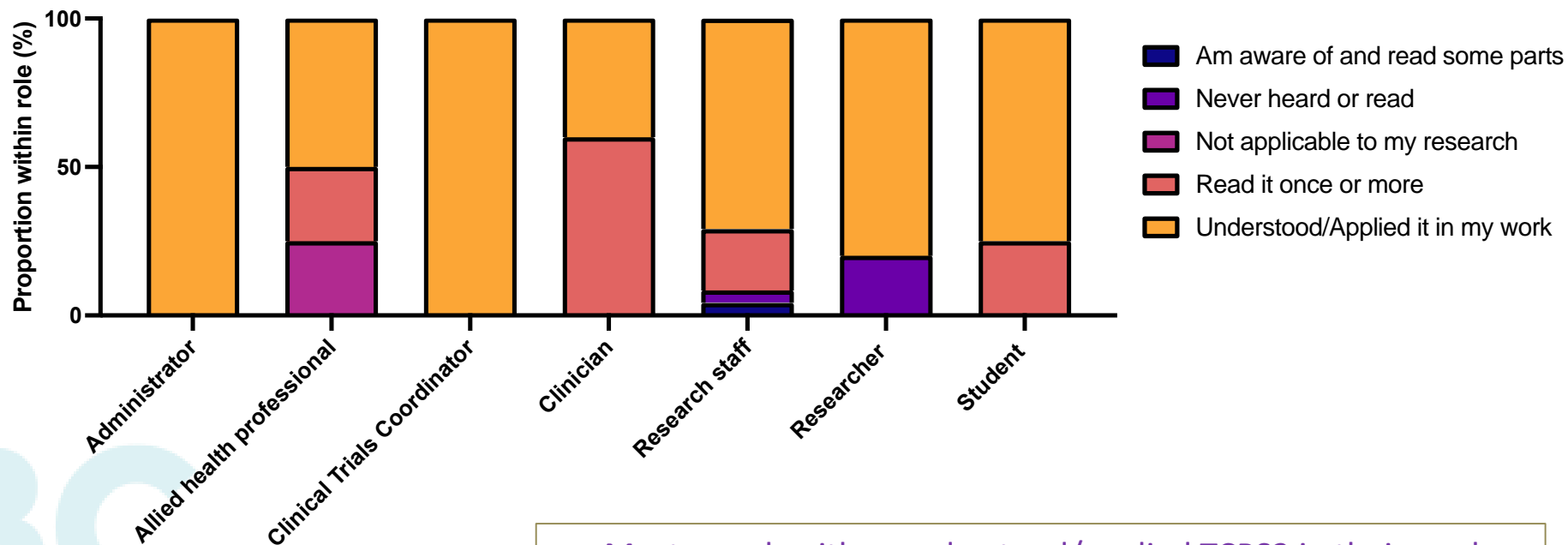
## Health Canada applications for Clinical Trials and Medical Devices



- 21.57% Am aware of and read some parts
- 11.76% Never heard or read
- 13.73% Not applicable to my research
- 19.61% Read it once or more
- 33.33% Understood/Applied it in my work

# Familiarity with TCPS2 at BC Cancer

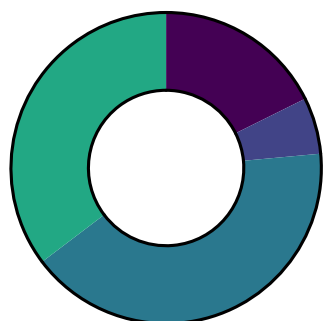
Familiarity of TCSP2 in Role at BC Cancer



- Most people either understood/applied TCPS2 in their work or at least have read it once or more.

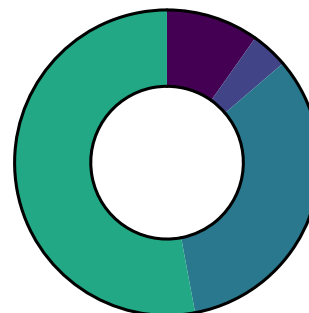
# Familiarity with Institutional Policies/Guidance

## PHSA Research Policies



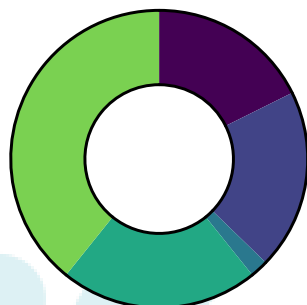
- 17.65% Am aware of and read some parts
- 5.88% Never heard or read
- 41.18% Read it once or more
- 35.29% Understood/Applied it in my work

## BC Cancer Research Ethics Guidance



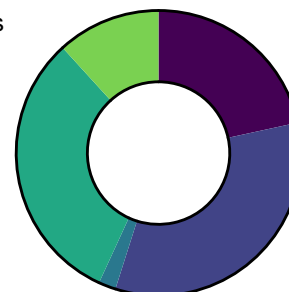
- 9.80% Am aware of and read some parts
- 3.92% Never heard or read
- 33.33% Read it once or more
- 52.94% Understood/Applied it in my work

## BC Cancer ICF Templates



- 17.65% Am aware of and visited/read some parts
- 19.61% Never heard, read, or visited
- 1.96% Not applicable to my research
- 21.57% Read/Visited once or more
- 39.22% Understood/Applied it in my work

## BC Cancer Research Ethics Newsletter

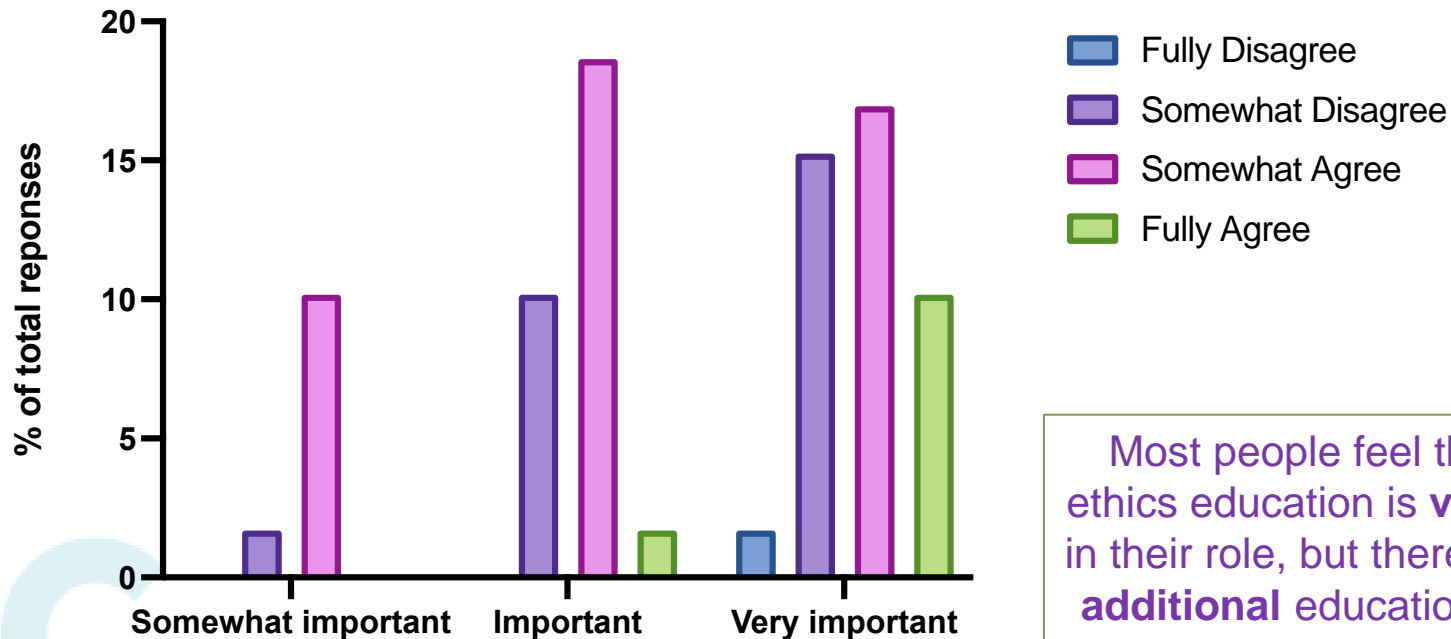


- 21.57% Am aware of and visited/read some parts
- 33.33% Never heard, read, or visited
- 1.96% Not applicable to my research
- 31.37% Read/Visited once or more
- 11.76% Understood/Applied it in my work

<http://www.bccancer.bc.ca/our-research/ethics-oversight/researchethics>

# Is there adequate Research Ethics resource available? How important is this for you?

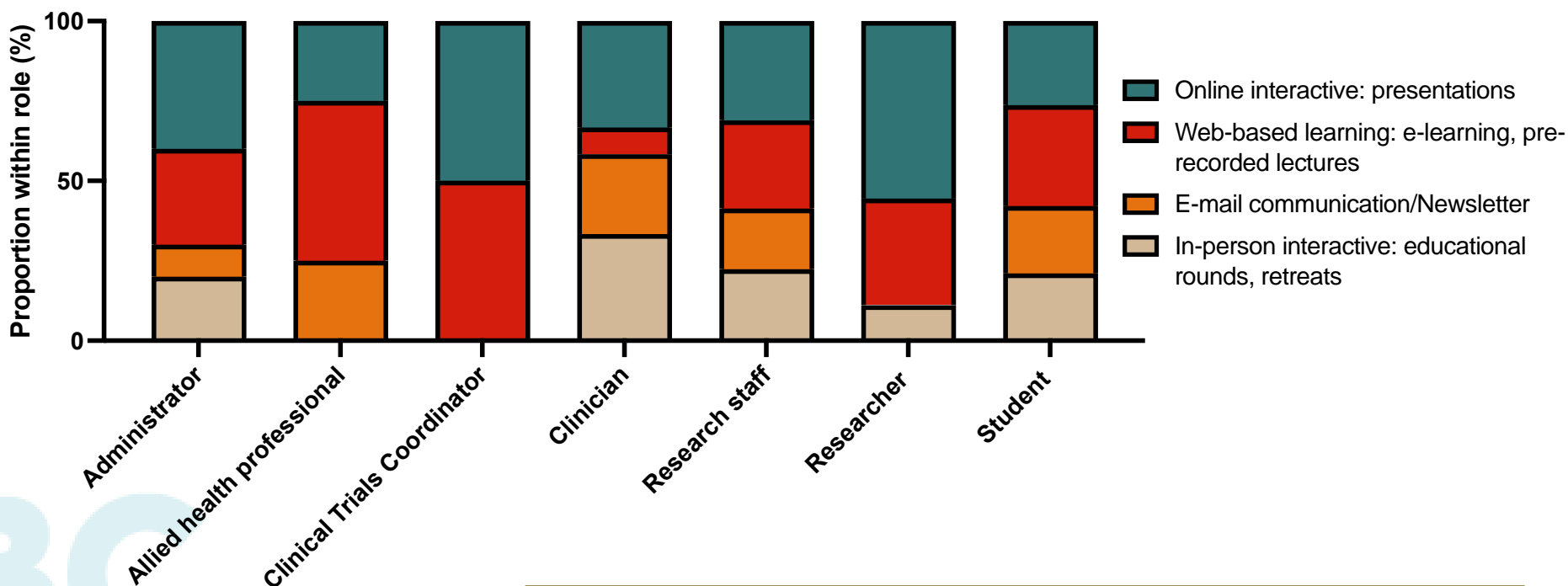
## Adequate resources and frequency of educational resources at BC Cancer Research Ethics



Most people feel that research ethics education is **very important** in their role, but there is a **need for additional** educational resources

Importance of research ethics education in current role

# How do you prefer to learn?



- Most people collectively chose online/web-based methods
- Least preferred was e-mail communication/newsletter

# What Topics are of Your Interest?

---

## **Research Development:**

- Research methodology
- QA/QI vs Research
- Ethics review process

## **Indirect Human Studies**

- Databases/registries/biobanks
- Secondary use of data/samples
- Waiver of consent

## **Direct Human Studies**

- Recruitment, informed consent process, capacity issues
- Privacy/Confidentiality
- Genetic/hereditary/incidental findings

## **Clinical Trials**

- Institutional approvals
- Adverse events
- Interaction with industry

## **Dissemination of Results**

- Knowledge translation
- Results dissemination

**THANK YOU!**

**Questions & Answers**



Go to [www.menti.com](http://www.menti.com) and use the code 3791 6911

# Which Research Ethics topic(s) do you feel you'd like more support in? Mentimeter



GO TO  
**menti.com**  
ENTER THE CODE  
**3791 6911**  
7