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# PHO Webinar: Public Health Ontario's (PHO) Ethics Review and Support Services: Information Session

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Ontario's 34 Public Health Units[1]

- Algoma Public Health
- Brant County Health Unit
- Chatham-Kent Public Health
- Durham Region Health Department
- Eastern Ontario Health Unit
- Grey Bruce Public Health
- Haldimand-Norfolk Health Unit
- Haliburton, Kawartha, Pine Ridge District Health Unit
- Halton Region Health Department
- City of Hamilton Public Health Services
- Hastings Prince Edward Public Health
- Huron Perth Public Health
- Kingston, Frontenac, Lennox & Addington Public Health
- Lambton Public Health
- Leeds, Grenville and Lanark District Health Unit
- Middlesex-London Health Unit
- Niagara Region Public Health

- North Bay Parry Sound District Health Unit
- Northwestern Health Unit
- Ottawa Public Health
- Peel Public Health
- Peterborough Public Health
- Porcupine Health Unit
- Public Health Sudbury & Districts
- Renfrew County & District Health Unit
- Simcoe Muskoka District Health Unit
- Southwestern Public Health
- Thunder Bay District Health Unit
- Timiskaming Health Unit
- Toronto Public Health
- Region of Waterloo, Public Health
- Wellington-Dufferin-Guelph Public Health
- Windsor-Essex County Health Unit
- York Region Public Health
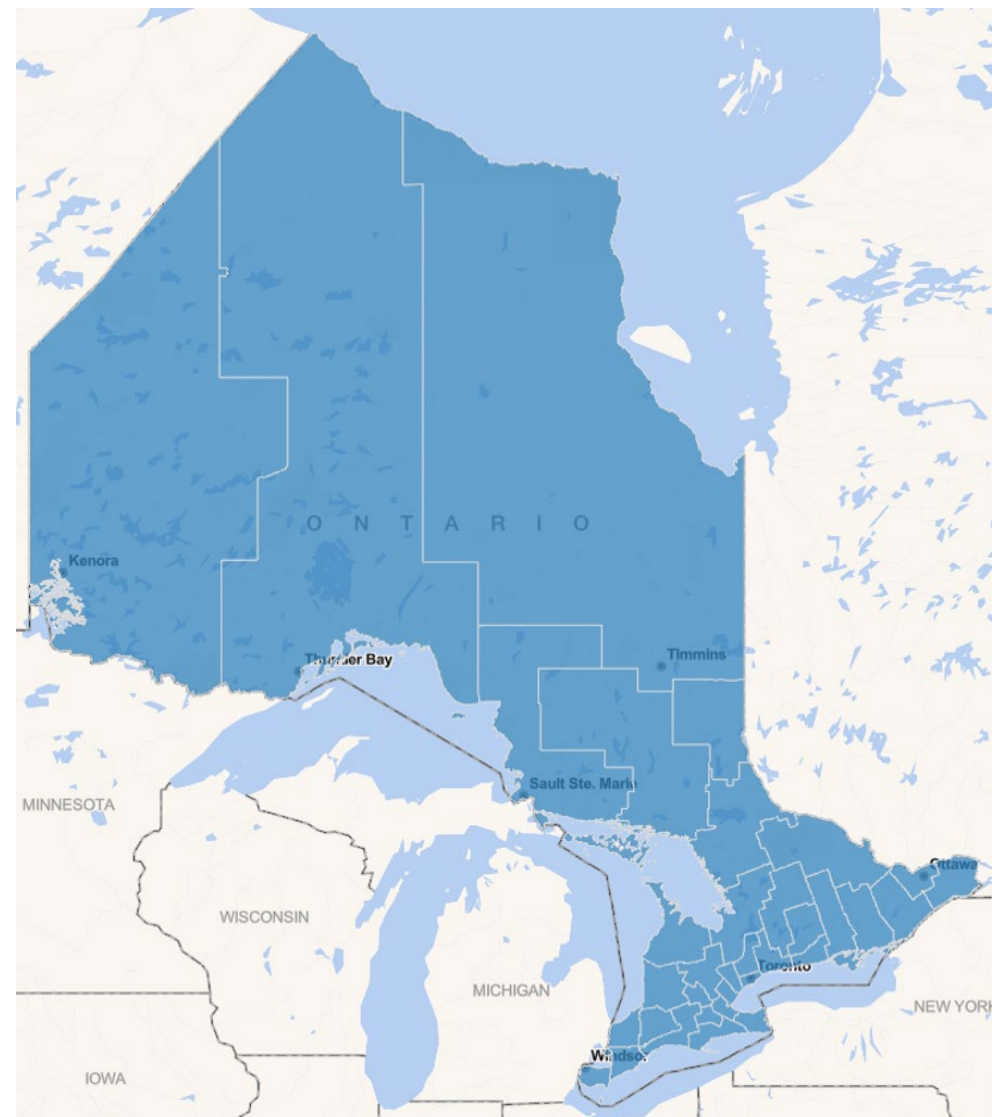
By the end of this session, participants will be able to:

Describe PHO's ethics review framework and model

Explain the various types of ethics review and capacity building support services offered to PHUs

Describe the ethics review submission and review process

List current resources and tools as well as future ideas for education and training sessions

Let's hear from you!

PHO's Ethics Services: Who We Are?

PHO's Ethics Services Team

- **Nancy Ondrusek** | Director of Research and Ethics Services

- **Jo Cenaiko** | Research Ethics Coordinator

- **Charoula Tsamis** | Research Ethics Officer

- **Elizabeth Peter** | Ethics Review Board (ERB) Chair

- **ERB Members** (16)

Role of Research Ethics Coordinator (REC)

- Liaise with applicants, ERB members and Chair

- Coordinate project submission process, assignment of reviews

- Assist with education and training sessions

- **Primary contact for submissions and questions or concerns**

Jo Cenaiko
Research Ethics Coordinator

Role of Research Ethics Officer (REO)

- Conducts low-risk reviews on behalf of the ERB

- Conducts pre-review (including RST validation) of all ERB submissions to ensure that they are complete and comprehensive

- Develops resources and tools

- Manages education and training sessions

- Provides ethics consultations

- **Primary contact for ethics consults and PHU capacity building initiatives**

Charoula Tsamis
Research Ethics Officer

Ethics Review Board (ERB) Chair

- Professor at the Lawrence S. Bloomberg Faculty of Nursing, University of Toronto

- Member of the Joint Centre for Bioethics

- Chair of the Health Sciences REB at the University of Toronto from 2013 to 2019

- Interdisciplinary background in nursing, philosophy and bioethics

Elizabeth Peter
Research Ethics Board Chair

PHO's Ethics Review Board (ERB)

- Receives administrative support from PHO's Ethics Services team

- Independent in its operations and decision making

- Compliant with national research ethics standards *(Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) 2022)*[1]

- Members are selected from a variety of organizational settings and geographical regions across Ontario

- Members represent a range of methodological expertise in public health

PHO's Ethics Review Board: Public-facing Website

Ethics Review Board

PHO's Ethics Review Framework and Model

Traditional Approach to Research Ethics Review:

Tri-Council Policy Statement

Ethical Conduct for Research Involving Humans

TCPS2 2022

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Government of Canada Gouvernement du Canada
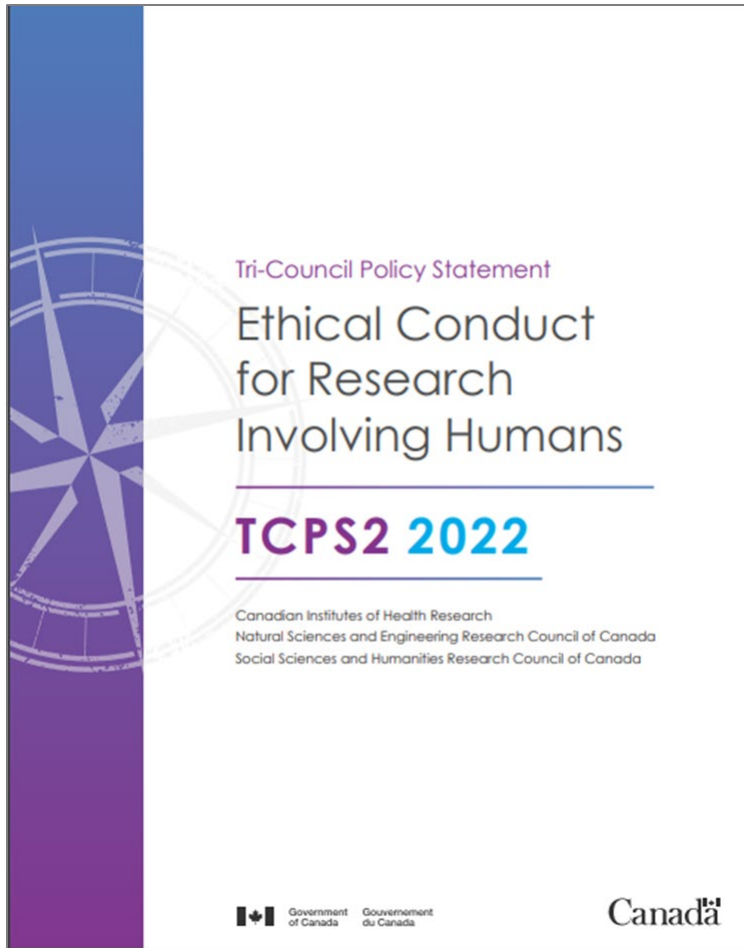
Canada

Canada's research ethics guidelines

- **Recent updates: TCPS 2 (2022)[2]**
  https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

- **TCPS 2: CORE-2022
  (Course on Research Ethics):**
  https://tcps2core.ca/welcome

Traditional Approach to Ethics Review
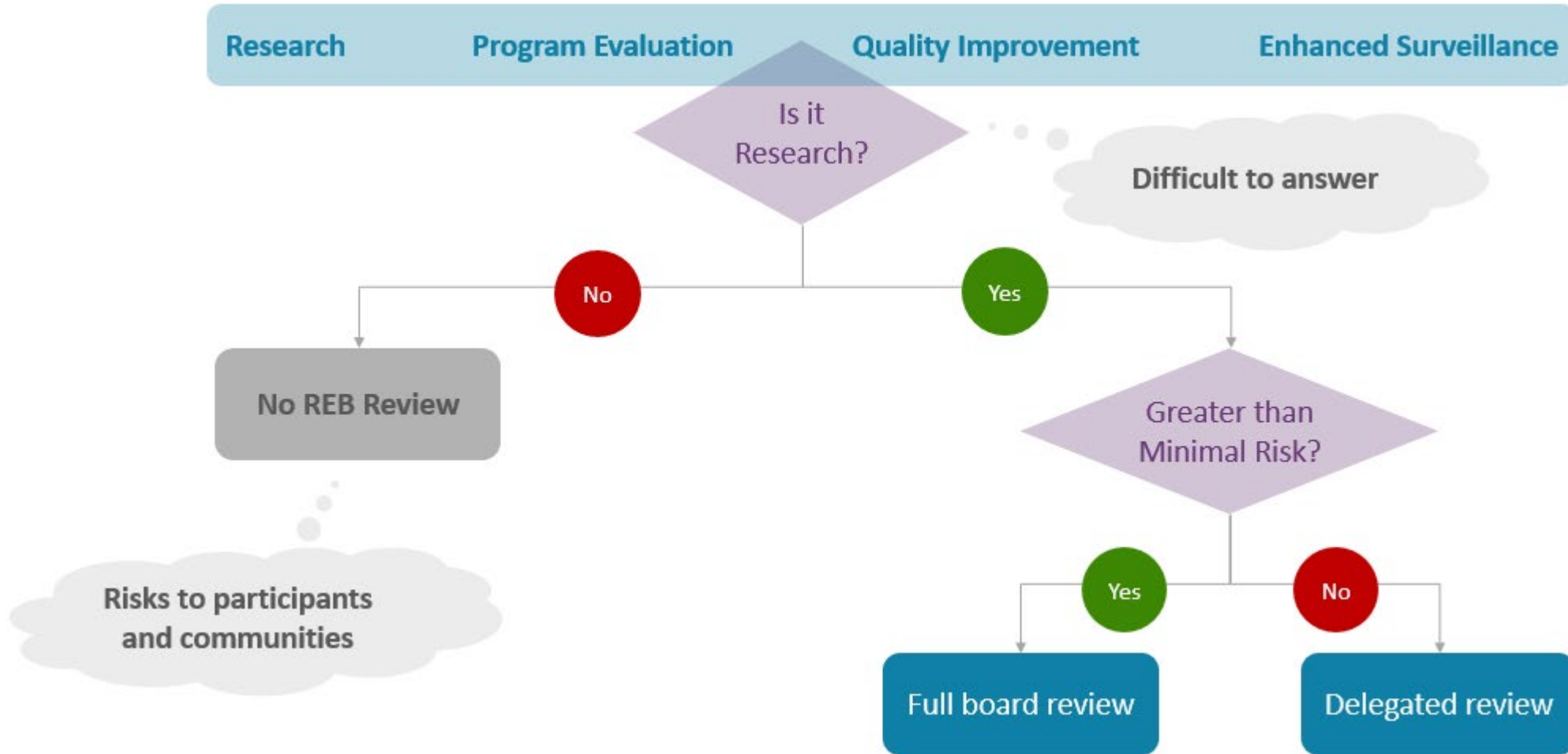
PH Evidence-Generating Activities

Research

Evaluation

Enhanced Surveillance

Quality Improvement

- All involve systematic collection of information to extend knowledge and inform action

- Use Similar Methods:
  - Surveys
  - data analysis
  - Interviews
  - Focus groups

The Framework

A Framework for the Ethical Conduct of Public Health Initiatives

April 2012
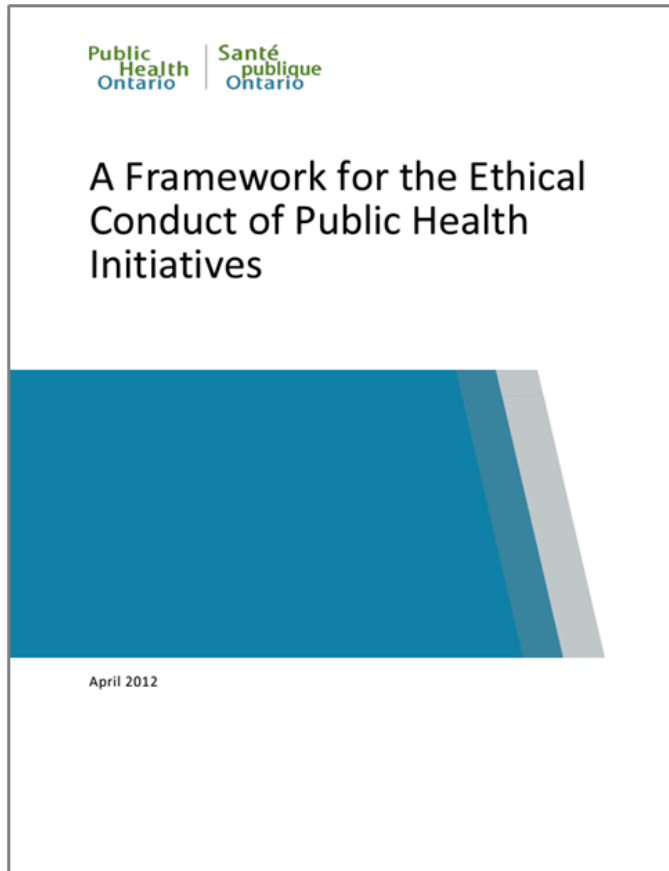
- "TCPS 2 plus"

- meets the requirements of relevant laws and policies

- all evidence-generating initiatives receive ethical scrutiny, proportionate to risk

- emphasis is on ethical integrity (what should we do) instead of compliance (what do we have to do)

- incorporates a population and public health perspective

PHO's Risk Screening Tool

Purpose:

1. Promote ethical reflection

2. Support systematic consideration of ris

3. Sort projects proportionate to risk leve

Risk Screening Tool (RST)
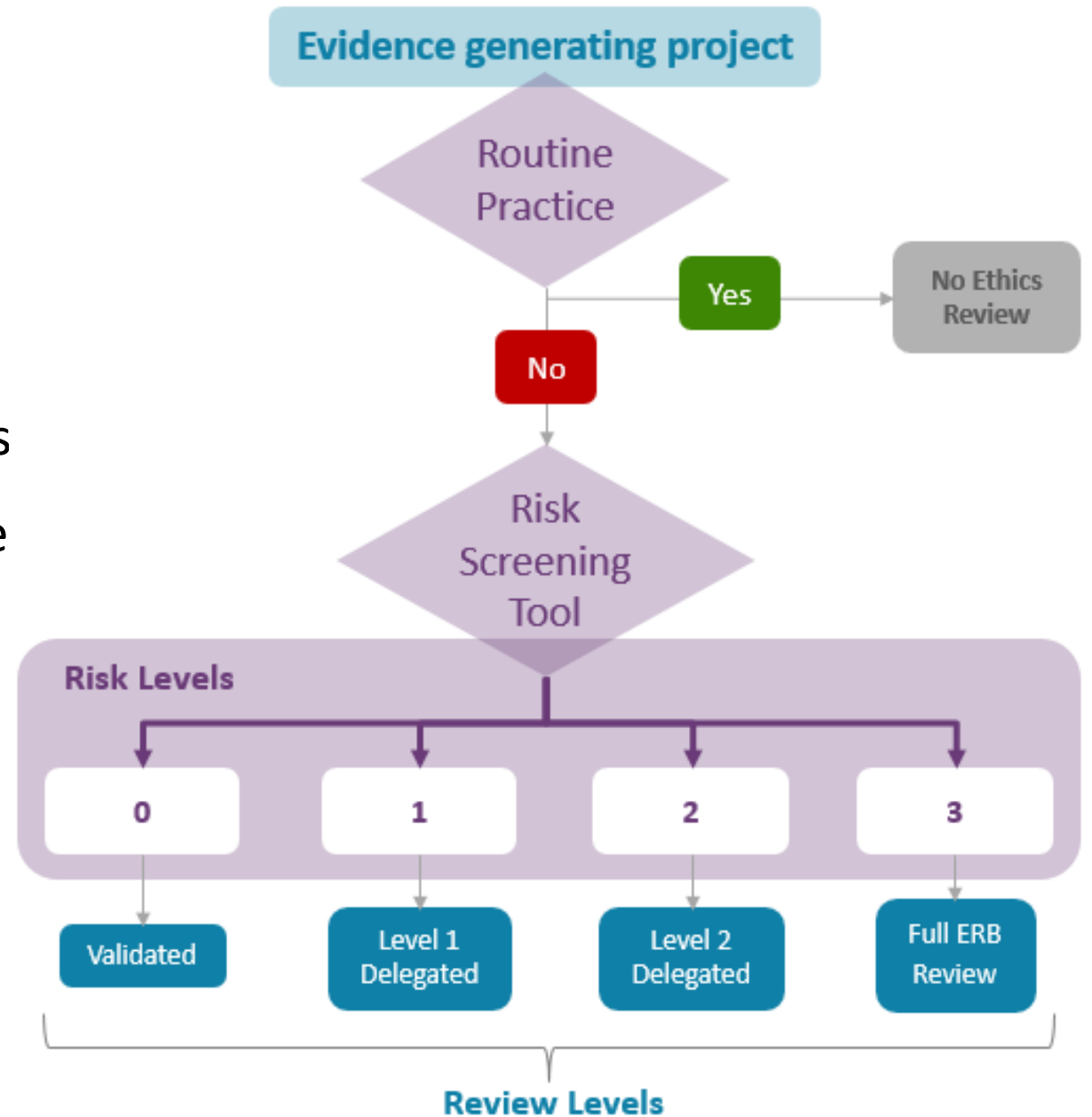
PHO Ethics Review and Support Services

PHO's Ethics Review and Support Services

Ethics Review and Oversight Services

- TCPS 2-compliant review of evidence-generating projects
- A single, centralized ethics review for projects involving multiple PHU

Capacity Building and Support Services

- Ethics consultations on project-related issues
- Support to develop capacity in the assessment of ethical risks and review of low risk projects
- Ongoing education and training
- Access to resources

When to Use PHO Ethics Services?

Throughout the life-cycle of your project:

- Recruitment & consent process considerations
- Project risks

Project Planning

Ethics Submission

- ERB Application
- RST Completion & Validation
- Ethics review process

- Annual renewals
- Amendments
- Unanticipated or adverse events

Implementation

Project Closure

- ERB Closure form
- Dissemination plan considerations
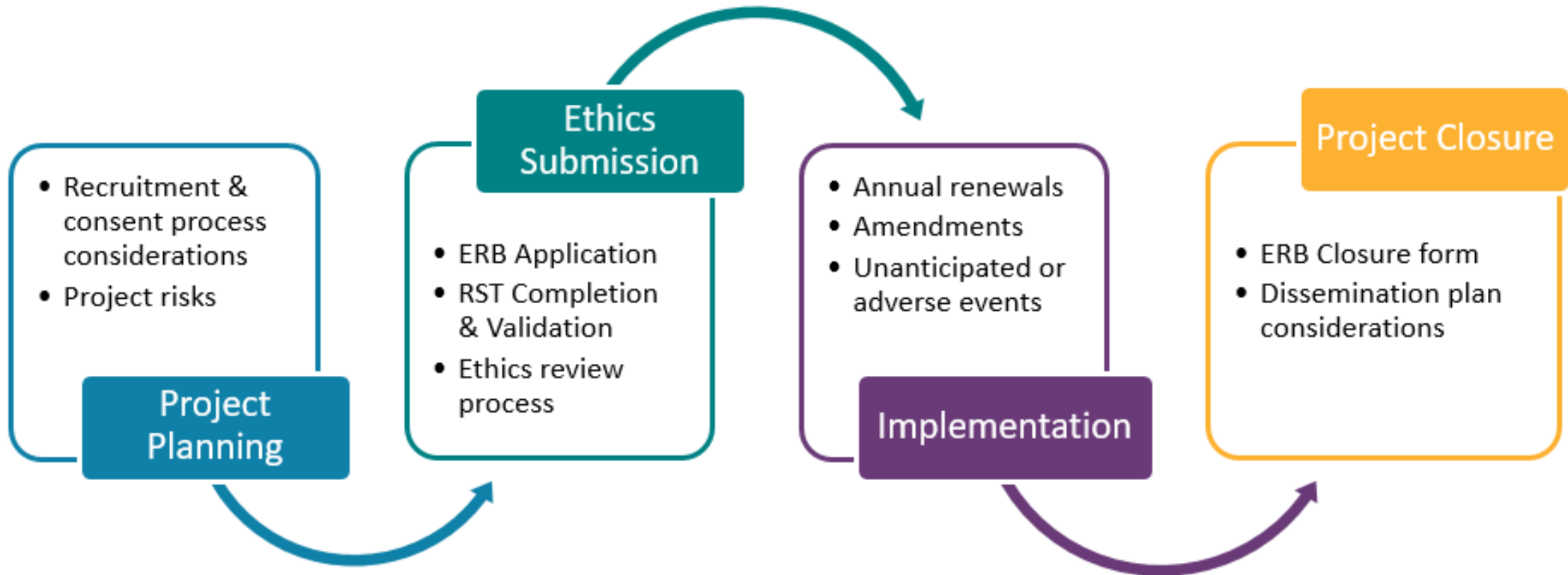
Ethics Review and Oversight Services

- TCPS compliant review of any evidence-generating projects with a validated level 2 or 3 RST score

- Includes level 1 projects or administrative reviews that require a TCPS 2 compliant ethics review, e.g.:
  - Sponsor/funder requirements (e.g. Locally Driven Collaborative Projects)
  - Privacy requirement (e.g., PHIPA section 44 disclosure)

Board of Record Agreements

To use PHO's ethics review services, PHUs are required to have a **Board of Record agreement (BOR)** with PHO's ethics board

- PHU's are responsible for determining which projects will be submitted to PHO

- Use of PHO's ERB for any given project is completely optional

- Refer to our website for current list of 26 PHUs that have a BOR agreement with us

PHU BOR Agreements

Multi-Site Projects

- Multi-site review board: a single, centralized ethics review board for projects involving multiple PHUs

- Refer to our FAQ for more information:
  PHO's Centralized Ethics Review Process

Ethics Designate (ED)

- PHU's assign an ED when signing a BOR agreement

- The ED role is evolving and flexible and will depend on PHU capacity and service needs

- Expectations of the role (NOT requirements) include:

  - Liaise with PHO Ethics Services

  - Coordination of BOR agreement

  - Facilitating implementation and uptake of services

  - Capacity development

Ethics Consultations on Project-related Items

Send inquiries to ethics@oahpp.ca

Examples:

- support completing risk screening tool

- consent and capacity issues

- ethical recruitment strategies

- community engagement plans

- identifying risks and mitigation strategies

Support to develop capacity in the assessment of ethical risks and review of low risk projects

- Co-review of low risk projects

- Advice on internal review processes

- Coordination of ethics designate forum/community of practice

- Access to resources and tools for the review of low-risk projects

Available Resources

Website

- PHO's Framework for the Ethical Conduct of PH Initiatives

- Risk Screening Tool

- Multi-jurisdictional review FAQ

- Harmonized forms (application form, reviewer form)

- Consent Form Guidelines and Templates

- New resources coming soon!

Submit an Ethics Review Board Application

Let's hear from you!

Education, Training and Resources

PHO's Ethics Submission and Review Process

PHO's Ethics Services Website
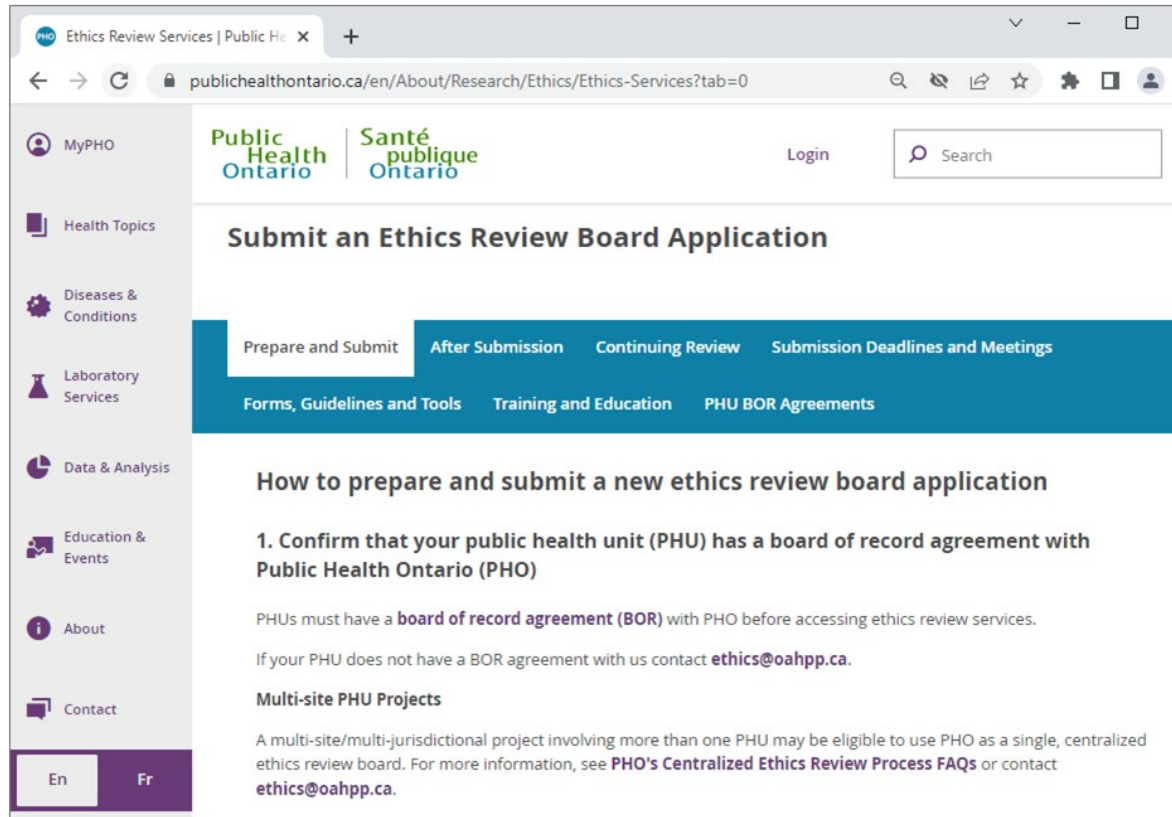
- Information on how to submit an ethics application

- Submission deadlines and ERB meeting dates

- Access to tools and resources

- Access to forms

Ethics Review Services

Submission Process – Tips and Lessons Learned

What makes a quality application?

Complete/ Comprehensive ERB Application and Materials

Methodological or Scientific Review

Institutional Approval/Support

Complete and Comprehensive Application

ERB Application & Project Materials

Request to Appoint Form

Completed RST

Lead TCPS 2 Certificate

PHU submits application

RST Validation

Completeness and Quality Check

PHO confirms submission

Submit for Review

PHO sends application for review
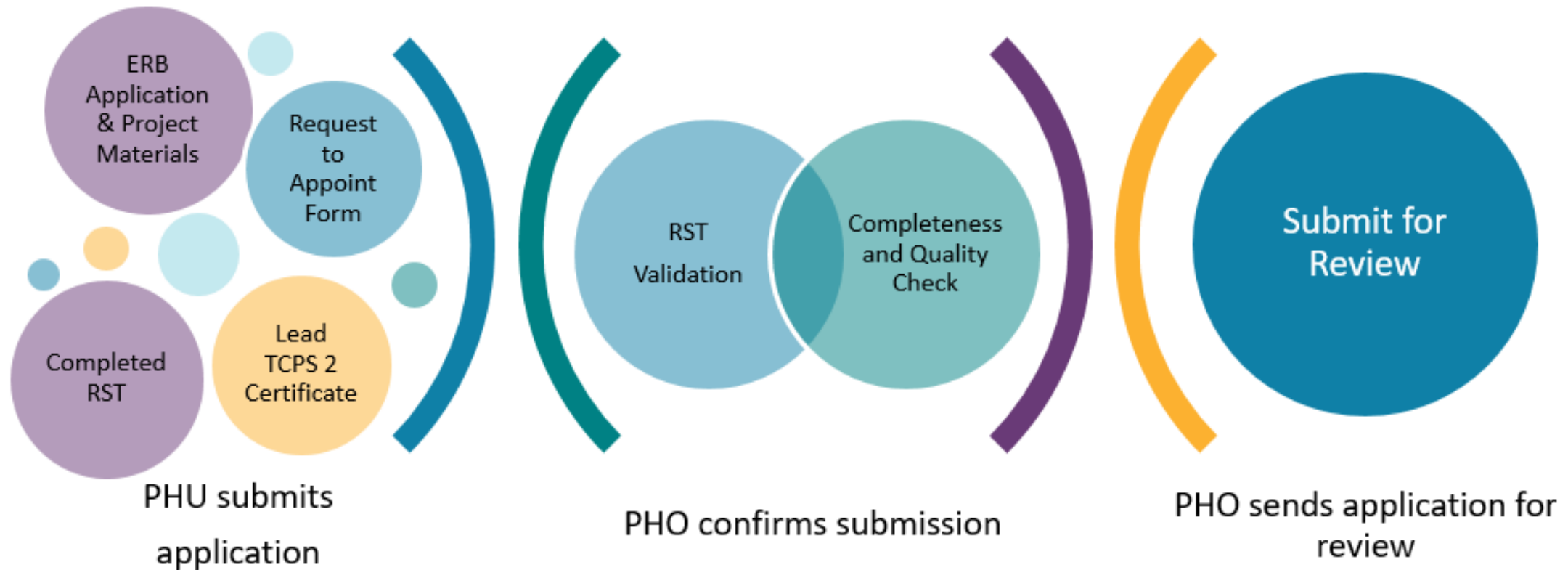
Scientific or Methodological Quality Review (E.2)

Methodological quality review should be conducted:

- By individual(s) with relevant methodological knowledge and experience who is separate from the project team

    or

- Through a competitive review and approval process through an external granting agency (e.g. peer review committee such as LDCP)

    or

- By existing internal PHU review committee

Privacy Review (E.3 in Application Form)

- PHU is expected to follow their internal policies regarding privacy review and explain these clearly in the ERB Application Form

- If working with external vendors or services then those agreements will have privacy aspects that should be included in the Application

Request to Appoint Form

- Found on the last page of the application form

- Signed by someone with signing authority for the unit (same requirement as BOR)

- Names PHO ERB as the BOR for the project

- Confirms that PHU considers project to be feasible and methodologically sound

- Obligates the unit to PHO ERB's decisions and continuing review requirements for that project

Ideally, ED has a supporting role throughout the submission and continuing review phases.

How Long Do Reviews Take?

Level Two Delegated Review

- 3-4 weeks from when complete application is received

Level Three Full Board Review

- 5 weeks minimum from the submission deadline (listed on our site)
- Level 3 reviews are tied to monthly board meeting dates
- If a project is submitted but it is not complete or ready to review at the deadline then it will be scheduled for the next month's board meeting

Questions

References

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council. Tri-council policy statement: ethical conduct for research involving humans [Internet]. Ottawa, ON: Her Majesty the Queen in Right of Canada; 2018 [archived; cited 2023 Oct 6]. Available from: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

2. Ontario. Ministry of Health. Public health unit boundary [data set]. Toronto, ON: Ontario GeoHub; 2020 [updated 2020 May 15; cited 2023 Oct 6]. Available from: https://geohub.lio.gov.on.ca/datasets/lio::ministry-of-health-public-health-unit-boundary/explore?location=48.829042%2C-85.860354%2C4.68

For More Information About This Presentation, Contact:

PHO Ethics Services: ethics@oahpp.ca

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Ontario