Public Health Ontario | Santé publique Ontario

Ethics Review @ PHO

Nancy Ondrusek, Director, Research and Ethics Services

February 10, 2020

Council for State and Territorial Epidemiologists IRB Workgroup

Outline

- Framework:
  - Review Guidance
  - Scope of review
- Implementation:
  - Exemption Criteria
  - Fast Track Checklist
  - Risk Screening Tool

Public Health Ontario (PHO)

- Provincial public health agency; established in 2008
- Mandate:

  Provide scientific and technical advice and support to clients working in government, public health, health care and related sectors.

Users of PHO Ethics Support Services

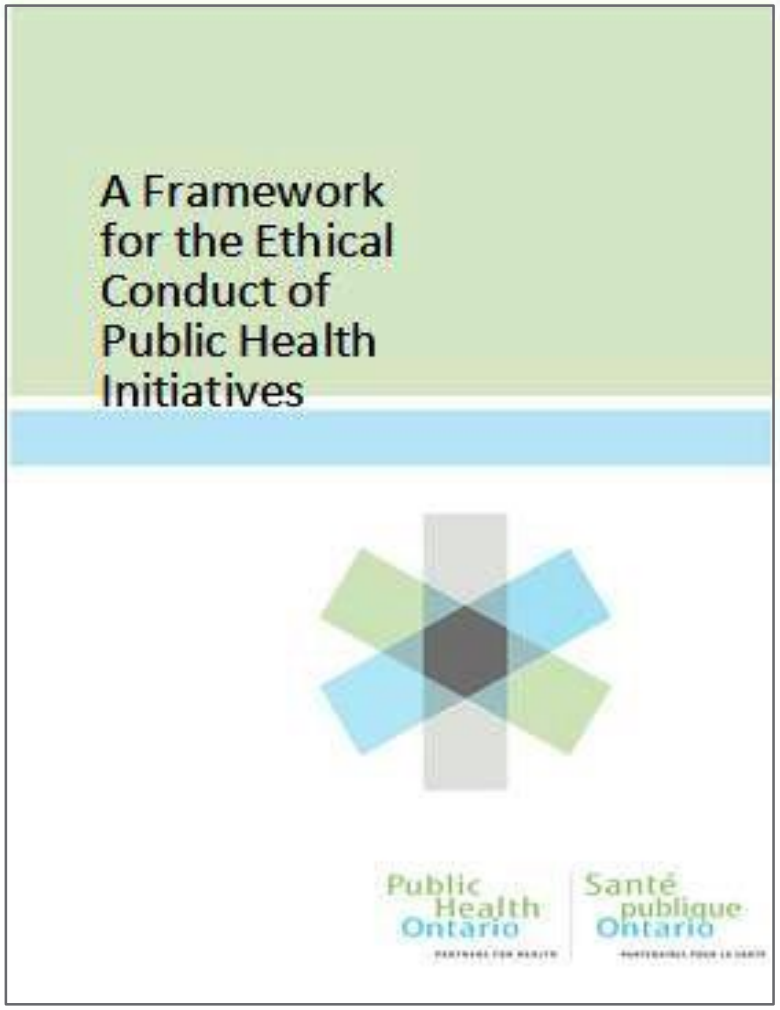
- PHO
  - Approximately 40 scientific/medical staff (varying blend of research and operational roles)
  - Trainees (e.g., graduate students, postdoctoral fellows, medical residents)
  - Evidence-generating activities include research (wide range, e.g., health promotion, epidemiology, lab science), evaluation, enhanced surveillance

- Public Health Units (PHU)
  - 34 PHUs across Ontario
  - Deliver public health programs and services
  - Evidence-generating activities include research, evaluation, community consultations, need assessments

Poll: Does your organization currently provide ethics review of non-research?

- ❑ Yes, via same process used for research
- ❑ Yes, through different process
- ❑ Yes, but rarely
- ❑ No, only research
- ❑ No, only research, but interested in expanding scope
- ❑ Other

The Framework



Willison et al. BMC Medical Ethics 2014, 15:61
http://www.biomedcentral.com/1472-6939/15/61

BMC Medical Ethics

DEBATE Open Access

What makes public health studies ethical? Dissolving the boundary between research and practice

Donald J Willison[1,2,3*], Nancy Ondrusek[4], Angus Dawson[5], Claudia Emerson[6,7], Lorraine E Ferris[1], Raphael Saginur[8], Heather Sampson[10,11] and Ross Upshur[1,9,10]

Abstract

Background: The generation of evidence is integral to the work of public health and health service providers. Traditionally, ethics has been addressed differently in research projects, compared with other forms of evidence generation, such as quality improvement, program evaluation, and surveillance, with review of non-research activities falling outside the purview of the research ethics board. However, the boundaries between research and these other evaluative activities are not distinct. Efforts to delineate a boundary – whether on grounds of primary purpose, temporality, underlying legal authority, departure from usual practice, or direct benefits to participants – have been unsatisfactory.

Public Health Ontario has eschewed this distinction between research and other evaluative activities, choosing to adopt a common framework and process to guide ethical reflection on all public health evaluative projects throughout their lifecycle – from initial planning through to knowledge exchange.

Discussion: The Public Health Ontario framework was developed by a working group of public health and ethics professionals and scholars, in consultation with individuals representing a wide range of public health roles. The first part of the framework interprets the existing Canadian research ethics policy statement (commonly known as the TCPS 2) through a public health lens. The second part consists of ten questions that guide the investigator in the application of the core ethical principles to public health initiatives.

The framework is intended for use by those designing and executing public health evaluations, as well as those charged with ethics review of projects. The goal is to move toward a culture of ethical integrity among investigators, reviewers and decision-makers, rather than mere compliance with rules. The framework is consonant with the perspective of the learning organization and is generalizable to other public health organizations, to health services organizations, and beyond.

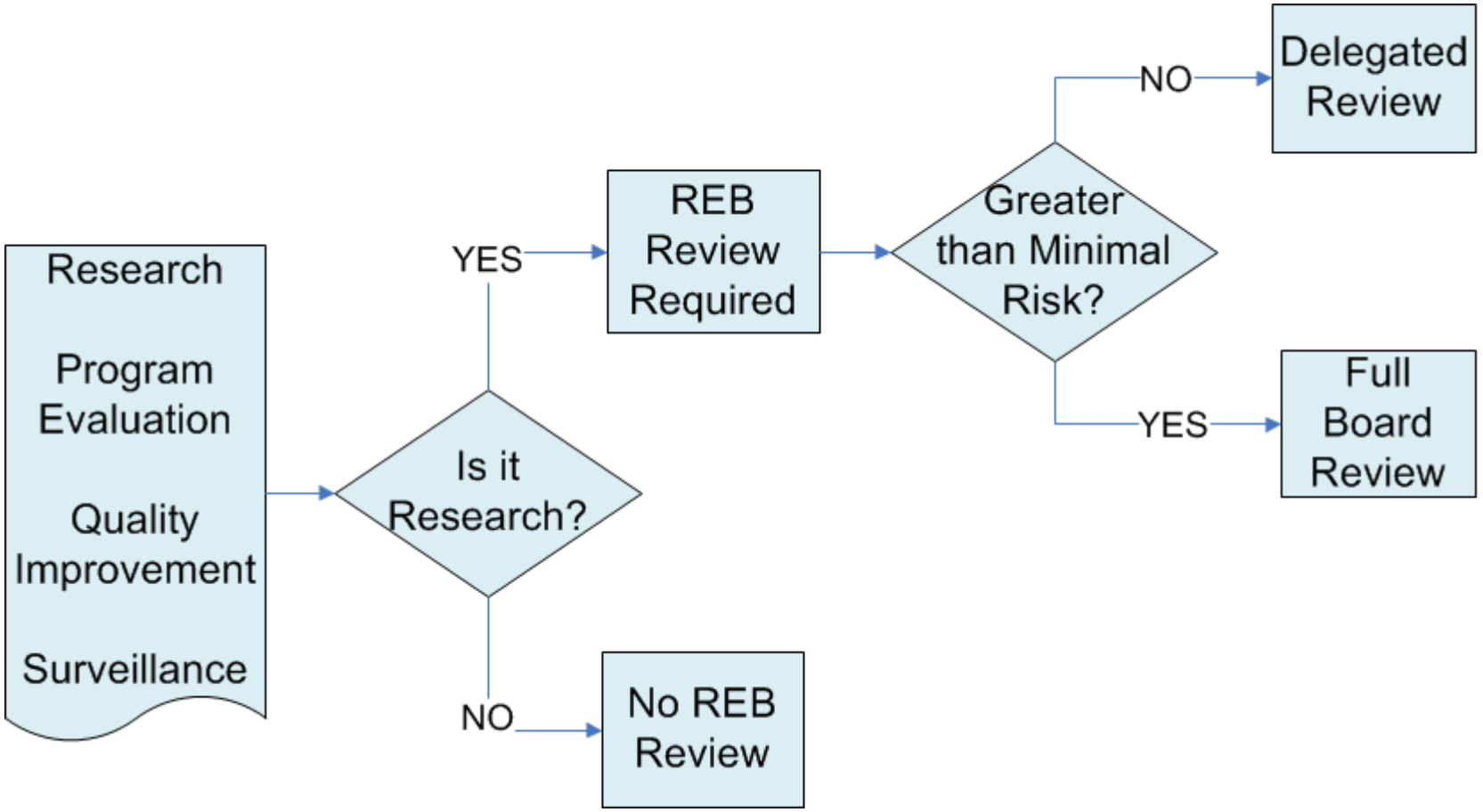
Summary: Public Health Ontario has developed an ethics framework that is applicable to any evidence-generating

Overarching Objective of the Framework

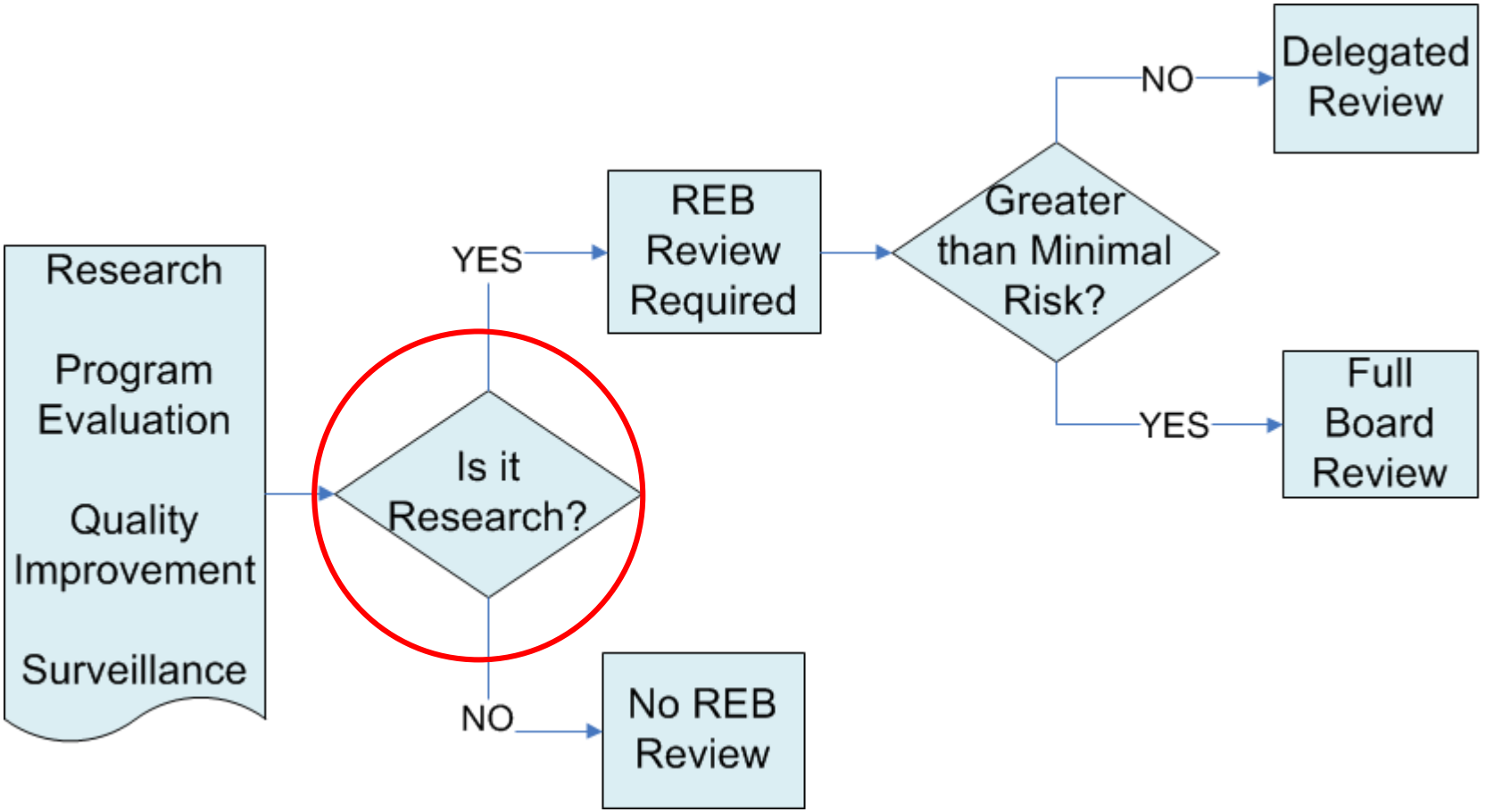
To develop an ethics support process that:

- takes a population and public health perspective
- addresses both research & other evaluative activities involving humans, their data, or samples
- is proportionate to risk to human participants
- meets the requirements of relevant laws and policies
- **“TCPS plus”**

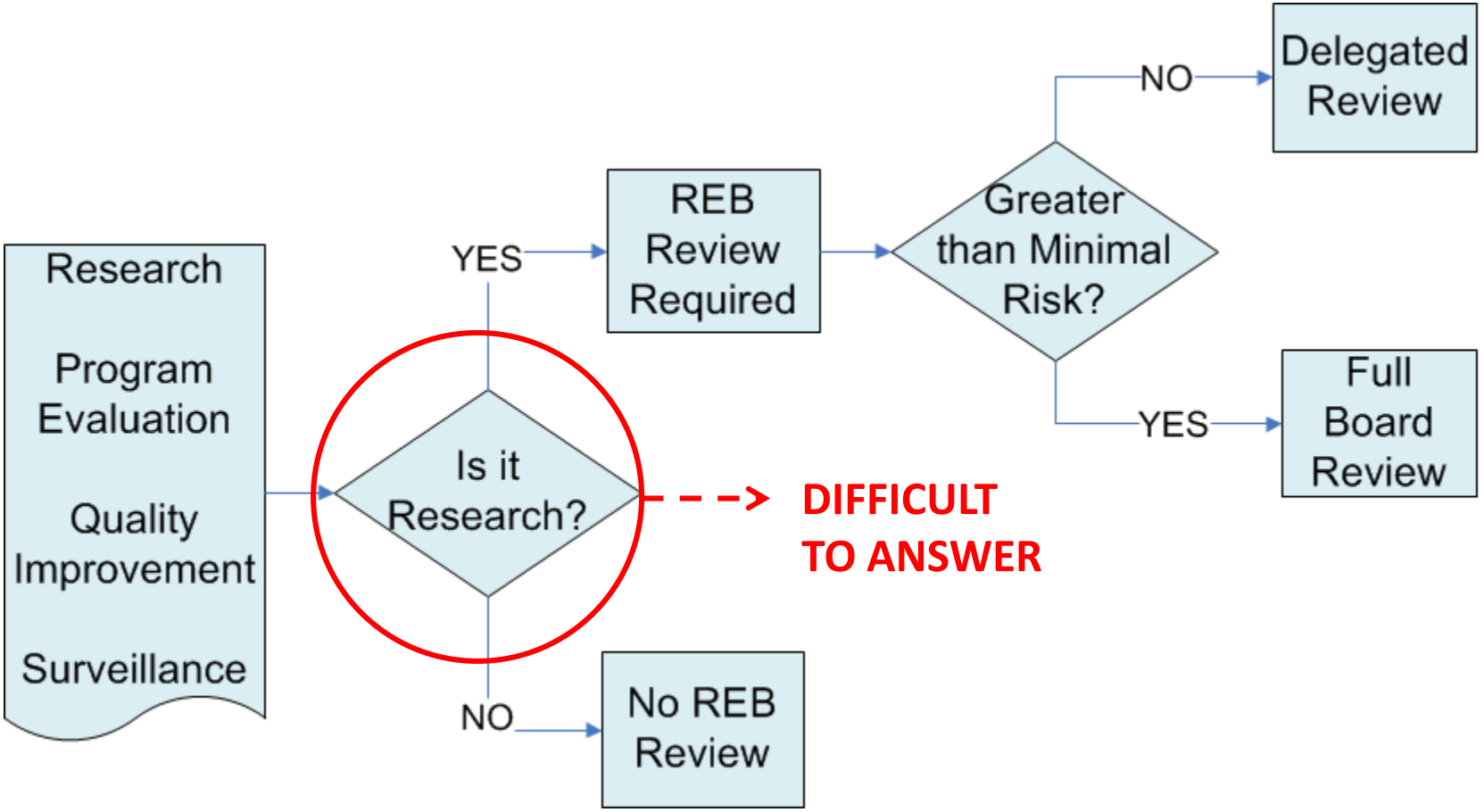
Traditional Approach to Ethics Review



Traditional Approach to Ethics Review



Traditional Approach to Ethics Review



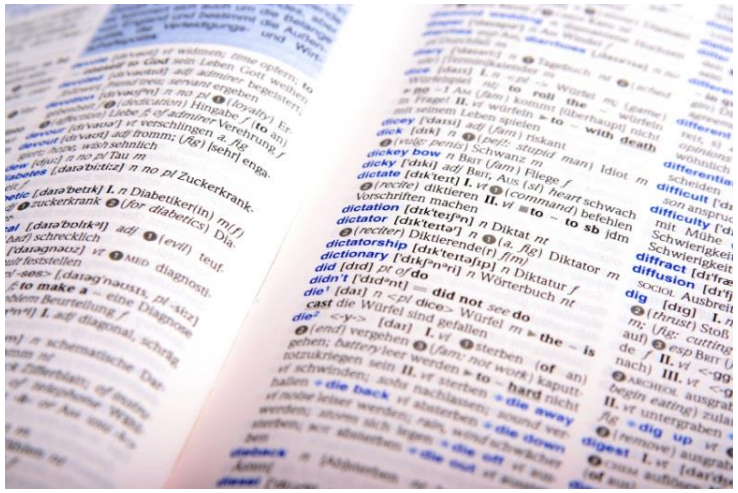
Evidence-Generating Public Health Activities

- Research
  - "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation" (TCPS 2, 2018)
  - "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46, 2018)
- Surveillance
  - "systematic and ongoing collection, collation, and analysis of health-related information that is communicated in a timely manner to all who need to know, so that action can be taken." (Ontario Public Health Standards, 2008)
- Program Evaluation
  - "the systematic gathering, analysis, and reporting of data about a program to assist in decision-making." (Ontario Public Health Standards, 2008)

Attempts to Distinguish Research and Non-Research

Challenges with Distinguishing Research and Non-research

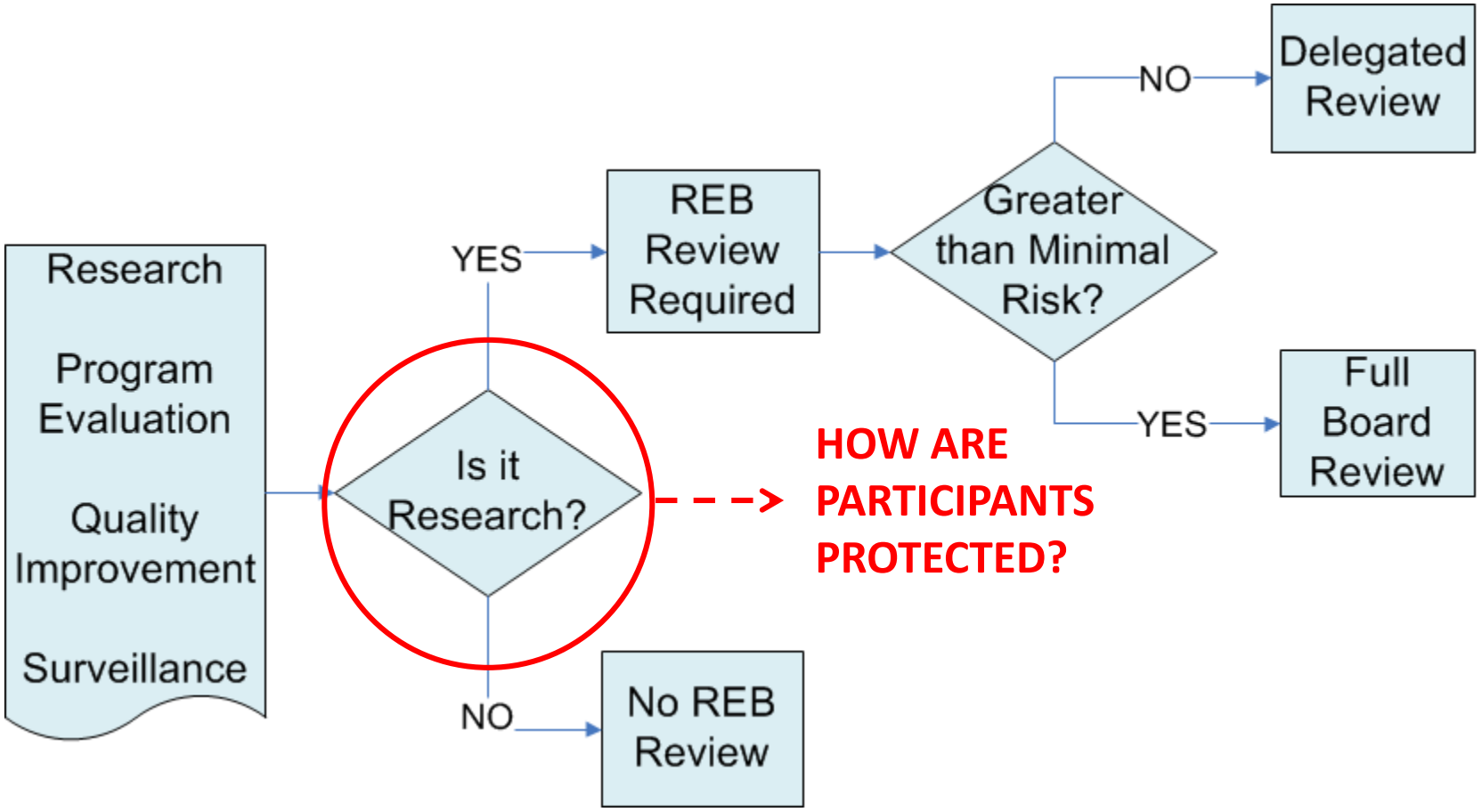
- Inconsistency in application of definitions.
- Time consuming—is it or isn't it?
  - Send for REB review "in case"
- Gaming the system



Participant Question

Does your organization encounter challenges in deciding “to IRB or not to IRB”?

Traditional Approach to Ethics Review



Support for Review "Non-Research"

- *Activities outside the scope of research…may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance…* — TCPS 2, 2018
- *Even where activities do not require…review by a full HREC…institutions are encouraged to ensure that HRECs establish policies to allow efficient review of quality assurance proposals…* —Australia NHMRS 2003
- *QI requires oversight to ensure that it is conducted ethically.* — Hastings Report 2006

Public Health Ontario Approach

- Shift focus from “Is it Research?” to “How are participants protected?”
- All non-routine evidence-generating initiatives receive ethical scrutiny
- Ethical scrutiny proportionate to risk
- Switch from emphasis on compliance (what do we *have to* do) to focus on ethical integrity (what *should* we do)

Challenges to Expanding Scope of Ethics Scrutiny

- Increased volume of projects to manage
- Broader range of activities—expertise to review?
- Legal mandate for PH practice
- Resistance from investigators:
  - Burden—process; proposal development
  - Time constraints
  - Ethics review unwarranted/culture of no review

Approaches to Address Challenges

Optimize use of resources for human participant protections

- Risk-based approach
  - More invasive or harmful projects receive greater scrutiny
  - Limited review where appropriate
- Expanded options for ethics review
  - “Scrutiny” vs “Review”
- Standardized review for common issues

“Facilitate the progress of research” by “reducing unnecessary impediments” (TCPS 2, 2018)

Key Components of the PHO Review Process

- Screening tool for exemptions
- Templates to standardize review of common evidence-generating activities
  - Fast-track review checklists
- Proportionate review according to risk:
  - Risk Screening Tool for sorting
  - Range of review and submission options

Screening Tool for Exemptions

- 10-item checklist
- Screens out certain low risk projects
- Developed with users (Delphi)—*validity and buy in*
- Users self-screen

LOW-RISK PROJECT EXEMPTION CRITERIA CHECKLIST

Checklist for internal Public Health Ontario projects that do not require ethics review and approval		
1	☐	**Project Purpose:** The overall purpose of the project is to inform the development or improve the quality, design and user experience of a Public Health Ontario (PHO) product or service.
2	☐	**Participant Selection:** Participants are selected or suggested (e.g., by manager) using (a) publically available information or (b) member/registration lists (e.g., SRM list), where PHO staff have the authority to access and use this information.
3	☐	**Participant Recruitment:** Participants are asked to participate in their professional capacity or on behalf of their organization.
4	☐	**Participant Recruitment:** The recruitment process allows participants to voluntarily decide whether they want to participate or not.
5	☐	**Participant Incentives:** Incentives (i.e. gifts, monetary or otherwise, offered to participants to encourage participation) will not be offered
6	☐	**Data Collection:** Questions are about organizational practices, products, services or strategies. Demographic questions are also permitted.
7	☐	**Data Collection:** Information being collected does not include the assessment of the performance or decisions of specific individuals or organizations in relation to a regulation, policy, or practice where the organization or individual can be held accountable or liable.
8	☐	**Data Use & Dissemination:** Any inadvertent identifying information (e.g. in qualitative comments) will be deleted prior to analysis.
9	☐	**Data Use & Dissemination:** No information is being collected or used in this project that, if released, is likely to lead to social or psychological, harm (e.g., discrimination, harm to reputation), or professional, legal or economic consequences (e.g., loss of property value) for participants, organizations or non-participants.
10	☐	**Data Use & Dissemination:** Results disseminated beyond the project team will not link responses to an identifiable individual, department, health unit, or organization.

Screening Tool for Exemptions

- Questions cover purpose, participant selection and recruitment, data collection, dissemination, e.g.:

  1. Project Purpose: The overall purpose of the project is to inform the development or improve the quality, design and user experience of a Public Health Ontario (PHO) product or service.

  3. Participant Recruitment: Participants are asked to participate in their professional capacity or on behalf of their organization.

  6. Data Collection: Questions are about organizational practices, products, services or strategies.

- Exempts project categories e.g., needs assessments, product evaluation—but also must be low risk

Fast-Track Checklists (FTCs)

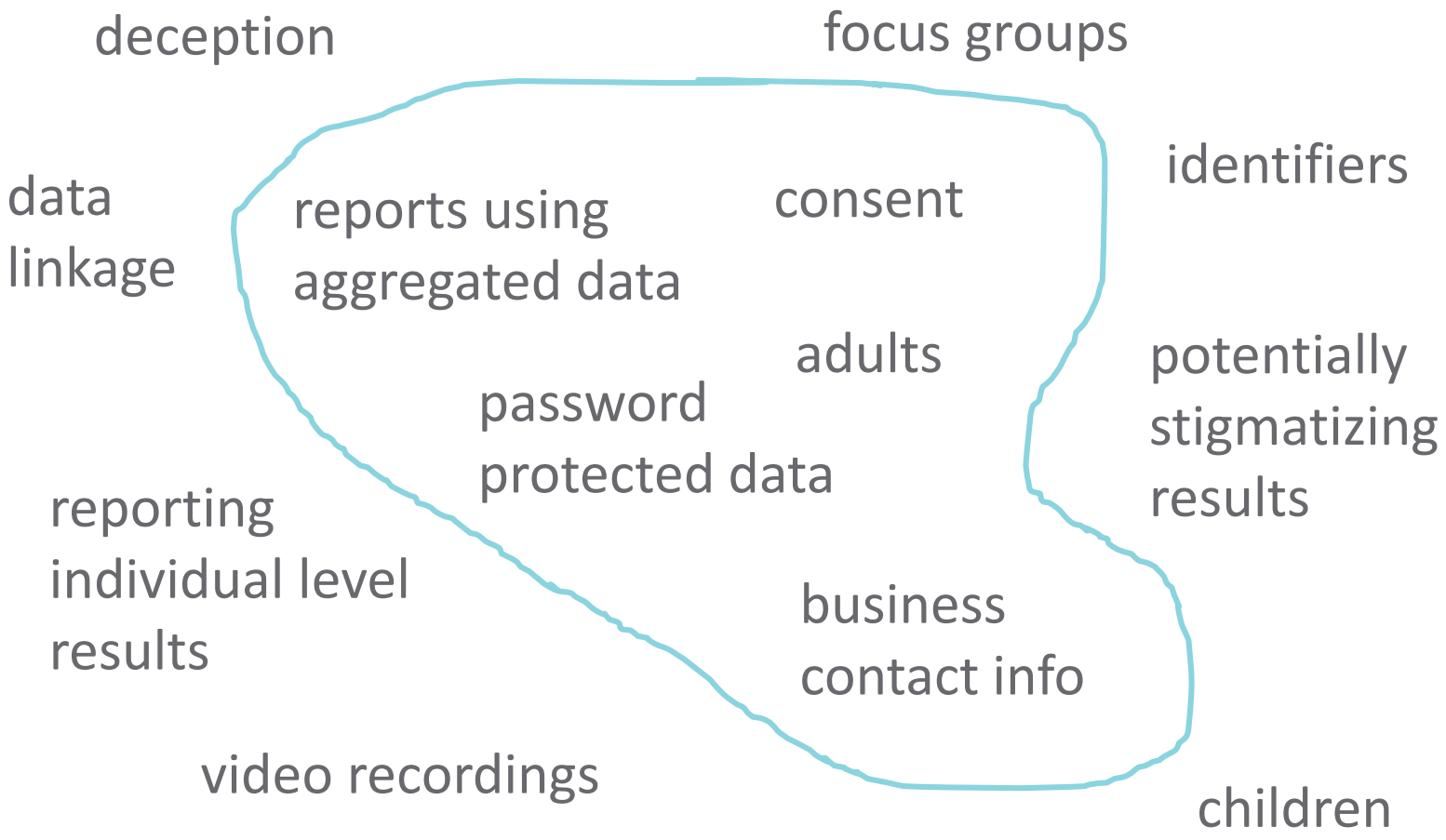
- Checklist with set of of Ethics Review Board (ERB) approved parameters or conditions that delineate a project
- Excludes activities that warrant additional ethics scrutiny
- Projects conforming to approved FTC do not require additional ethics review
  - Fit validated by ethics office
- Streamlines review while maintaining ethical scrutiny

Fast-Track Checklists (FTCs)

Conditions to be standardized may include:

- Recruitment method
- Limits to data collection, use and disclosure
- Need for and approaches to obtaining consent
- Data storage, retention and destruction

FTC Development



Fast Track Checklist Example

For projects involving secondary use of human biological materials (excerpt)

Data Collection and Use:
✓ Use only residual materials previously collected for another purpose
✓ Use only health data previously collected for another purpose
✓ Materials and associated data used for analysis will be **non-identifiable** or **anonymized**

Participant Question

Are there any projects or activities in your own organization for which this approach might be applicable?

Risk Screening Tool

- Applied to all evidence-generating initiatives that do not meet Exemption Criteria or do not conform to an approved Fast-Track Checklist
- Supports systematic consideration of risks
- Sorts projects proportionate to risk level
- Four levels of ethics review

RST Domains of Risk

- Sensitivity of Information
  - Embarrassing or disturbing questions
  - Potential for legal, professional, social or economic repercussions to individuals or groups
- Participant Selection, Recruitment and Consent
  - Privacy/access issues
  - Special considerations re consent
- Data/Sample Collection or Access
  - Direct participation (e.g., interviews, blood samples)
  - Secondary use of data or biological materials
- Identifiability and Privacy Risk
  - Collection of direct or indirect identifiers
  - Individuals or groups
- Commercial interests

Public Health Ontario | Santé publique Ontario

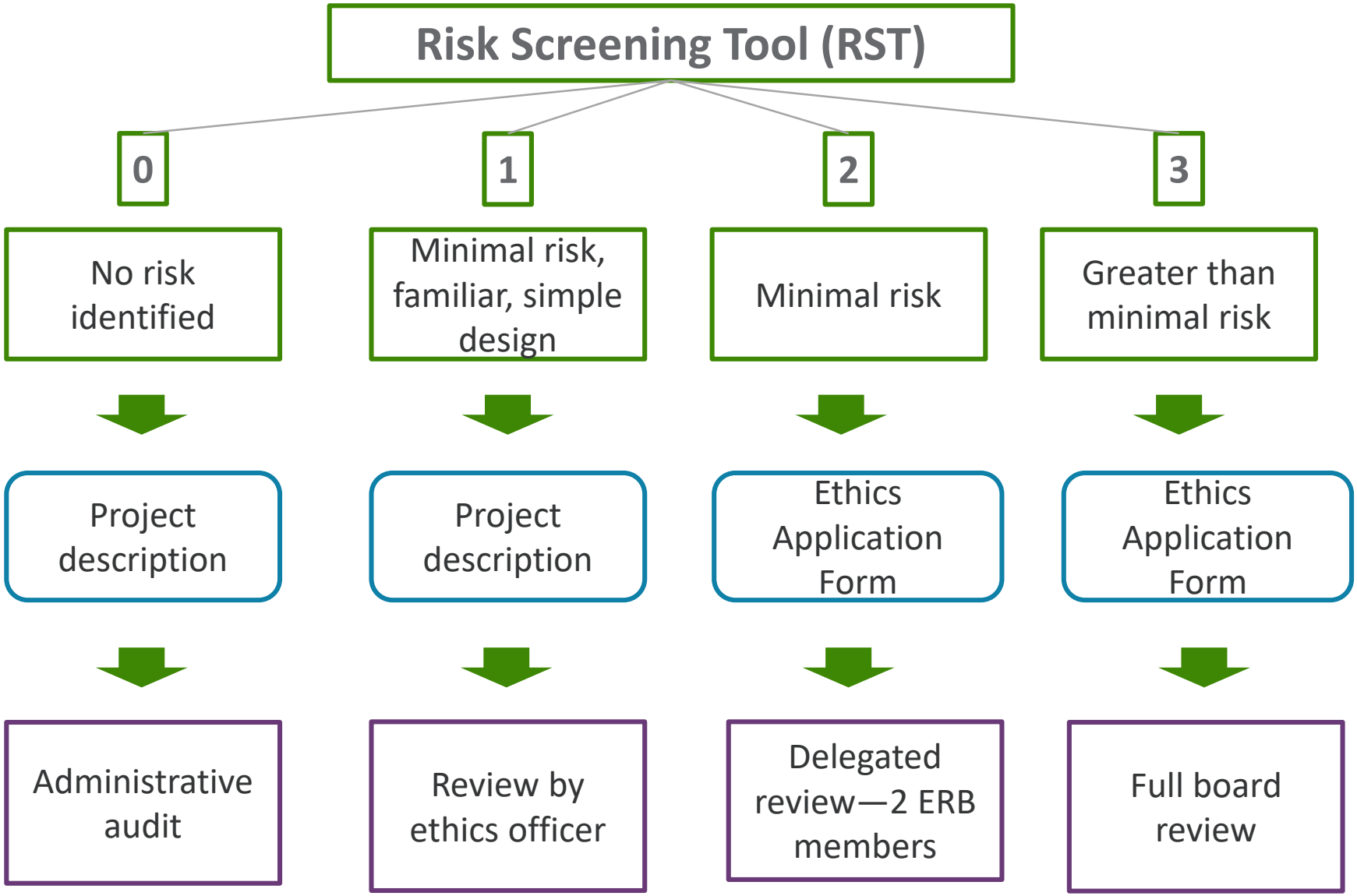
Login

3.2 Will you be obtaining consent (and assent if applicable) from individual par decision makers as appropriate)?

- ○ No
- ● Yes

Will you include any of the following groups who might have reduced ca that apply.

- ☐ Children (0 to< 18 years of age)
- ☐ Adults (18 or more years of age) with impaired cognitive function ⓘ
- ☐ People who, because of their current circumstances, may feel pressurec students, employees, institutionalized individuals)
- ☐ Unsure
- ☐ None of the above


Risk Screening Tool (RST)
0
1
2
3
No risk identified
Minimal risk, familiar, simple design
Minimal risk
Greater than minimal risk
Project description
Project description
Ethics Application Form
Ethics Application Form
Administrative audit
Review by ethics officer
Delegated review—2 ERB members
Full board review

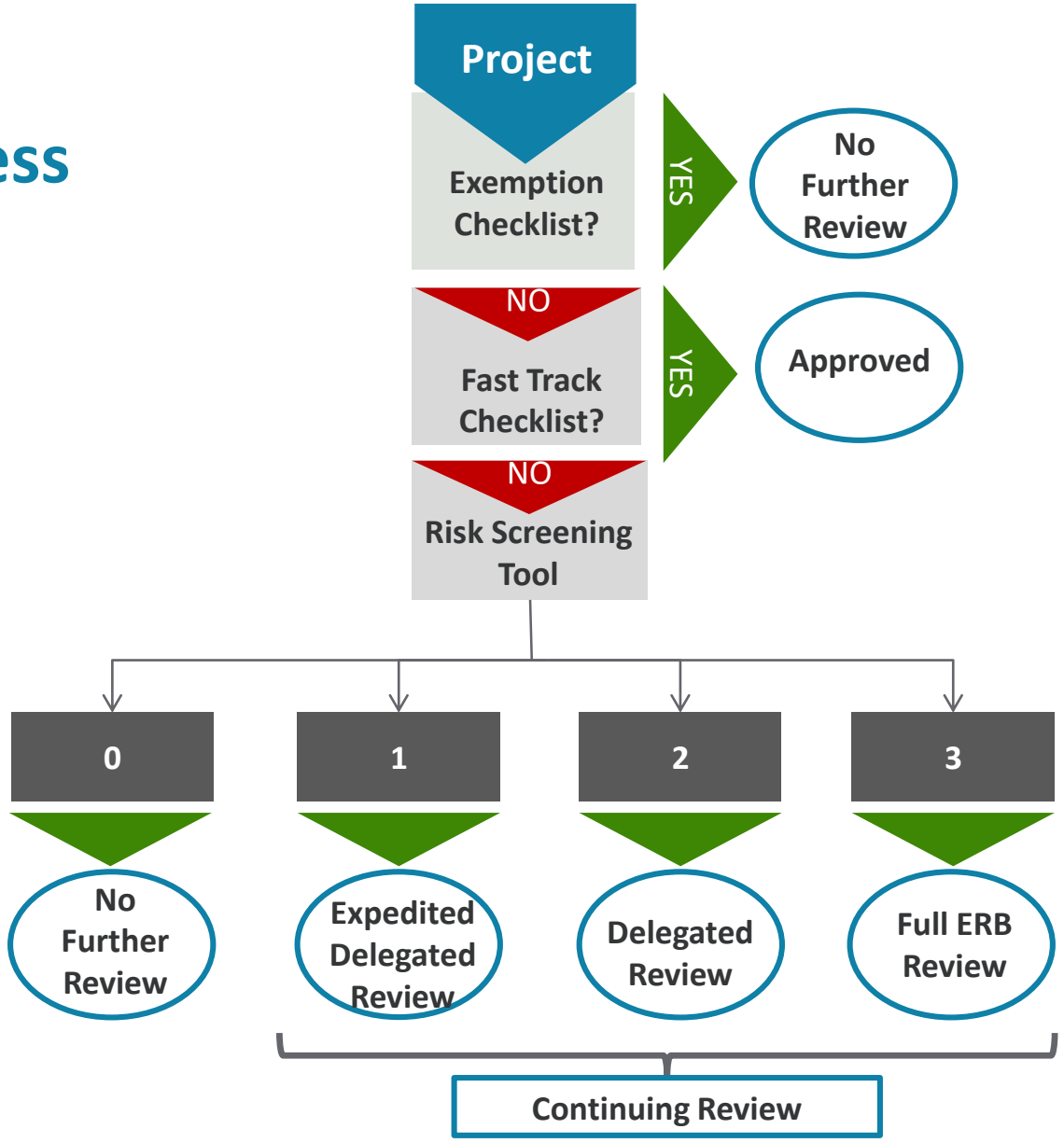
Level 0 Project Examples

- Secondary use of de-identified isolates from the lab (bacteria, viruses)
- Use of aggregated, anonymized data
- Analysis of publically available information

Level 1 Delegated Review Project Examples

- Secondary use of data or specimens
  - Non-sensitive
  - De-identified or Anonymous
- Surveys or interviews with individuals in their professional capacity
- Projects previously approved by REB at the primary research site (administrative review)

PHO Ethics Review Process



PHO Model: Potential Challenges

- Change management
  - New process, expanded scope
- Balancing innovation with institutional accountability and compliance requirements
- Project content/methods highly variable
  - How much customization of process?
- Potentially resource intensive service

PHO Model: Enablers

- Support from senior leadership
- Expanded scope of review consistent with current practice in public health units
- Experienced ERB Chair
- Diverse membership/expertise of Board
- Ethics expertise of office staff
- Incorporation of streamlining mechanisms
- Engaging with service users

PHO Model: Benefits

- Makes ethical reflection routine for all projects
- Optimizes use of resources for investigators and reviewers
- Investigators see for themselves where their project fits; Transparency of process helps relationships between ethics board and investigators
- For projects not requiring further review, investigators have documentation of ethics oversight (e.g., to meet journal requirements)

For More Information About This Presentation, Contact:

Nancy Ondrusek at nancy.ondrusek@oahpp.ca

The PHO Risk Screening Tool is available at:
https://www.publichealthontario.ca/en/about/research/ethics/ethics-services/risk-screening-tool

Public Health Ontario keeps Ontarians safe and healthy.
Find out more at **PublicHealthOntario.ca**