Trillium Health Partners
Institute for Better Health
Operations' Orientation

AGENDA

1. Introductions
2. Mapping of Research Operations (RO) functions
3. Trillium Health Partners (THP) Administration Approval Process
4. How to Navigate the Research Ethics Board (REB) process
5. Questions

GETTING TO KNOW YOU

- What would you like to get out of today's session? What are you interested in?
- Do you have any questions about our study initiation process?
- Have you ever participated in a research project or submitted to the REB?

TEAM WORK

ROLE SPECIFIC RESPONSIBLITIES

Grants & Awards Management	• Grant & Award application and budget support • Grand & Award quality assurance reviews • Granting agency relationship management
Research Study Feasibility	• Local resource impact support, confirmation and assessment • Local feasibility/resource impact documentation management
Research Study Budgets	• Study budget development • Study budget review & analysis • Study budget negotiation
Research Agreements Management	• Draft, review, negotiation and execution of research agreements • Legal, liability and compliance risk assessments • Legal consultation
Financial Management	• Study financial modelling • Study financial monitoring (analysis, interpretation) • Study financial processing (invoicing, reconciliation, reporting)

PORTFOLIO DISTRIBUTION

Research Operations Team

Manager, Business Operations

- Joshua Adedamola

Research Operations Analyst (ROA):

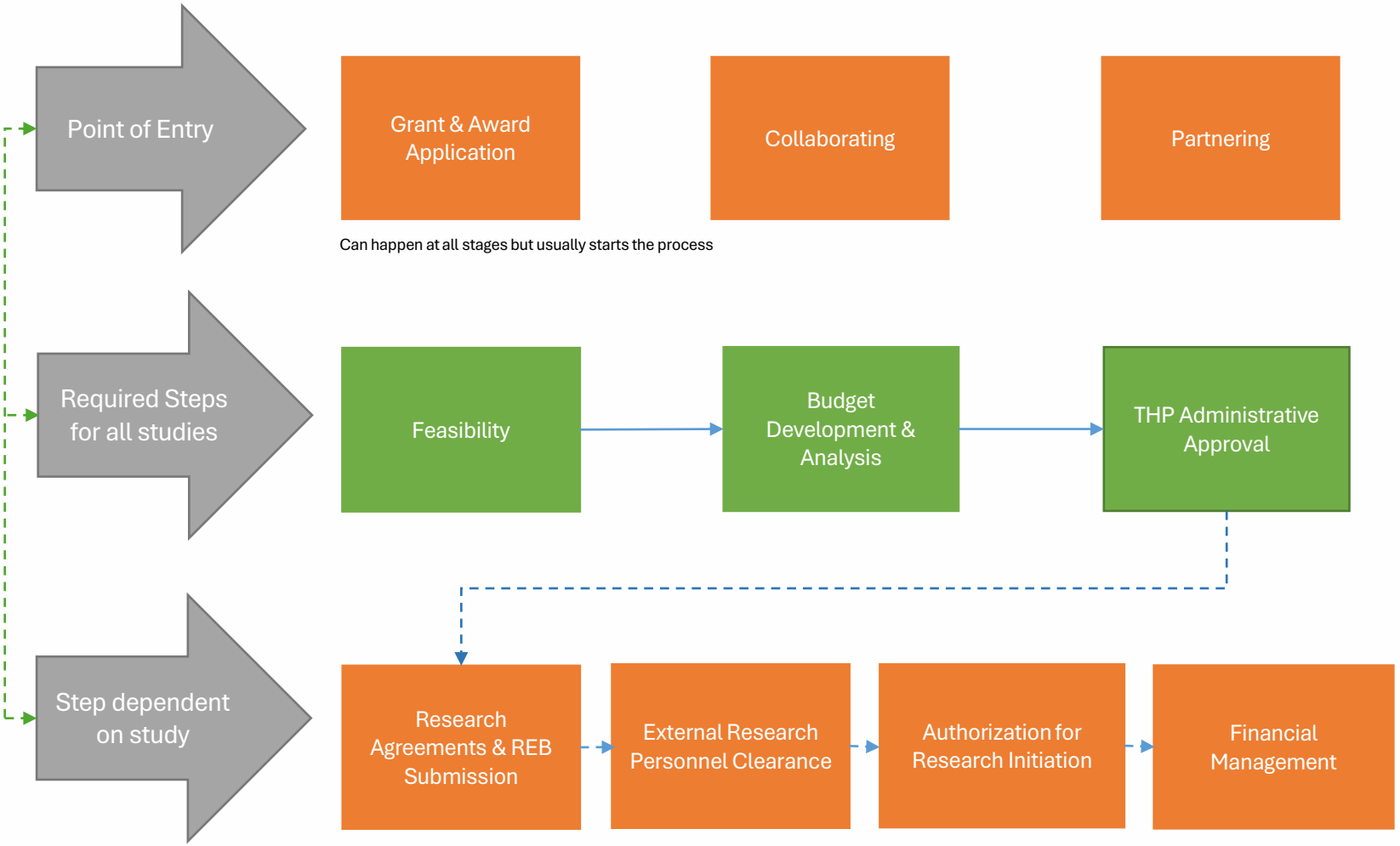
- Mobina Khurram
- Harleen Kaur
- Paige Adams

Research Operations Advisor

- Samyukta Jagadeesh

	Mobina Khurram	Harleen Kaur	Paige Adams	Operations Advisor (TBD)
Research Chairs	Implementation & Evaluation Science (Walter Wodchis)	Community/Population Health (Laura Rosella) Learning Health Systems (Rob Reid)	Patient and Family-Centred Care (Kerry Kuluski)	
IBH Core Scientists & Staff	• Judith Versloot • Dr. Terence Tang • Dr. Andrew Feifer • Dr. Kate Pulman • Dr. Sachin Sud • Lisa McCarthy • Simona Minotti	• Dr. Ben Fine • Machine Learning/Manager Data Insights • Laura Desveaux • Susan Law • Delilah Ofosu-Barko*	• Dr. Ian Zenlea • Dr. Matt Schlenker • Dr. Ike Ahmed • Elizabeth Mansfield • Dianne Fierheller	
IBH Core Programs	• Corporate Files	• Data & Insights	• Innovation	
THP Clinical Programs	• Nephrology • Infectious Disease • Urology • Medicine (including Dermatology) • ICU	• Cardiology • Emergency • Mental Health • Neurosciences/MSK • Oncology (Surgical Onc) • Surgery &Anaesthesia	• Children's Health • Women's Health • Endocrinology • Primary Care, Rehab, CCC, Palliative Care & Seniors Services • Oncology (Clinical Trials + Gyne Onc) • Ophthalmology	• MTAs for externally lead research
THP Clinical Enabling Services	• Genetics • Pharmacy Services • Laboratory Medicine • Information Systems & • Privacy (including HIS, IS and HIM) • Human Resources (including Volunteer Resources, and Talent Management) • Capital Planning & Redevelopment • Finance & Decision Support	• Radiology • Nursing • Occupational Health • Medical Education • Operational Effectiveness • Communications, Health Hubs and Partnerships • Legal, Strategy Management and Facilities • Corporate Services	• Diagnostic Imaging • Marketed Services • Food & Nutrition Services • Quality & Patient Safety • Ethics • Patient Relations • Enterprise Risk Management	

MAPPING OF RO FUNCTIONS



REQUIREMENT FOR "INVESTIGATOR" INITIATING RESERACH

IBH Investigator Appointment – A Pre-requisite

- Appointment - Trillium Health Partners (THP) Institute for Better Health (IBH)
- Required for all individuals who wish to lead research as a PI at THP
- Requires completion of essential trainings

Required Training

Mandatory Training Requirements for all THP Investigators

- Tri-council Policy Statement 2, Course on Research Ethics (TCPS 2 CORE)
- Responsible Conduct of Research (RCR) – Life Science Course
- THP Research Related Privacy Training

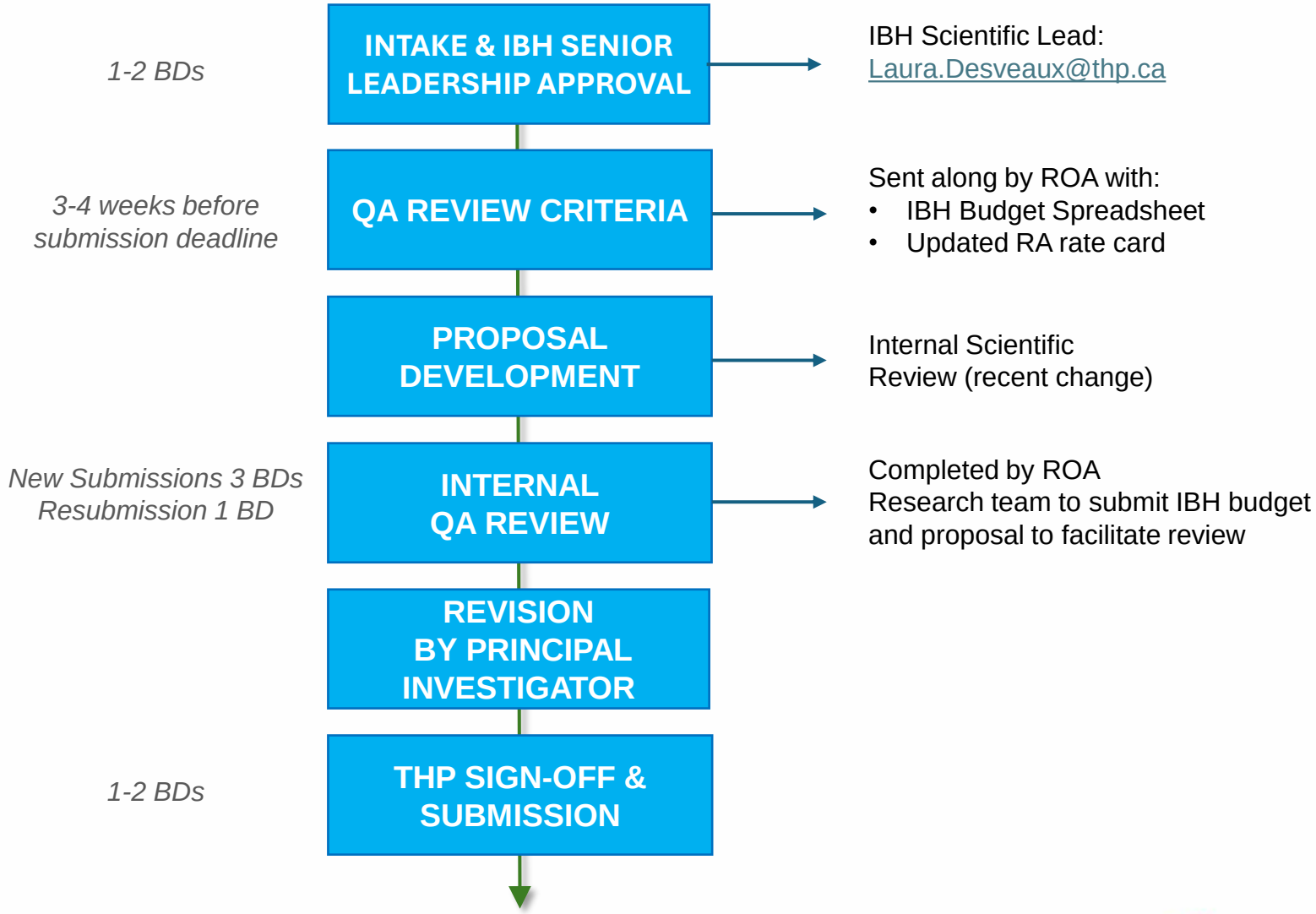
Additional Training requirements for Interventional Clinical Trials & Regulated Clinical Trials

- Good Clinical Practice Basic & Refresher Course
- Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects Course

GRANT & AWARD MANAGEMENT - OVERVIEW

- **RO team works in collaboration with the researcher to support their grant and award (G&A) applications to various funding agencies**
- **ROA supports the researcher application by performing a Quality Assurance (QA) review including:**
  - ❑ Applicant eligibility
  - ❑ Completeness and accuracy of the information
  - ❑ Compliance with grant requirements
  - ❑ Review grant budget to ensure alignment with grant criteria and institutional policies
  - ❑ Review documentation (e.g. letters of support, trainings, CCV)
  - ❑ Inconsistencies in study details (e.g. discrepancy between budget and application form)
- **ROA will obtain institutional sign-off for the grant application once above criteria are satisfied**

GRANT & AWARD MANAGEMENT - TIMELINE



RESEARCH STUDY FEASIBILITY - OVERVIEW

WHAT IS STUDY FEASIBILITY ASSESSMENT?

This assessment allows both the organization and the investigator to review the study and determine whether it is practical to conduct the study at THP, prior to resources being expended on study start-up activity. The Research Operations department can assist investigators and the organization in this determination by submitting the study to the THP Research and Innovation Working Group.

CONSIDERATION DURING FEASIBILITY ASSESSMENT

- Required Resources
- Sufficient Funding
- Time Commitment
- Departmental Support
- Health Records

RESEARCH STUDY FEASIBILITY

Questions to ask:

- Is there an impact on any department in the hospital?
- Do I require assistance with identifying, recruiting or consenting my study population?
- Do I require space or resources from any department or area in the hospital?
- Will the study change standard practices at THP?
- Is staff time required for this study?

→ **If yes to any of the above:**

RESEARCH STUDY FEASIBILITY

Communicate and share study details with Directors of impacted department:

- Submit all study documents to the director/manager including completed **THP Research Study Impact Approval Form**
- You will need to determine whether there is a fee associated with the impact (e.g. Images from DI, charts form health records, samples from the lab, re-imbursement for staff time)
- Can the department support study activities?
- A **THP Research Study Impact Approval Form** is required for each impacted department

Share completed THP Research Study Impact Approval Form(s) with your dedicated ROA along with all study documents including study proposal, budget, ICFs and CRFs, etc.

RESEARCH STUDY BUDGETS - REQUIREMENTS

- THP's responsibility to ensure that participation in research projects does not decrease funding available for its primary focus of provision of patient care
- RO team manages the study budget analysis and negotiation on behalf of the hospital
- *Departmental Impact Costs* - costs may include the following:
  - ❑ Diagnostic testing, and imaging, Sample analysis, Scan/image analysis, Additional workload (i.e. nursing)
  - ❑ Sample storage, Sample processing, Sample transfer
  - ❑ Chart abstractions
- *Research Ethics Board Fees* cover the submission and review of new study applications and continuing review (renewal submissions) of active studies**
- *Indirect Costs/Hospital Overhead* – Indirect costs (Hospital Overhead) are those expenditures incurred by the Hospital in the conduct of research which are not readily identifiable as specific expenses**

***implemented based on funding source*

RESEARCH STUDY BUDGETS - ROLES & RESPONSIBLITIES

Project Team Role/Responsibilities

- Study team to identify what aspects of the study are standard of care (SOC) at THP and which activities are specific to the study or above SOC
- All study specific activities and cost should be captured on the **THP Research Study Impact Approval Form**
- **THP Research Study Impact Approval Form** is required for each specialized THP service to assess on workflow impact in terms of resources and finance
  - For example: a study specific CT scan will cost $200 per patient. Diagnostic imaging leadership will confirm the cost per unit and whether technicians are available to perform this test

RESEARCH STUDY BUDGETS - ROLES & RESPONSIBLITIES

RO Role/Responsibilities

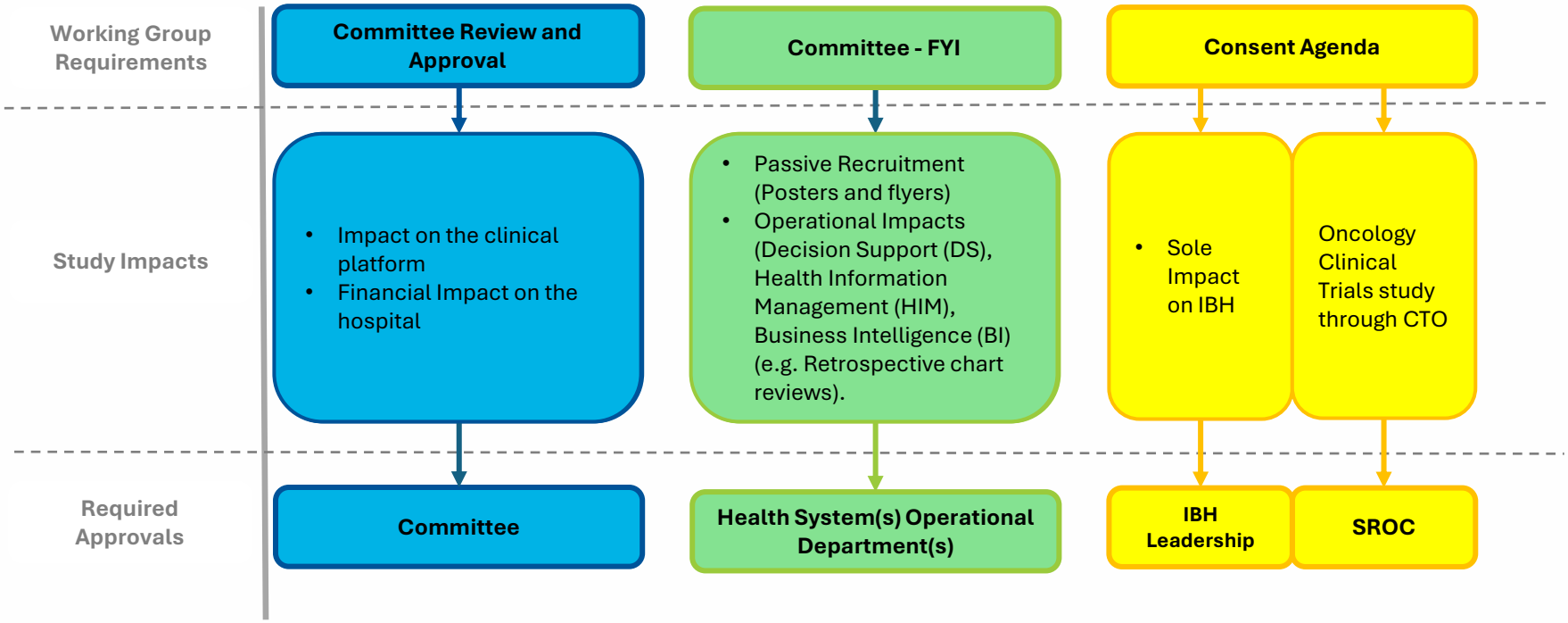
- Reconcile study budget with department impact form
- If study is externally funded, budget negotiations will be led by ROA to meet the standard THP costs
- Track the budget over the project lifetime (clinical studies)
- Inform the study team of budget variances

Trillium Health Partners (THP) Administration Approval Process OVERVIEW
THP "Research and Innovation Committee (R&IC):

The R&IC is responsible for the Oversight of THP's research and innovation activities

- All projects that have an impact on THP or are being conducted under the auspices of THP are required to be submitted to R&IC
- The R&IC includes clinicians, staff and administrative leads from different departments throughout the hospital that support research and innovation projects.
- Projects impacting the clinical platform and/or have a financial impact on THP, the R&IC is responsible for ensuring:
  - ❑ Projects are meaningful to patients
  - ❑ Assessing the impact(s) to the THP clinical and operational platform
  - ❑ Impact to research resources and
  - ❑ granting institutional approval

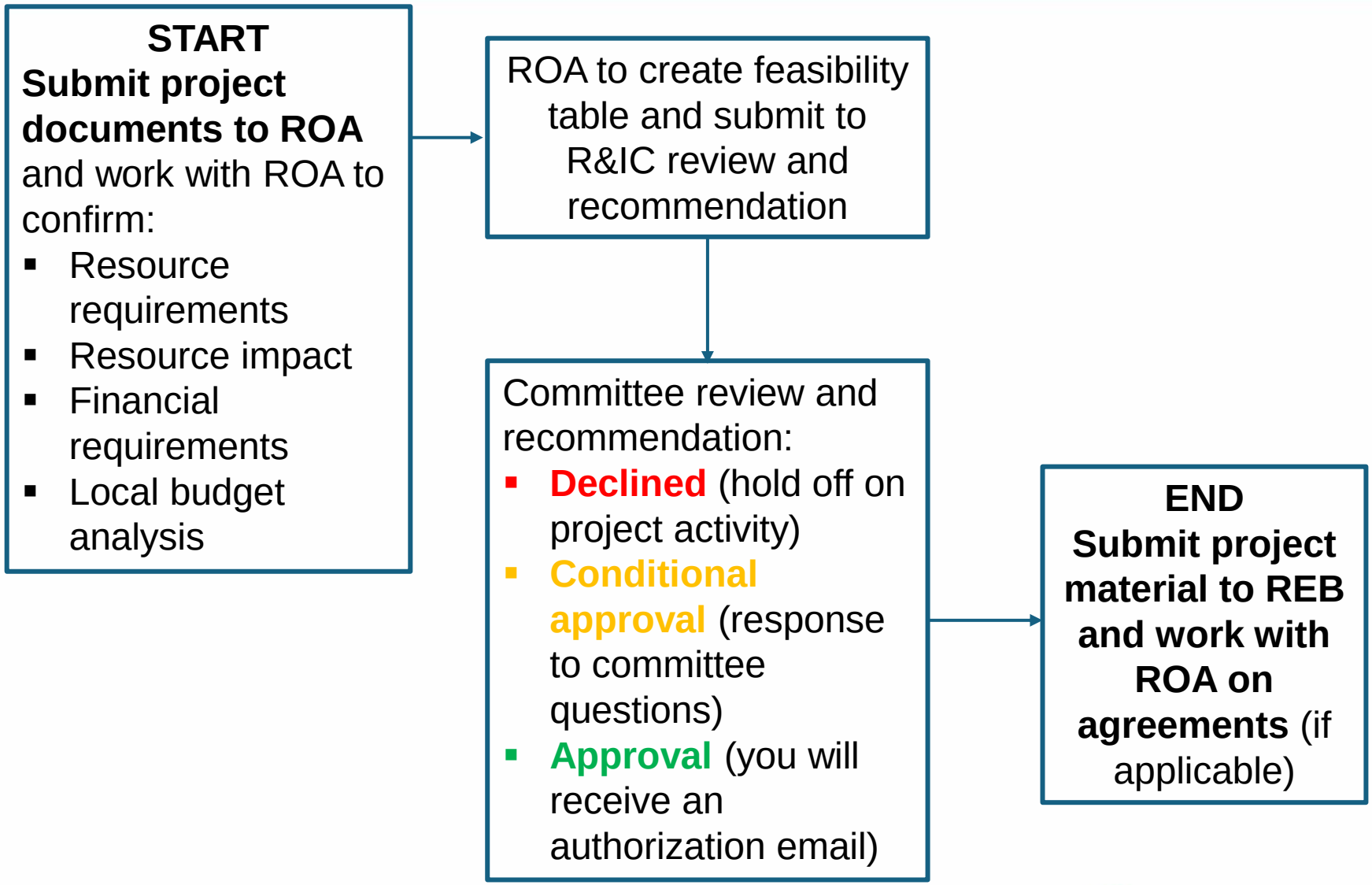
COMMITTEE– ADMINISTRATIVE APPROVAL PROCESS



R&IC meets every Wednesday

IBH: Institute for Better Health
CTO: Clinical Trials Ontario
SROC: Scientific Review and Oversight Committee

COMMITTEE– ADMINISTRATIVE APPROVAL PROCESS



AGREEMENTS - OVERVIEW

What is an agreement?

- A legally binding document that outlines the rights, obligations, responsibilities and liabilities of the parties engaging in project activities
- Enhances the protection of the rights of the study subjects, the institution (THP), its staff and the physician principal investigators/researcher
- Allocates risks, delineates responsibilities and covers financial aspects of the respective parties to the agreement

When is an agreement required?

- For any project activity that involves: (1) the collection and disclosure of THP staff and/or patient information, and/or (2) the participation of THP Staff and/or patients

Research Operations works closely with the project team to determine if an agreement is required

AGREEMENTS - ROLES/RESPONSIBILITIES

RO Role/Responsibilities

- Research Operations Analysts (ROA) manage the agreement review, negotiation and execution process by:
  - ❑ Determining if an agreement is required and the appropriate type
  - ❑ Undertaking the institutional review, negotiation and execution of all agreements
  - ❑ Drafting agreements and obtaining legal advice through consultation
  - ❑ Ensuring institutional compliance with executed agreements
  - ❑ Managing key stakeholder relationships

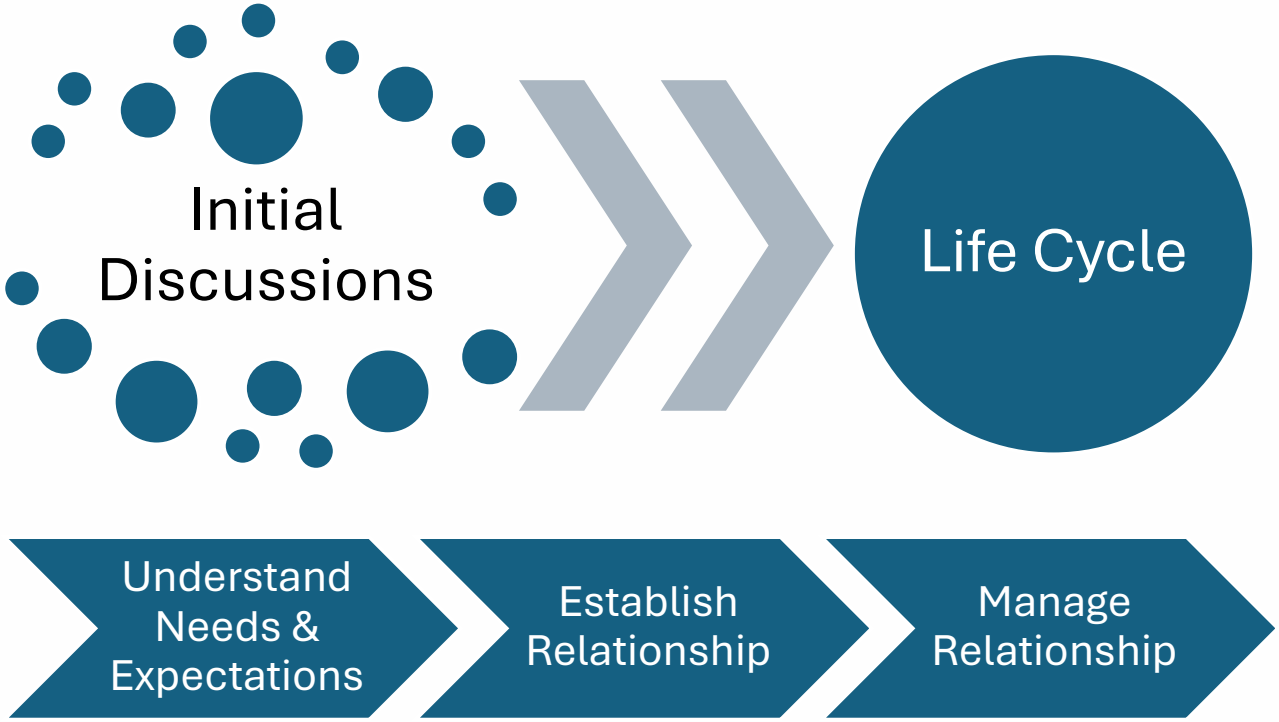
Project Team Role/Responsibilities

- Work closely with the dedicated ROA to ensure they have a clear understanding of scope of study conduct and activity
- Once the agreement is finalized, the local PI reviews and approves the agreement

FINANCIAL MANAGEMENT

- ✓ Opening Study Cost Centre
- ✓ Budget Reconciliation & Tracking
- ✓ Invoicing
- ✓ Receipt of Funds
- ✓ Funds disbursement
- ✓ Fund Transfer
- ✓ Financial Reporting
- ✓ EPIC study maintenance and billing review (clinical)
- ✓ Closing, etc.

RELATIONSHIP MANAGEMENT



WHAT IS A RESEARCH ETHICS BOARD (REB) AND THEIR ROLE?

What is a Research Ethics Board (REB)?

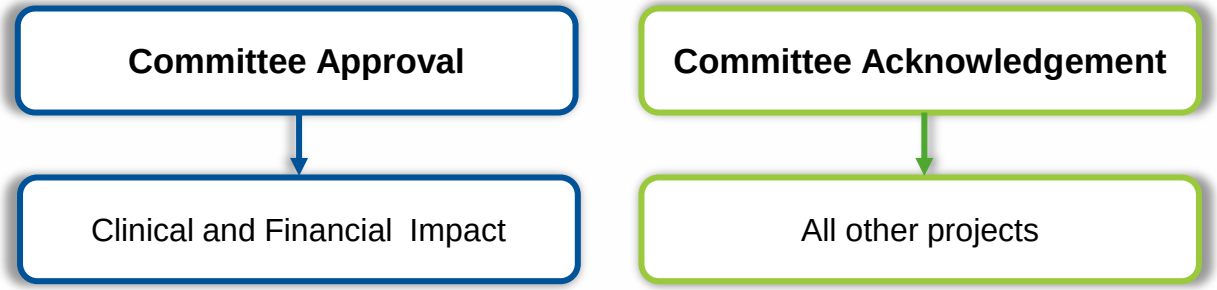
- The REB is comprised of members including:
  - ❑ Those with expertise in research, ethics, law
  - ❑ Community members

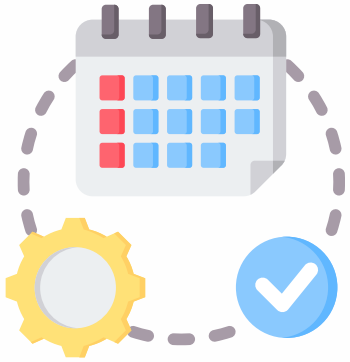
- The REB was established by the THP Board of Directors to review the ethical acceptability of research being conducted under the auspices of THP.

- The primary goal of the REB is to protect the rights and welfare of people who participate in research.

When Can I Submit to the REB?

1. Research and Innovation Committee





*Your dedicated ROA will inform you when you can submit to the REB

2. Board of Record (BOR)

a. The THP REB has been granted primary authority of a research project that is not taking place under the auspices of THP.

BOARD OF RECORD PROCESS

Use of External REBs

Institutional approval is required and a request containing the following items must be submitted the THP REB:

- ❑ A 1-page summary explaining why you wish to delegate REB overview to an external REB,
- ❑ REB approval letter from lead site, and
- ❑ A copy of the protocol.

If approved, a board of record agreement will be put in place.

Your Dedicated ROA will support you through this process.

INSTITUTIONAL APPROVAL VS. REB APPROVAL

What's the Difference Between the R&IC and the REB?

Research and Innovation Committee (R&IC)	Research Ethics Board (REB)
▪ Responsible for the feasibility and logistics of a research project	▪ Operates at an arm's length from IBH/THP ▪ Focuses on research ethics ▪ Adopts the "participant perspective" ▪ Responsible for ensuring that research is in accordance with the highest scientific & ethical standards

WHEN TO REACH OUT TO THE THP REB

Determining the Scope and Jurisdiction of REB Review

- ❑ Whether an activity is research

- ❑ Involves human participants

- ❑ Is conducted within or under the auspices of the organization

SUPPORTS PROVIDED BY THE REB

Human Subject Research Determination Request

Submit to REB:

- Project Charter/Protocol
- ARECCI screening tool results
- THP REB human subject research determination form

Consultation Service

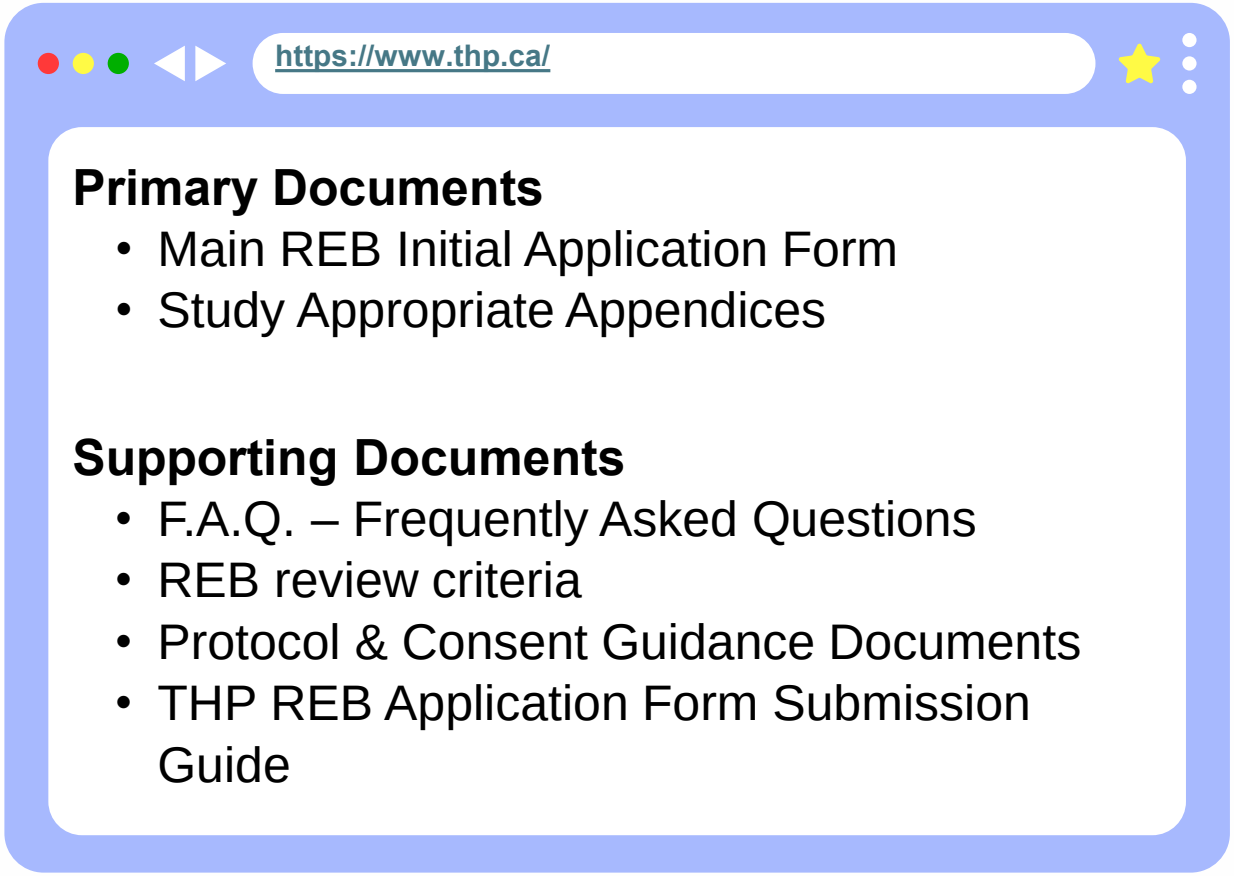
Email: THPREB@thp.ca

Tel: 437-777-2083

PREPARING YOUR SUBMISSION PACKAGE

Where Can I Find REB Submission Forms?

All THP REB supporting documents and application form can be found at: Research Ethics Board (thp.ca)



PREPARING YOUR SUBMISSION PACKAGE

What Forms Need to be Submitted?

- Main REB Initial Application Form
- Appendices – depend on the type of study you are conducting
  - ❑ Interventional study
  - ❑ Retrospective study
  - ❑ Prospective study (non-interventional)
  - ❑ Genetics/biobank

- Additional Forms (if applicable):
  - ❑ External Research Advertisement/Recruitment Application Form
  - ❑ Case Report and Case Study Form

PREPARING YOUR SUBMISSION PACKAGE

What Additional Forms Should be Submitted?

- ❑ Data collection forms (e.g., excel spreadsheet, Case Report form (CRF), database screen shot, etc.)
- ❑ Consent Form or waiver of consent document
- ❑ Questionnaires, Surveys, and interview questions

- ❑ Scripts (e.g., telephone, recruitment, interview, etc.)
- ❑ Posters, flyers and brochures
- ❑ Investigational brochures and Product monographs

- ❑ No Objection Letter (NOL) / Health Canada Authorization
- ❑ Peer review and other REB approval letters

POST REB APPROVAL APPLICATION FORMS

What Forms are Submitted Post Approval?

Amendment Submission form

Annual Renewal Application

Additional Forms When Required:

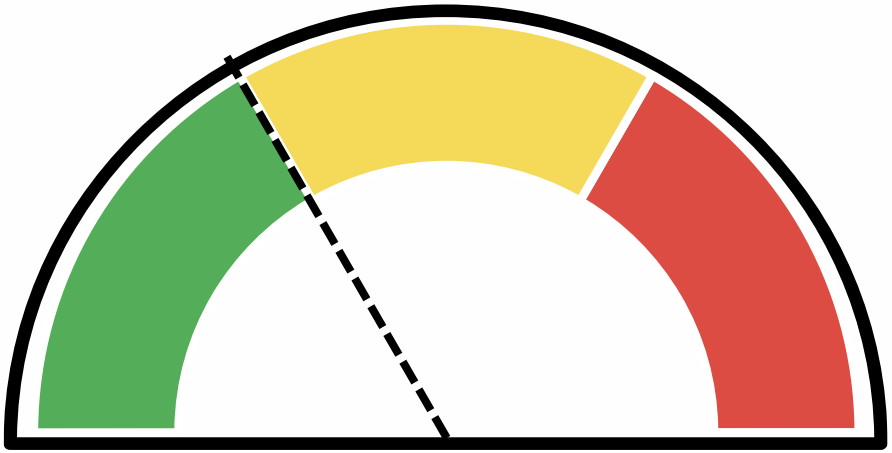
- ❑ Study Closure/Termination Form
- ❑ Change in Investigator/Study Personnel Form
- ❑ Protocol Deviation/Violation Reporting Form
- ❑ Supplemental Safe Research Practices Form
- ❑ Serious Adverse Events (SAE) reporting form

NAVIGATING THE RESEARCH ETHICS BOARD PROCESS

REB Risk Assessment

Minimal Risk

Delegated Review



Above Minimal Risk

Full Board Review

Minimal risk: “the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.” (TCPS 2, article 2.8)

NAVIGATING THE RESEARCH ETHICS BOARD PROCESS

REB Timelines

Delegated Review	Full Board Review
• No submission deadline • The REB aims to respond within 10 business days of a complete submission	• Submit by the 1st business day of the month • The full board meets every third Thursday of the month • The REB aims to respond within 10 business days after the full board meeting

Submission Requirements: Process Overview – Research Ethics Board Review (Outcomes)

REB Determination	Correspondence Type	Likely Explanation	Required Next Steps
Approval	Approval Letter	• Proposed study, study conduct and associated study documents are deemed ethically acceptable	• Proceed with next steps
Conditional Approval (delegated review)	Conditional Approval Letter	• Proposed study deemed acceptable • Minor issues/concerns identified requiring resolution and response.	• Address all concerns raised by the REB • Make any necessary revisions to study documents • Submit responses and updated documents to REB
Conditional Approval (full-board)			
Cannot Approve as Submitted	Review Letter	• Significant concerns identified • Requires significant revisions/resubmission	• Consultation with REB • Redesign study
Decline	Letter of Decline	• Significant concerns identified • Unfavorable risk/benefit ratio	

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

- Is the behaviour expected of anyone who conducts or supports research activities throughout the life cycle of a research project
  - ❑ formulation of the research question, and design,
  - ❑ conduct, collection of data, and analysis of the research,
  - ❑ reporting, publication and dissemination,
  - ❑ management of research funds.

- Both Compliance and Research Ethics are required for the Responsible Conduct of Research.

RESEARCH CONDUCT AND COMPLIANCE

- Tri-Council Policy Statement Ethical Conduct for Research Involving Humans TCPS2 2022
- Good Clinical Practices (GCP) Consolidated Guideline
- Tri-Council Policy - Policy on Sensitive Technology Research and Affiliations of Concern
- The Canadian Food and Drugs Act and its applicable Food and Drug Regulations, in particular, Part C, Division 5.
- International Council for Harmonization (ICH)
- National Security Guidelines for Research Partnerships
- Tri-Agency Guidance on the STRAC Policy
- Personal Health Information Protection Act, 2004 (PHIPA) and its applicable regulations.

MANDATORY RESEARCH TRAINING & CERTIFICATIONS FOR THP INVESTIGATORS

Tri-council Policy Statement 2, Course on Research Ethics (TCPS 2 CORE)	▪ One Time Completion ▪ http://tcps2core.ca/welcome
Responsible Conduct of Research (RCR) – Life Science Course	▪ Every 2 years ▪ CITI
THP Research Related Privacy Training	▪ One time Completion ▪ Evaluation Survey surveymonkey.com
Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects Course	▪ PI involved in Regulated Clinical Trials ▪ Every 5 years ▪ CITI
Integrating Sex & Gender in Health Research Training Module	▪ PI involved in Regulated Clinical Trials ▪ One-time Completion ▪ http://www.cihr-irsc.gc.ca/e/49347.htm

HOW WE SUPPORT YOUR RESEARCH

Responsible Conduct of Research/Research Integrity

Research Ethics Compliance

Research Security

EXTERNAL RESEARCH PERSONNEL CLEARANCE

- Mandatory requirements and procedural steps for granting external research personnel (ERP) access to THP premises and resources,
- Project should have executed research agreement and REB approval
- Complete mandatory clearance requirements:
  - ❑ Health Clearance**
  - ❑ THP Research Related Privacy Training
  - ❑ Mandatory Policy Review Attestation Form: Privacy Policy, Acceptable Use Policy, Password Policy, THP Information Security Policy
  - ❑ Confidentiality Agreement
  - ❑ Mandatory Training: Fire, WHMIS, Hand Hygiene**
  - ❑ Electronic Medical Record Access
  - ❑ VPN Access

If **remote access to THPs Electronic Medical Record only; then these two trainings are not required. However, should this change ERP will be required to complete these requirements.

RESEARCH PROJECT MANAGEMENT TEAM (RESEARCH SUPPORT SERVICE)

Research Project Management Service Model Operations	• Grant and award application development/submission • Project level support across the lifecycle of a project • Project participant identification, recruitment & relationship management
Project Management TOols & Process Management	• Project documentation, tracking and reporting • Project regulatory and administrative submissions • Project financial transactions
Scientist & Investigator Relationship Management	• Project specific support • Portfolio support
IBH Partnered* Projects Management	• Project level support across the lifecycle of a project • Project partner relationship management

**Non-IBH related projects seeking IBH capabilities to support project development and/or execution*

- Fee-for-service model
- Support full lifecycle of research, can be leveraged at any stage
- Expertise in Qualitative, Quantitative, Mixed-Methods and Clinical Research
- We work closely with the PI's and ROA's during the study budget development to ensure appropriate support needs are captured in the budget

Contact: Crystal Williams, Manager, Research Programs (crystal.r.williams@thp.ca)

Thank You!

If you have any questions, please contact us at:

Research Operations – ResearchOperations@thp.ca
THP Research Ethics Board - THPREB@thp.ca
Research Conduct of Research - RCR@thp.ca

Trillium Health Partners
Better Together