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

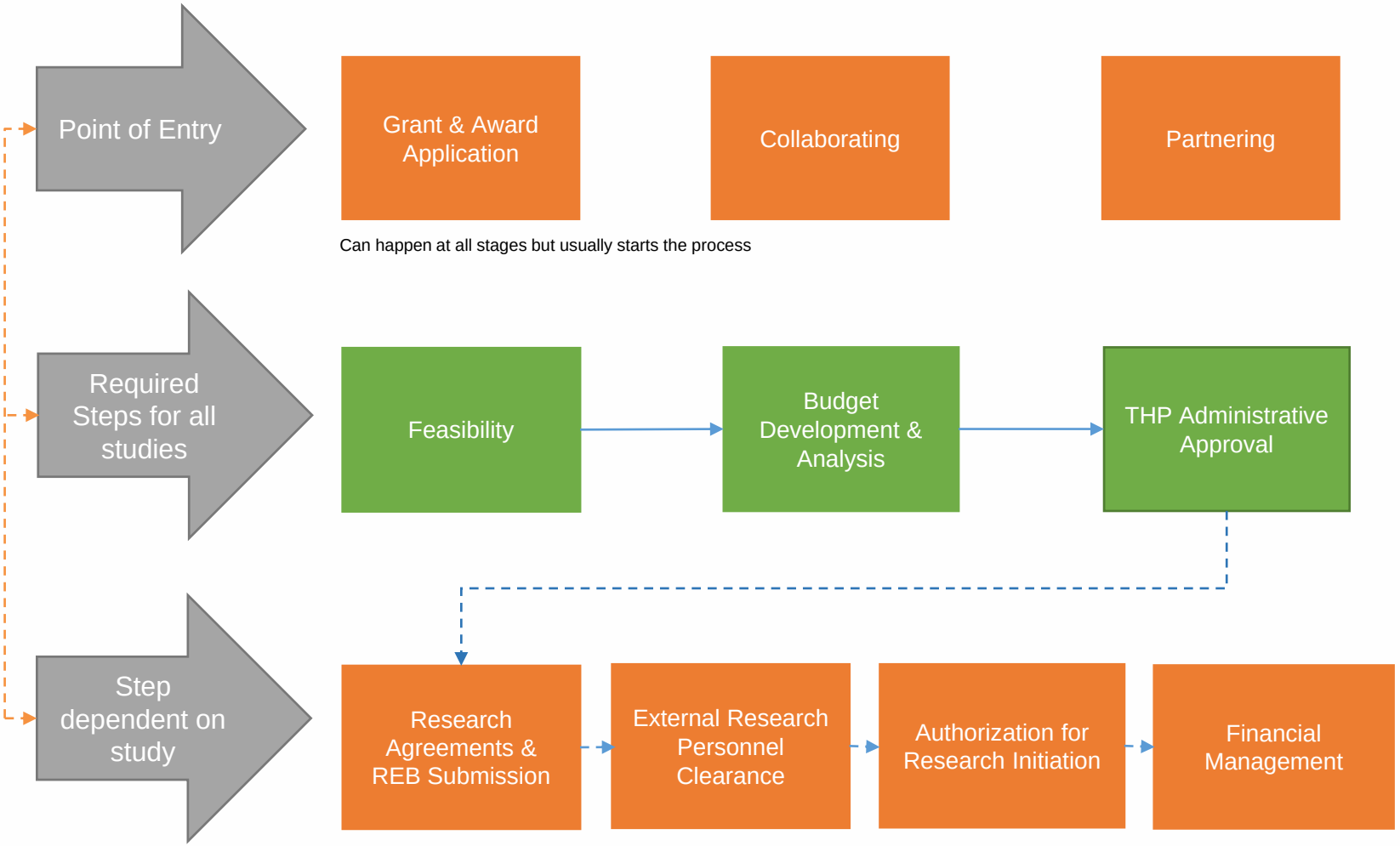
- What would you like to get out of today's session? What are you interested in?
- Do you have any questions about our study initiation process?
- Have you ever participated in a research project or submitted to the REB?

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
Grants & Awards Management	• Study financial modelling • Study financial monitoring (analysis, interpretation) • Study financial processing (invoicing, reconciliation, reporting)

MAPPING OF RO FUNCTIONS



PORTFOLIO DISTRIBUTION

Research Operations Team

Manager, Business Operations
- Joshua Adedamola

Research Operations Analyst (ROA):
- Mobina Khurram
- Harleen Kaur
- Paige Adams

Research Operations Advisor
- Amna Ali (interim)

	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	

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

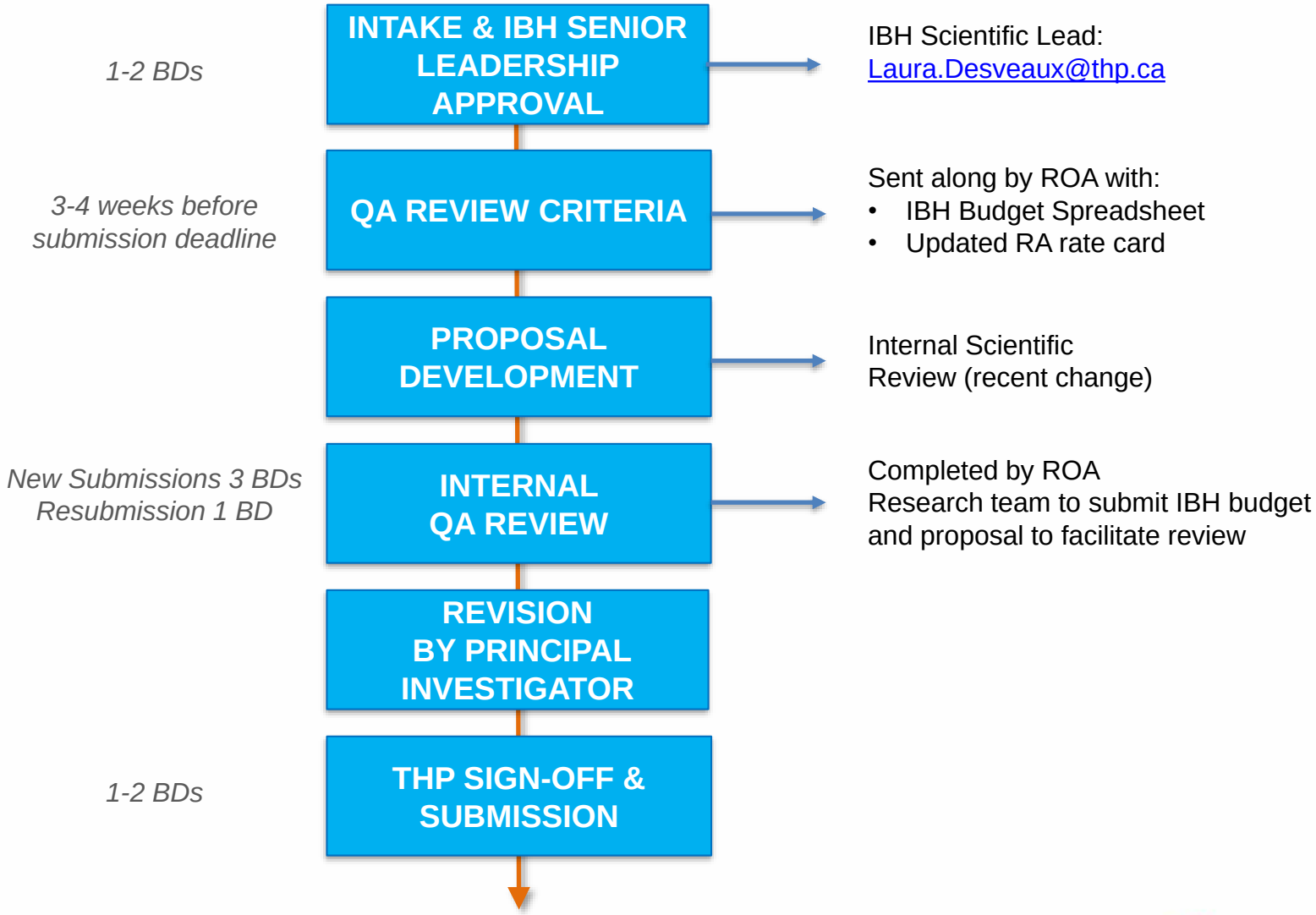
Additional Training requirements for Interventional Clinical Trials & Regulated Clinical Trials

- 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 Appendix A
- 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?
- An Appendix A is required for each impacted department

Share completed Appendix A(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 Resource Impact form (Appendix A)
- Appendix A 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

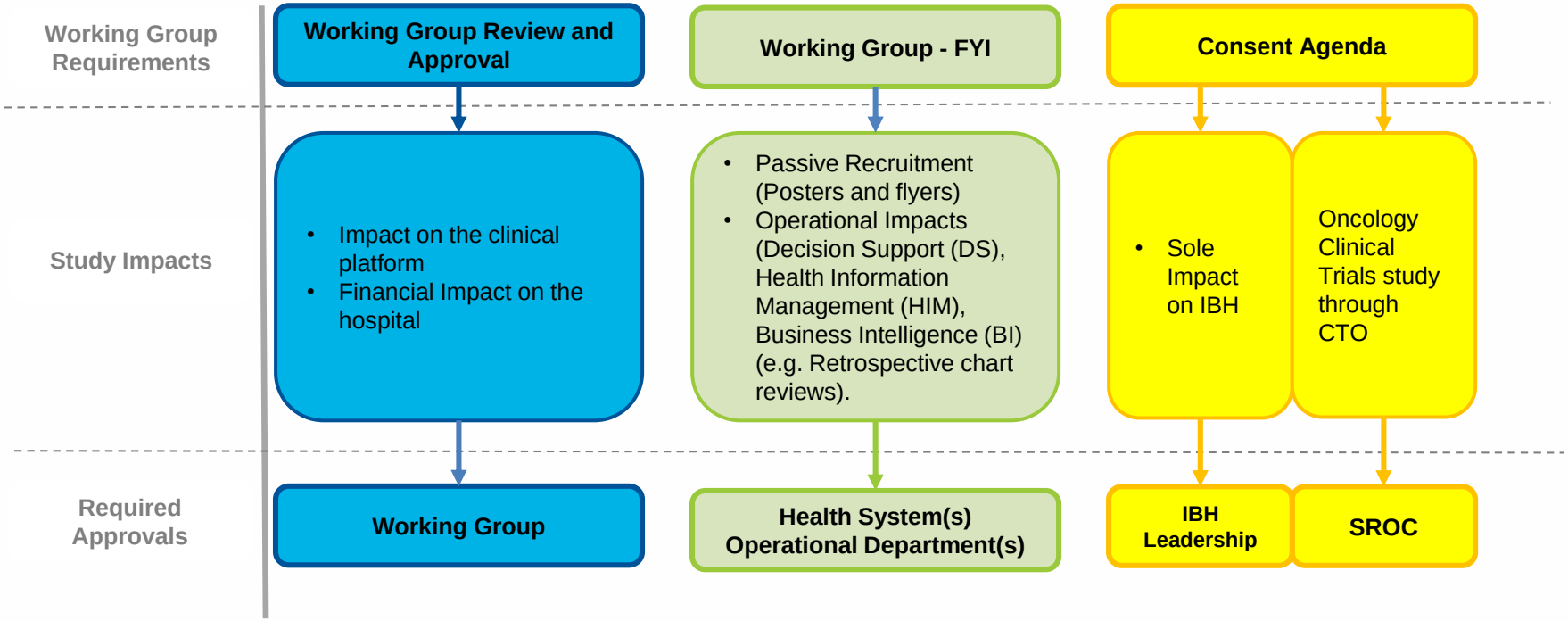
Trillium Health Partners (THP) Administration Approval Process OVERVIEW

THP "Research and Innovation Working Group (RIWG):

The RIWG 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 RIWG
- The RIWG 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 RIWG 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

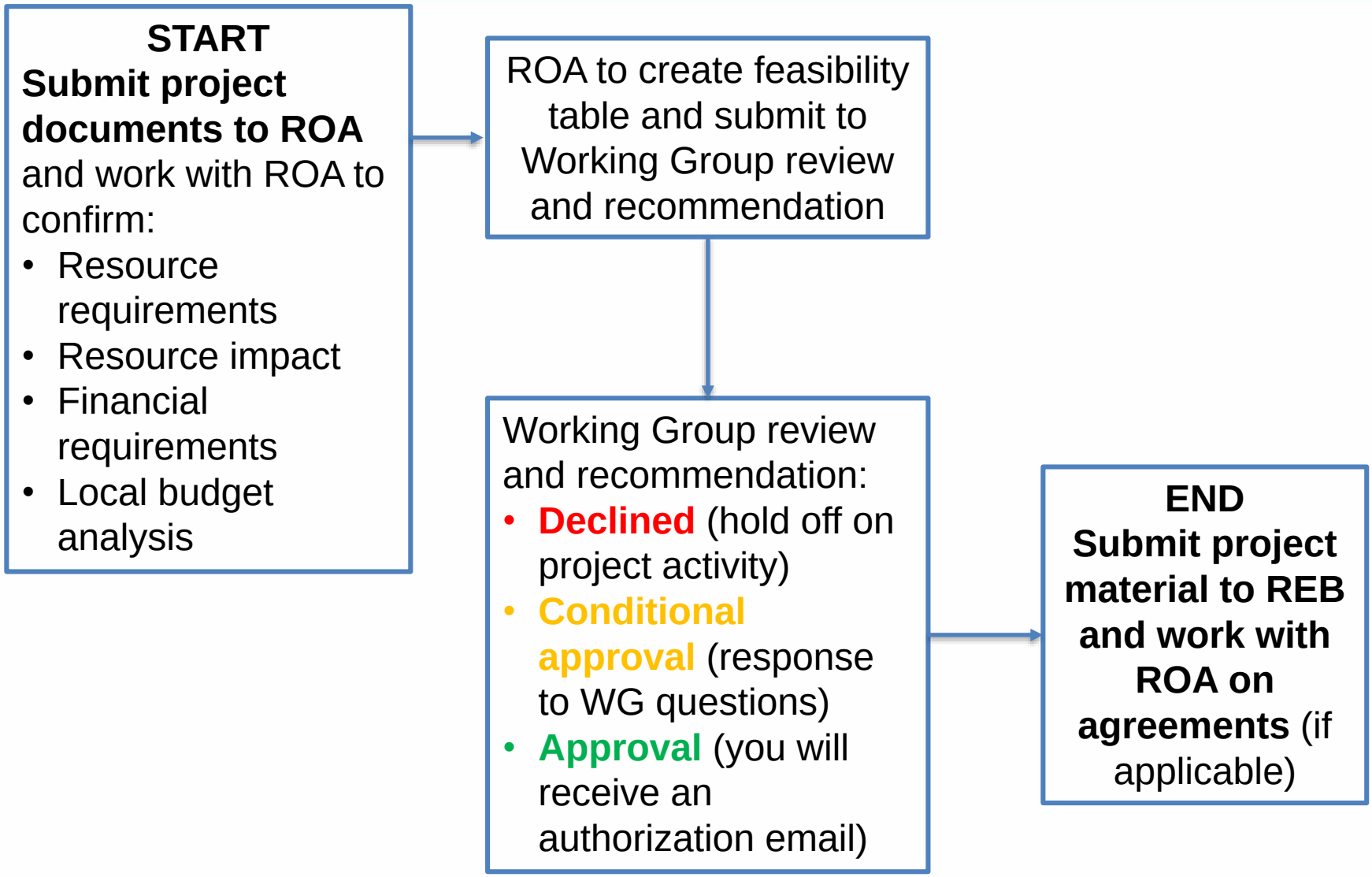
WORKING GROUP – ADMINISTRATIVE APPROVAL PROCESS



RIWG meets every Wednesday

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

WORKING GROUP – 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

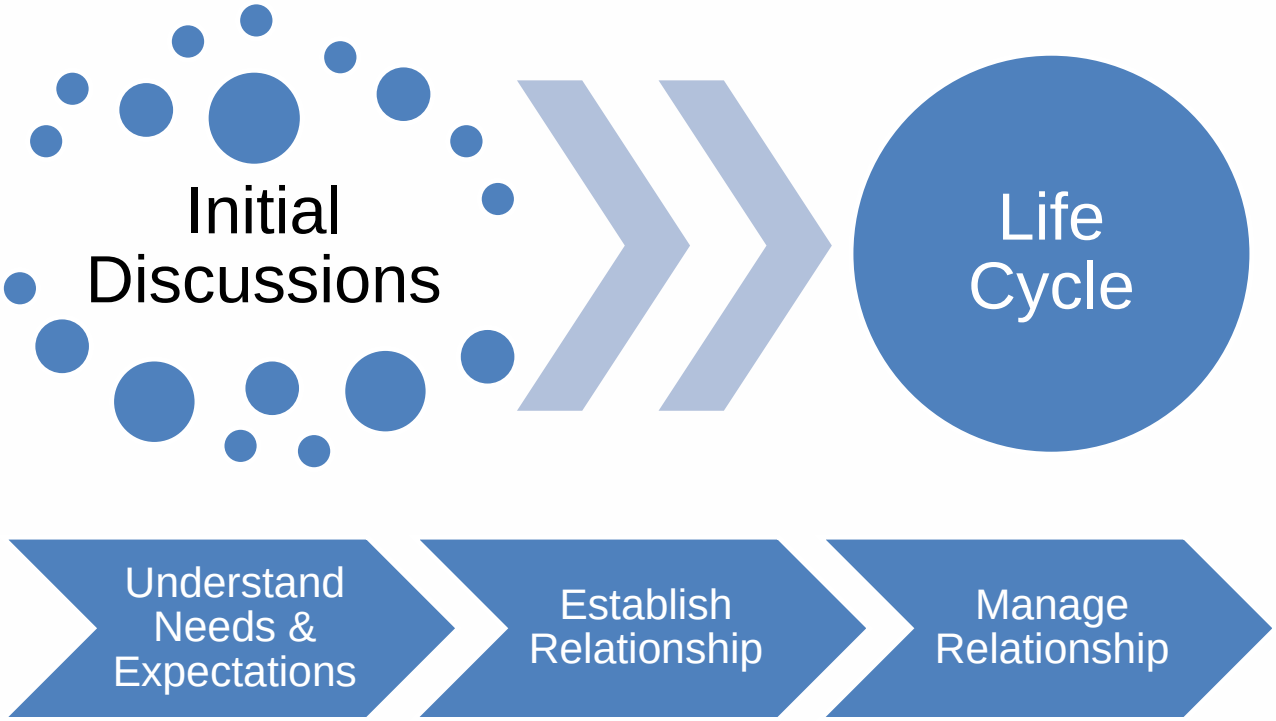
Project Team Role/Responsibilities

- 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

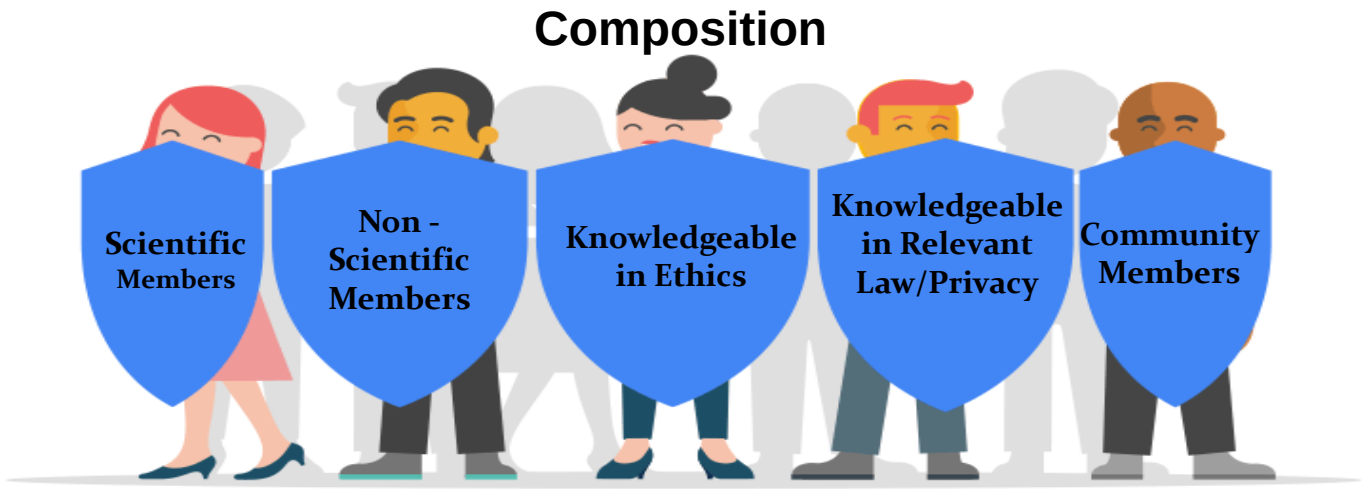
RELATIONSHIP MANAGEMENT



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

What is a Research Ethics Board (REB)?

- The REB is comprised of members (including community representation) with expertise in research, ethics and laws. The REB is established by Trillium Health Partners' (THP) Board of Directors, to independently review the ethical acceptability of all research involving human subjects that is being conducted under the auspices/jurisdiction of THP, in order to protect the rights and welfare of people who participate in research.



TRILLIUM HEALTH PARTNERS RESEARCH ETHICS BOARD

When Can I Submit to the REB?

1. Research and Innovation Working group approval or acknowledgement
   - Approval is required for studies with an impact on the clinical platform (excluding OCT).
   - Submission to the REB once an approval email is received from the Working Group.

   - All other studies are acknowledged by the working group
   - Submission to the REB once directed by your dedicated ROA.

2. Board of Record (BOR)
   - The THP REB has been granted primary authority for the scientific review, ethical review, and ongoing monitoring of a research project that is not taking place under the auspices of THP .

BOARD OF RECORD PROCESS

Use of External REBs

- Institutional approval/authorization to go forward with submission to external REB (not required for COVID related studies OCT studies going through CTO)
  - Submit a 1 page letter explaining why you wish to delegate REB overview to an external REB. (ROA will provide criteria to include in letter).
  - REB approval letter from lead site
  - A copy of the protocol

Board of record agreement is required for studies that are not going though CTO or OCREB

❖ Your Dedicated Research Operations Analyst will support you through this process.

REB DELEGATION REQUEST

An email request should be sent to Kylie Walcott, Manager of Research Ethics, Infrastructure & Oversight: Kylie.Walcott@thp.ca

Outline

- Clear rationale/justification for use of the external REB
- How external REB best serves the needs of the project
- How external REB best serves the needs of participants

INSTITUTIONAL APPROVAL VS. REB APPROVAL

We work together… but the THP REB is

1. Arm's length from IBH/THP

2. Independent in its review
   - R&IWG – feasibility & logistics (departmental support, funding, institutional impacts, etc.)

   - REB
     - Ethics (privacy, confidentiality, risk, consent, COI, etc.)
     - 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

THE SCOPE AND JURISDICTION OF REB REVIEW IS DETERMINED BY:

1. Whether an activity is research;

> **RESEARCH:** "An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation." (TCPS 2)

2. Involves human participants, data obtained from human participants (e.g. chart reviews, interviews, questionnaires, etc.), and human biological materials (e.g., stem cell research, blood samples, saliva samples, etc.);
3. Is conducted within the organization, or under the auspices of the organization.

> "by the organizations employees, **privileged staff**, **professional staff**, agents, contractors, **students**, and volunteers **in relation to their role within the organization**"

SUPPORTS PROVIDED BY THE REB

HUMAN SUBJECT RESEARCH DETERMINTION REQUEST

Submit to REB:

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

CONSULTATION SERVICE

REB Consultation Service
Email: thpreb@thp.ca
Call: Mobile 1-437-777-2083

THP REB HUMAN SUBJECT RESEARCH DETERMINATION PROCESS

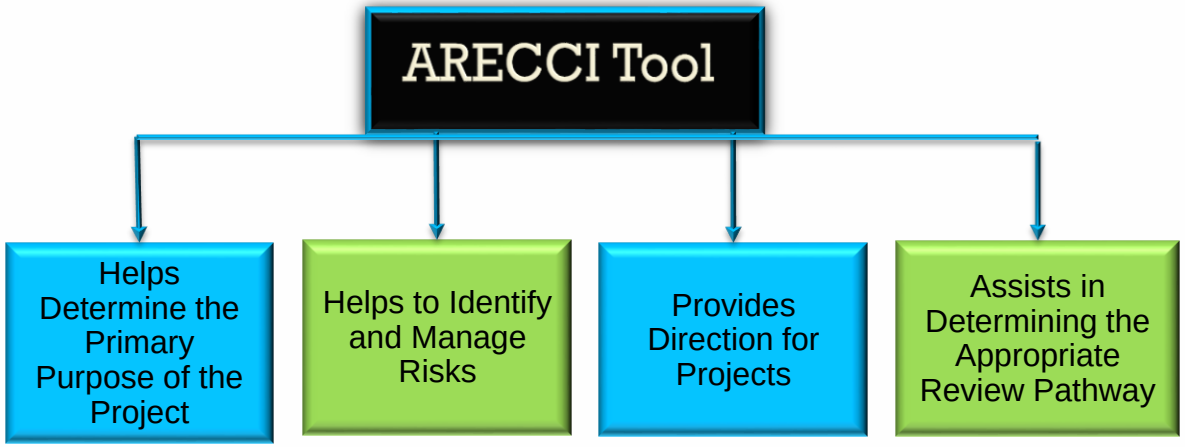
Submit

- Project Charter/Protocol + other related documentation
- ARECCI results
- THP REB human subject research determination form

Outcomes

- **Not research or non-human subjects research** - Determination letter issued.
- **Human subjects research -** Submit an REB application and all relevant document (i.e. protocol, data collection form, etc.) for review and feedback by the THP REB.

RESOURCES TO SUPPORT CATEGORIZATION



PREPARING YOUR SUBMISSION PACKAGE

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

Supporting Document:

- F.A.Q. – Frequently Asked Questions
- REB review criteria
- Protocol & Consent Guidance Documents
- THP REB Application Form Submission Guide

PREPARING YOUR SUBMISSION PACKAGE

Application Forms:

1. Main Research Ethics Board Initial Application Form

    - Appendices – depend on the type of study you are conducting, e.g.
        - Interventional study
        - Retrospective study
        - Prospective study (non-interventional)
        - Genetics/biobank

Additional Forms:

1. External Research Advertisement/Recruitment Application Form

2. Case Report and Case Study Form

PREPARING YOUR SUBMISSION PACKAGE

SUPPLEMENTARY DOCUMENTS YOU MAY NEED TO SUBMIT:

- ❑ Data collection forms (e.g. excel spreadsheet, Case Report form (CRF), database screen shot, etc.)
- ❑ 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
- ❑ Consent Form/ Waiver of consent document

POST REB APPROVAL APPLICATION FORMS

Submission Documents

- Amendment Submission form
- Annual Renewal Application
- Study Closure/Termination REB Form
- Change in Investigator/Study Personnel Form
- Protocol Deviation/Violation REB Reporting Form
- Supplemental Safe Research Practices Form
- Serious Adverse Events (SAE) reporting form

PREPARING YOUR SUBMISSION PACKAGE

SUBMISSION REQUIREMENTS: PROTOCOL

WHY DO WE NEED A PROTOCOL?

NAVIGATING THE RESEARCH ETHICS BOARD PROCESS

SUBMISSION TO THE REB – RISK DETERMINATION

REB Risk Assessment

NAVIGATING THE RESEARCH ETHICS BOARD PROCESS

SUBMISSION TO THE REB – TIMELINES

Full-Board Review

1st business day of the month

2 weeks (10 business days) of the meeting date

Response time

Meeting Date:
Every third Thursday of the Month

Delegated Review

No submission deadline

2 weeks (10 business days) of complete submission documents

Response time

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 study conduct
Conditional Approval (response to Chair & Vice Chair or Reviewer)	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 (response to 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	

NAVIGATING THE RESEARCH ETHICS BOARD PROCESS

REB Submission Pitfalls

- ❑ Missing documentation
- ❑ Failure to address/respond to issues raised by REB
- ❑ Lack of clarity regarding proposed study conduct
- ❑ Inconsistencies in study details (e.g. discrepancy between protocol and application form).
- ❑ The research question and methodology lacks sufficient detail to permit evaluation of the merit of the project
- ❑ Missing submission deadlines

CONSIDERATIONS IN PREPARING SUBMISSIONS TO THE REB

Local Tools & Resources

- ARECCI Ethics Screening Tool
- Human Subject Research Determination Request Form
- Protocol Guidelines Document
- Consent Form Guidelines Document
- Justification Criteria for Waiver of Consent in Human Subjects Research
- REB Submission Dates and Meeting Dates Document
- Trillium Health Partners REB Terms of Reference
- REB Review Criteria (REB Reviewer Checklist)
- F.A.Q. – Frequently Asked Questions
- Research Ethics Board (thp.ca) or https://www.thp.ca/researchandinnovation/pages/research-ethics-board.aspx

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.

Thank You!

If you have any questions, please contact us at:

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

Trillium Health Partners
Better Together