McMaster University

Family Medicine

David Braley Primary Care Research Collaborative

FUNdamentals of Ethics Review

Neha Arora, Clinic Research Coordinator

Laura Cleghorn, Managing Director, Research

Presenter's Twitter Handle

@McMasterFamMed

Michael G. DeGroote SCHOOL OF MEDICINE

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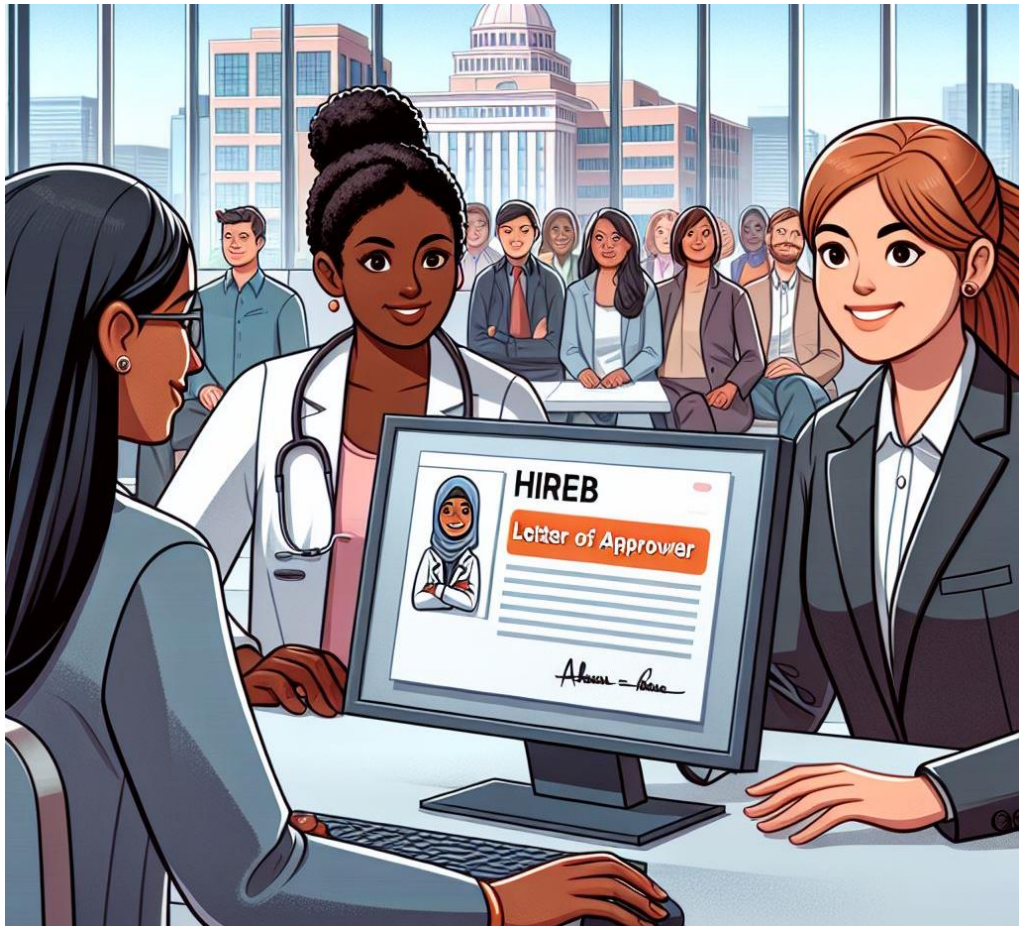
Disclaimer

We are not experts, but we are sharing what we have learned over the years and a few things that are new.

The fun part is: we are all in this together!



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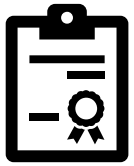


Types of HiREB Approvals/Requests

- ProTem (in principle) approval
- Quality Assurance/Improvement review
- Retrospective Review of Medical Charts/Health Data application
- General Research Application

ProTem Approval (aka In-Principle Approval)

- Allows McMaster Health Research Services to open a research funding account while waiting for ethics approval
- Once ethics approval is received, send the Approval Letter to McMaster HRS
- Important: This is NOT an ethics approval
- Research activities for a funded project cannot begin until ethics approval is received

☆Email Michelle Sylvain to get this process started sylvaim@mcmaster.ca

Quality Assurance or Quality Improvement Review

QA/QI studies, and program evaluation activities when used exclusively for assessment, management or improvement purposes, do not constitute research and do not require a full HiREB review

Projects can be exempted under one of the Tri-Council Policy Statement (TCPS 2)

This exemption does not allow you to use any participant data, or analyses based on that data, in a research publication

If data are collected for non-research use and then re-used for research, REB review and approval is required

If a project contains both Research and non-Research activities, the Research activities require REB review and approval

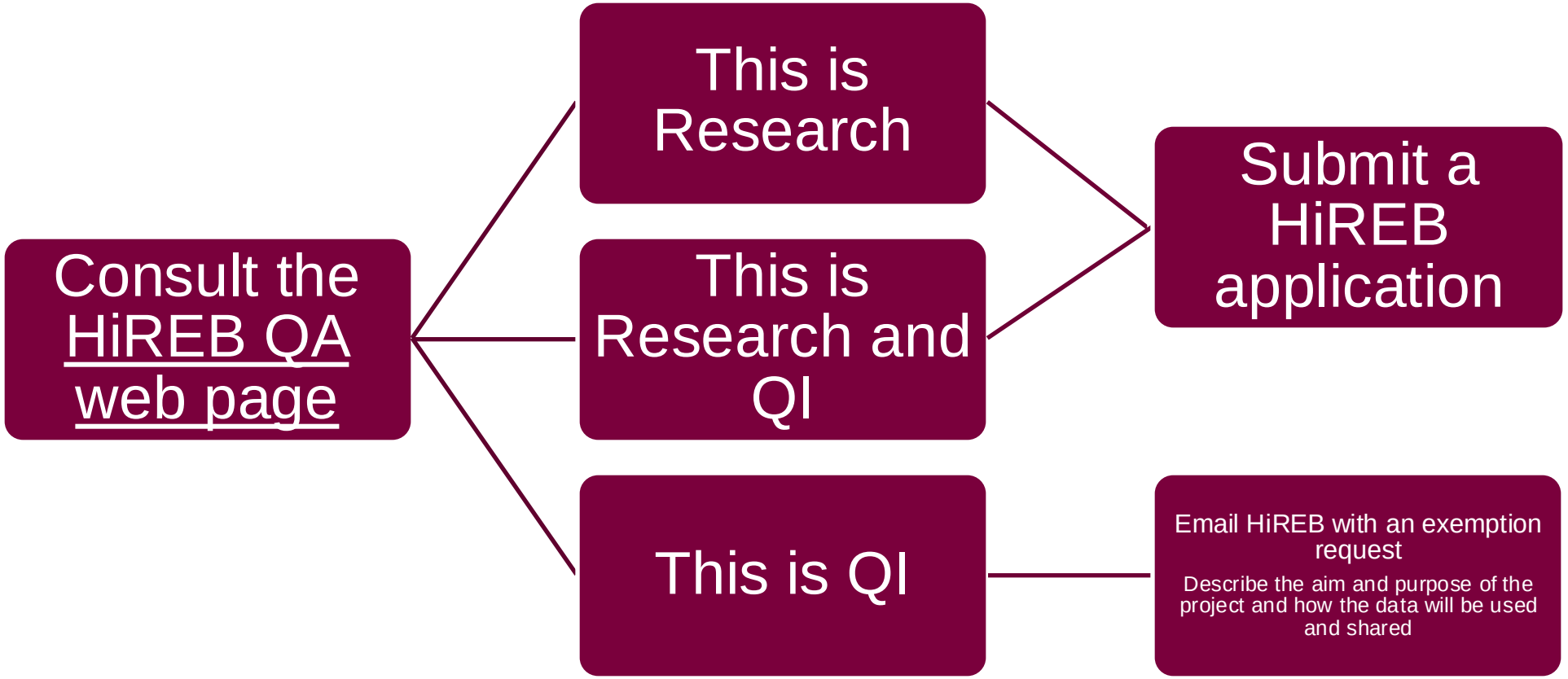
Determining Research vs. Non-Research Projects

Consult the HiREB QA webpage for guidance

- Co-design, Consultation (gathering input on research design, methods or findings)
- Program Evaluation (quality of program)
- Quality Improvement (improve performance or service)
- Usability Studies (testing an app)
- Creative Practices (creation or study of works of art)

Check out this TMU guide to determining research from non-research on the HiREB web site

Determining Research vs. Non-Research Projects



☆Contact Neha Arora for assistance (narora@mcmaster.ca)

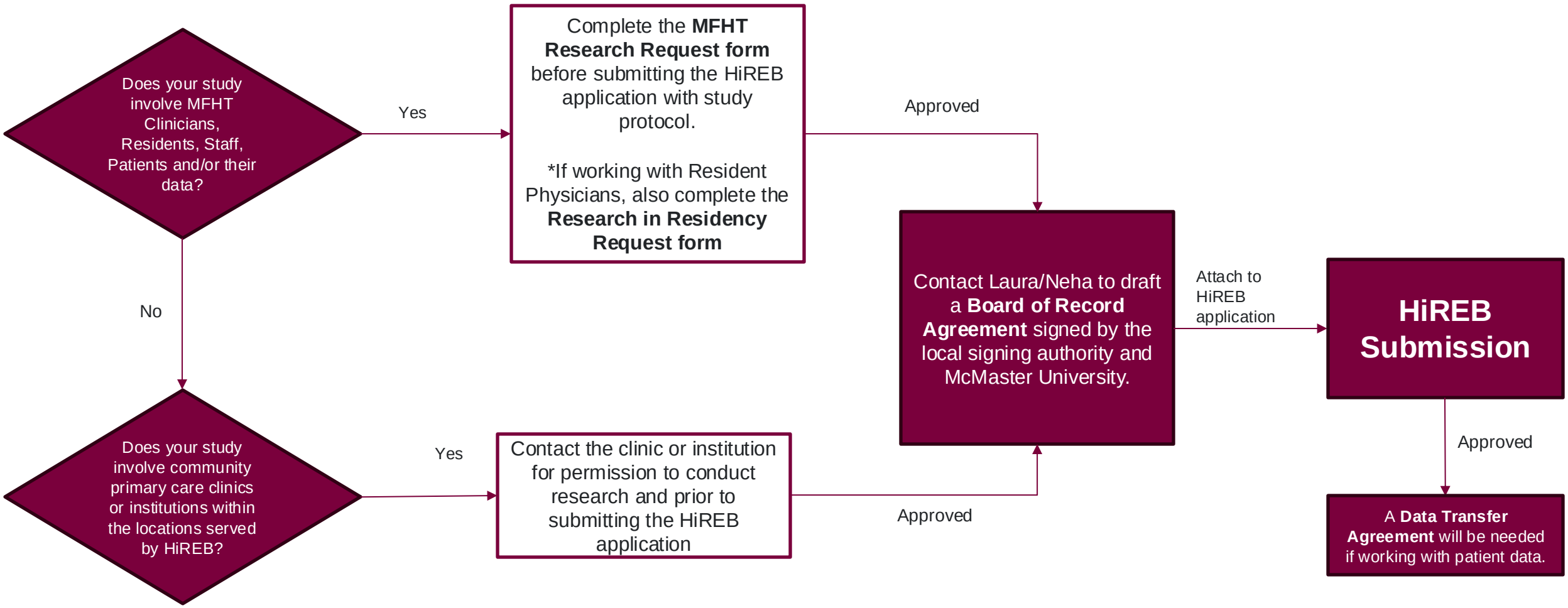
Full Research Application

- Any work that has a clearly stated research question that seeks to extend human knowledge through systematic inquiry is research
- Research applications must accompany TCPS 2 certification for the Principal Investigator (required) and staff (recommended)
- If you are conducting a clinical trial, Good Clinical Practice (CITI-GCP) Tutorial is also required

Retrospective Review of Medical Charts/Health Data Application

- For research involving the secondary use of information for research purposes, i.e., research that re-uses information originally collected for a different purpose (e.g. EMR and admin health data)
- You can also add chart review details to a full research application if also using other methods
- Chart review applications must accompany HiREB chart review tutorial certification (aka Privacy tutorial)

HiREB Application Process Summary



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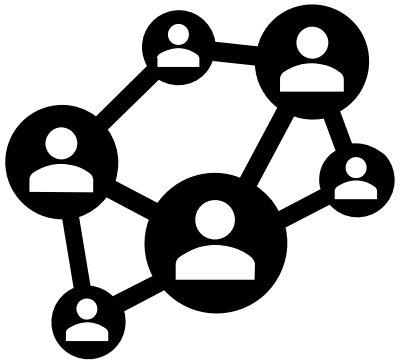


HiREB Jurisdiction

HiREB Jurisdiction

HiREB's jurisdiction is the ethical review and ongoing oversight of research activities conducted at these institutions: HHS, St. Jo's, most McMaster University clinical settings, Niagara Health

McMaster Family Practice, Stonechurch Family Health Centre, and other clinical settings located in the community operate as separate legal entities and are outside of HiREB's jurisdiction (for example, long term care homes, FHTs, solo or group practices)

HiREB requires a Board of Record Agreement to be submitted with an application for ethical review of any studies outside its jurisdiction. HiREB can still provide ethics review to determine that a project is ethically sound

Board of Record Agreement (BoR)

Why is a BoR needed?

- Informs the Delegating Institution of the limits of HiREB's jurisdiction for oversight of the research taking place and delineate roles and responsibilities of each party

- HiREB is responsible for ethics review and oversight and protect the right, safety and wellbeing of Study participants

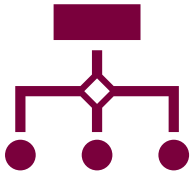
- Host Institution is responsible to conduct the study in compliance with Applicable Laws, Regulations, TCPS2, and the Tri-Agency Framework for Responsible Conduct of Research (2021)

Who signs a BoR?

- Signed by the Signatory of the REB Host Institution at McMaster (Jonathan Bramson) and the Signatory of the Delegating Institution (clinic leadership)

- Establishes a mechanism for patient complaints and verifies protections of patient information under PHIPPA and other laws and regulations

- Requires the Delegating Institution to identify a "Representative" (not the PI) to receive "notices of events"



How do I get a BoR?

- If the study is collecting data from site(s) outside of HiREB's jurisdiction, a BoR Agreement will be required

- Laura or Neha can assist with preparation of the agreement and liaise with HRS to acquire signatures

- Once signed, it can be submitted at the same time as the ethics application

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Data Transfer Agreement (DTA)

What is a DTA?

A legal contract that governs the transfer of data between organizations, including the rights, obligations, and protections of each party.

Why do we need DTAs?

DTAs are used to ensure that data is transferred securely and in compliance with applicable laws and regulations.

Protect the privacy and confidentiality of the data, especially if it includes sensitive or personal information

Must outline the specific personal information that is involved in the data sharing, the purpose, as well as additional items to support the university's compliance with FIPPA.

How do I get a DTA?

With HiREB provisional or final approval, PI will be advised to create a DTA

Contact Jonathan Lambert at Health Research Services (lamberj@mcmaster.ca)

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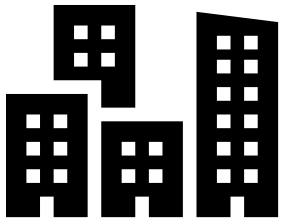


Institutional (Site) Approvals

Engaging Sites in a Study

Sites will all have processes for approval to conduct research with clinicians, patients and/or learners

Typically occurs at the grant proposal stage

+

Especially important if clinic is not part of the research team

+

Clinic may be helping with chart review, recruitment, etc.

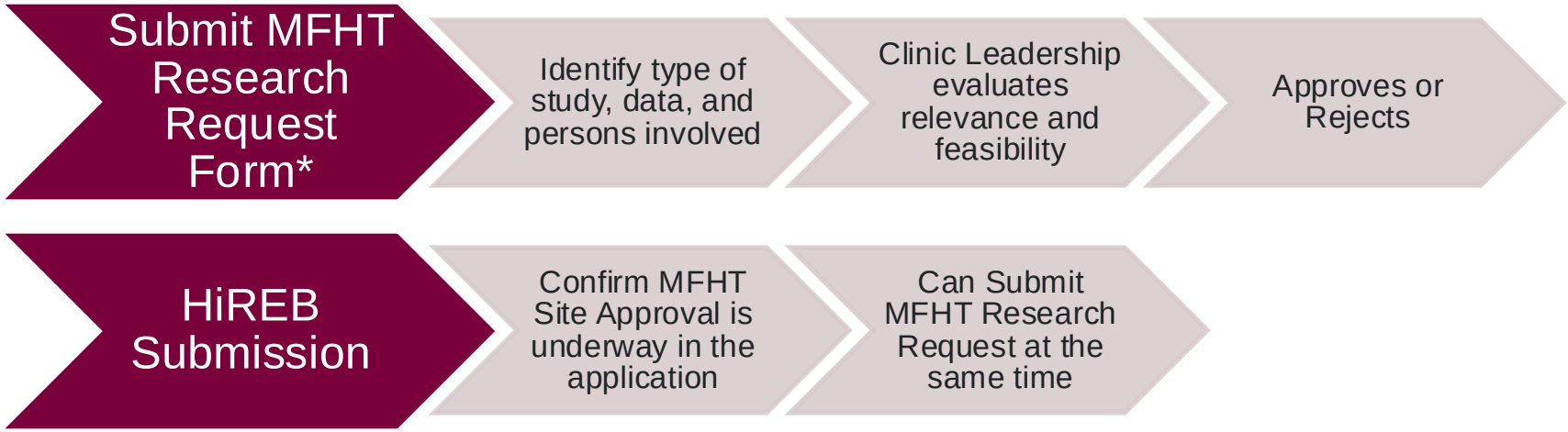
→

HiREB will require assurance that the Site approves the study.

The Site may have a formal or informal process for this

Engaging in Research at the McMaster Family Health Team (MFHT)

Stonechurch Family Health Centre, McMaster Family Practice, Maternity Centre of Hamilton



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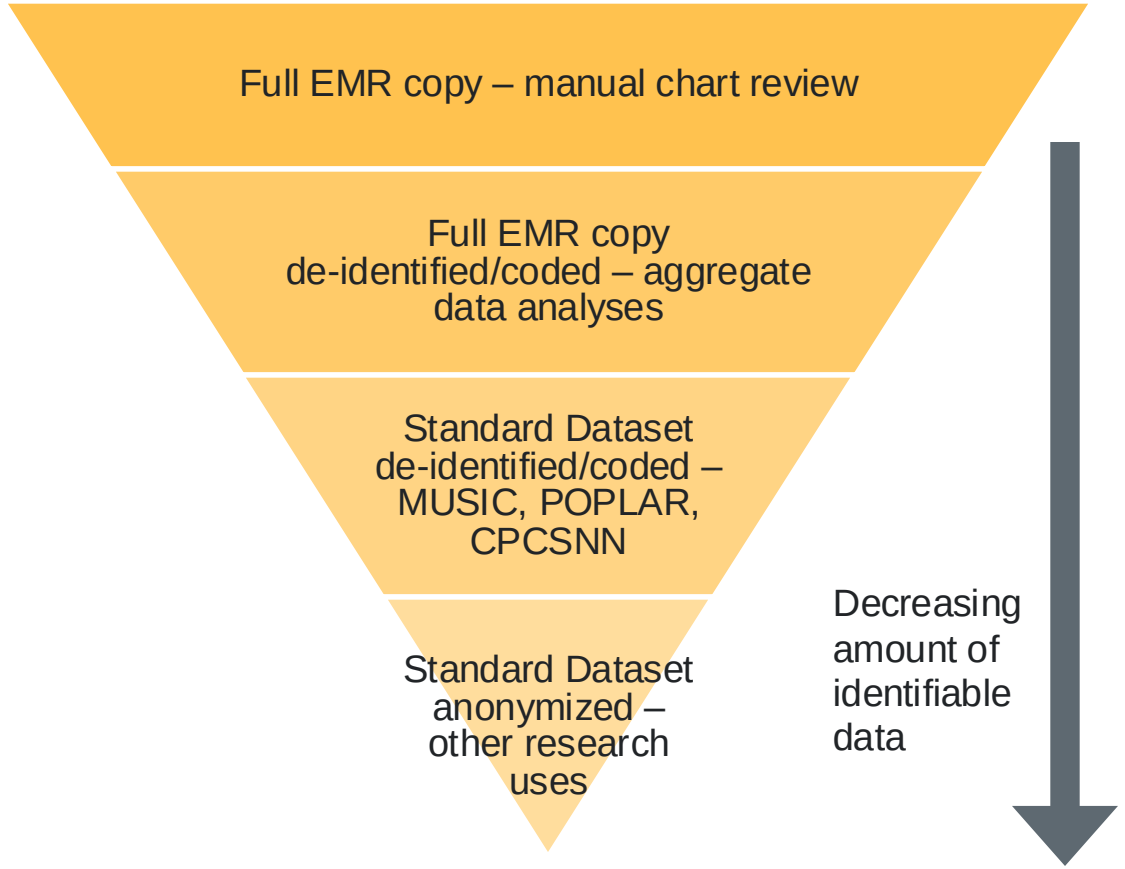
MFP and Stonechurch Data Infrastructure

- Data is governed by the Family Health Organization (FHO)
- Managed by Kris Adamczyk, Health Information Custodian (HIC) Agent
- FHO and FHT are updating the privacy policy for access and use of health data
- The type of data being accessed has implications for consent (informed consent or waiver of consent)
- Data requests can begin with the MFHT Research Request Form



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Important: Patient Data at MFP and SFHC

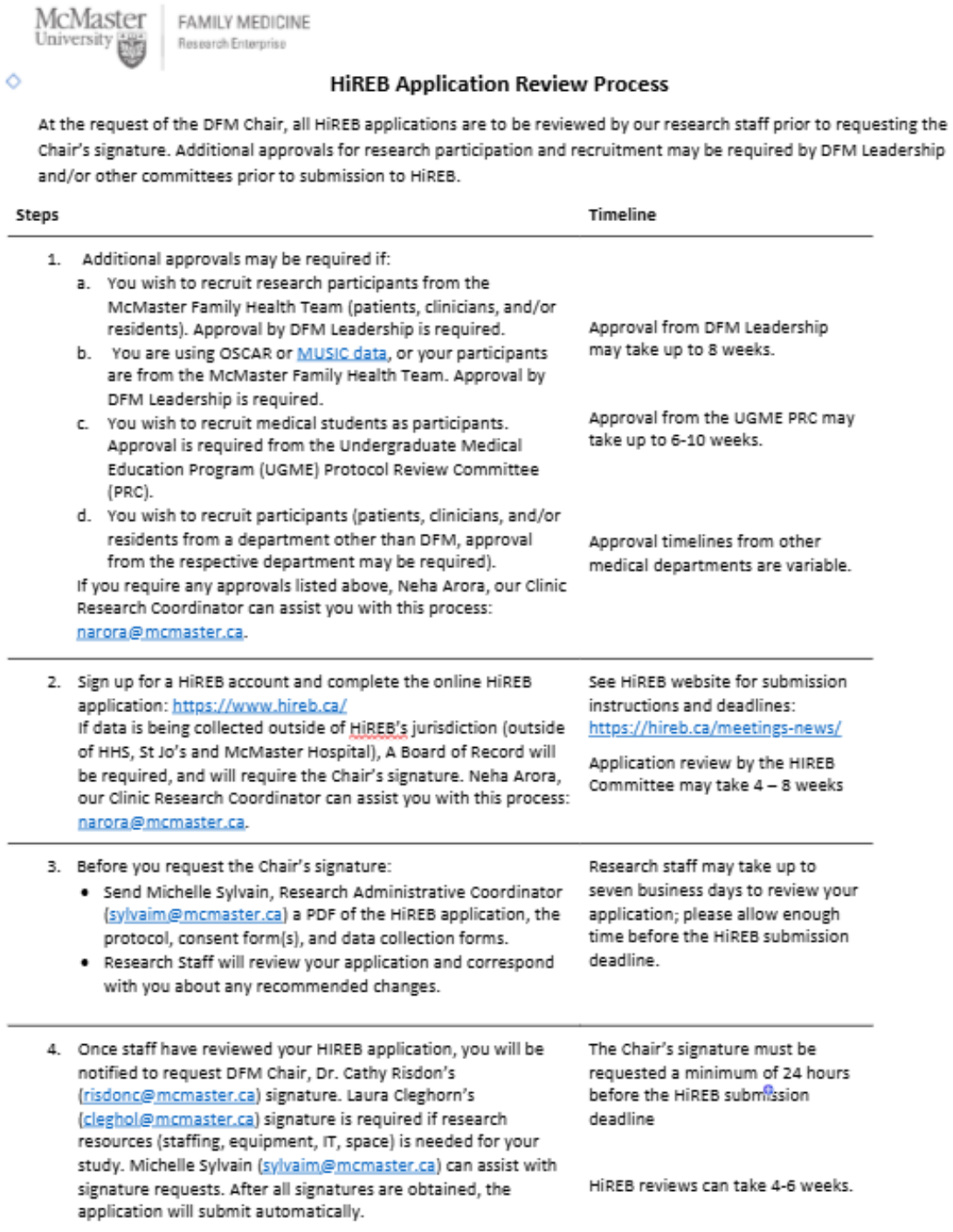
- Patient data is the responsibility of the Most Responsible Physician (MRP)
- The MRP is the Health Information Custodian (HIC) of their patients' data
- Patients are informed that their data may be used for research purposes via the MFHT privacy notice
- If a project is using identifiable information and/or when patient consent is required for research, MRPs must review all documents
  - Recruitment list, invitation letter, letter of information and consent
- **This step is <u>crucial</u> and Neha will assist with MRP review and approval of documents**

HiREB Internal Review and Submission Process

HIREB Application Review Process

- Outlines additional internal approvals needed and timelines.
- BOR agreement request
- HiREB application
- Internal review process
- Request for Chair's signature and Laura Cleghorn's signature
    - Facilitated by Michelle Sylvain

⭐Contact Neha or Michelle to assist
narora@mcmaster.ca
sylvaim@mcmaster.ca



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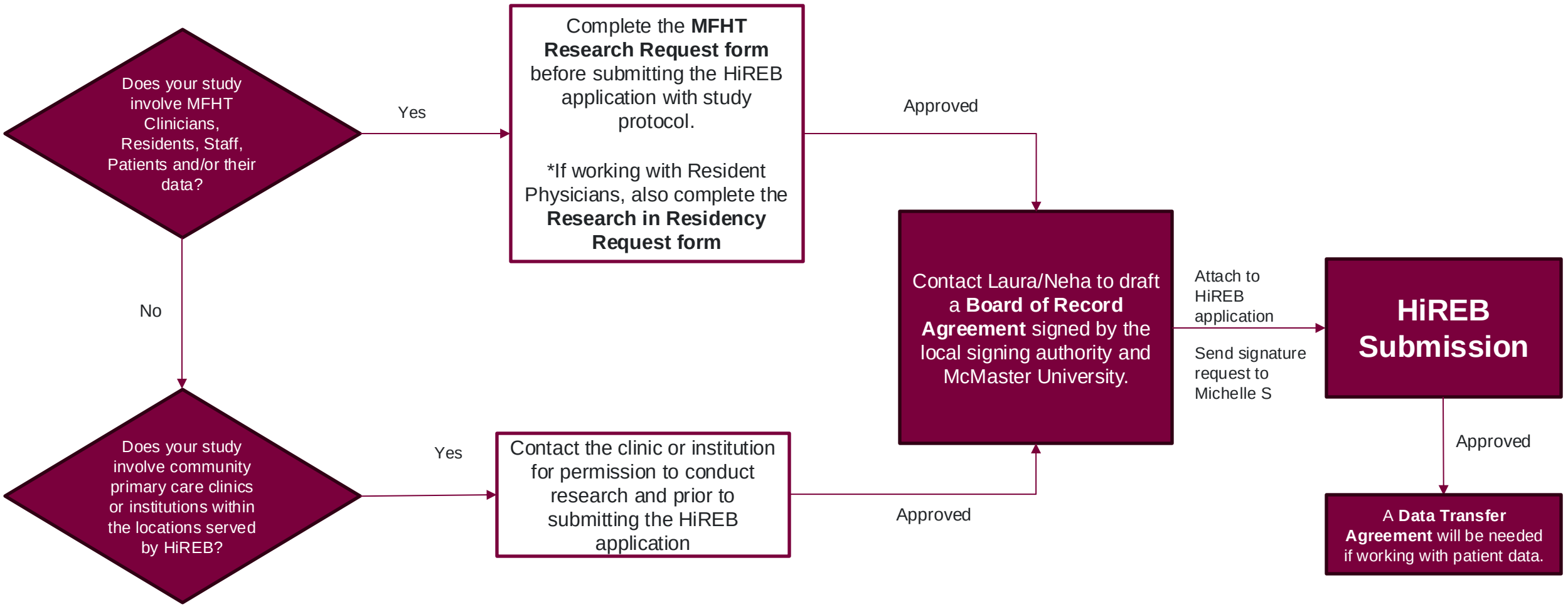
HiREB Application Review Process

At the request of the DFM Chair, all HiREB applications are to be reviewed by our research staff prior to requesting the Chair's signature. Additional approvals for research participation and recruitment may be required by DFM Leadership and/or other committees prior to submission to HiREB.

Steps	Timeline
1. Additional approvals may be required if: a. You wish to recruit research participants from the McMaster Family Health Team (patients, clinicians, and/or residents). Approval by DFM Leadership is required. b. You are using OSCAR or MUSIC data, or your participants are from the McMaster Family Health Team. Approval by DFM Leadership is required. c. You wish to recruit medical students as participants. Approval is required from the Undergraduate Medical Education Program (UGME) Protocol Review Committee (PRC). d. You wish to recruit participants (patients, clinicians, and/or residents from a department other than DFM, approval from the respective department may be required). If you require any approvals listed above, Neha Arora, our Clinic Research Coordinator can assist you with this process: narora@mcmaster.ca.	Approval from DFM Leadership may take up to 8 weeks. Approval from the UGME PRC may take up to 6-10 weeks. Approval timelines from other medical departments are variable.
2. Sign up for a HiREB account and complete the online HiREB application: https://www.hireb.ca/ If data is being collected outside of HiREB's jurisdiction (outside of HHS, St Jo's and McMaster Hospital), A Board of Record will be required, and will require the Chair's signature. Neha Arora, our Clinic Research Coordinator can assist you with this process: narora@mcmaster.ca.	See HiREB website for submission instructions and deadlines: https://hireb.ca/meetings-news/ Application review by the HIREB Committee may take 4 – 8 weeks
3. Before you request the Chair's signature: • Send Michelle Sylvain, Research Administrative Coordinator (sylvaim@mcmaster.ca) a PDF of the HiREB application, the protocol, consent form(s), and data collection forms. • Research Staff will review your application and correspond with you about any recommended changes.	Research staff may take up to seven business days to review your application; please allow enough time before the HiREB submission deadline.
4. Once staff have reviewed your HIREB application, you will be notified to request DFM Chair, Dr. Cathy Risdon's (risdonc@mcmaster.ca) signature. Laura Cleghorn's (cleghol@mcmaster.ca) signature is required if research resources (staffing, equipment, IT, space) is needed for your study. Michelle Sylvain (sylvaim@mcmaster.ca) can assist with signature requests. After all signatures are obtained, the application will submit automatically.	The Chair's signature must be requested a minimum of 24 hours before the HiREB submission deadline HiREB reviews can take 4-6 weeks.

HiREB Application Process Summary



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Research Team Training and Certifications

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Preparation for all DFM research faculty and staff

1. Tri-council Policy Statement 2: Course on Research Ethics (TCPS 2: CORE) - required for HiREB
2. DFM Confidentiality Agreement
3. DFM Statement on Conflict of Interest (COI)
   - Researchers and research staff should identify and manage COI to maintain public confidence and trust, and to maintain the independence and integrity of the research process.
   - If a COI cannot be avoided, procedures should be in place to manage and/or mitigate the conflict.
   - The declaration and management of a COI is found in the HiREB application form.

Training for researchers conducting chart reviews

1. HiREB Chart Review Tutorial (once)
2. N2 - Foundations of Privacy in Research (once)
3. McMaster PHIPA for Health Professionals Course (yearly)

Training for researchers conducting clinical research/trials

1. Good Clinical Practice (GCP)
2. GCP – Social and Behavioral Research for Clinical Research

See the McMaster and HHS Harmonized Research Training Framework for more information

Preparing your HiREB Submission

Preparing a HiREB Submission

Adapt Study Protocol

Data Collection and consent

Certificates and Training

Study Budget

Agreements and Approvals

Data management and security

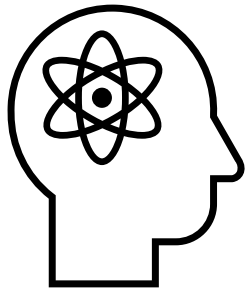
Provisional Approval

- Customary to receive provisional approval
- Follow HiREB's steps to respond to provisional approval
  - Provide a clear cover letter addressing all points
  - If the team provides significantly new information in response to a provisional approval, HiREB may assign a new reviewer or multiple reviewers
  - Reach out to the Ethics Coordinator handling the file to clarify any questions before resubmitting; sometimes comments lack nuance

Amendments and Annual Renewals

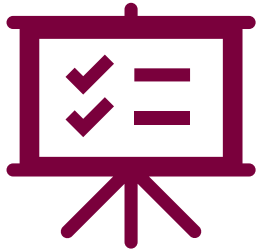
- Any changes is protocol or study instruments need to be reported and approved by HiREB by using the Amendment Sub-form

- Researchers must ensure that their study has continuous ethics approval by submitting an Annual Renewal Sub-form
  - renewal forms should be submitted 30 days prior to the expiry date to avoid study suspension



Knowledge Dissemination

Communicating Findings



Non-Research

Dissemination describes the process followed and a general description of impact

Dissemination describes the way in which a project was designed and implemented

Include that the project was assessed for an ethics board for exemption

Research

Dissemination includes participant data, or analyses based on that data, in a research publication

Dissemination intends to demonstrate effectiveness of a tool, pathway, education module, etc.

Include HiREB Approval Number in the publication

Key Contacts

HiREB Applications, Processes and Institutional approvals:
Neha Arora
narora@mcmaster.ca

REB Board of Record Agreements, DTAs, Process Improvements:
Laura Cleghorn
cleghol@mcmaster.ca

HiREB Help Desk, Mirela Lukac,
eREBhelpdesk@hhsc.ca

HiREB Manager, Erin Bell
belle@hhsc.ca

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Any Questions or Comments?

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Faculty of Health Sciences

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