The Fraser Health Authority Integrated Research Quality Framework

"Quality by Design"

Research, Evidence, Care.

Fraser Health is a leader in developing and using research that maximizes the well-being of the people we serve.

Research conducted in Fraser Health strives to:

- ✓ Make knowledge count for patients
- ✓ Transfer evidence based knowledge into practice and policy
- ✓ Embed research into program planning
- ✓ Focus on patient-centred research

The **Integrated Research Quality Framework** applies to the conduct of regulated and non-regulated research in the Fraser Health Authority to demonstrate that Fraser Health promotes and conducts high quality research for the benefit of its patients, clients and residents.

The purpose of the **Framework** is to:

INFORM	ENABLE	ADHERE
•Our patients, clients and residents and the public recognize that research conducted in Fraser Health adheres to the highest quality standards for the conduct of research.	•Our research sites in Fraser Health have the information and guidance they need to set up, implement, conduct and support research studies.	•Our researchers understand and fulfill their institutional obligations for the conduct of research involving human subjects.

THE QUALITY FRAMEWORK WILL:

1. Help researchers be aware of their obligation to adhere to current standards for research ethics and institutional (i.e. Fraser Health) approval, research conduct from study start up to completion, and knowledge transfer.

2. Provide researchers with tools and resources to maintain these standards.

3. Provide researchers and study sponsors with predictable timelines for ethics and contract review.

QUALITY IS DEFINED AS:

- Research design that meets scientific standards of validity and reliability (i.e. reproducibility).

- Research conduct that meets current regulatory and ethical standards including international clinical practice standards when applicable.

- Efficient and effective research administration.

- Research that aims to transfer knowledge and improve practice.

The Framework has two levels:

Institutional

Researcher

Institutional (Fraser Health) Level

The **Institutional Level** describes standards that Fraser Health adheres to as the legal entity responsible for research activities conducted in or by the health authority's employees, privileged physicians and academic affiliated researchers.

International Standards

- ✓ Fraser Health Research Ethics Board is registered by the Office of Human Research Protections, United States under its IORG (Institution/Organization) registration number **(IORG0004093)** and its Federal Wide Assurance Number **(00008668)**
  - Source: http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc

- ✓ Fraser Health Research Ethics Board and regulated clinical trial researchers adhere to International Conference on Harmonization Good Clinical Practice Guidelines (ICH GCP)
  - *Source:* http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/index-eng.php

- ✓ All clinical trials are registered at clinicaltrials.gov
  - Source: www.clinicaltrials.gov

National Standards

- ✓ Fraser Health Research Policies adhere to Canadian Institutes of Health Research requirements

- ✓ Fraser Health Research Ethics Board adheres to the Tri-council Policy on Research Involving Human Subjects
  - Source: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

- ✓ Fraser Health Research Ethics Board adheres to Health Canada Food and Drug Act Regulations Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects
  - Source: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-281.html

- ✓ Fraser Health Research Ethics Board notifies researchers in advance of their annual renewal date in order to enable studies to be renewed within the one year expiry date of the initial research ethics approval or annual renewal date

- ✓ Fraser Health Research Inquiry and Investigation Committee investigates research misconduct (no investigations or research subject complaints to date).

Provincial Standards

- ✓ Fraser Health adheres to the Freedom of Information and Protection of Privacy Act to ensure the confidentiality of patient personal information that is also used for research purposes

Fraser Health Authority Standards

- ✓ Risk Management Framework for the Conduct of Research identifies checks and balances put into place to mitigate risk arising from the conduct of any research related activity
- ✓ High risk clinical trials inspected on a bi-annual basis according to the Fraser Health Research Ethics Board Research Quality Management Program
- ✓ Data security assessed and approved by Fraser Health Privacy Office
- ✓ Efficient timelines maintained for contract and ethical review:
    - Median # of business days from date of receipt of contract to date of first review sent to sponsor: 12
    - Target median # of business days from date of receipt of contract to negotiation completed: 35
    - Target median # of business days for Fraser Health Research Ethics Board approval from date of initial decision: Delegated 14 days; Full Board 35 days
- ✓ Data access and privacy requirements integrated into the Fraser Health Research Ethics Board initial ethics application to minimize number of required forms and create one entry point for researchers

Researcher Level

The **Researcher Level** describes the standards and best practices that the principal or qualified investigator must meet. These also extend to the entire research team. The study principal/qualified investigator is responsible for all research-related activities including financial arrangements. 'Qualified Investigator' is the term assigned to the principal investigator who is conducting clinical trial research that is regulated by Canadian (Health Canada) or American (Food and Drug Administration) regulatory bodies.

The study site works with study sponsors to ensure that sponsors understand their obligations to Fraser Health.

For Regulated Clinical Trial Researchers

- ✓ ***Best Practice:*** Follow the flowchart for industry sponsored and regulated research

- ✓ ***Best Practice:*** Utilize the Study Start-up Toolkit to maximize site ability to implement clinical trials according to Health Canada requirements

- ✓ Adhere to Network of Networks (N2) Standard Operating Procedures (SOPs) for regulated clinical trials

- ✓ Ensure all research team members involved in conducting regulated clinical trial research (including the qualified investigator) complete a comprehensive ICH GCP training and refresher training as appropriate (recommended every two years)

- ✓ Ensure adequate experience, training and licensure (as required) of the study team (refer to SOPs above)

- ✓ Implement training (Division 5 training) in preparation for Health Canada inspection

- ✓ Utilize the harmonized clinical research consent form that meets ICH GCP requirements for clinical trials
    - Source: http://www.msfhr.org/sites/default/files/BC-common-clinical-informed-consent-template.doc

- ✓ ***Best Practice:*** Utilize Association of Clinical Research Professionals on-line training

- ✓ ***Best Practice:*** Obtain Society of Clinical Research Associates (SoCRA) continuing education credit for participation in Fraser Health's Clinical Trials Symposium during our annual Research Week

For All Researchers

- ✓ Adhere to the requirements of Fraser Health Research Policies and the Tri-council Policy on the Ethical Conduct of Research Involving Humans http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf
- ✓ Follow the Fraser Health Research Ethics Board Policy on Protocol Requirements
  - ***Best Practice:*** Utilize protocol templates
- ✓ Utilize the Fraser Health Research Ethics Board templates for non-clinical and non-regulated clinical research
- ✓ Use the DAR Form to obtain agreement from Fraser Health departments to provide research-related services, e.g. lab, pharmacy, health records
- ✓ ***Best Practice:*** Implement strategies to meet and maximize participant recruitment targets
- ✓ ***Best Practice:*** Implement strategies to ensure adherence to protocol
- ✓ ***Best Practice:*** Utilize on-line resources provided by the Department of Evaluation and Research Services
- ✓ Ensure initial and ongoing consent process is well documented to demonstrate that it is based on an iterative conversation with the prospective participant
- ✓ Implement procedures to ensure protection of patient's personal information used for research purposes
- ✓ Follow Corrective Action and Preventive Plan (CAPA) guidelines for correcting non-conformities
- ✓ ***Best Practice:*** Ensure publications/presentations are submitted to us for upload onto the Fraser Health Research Study Database at http://researchdb.fraserhealth.ca/ersweb/