niagarahealth
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New Niagara Health Researcher Guidance Document

PART I: TRAINING

Research Training Requirements

Human subjects are essential to the conduct of research intended to increase our scientific knowledge and improve human health. Research at Niagara Health must be conducted with the highest ethical and clinical research standards since protection of research subjects is fundamental to all research involving humans. Additionally, clinical research operations must be carried out in a safe environment for both research subjects and staff. The key to effective conduct of research is education and training of all people involved in research.

All individuals working in ANY research capacity at Niagara Health must complete or provide documentation of up-to-date training.

Mandatory Research Training

Individuals can be involved in a variety of research studies, and are thus expected to comply with certain regulations or guidelines that depend on the type of research they are conducting. A listing of various types of research studies and the associated mandatory research training can be found in the table below. The following research training modules are required, at a minimum, based on the type of study that is being conducted. Investigators and study team members are advised to consult with Research Administration if there are any questions or ambiguities about the necessity of any research training modules:

Type of Study*	Required Training	Duration
Clinical studies that require approval from a Research Ethics Board (REB) and require the use of patient chart(s) and/or identifiable information	• ICH GCP • CITI Privacy Training • NH Privacy Training	• Every two (2) years • Every two (2) years • Annual
Clinical studies that require approval from a Research Ethics Board (REB) and are regulated by Health Canada	• ICH GCP • Division 5 of the Canadian Food and Drug regulations	• Every two (2) years • Every two (2) years
Retrospective studies not involving human subjects	• CITI Privacy Training • NH Privacy Training	• Every two (2) years • Annual
Studies involving humans sponsored by any of the Tri-Council Agencies of Canada (CIHR, NSERC, SSHRC)	• Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)	• Every two (2) years

***Should research studies fall under more that one of the categories listed, both categories' required training must be completed.**

ICH GCP = International Council of Harmonisation Good Clinical Practice
CITI = Collaborative Institutional Training Initiative
NH = Niagara Health
TCPS2 = Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

CIHR = Canadian Institutes of Health Research
NSERC = Natural Sciences and Engineering Research Council of Canada
SSHRC = Social Sciences and Humanities Research Council of Canada

PART II: CONTRACT REVIEW

Hamilton Health Sciences reviews, drafts and negotiates research agreements on behalf of Niagara Health Researchers, including:

- Non-Disclosure Agreements (Confidentiality Agreements)
- Data Transfer Agreements
- Material Transfer Agreements
- Research Study Agreements
- Clinical Trial Agreements
- Service Agreements

How to Submit a Contract for Review:

Email your contract to researchagreements@hhsc.ca with a CC to Barbara.Wiinholt@niagarahealth.on.ca

Include the following information:

- Name and contact information of the person responsible for review and negotiation of the agreement at the sponsor or collaborator level
- Highlight any concerns or questions you may have around publication, intellectual property, liability or budget
- Highlight any timelines if there are urgent turn-around times required
- If you are submitting on behalf of another investigator please include his/her name in the submission

The contract reviewer will review the submission and will negotiate directly with the other party on behalf of Niagara Health (NH) and the NH Researcher. Any correspondence between the parties during the negotiation will include the NH Researcher.