Nova Scotia Health Authority
90 Lovett Lake Court, Suite 201
Halifax, Nova Scotia B3S 0H6

WELCOME TO RESEARCH @ NOVA SCOTIA HEALTH

INTRODUCTION

Contractual Contacts, Parties, and Signatories

Initial contact and provision of these agreements is often to the research team or principal investigators and all research contracts (including CDA/NDAs) and budgets are to be sent for review and final approval for signature to ResearchContracts@nshealth.ca.

Our *contractual legal entity name is*: Nova Scotia Health Authority, a body corporate pursuant to the *Health Authorities Act* (Nova Scotia).

Our *principal place of business address* is 90 Lovett Lake Court, Suite 201 Halifax, Nova Scotia B3S 0H6 *Please note: this may differ from previously communicated addresses for research.

Physician PIs are not employees of our institution and therefore must be included as a separate legal party and signatory on all research contracts. Each physician has his/her own office address and have *medical appointments* pursuant to the Nova Scotia Health Authority medical appointment by-laws.

Although Nova Scotia Health is a *government reporting entity*, none of its employees, appointed medical staff, or agents are considered "*government officials*".

The *Institutional Signatory* on Research, Innovation, and Discovery Contracts for Nova Scotia Health Research and Innovation is:

Dr. Gail Tomblin Murphy PhD
VP Research, Innovation, and Discovery, CNE

Acceptable Signing Platforms:

Our preferred signing platform is DocuSign; however, we can sign and accept signing of contracts through the following platforms/processes:

- DocuSign
- Certified Adobe Sign
- Adobe "Fill and Sign"
- Wet ink

Please note: we are unable to sign via Adobe Acrobat Sign, which is a cloud based e-signature service that allows the user to send, sign, track, and manage signature processes using a browser or mobile device. It is part of the Adobe Document Cloud suite of services.

Regulatory Requirements and Personal Health Information

Health Canada is the applicable Canadian federal authority that administers and enforces the *Food and Drugs Act,* which includes the *Medical Devices Regulations* (SOR/98-282) and pursues its regulatory mandate under the Food and Drug Regulation.

The *Personal Health Information Act*, S.N.S. 2010, c. 41 *(**PHIA**)* is Nova Scotia's health privacy law that governs how regulated health care professionals and organizations collect, use, disclose and maintain personal health information. *PHIA* comes into force on June 1, 2013.

The *Personal Information Protection Electronic Documents Act* S.N.S. 2006, c. 3 *(**PIPEDA**)* is the federal privacy legislation that establishes the rules to govern the collection, use and disclosure of personal information. *PIPEDA* applies to any "commercial" activity, including the delivery of health services considered to be commercial.

The *Personal Information International Document Protection Act* ("PIIDPA") This Act provides additional protection to the personal information held by Nova Scotia "public bodies" and municipalities when that personal information is being collected, used, or disclosed by those organization

Foreign Privacy Legislation

As a Nova Scotia and Canadian organization, Nova Scotia Health can only confirm compliance with provincial and federal privacy legislation or guidelines. If compliance with any foreign legislation is required to participate in a particular research study, further consideration and discussion will be necessary but may not result in compliance assurance.

Privacy Impact and Data Protection Approval

Nova Scotia Health is governed by provincial privacy legislation specific to Personal Information (PI) and Personal Health Information (PHI), namely the Nova Scotia *Personal Health Information Act* ("PHIA") and the Nova Scotia *Personal Information International Disclosure and Protection Act* ("PIIDPA"). In addition to this, health information access, transfer of data as well as adding to/using NSHealth IT platforms or the NSHealth network must be reviewed prior to implementation. The NSHealth Privacy Office is the primary contact for compliance with privacy requirements, information practices, complaints and organizational practices and procedures in relation to PHI. NSHealth is the legal Custodian of all NS Health patient PHI including any PHI collected for the purpose of NSHealth Research Ethics Board (REB) approved research. Individual health care providers are not the Custodian of the PHI of their patients. Research, Innovation

and Discovery has a Privacy Officer that reviews research for compliance, via data access assessments, privacy impact assessments (PIAs), and data impact protection assessments (DPIAs).

Insurance Requirements for Sponsored Clinical Trials and Non-regulated Clinical Research

The following outline the insurance limits required for Sponsored Clinical Trials and Non-regulated clinical research being conducted at the Nova Scotia Health Authority.

- Phase 1 and 2 Clinical Trials, a minimum of $10M CAD per occurrence/claim and in the aggregate for both General and Product Liability insurance.
- Phase 3a/b Clinical Trials, a minimum of $5M CAD per occurrence/claim and in the aggregate for both General and Product Liability insurance.
- Phase 4/observational study a minimum of $2M CAD per occurrence/claim and in the aggregate of General and Product Liability insurance.
- For non-regulated clinical research, a minimum of $2M CAD per occurrence/claim and in the aggregate of General Liability insurance.
- CROs (if applicable) should provide General Liability insurance of at least $5M CAD per occurrence/claim and in the aggregate.

Proof of global insurance must be made available upon request (if the policy is held by a non-Canadian Sponsor). It is the expectation that the insurance policy be provided by a properly licensed insurer recognized in Canada. If a Sponsor's insurance policy is limited to a specific clinical trial and is on an annual/within a defined time basis, proof of annual renewal must be provided to ensure continuity of coverage for the duration of the clinical trial and to cover claims after the completion of the study as outlined in the terms and conditions of the signed Clinical Trial/Research Agreement/Contract.

Nova Scotia Health holds Worker's Compensation insurance within statutory limits, Employer's liability insurance not less than $10M CAD per occurrence, Commercial General Liability insurance not less than $10M CAD per occurrence and Professional Liability insurance not less than $10M CAD per claim.

The Principal Investigator (if a physician) shall rely on and maintain membership in good standing with CMPA (Canadian Medical Protective Association) for the duration of the Study and while maintaining medical practice privileges and appointments at NSHA. *Note: as this is a defense fund rather than insurance, it does not have specific minimum coverage amounts.*

Indemnity and Study Participant Reimbursement

Nova Scotia Health is a body corporate under the Health Authorities Act (Nova Scotia) and a Nova Scotia Government Reporting Entity. Pursuant to the *Finance Act (*Nova Scotia*)*, there are restrictions on the ability of Nova Scotia Health Authority (NSHA) to enter a contract that includes an indemnity. As a "Government Reporting Entity" as defined in the Act. Section 77,

Nova Scotia Health is precluded by law from entering "net debt obligations" and an indemnity is listed within the definition of a net debt obligation within the category of contingent liabilities. Nova Scotia Health and the PI will be responsible and accept liable provided that the failure causes the claim, Its/his/her negligence or gross negligence or intentional wrongdoing - Failure to comply with applicable law/rules and regulations and Failure to follow the protocol (except for deviations due to medical necessity)

It is the expectation that the Sponsor of a research study indemnify and hold harmless the PI and Nova Scotia Health its/her/his trustees, directors, officers, affiliates, employees, agents, appointees (including Investigator and sub-investigators), students (if applicable), sub-contractors (if applicable), each being a separate indemnitee. To the extent the claims arise out of or are caused by conduct of study (anything required by the protocol, including without limitation injury to study subjects arising from administration of study drug/device/placebos/comparators or study procedures), sponsor's negligence or intentional wrongdoing; including without limitation failure to conduct study in accordance with applicable laws, and sponsor's use of results

*Indemnification is expected to be provided directly by Sponsor either in the clinical trial agreement or in a separate indemnification/insurance/warranty agreement made with Nova Scotia Health and PI***.** If the clinical trial agreement is between sponsor's agent contract research organization (CRO) Nova Scotia Health and PI, Sponsor must at minimum provide written confirmation/representation to Nova Scotia Health and PI that CRO has authority to bind Sponsor to the agreement as a principal.

Study subject reimbursement (medical care of study subjects): Sponsor will reimburse institution/investigator/subject as applicable for costs of reasonable medical expenses required due to injury arising from study drug/device/materials, from protocol procedures. Reimbursement may be denied by sponsor to the extent that: government sponsored insurance pays for treatment, the injury is caused by Institution/Investigator negligence. Subjects should not be excluded due to own negligence.

GOVERNING LAW

Nova Scotia Health can only agree to the Governing law/jurisdiction of a Canadian province, preferably Nova Scotia and the federal laws/courts appliable therein. Nova Scotia Health is unable to agree to the governing law and jurisdiction of the Province of Quebec and countries outside of Canada. Should the parties not be able to agree on governing laws and jurisdiction, silence may be accepted.

FORM 1572

As an ICH/GCP compliant foreign site, Nova Scotia Health is not required to be listed on the IND as this is not required by the FDA, see 21 CFR 312.120 and 2010 FDA guidance, "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" – sections 9 – 15 re: foreign sites http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf and thus are not required to complete a Form 1572. Please do not include Nova Scotia Health or the Nova Scotia Health PI on this Form. If either are included, an REB waiver to participate is required to be requested and provided by the Sponsor.

IMPORTER OF RECORD

Should a Study require the importing of materials, drugs, or devices outside of Canada, Nova Scotia Health requests that it nor any PI be listed as the "Importer of Record." In the event a Sponsor or third party does NOT have a Canadian supplier, then Nova Scotia Health may be able to clear the goods and be listed as the importer of record. If there are associated brokerage fees that are assumed by NSH, it is the expectation that these fees be invoiced to and covered by the Sponsor or associated third party.

BUDGETING RESOURCES

Overhead

Nova Scotia Health charges 30% overhead on industry sponsored/invested/partnered research and 15% overhead on investigator driven research funded by industry, government agencies, and foundations. This overhead is applied to ALL direct study related costs outside standard of care. Those items not subject to overhead will be listed separately in the line-item study budget.

Research Ethics Board (REB)

As a cost-recovery means to support research ethics reviews, the Research Ethics Office charges a required initial review fee of $4,000 for each new study funded by a for-profit entity (industry sponsored and industry funded studies). This fee is charged regardless of the outcome of the review. A new REB annual maintenance of $500/year and a protocol amendment fee of $250/amendment is also being implemented for active studies. This fee structure is based on review of national standards, the increase in research studies being reviewed by the REB, inflation, and digital structure. The Research Ethics Office monitors the inclusion of the REB Invoice template billing form in submissions for all industry sponsored AND industry funded studies and a request for invoice generation sent to Research Finance.

Archiving/Document Storage

As per Good Clinical Practice (GCP), Health Canada regulations, and applicable Nova Scotia Health requirements, research records must be stored for a minimum of 7 (seven) years or a maximum of 15 years. To offset the cost of storage of these records on premised owned or leased by Nova Scotia Health, a record retention fee of $1,500.00 (Phase I-III) or $750 (Phase IV) is required. This fee is directly invoiced by Research Finance at the completion of the study.

Equipment Inspection and Approval

Nova Scotia Health's Department of Biomedical Engineering is responsible for ensuring that medical devices, equipment, and/or technology entering NSH facilities are in compliance with the applicable standards and guidelines established by the Federal and Provincial governments as well as certain policies and procedures of NSH. This inspection could result in an hourly fee depending on the time required. For more information, please see the following link.

Banking/EFT Information, Invoicing, and Financial Reporting

All requests for and documentation specific to Nova Scotia Health's Banking Information and to notify Nova Scotia Health of a payment, please contact NSHAResearch@nshealth.ca.

All other research finance inquiries should be directed to ResearchFinance@nshealth.ca, Room 813 Bethune Building, 1276 South Park Street, Halifax, Nova Scotia B3H 2Y9

ADMINISTRATIVE RESEARCH COSTS

It is an institutional requirement that all direct costs of research, outside standard of care, are covered by the Research Budget. It is the shared responsibility of RID and the Research Team/PI to ensure that all related costs are covered. These costs include administration fees, personnel time, institutional departmental mandated service fees, protocol related supplies, per participant fees related to protocol activities, and institutional fees such as overhead, ethics, and archiving/records retention. These fees can vary based on the complexity of the research protocol, the expertise and training required by research staff (for example a regulated vs non-regulated research coordinator), training required specific to protocol related activities, creation of internal budgets, quotes, contract review and others. The following is a benchmark of standard fees charged by all research teams at Nova Scotia Health.

PLEASE NOTE: All fees are Effective 2023 but may be subject to change and updated annually

Institutional Mandated Fees

Budget Item	Fee
1. Overhead: applied to all direct study costs	
Industry Sponsored studies	30% on per patient costs
Industry funded studies	15% on total funding
2. REB Fees:	
Initial Review	$ 4,000.00
Annual Maintenance	$ 500.00
Amendment Fee (each)	$ 250.00
3. Archiving/Storage Fees:	
Phase I - III	$ 1,500.00
Phase IV	$ 750.00

Administrative Study Fees Summary

Budget Item	Fee:		
1. Team Start-up Fee*	$5,000.00	$7,000.00	$9,000.00
2. Annual Admin & Maintenance Fee*	-	-	$1,750.00
3. Study Close Out Fee*	-	-	$1,200.00
4. Safety & Quality Reporting			
a. Serious Adverse Events (SAEs)	$150 - $300 per event**		
5. Auditing Fee	Negotiated based on Sponsor expectation and time involved (hourly or per day)		
6. Monitoring Fees			
a. Visit (in-person/remote)	$520 per day (inclusive of OH)		
b. Site update calls	$97.80 per call (inclusive of OH)		
7. Amendment Fees			
a. Major (protocol amendments requiring REB changes and reconsenting participants)	$850 each		
b. Minor (protocol amendments requiring REB changes)	$300 each		

*Documentation outlining these fees can be provided upon request.

**Amount requested will be based on the complexity of study, patient population, severity of event, etc.

Mandated Shared Services Fees

Budget Item	Fees
Pharmacy Start -up Fee	$800.00 - $1,700.00
Pharmacy Annual Maintenance	*
Pharmacy Close Out	$300.00
Lab Start Up	$500.00 - $1,500.00
Lab Annual Maintenance	$1,000.00
Lab Close out	$100.00
Diagnostic Imaging / Radiology Start-up Fee	$500.00 - $1,500.00
Radiologist Fee	$200.00/hr
Diagnostic Imaging / Radiology Amendment Fee	$275.00
Image De-identification and CD	$85.00 - $110.00
Heart Health Start Up (ECHO, ECGs, MUGAs)	$500.00
Medical Day Unit Start-up Fee	$500.00
Pulmonary Function Start-up Fee	$500.00

*currently charged quarterly and varies protocol to protocol

"Per-Patient" Protocol Activity Fees

Budget Item	Standard Fees * (plus 30% OH)
Assessment of Adverse Events	$75.00
Brief Physical Exam	$150.00
Recruitment	$25.00
Informed Consent	$150.00 - $250.00
Inclusion/exclusion criteria	$150.00
Coordinator Fee per Visit	$65.00/hr
Medical History	$150.00
Demographics	$65.00
Vital Signs	$25.00 - $65.00
Concomitant Medications	$65.00
Investigator Fee per Visit	$250.00
Complete Physical Exam	$250.00
Questionnaires	$50.00
Randomization Administration	$20.00
Patient Reimbursement Fee	$55.00 - $100.00**
Sample Collection & Processing Fee	$40.00 - $90.00***
On Site drug administration	$65.00
Data Entry Fee	$65.00/hr

*fees are based on an average across a representative sample of previously negotiated budgets

**may vary/exceed this amount based on visit complexity. Please note, this does not include travel reimbursement as listed below.

***with or without dry ice

Participant Stipend

The standard per visit rate for participant reimbursement is $55 - $100 per visit and is required to be included in the per participant budget.

Participation Reimbursement

Published guidelines generally agree that to protect human subjects, reimbursements specific to participation in clinical research should be limited to compensation for time, lost earnings, travel, and other expenses incurred in taking part in a study; that no payment should be given for the assumption of risk; and subjects may be paid or otherwise compensated for inconvenience. At NSHealth, these payment amounts are standardized and based on institutional reimbursement policies.

Participant Travel Reimbursement

Any additional funds required to cover long distance travel (in excess of 80 Km round trip), overnight stays, additional meals, or support companions will be requested as outlined below and upon approval of the Sponsor/Lead Site prior to such costs being incurred or invoiced for payment.

Gas Mileage if the participant is travelling in excess of 80 Km round trip*	NSHA Mileage rate 57 cents/Km
Hotel Accommodations	Accommodations may be applicable for those traveling long distance and will be decided on a visit-to-visit basis. Minimum nightly rate is $169 CAD
Breakfast (offsite)	Hotel breakfast covered up to $20 with receipt
Dinner (offsite)	Hotel dinner covered up to $40 with receipt
Caregiver/ Support person Meals	Same as Study Participant. See above for applicable amounts.

*as applicable and determined by the Research Teams