

## RESEARCH BUDGETING OVERVIEW & COSTS SUMMARY

### *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 premises 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](mailto:NSHAResearch@nshealth.ca).

All other research finance inquiries should be directed to [ResearchFinance@nshealth.ca](mailto: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, protocol related tests, procedures, institutional departmental service fees, protocol related supplies and institutional fees such as overhead, ethics and archiving. 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
<b>1. Overhead:</b> applied to all direct study costs	
Industry Sponsored studies	30% on per patient costs
Industry funded studies	15% on total funding
<b>2. REB Fees:</b>	
Initial Review	\$ 4,000.00
Annual Approval	\$ 500.00
Amendment Fee (each)	\$ 250.00
<b>3. Archiving fee:</b>	
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*	-	-	\$1,200.00
4. Safety & Quality Reporting			
a. Serious Adverse Events (SAEs)	\$150 - \$300 per event**		
5. Auditing	Negotiated based on Sponsor expectation and time involved (hourly or per day)		
6. Monitoring			
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" Fees Summary

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 Team