



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

STUDY CLOSE OUT FEE

PURPOSE: To ensure that Nova Scotia Health obtains sufficient funds to cover administrative costs associated with preparing to conduct, maintain, administer, support, or close out activities related to fee for service clinical research at Nova Scotia Health. As a publicly funded organization, Nova Scotia Health is not able to take on the direct financial burden associated with fee for service research studies, nor is it permitted to bill the Nova Scotia Provincial Health Care System for research related costs. These fees are for administrative/personnel cost coverage only and are not subject to institutional overhead.

Some fees are mandatory, non-negotiable, and non-refundable regardless of patient recruitment. This is above and beyond the sponsor's proposed budget for the patients per case funding. This fee is **payable upon execution of the Contract or upon receipt of invoice.**

Attached is information to support and justify the amounts requested or required.

Thank you for your cooperation.

STUDY CLOSE OUT ACTIVITES AND COSTS
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1. Close Out Preparation and Post Close Out Requirements	\$300
<ul style="list-style-type: none">• CRO/monitor visit preparation:• Review Patient health records for the duration of the study to ensure that proper reporting was provided. Have queue ready for monitor on close out visit• Review of patients' electronic hospital record for any new adverse events until close out date• Final study clarifications (as per monitor) reported and documented	
2. Site Preparation for Ethics Board Closure	\$300
<ul style="list-style-type: none">• Completion and submission of REB required documentation• Ensure that all unanticipated problems (including local serious reactions and minor and major study violations) and safety updates (DSMB reports, periodic safety report updates) have been submitted to REB and study monitor as applicable	
3. Archiving/Record Retention/Storage	\$300
<ul style="list-style-type: none">• Identifiable filing and preparation for storage of all study related documents	
4. Financial and Departmental Agreements	\$300
<ul style="list-style-type: none">• Communicate with individual Service Departments involved in study that the study is closing• Retrieve any binders and study related documentation from the respective Service Departments• Have protocol related activities finalized and finished• Review financial account, expenditures, and receipts to ensure that all outstanding institution invoices have been paid. Notify Sponsor of any outstanding invoices• Completion of all required documentation and obtain all required signatures to close study account	
<u>TOTAL</u>	<u>\$ 1200</u>