



## ***Research Agreements at NSHA***

Research studies may require agreements outlining the terms and conditions of NSHA and the PI's participation and responsibilities involved in the research study. These may include reporting, payment, transfer, IP, confidentiality/privacy and/or termination details and protections. The following is a list of the most frequently used or requested agreements negotiated and prepared by the NSHA Research Services Grant Coordinator.

### **1. Data and Materials Transfer Agreement**

Some research protocols require transferring materials or data from CH to another party ("**Recipient**"). For purposes of this document, **NSHA** and the **NSHA** Investigator will be referred to as the "**Provider**".

This research may be:

- Initiated by investigators conducting research at Nova Scotia Health (**NSHA**) who are collaborating with an investigator at another institution or an outside third party (i.e., lab, database management company etc.);
- Required as part of a **NSHA** investigator's participation in research studies which are lead by investigators outside **NSHA** or
- Requested by an outside party.

Recipients may include any individual, institution (academic, non-profit), or industry, not physically located at **NSHA** or part of the Nova Scotia Health Authority (**Please note: this also pertains to any transfer to Dalhousie.**). Recipients may be located in Canada or elsewhere. In order to ensure that the appropriate terms and conditions regarding this transfer are in place and agreed to by all parties involved, a Data or Material Transfer Agreement may be required. All non-employee Researchers and **NSHA** plus the Recipient are parties and signatories to these agreements.

DTA/MTAs are an important and required aspect of the management of research involving human data and samples. If you are sending data or materials outside of **NSHA** and the terms of such transfer are not covered in a participating site or clinical trial agreement, please contact the Grant Coordinator. There are a number of agreement templates currently in use, the Grant Coordinator will prepare and provide the one most appropriate for your research study. Alternatively, the Recipient institution may provide a transfer agreement template for consideration. Please also send this to the Grant Coordinator for review and approval.

## 2. Confidentiality/Non-Disclosure Agreements (CDA/NDA)

The overall purpose of confidentiality/non-disclosure agreement is to protect proprietary or academic information of NSHA or an NSHA Investigator by restricting the recipient of this information from sharing certain information with others. Any information or ideas generated as part of a proposed research study or research collaboration is proprietary and could be misused without a confidentiality agreement in place to limit its use. It is recommended that NSHA Investigators provide potential partners, co-investigators, collaborators or industry funders with a CDA/NDA prior to sharing a research protocol or details in order to protect his/her ideas and proprietary or potentially commercializable information. A non-disclosure/confidentiality agreement (NDA/CDA) is often sent by the Grant Coordinator, to participating sites on behalf of a NSHA investigator for review, approval and signature in advance of sending the protocol site agreement and budget (if required for IIR research at NSHA) or an NDA/CDA is received directly by the Investigator or Contracts/Grants Office and is reviewed, approved by the Grant Coordinator and signed in advance of receiving/sending the protocol, site agreement and budget.

## 3. Site Agreements

If a research study is being lead by an external site (other than NSHA); a draft participating site agreement and budget may be emailed to the Grant Coordinator. Sometimes it is sent directly to the PI or research coordinator who then forwards it to the Grant Coordinator for review and negotiation.

If the research study is being lead by a NSHA Investigator; participating site agreements with accompanying budget are prepared by the Grant Coordinator in consultation with the Lead Investigator/Sponsor and research team and then sent to participating sites. Sites and participating investigators are often identified in advance by the Lead Investigator. The Lead Investigator and research team often already have a study budget prepared as it has been the starting point for obtaining the funds to support the study (whether as a result of a funding application/competition or request).

## 4. Funder Agreements

Sometimes Investigators contact external funders (industry, pharma, gov't) and request financial support to cover the costs associated with a Study Protocol written independently by the Investigator. Before such a request is sent, please review the proposed budget with NSHA Research Services to ensure that all required budget items and considerations are included. Once support has been offered, a funder/support agreement detailing the terms of provision of funds and copy of the requested or confirmed budget is sent via e-mail by the Grant Coordinator to the contact person from Industry for consideration. Investigators may sometimes approach industry directly for support or apply through an industry directed funding competition. In some cases an IIR



Support agreement templates may be sent by the funder that still require review, modification and discussion with the research team by the Grant Coordinator.

## 5. Collaboration Agreements

If a NSHA Investigator and NSHA are collaborating with a commercial partner or outside organization and both parties have a mutual interest in and jointly define the design, and outcome of a research project to be conducted at NSHA, a Collaborative Research Agreement (CRA) may be put in place. The Grant Coordinator will request and negotiate such an agreement. The agreement template may be provided by the commercial partner or the NSHA CRA template will be proposed.

## 6. Amendments

If an amendment to an existing research agreement or budget is received by or is required for a research project being conducted at NSHA, the Grant Coordinator reviews or prepares the amendment. Before an amendment is approved or sent to other sites, the following is reviewed:

- The content of the amendment (timeline increase, participant number increase, increase or decrease in budget, major or minor protocol amendment)
- Additional involvement of NSHA service departments
- Budget implications
- Parties to the agreement

Should there be issues identified (insufficient funding, NSHA services agreement required, ethics resubmission, etc.) revisions will be made to the amendment with requests to cover these. The Grant Coordinator negotiates the terms of the amendment on behalf of the NSHA Investigator and finalizes with approval and sign off from the institution and other named parties to the amendment.