CLINICAL STUDY SUB-SITE AGREEMENT

This clinical study sub-site agreement (the "**Agreement**") is made effective as of the date of the last signature here below (the "**Effective Date**")

AMONG:

THE UNIVERSITY OF BRITISH COLUMBIA, a corporation continued under the *University Act* of British Columbia with offices at 103 - 6190 Agronomy Road, Vancouver, British Columbia, Canada V6T 1Z3 ("**UBC**") and **Provincial Health Services Authority** (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital) having its research administrative offices at 4500 Oak Street, Vancouver, British Columbia, Canada V6H 3N1 ("**PHSA**")

(UBC and PHSA will be referred to in the Agreement collectively as the "**Coordinating Institution**")

AND:

[redacted], having an address at, [redacted] (the "**Principal Investigator**")

AND:

MOTOL UNIVERSITY HOSPITAL having its administrative offices at V Úvalu 84, 15006 Prague 5, Czech Republic, represented by [redacted], acting on power of attorney (the "**Site**")

AND:

[redacted], having an address at V Úvalu 84, 15006 Prague 5, Czech Republic (the "**Site Investigator**")

(the Coordinating Institution, the Principal Investigator, the Site, and the Site Investigator are referred to in the Agreement individually as a "**Party**" and collectively as the "**Parties**")

WHEREAS:

The term "UBC" includes both UBC-Vancouver and UBC-Okanagan campuses.

It is UBC's objective to exploit its technology for the public benefit in harmony with the UBC Global Access Principles, outlined at https://uilo.ubc.ca/technology-transfer/ubc-global-access-principles, and to generate further research in a manner consistent with UBC's status as a non-profit, tax-exempt educational institution. Under UBC research policy and in agreement with its affiliated hospitals, UBC owns inventions, results, and/or data that arise from research performed by UBC and which are conceived and/or made by researchers who have an appointment with UBC.

The Principal Investigator designed and developed the protocol for a clinical study titled "[redacted] (the "**Study**").

The Coordinating Institution has received a grant for the Study from the Heart and Stroke Foundation of Canada ("the **Funder**").

The Principal Investigator and the Coordinating Institution wish to engage the services of the Site Investigator and the Site for the Study, and the Site Investigator and the Site wish to be so engaged.

THE PARTIES AGREE AS FOLLOWS:

1. 0 DEFINITIONS

1.1 In the Agreement:

(a) "**Confidential Information**" means the Protocol (as defined below) and all information, regardless of its form, that is disclosed by one Party (the "**Discloser**") to another Party (the "**Recipient**") and is clearly identified in writing as being confidential either at the time of disclosure or within 30 days thereafter, except that Confidential Information does not include information:

(i) possessed by the Recipient prior to receipt from the Discloser, other than through prior confidential disclosure by the Discloser, as evidenced by the Recipient's business records;

(ii) published or otherwise made available to the general public, other than through a breach of the Agreement;

(iii) obtained by the Recipient from a third party with a valid right to disclose it, provided that the third party is not under a confidentiality obligation to the Discloser in respect of the same; or

(iv) independently developed by employees, agents, or consultants of the Recipient who had no knowledge of or access to the Discloser's information, as evidenced by the Recipient's business records.

(b) "**Contract Period**" means the time period ranging from the Effective Date until the date of completion of the Study (the "**End Date**").

(c) "**Data**" means any and all data generated or collected during the Contract Period in the performance of the Study, including, but not limited to, medical information, diagnoses, and analyses of medical records.

(d) "**Data Collection Form**" means the document attached to the Agreement as Schedule "A" and/or an electronic case report form.

(e) "**Inventions**" means any and all knowledge, know-how, techniques, inventions, art, tools, technologies, processes, methods, or other intellectual property that are

conceived, invented, developed, improved, or acquired during the Contract Period in the performance of the Study.

(f) "**Protocol**" means the protocol for the Study attached to the Agreement as Schedule "B".

(g) "**Site Data**" means all Data solely generated or developed by the Site Investigator or the Site Researchers.

(h) **"Site Researchers"** means any agents, employees, contractors, representatives, or sub-investigators of the Site.

(i) "**Study Budget**" means description of compensation attached to the Agreement as Schedule "C".

(j) "**Study Samples**" means any Study samples acquired by the Site during the Contract Period in the performance of the Study.

2. 0 SCOPE OF WORK AND FUNDING

2.1 The Site Investigator will conduct the Study at the Site in accordance with the Protocol and any approved amendments which form an integral part of the Agreement. The Principal Investigator and/or the Coordinating Institution may amend the Protocol from time to time during the Contract Period, and a copy of any such amendment will be promptly provided by the Principal Investigator to the Site Investigator. The implementation of any such amendment by the Site Investigator and the Site will be subject to any approval that may be required by the Site's Research Ethics Board ("**REB**").

2.2 The Coordinating Institution will provide funds to the Site for the performance of the Study by the Site Investigator in accordance with the Study Budget. The Principal Investigator and the Coordinating Institution, acting reasonably, reserve the right to withhold payment or request return of funds to the extent that the Study participants were not properly enrolled under the terms of the Protocol, the Site Investigator has not provided the cooperation as referred in Section 4.1(f), or the Study was not conducted in accordance with the Agreement or the Protocol. The Parties acknowledge and agree that the funding of the Site is contingent upon the receipt of grant funding from the Funder by the Coordinating Institution. The funding provided by the Coordinating Institution to the Site may not be used for any indirect costs of research, which for the purpose of this Agreement would be any costs which cannot be directly associated with a particular research program or operating grant including costs associated with the general operation and maintenance of facilities (from laboratories to libraries); the management of the research process (from grant management to commercialization); regulation and safety compliance (including human ethics, animal care and environmental assessment); and generic institutional / departmental taxes/tithes related to services.

2.3 The Site will retain the accounts and financial records (the "**Records**") for the Study for at least 7 years from when they were created, and will permit any duly authorized representative of Coordinating Institution and the Funder to inspect the Records during the Site's normal business hours. The Site will provide to the representative all reasonable evidence necessary to verify the accounts and records, and will allow copies to be made of the Records. If applicable, Site shall return to Coordinating Institution all overpayment within 30 days of notice by Coordinating Institution to the Site.

2.4 The Site and Site Investigator agree that they will not use any funding from other sources for the conduct of the Study without the prior written consent of the Coordinating Institution.

3. 0 PERIOD OF PERFORMANCE

3.1 The Agreement will continue in full force and effect for the duration of the Contract Period; or if the Parties agree to extend the Study at the Site beyond the End Date, until such date as is mutually agreed upon in writing; or if the Agreement is terminated in accordance with Section 10.0 of the Agreement, until the date on which the Agreement is terminated.

4. 0 RESPONSIBILITIES OF THE SITE INVESTIGATOR

4.1 The Site Investigator will:

(a) exercise due care in conducting the Study in compliance with the International Council on Harmonization E6: Good Clinical Practice: guidelines Consolidated Guideline ("**ICH-GCP**"), the Funder's Framework: Responsible Conduct of Research (https://heartstrokeprod.azureedge.net/-/media/research/docs/responsible-conduct-of-research_final.ashx?la=en&rev=412d58ee7146488382e56fce65d8b207) and all applicable laws and regulations;

(b) provide to the Coordinating Institution, prior to screening Study participants or enrolling Study participants into the Study, a copy of the Study participant informed consent form that will be used in the Study and has been approved by the Site's REB; a copy of the *curriculum vitae* of the Site Investigator and any key Study personnel; and written evidence of the approval of the Protocol and any amendment to the Protocol by the Site's REB;

(c) assume responsibility for the conduct of the Study at the Site and conduct the Study at the Site in accordance with the Protocol (subject to any amendments approved by the Site's REB). Any changes in procedure set out in the Protocol will be made by the Site Investigator only if considered necessary by the Site Investigator to protect the safety, rights, or welfare of Study participants, provided that the Site Investigator promptly notifies the Principal Investigator of any such deviation. Such deviations from the terms of the Protocol will not constitute negligence, error, omission, malfeasance, or material breach of the Agreement on the part of the Site Investigator or the Site;

(d) ensure that any sub-investigators and any support staff who are participating in the Study at the Site will comply with the terms of the Protocol and any amendments to the same extent as the Site Investigator. The Site Investigator will take appropriate steps to inform each such person of his/her obligations and to obtain his/her agreement to abide by the terms and conditions of the Agreement;

(e) complete accurately and promptly the Data Collection Form and secure Study Samples in accordance with the Protocol and submit completed Data Collection Forms and Study Samples to the Principal Investigator on a timely basis and in accordance with the Protocol. Study Samples may only be used by the Principal Investigator and the Coordinating Institution for the limited purpose of performing the Study and in accordance with the Protocol, Study participants consent forms and all applicable laws. The Site retains ownership of the Study Samples. All unused Study Samples will be

returned to the Site or destroyed by the Principal Investigator and the Coordinating Institution at the request of the Site Investigator and/or the Site, and if destroyed, the Principal Investigator and the Coordinating Institution will certify such destruction in writing; and

(f) assist the Principal Investigator or his designate in a timely manner with the preparation of any financial, progress and final reports, as required by the Funder.

5. 0 RECORD KEEPING

5.1 The Site and Site Investigator shall maintain adequate and accurate records relating to the Study, including the Study participant informed consent and treatment records of the Study participants, for 25 years following completion or termination of the Study that is required by local laws, regulations, or guidelines.

6. 0 CONFIDENTIALITY

6.1 The Recipient will keep and use the Discloser's Confidential Information in confidence and will not, without the Discloser's prior written consent, disclose the Discloser's Confidential Information to any person or entity, except to the Recipient's directors, officers, employees, faculty, students, and professional advisors who require the Confidential Information in order to assist the Recipient in performing its obligations and/or exercising its rights under the Agreement.

6.2 If the Recipient is required by judicial or administrative process to disclose the Discloser's Confidential Information, the Recipient will promptly notify the Discloser of the requirement and allow the Discloser reasonable time to oppose the process before disclosing the Confidential Information. If the Discloser is unable to successfully oppose the disclosure or if the Discloser decides not to oppose the disclosure, the obligations under Section 6.1 shall not apply, though only for the legally required disclosure and only for such Confidential Information that is required to be disclosed.

6.3 The Parties agree that the provisions of this Section 6.0 will not prevent the Recipient from disclosing the Discloser's Confidential Information to: (i) the Recipient's REB; (ii) the REB of another site participating in the Study if it is necessary for the performance of the Study or for the safety of Study participants, provided that the Recipient notifies the Discloser in writing in advance of the Recipient's intention to do so; or (iii) Study participants, their doctors, or their legal representatives if required for the clinical or medical care or safety of the Study participants.

6.4 Notwithstanding any termination or expiration of the Agreement, the obligations set out in this Section 6.0 survive and continue to bind the Parties and their successors and assigns until 5 years after the date of such termination or expiration.

7. 0 PRIVACY

7.1 Notwithstanding anything to the contrary in the Agreement, the Parties will continue to treat as confidential all Information of Study participants as set out in the Study participant's consent form, this Section 7.1, the contract in the transfer of personal Data appended herein as Schedule D, and as required by law. Each Party will give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Information of any Study

participant.

8. 0 DATA AND INVENTIONS

8.1 Subject to Section 9.0 (Publication), the Coordinating Institution and the Principal Investigator own all right, title, and interest in any and all Inventions, Data (including Site Data) and Data Collection Forms. However, medical records of Study participants at the Site shall remain at all times the property of Site.

8.2 The Coordinating Institution and the Principal Investigator hereby grant to the Site and the Site Investigator a non-exclusive, royalty-free, irrevocable, perpetual right to use any and all Site Data for the purpose of the Study and internal and academic research purposes.

8.3 The Site and the Site Investigator will promptly disclose to the Principal Investigator and the Coordinating Institution any Inventions made or conceived by the Site Investigator and/or the Site Researchers.

9. 0 PUBLICATION

9.1 The Parties agree that the first publication of the Study will be a joint, multi-centre publication involving all the investigators and sites that participated in the Study. Authorship of the multi-centre publication will be determined in accordance with academic standards for authorship. If such a multi-centre publication has not been submitted to an academic journal within 12 months after the conclusion, abandonment, or termination of the Study at all sites participating in the Study, or if the Principal Investigator confirms in writing that there will be no multi-centre publication, the Site Investigator may publish any Site Data. The Site Investigator will have the right to disclose information resulting from the Study or any background information provided by the Principal Investigator or the Coordinating Institution that is necessary to allow other scholars to verify research results.

9.2 The Site Investigator and the Site Researchers will not be restricted from presenting Site Data at symposia or national or regional professional meetings or from publishing Site Data in journals or other publications (collectively, the "**Proposed Disclosure**"), provided that any Proposed Disclosure is submitted to the Principal Investigator for review for Confidential Information and for comment at least 30 days before the date of presentation of the Proposed Disclosure or the date of submission of the Proposed Disclosure for publication. Any information identified by the Principal Investigator or the Coordinating Institution as being Confidential Information will be deleted from the Proposed Disclosure, provided that the Principal Investigator and the Coordinating Institution will not request the deletion of, and the Site Investigator and the Site Researchers will not be required to delete, any data, results, or information related to research methods used in the Study. At the request of the Principal Investigator or the Coordinating Institution, any Proposed Disclosure will be delayed for a further period not exceeding 60 days to enable the Coordinating Institution to protect its rights in such Confidential Information. If the Site Investigator and the Site Researchers do not wish to delay the Proposed Disclosure, the Site Investigator and the Site Researchers will delete the Confidential Information identified by the Principal Investigator or the Coordinating Institution from the Proposed Disclosure prior to its presentation or submission for publication.

9.3 The support of the Funder must be acknowledged in all Proposed Disclosures by including the statement "Funding for this project is provided by the Heart & Stroke Foundation".

9.4 Other than with respect to Confidential Information, nothing in the Agreement will be construed as granting to the Principal Investigator or the Coordinating Institution any right to edit the Proposed Disclosure. The final analysis and interpretation of the Site Data remain with the Site Investigator and the Site Researchers. The Site Investigator shall provide the Principal Investigator with a copy of all Proposed Disclosures, once published or presented, which Principal Investigator shall be entitled to share with the Funder.

10. 0 TERMINATION

10.1 Any Party may terminate the Agreement upon 30 days' prior written notice to the other Parties. The 30 day notice will not be required if the Party wishing to terminate the Agreement, in its sole opinion, deems that the safety of the Study participants has been compromised provided that the Party wishing to terminate the Agreement due to safety concerns promptly notifies the other Parties of its decision to do so.

10.2 In addition, any Party may immediately terminate the Agreement by written notice of breach by any other Party if the other Party fails to remedy such breach within 15 days of receipt of such notice or such longer period as the Parties may agree to in writing, acting reasonably and giving consideration to the nature of the breach and time reasonably required to cure the same. Breach will be defined as a failure to comply with any provisions of this Agreement and documents incorporated herein.

10.3 No termination of the Agreement, however effectuated, will release the Parties from their rights and obligations under Sections 2.3, 5.0 (Record Keeping), 6.0 (Confidentiality), 7.0 (Privacy), 8.0 (Data and Inventions), 9.0 (Publication), 10.3, 10.4, 11.0 (Disclaimer of Warranty and Liability), 12.0 (Insurance), 13.0 (Use of Name), and 15.0 (General).

10.4 In the event of termination, the Coordinating Institution will reimburse the Site for all payments owing to the Site up to receipt of the written notice of termination, in accordance with the Study Budget, except that no such payment will be made in the event that the Agreement is terminated on the basis of Section 10.2 because of a breach by the Site or Site Investigator . The Site shall take all reasonable steps to minimize further costs after receiving notice of termination, regardless of the grounds for such termination.

11. 0 DISCLAIMER OF WARRANTY AND LIABILITY

11.1 The Parties will perform the Study in accordance with the Protocol and the terms of the Agreement. However, no Party promises success in achieving any particular result. Except as expressly provided in the Agreement, no Party gives any warranty whatsoever, express or implied, as to any matter, including, without limitation, as to the results of the Study or regarding Confidential Information that a Party may disclose to another Party. No Party will be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by any other Party as a result of the conduct of the Study or the performance of the Agreement.

11.2 The Parties acknowledge and agree that each Party will be responsible and liable for any damage or loss to the extent that such damage or loss arises as a result of its own negligence or willful or wrongful acts or omissions in the administration of this Agreement or in conducting the Study, such as a failure by that Party to: (a) adhere to the material terms of the Protocol; (b) comply with applicable governmental requirements or regulations of the country in which a Party operates; and (c) conduct the Study in accordance with the medical standards set out in the ICH-GCP. No Party ("the **First Party**") will be liable to any other Party (the "**Second**

Party") for any damage or loss that results from the use by the Second Party or third party of the Data or Inventions developed under the Agreement, Protocol, or Study, except to the extent that the damage or loss arises from the gross negligence or willful misconduct of the First Party.

12. 0 INSURANCE

12.1 The Coordinating Institution and the Site will each maintain, at its own expense, appropriate policies of liability insurance against any and all foreseeable risks of loss arising out of the Agreement or the Study. The Coordinating Institution and the Site will provide evidence of such insurance to each other upon written request, and will provide each other 30 days prior written notice of cancellation or non-renewal of their respective coverage.

12.2 The Site Investigator represents and warrants that he/she is, and that any other licensed physician involved in the Study at the Site, including any co-investigator and sub-investigator, is a member of the appropriate medical professional association.

13.0 USE OF NAME

13.1 Notwithstanding anything to the contrary in the Agreement and without further notice, the Parties agree that each Party may disclose the existence of the Agreement, the Parties to the Agreement, the amount of funding received by the Site from the Coordinating Institution and the title of the Study in annual reports or in any publication or presentation relating to the results of the Study. However, no Party may use the name of any other Party or any other Party's trademarks or insignia in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses services, organizations, or products, or for any other purpose other than that expressly permitted by the Agreement, without the other Party's prior written consent.

13.2 Site and Site Investigator acknowledge and agree that the Funder shall be entitled to disclose the existence of the Agreement, the Parties to the Agreement, the amount of funding received by the Site from the Coordinating Institution, the title of the Study and a lay summary in any of its publications or communications.

13.3 Neither the Site nor the Site Investigator shall use the name of the Funder or any of Funder's trademarks or official marks in any communication without the prior written approval of the Coordinating Institution, unless specifically foreseen in this Agreement. The Site and Site Investigator shall furthermore not use the name of the Funder in association with the raising of funds for a private or public company, partnership, or any other business arrangement, or indicate in any manner that the Funder is in "association" with or "partner" of "joint venturing" with any other person or agency.

14.0 NOTICES

14.1 All payments, reports, notices, or other documents that a Party is required or wishes to deliver to any other Party will be delivered:

(a) in writing, and

(b) either by personal delivery or by registered or certified mail (with all postage and other charges prepaid) at the address for the receiving Party as set out in Section 14.2 or as varied by any notice.

Any notice that is personally delivered is deemed to have been received at the time of delivery. Any notice that is mailed in accordance with this Section 14.0 is deemed to have been received at the end of the fifth business day after it is posted.

14.2 Addresses for delivery of notices:

To the Coordinating Institution
If to UBC:

Contracts Officer
UBC File No. F22-02815
The University of British Columbia
University-Industry Liaison Office
#103 - 6190 Agronomy Road
Vancouver, British Columbia
Canada V6T 1Z3
Tel: [redacted]
Email: [redacted]

To the Principal Investigator
[redacted]
BCCH – Children's Heart Centre
4480 Oak Street
Vancouver, British Columbia
Canada V6H 3V4
Tel: [redacted]

If to PHSA

Provincial Health Services Authority
(on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital)
[redacted]
Interim Senior Executive Director, B.C. Children's Hospital Research Institute
A2-151, 938 West 28th Avenue
Vancouver, British Columbia
Canada V5Z 4H4
[redacted]

To the Site:

MOTOL UNIVERSITY HOSPITAL
V Úvalu 84, 15006 Prague 5, Czech Republic
[redacted]

To the Site Investigator

[redacted]
V Úvalu 84, 15006 Prague 5, Czech
[redacted]

15.0 GENERAL

15.1 Nothing contained in the Agreement is to be deemed or construed to create between the Parties a partnership or joint venture. No Party has the authority to act on behalf of any other Party, or to commit any other Party in any manner at all or cause any other Party's name to be used in any way not specifically authorized by the Agreement.

15.2 In the event of any dispute related hereto, the validity, construction and performance of the terms of this Agreement shall be governed by the law of the defending party, and any claims shall be submitted and subject to the determination of the courts of the defending party's domicile.

15.3 No condoning, excusing, or overlooking by any Party of any default, breach, or non-observance by any other Party at any time or times regarding any terms of the Agreement operates as a waiver of that Party's rights under the Agreement. A waiver of any term or right under the Agreement will be in writing signed by the Party entitled to the benefit of that term or right, and is effective only to the extent set out in the written waiver.

15.4 No exercise of a specific right or remedy by any Party precludes it from or prejudices it in exercising another right or pursuing another remedy or maintaining an action to which it may otherwise be entitled either at law or in equity.

15.5 No right or license is granted under the Agreement by any Party to any other Party either expressly or by implication, except as specifically set out in the Agreement. Nothing contained in the Agreement will impose an obligation of exclusivity on one Party by any other Party. Each Party reserves the right to enter into and participate in other activities (either alone or with a third party), including, but not limited to, clinical trials and other research projects.

15.6 All terms in the Agreement which require performance by the Parties after the expiry or termination of the Agreement will remain in force despite the Agreement's expiry or termination for any reason.

15.7 Part or all of any section of the Agreement that is indefinite, invalid, illegal, or otherwise voidable or unenforceable may be severed from the Agreement, and the balance of the Agreement will continue in full force and effect.

15.8 Each Party will execute and deliver such further agreements and other documents and do such further acts and things as the other Parties reasonably request to evidence, carry out, or give full force and effect to the intent of the Agreement.

15.9 The Agreement and the Schedules set out the entire understanding between the Parties and no changes to the Agreement are binding unless in writing and signed by the Parties to the Agreement. The Parties will be bound by the Schedules, except to the extent that they may conflict with the terms and conditions contained in the Agreement, in which case the terms and conditions of the Agreement will govern.

15.10 Each Party acknowledges that it/he/she has been advised by the other Parties to seek independent legal advice with respect to the Agreement and that it/he/she has not relied upon any of the other Parties for any advice, whether legal or otherwise, with respect to the Agreement.

15.11 The Agreement may be executed in 4 counterparts electronically signed by the Parties.

15.12 In this Agreement, unless the contrary intention appears, "days" means calendar days.

15.13. The Parties hereby consent to the publication of the Agreement by the Site for the sole purpose of enabling the Site to fulfill its obligations imposed by the Site's local effective legal

regulations as applicable, in particular by the Act No. 340/2015 Coll. on Registry of Contracts, as amended, and by the guidelines and decisions of the Ministry of Health of the Czech Republic; subject to the conditions below:

a) The Site will ensure that when publishing the Agreement in compliance with the abovementioned legal regulations, it shall not disclose any personal data of natural persons including Information as defined in Section 7.0 (Privacy), which are not publicly available in public registers, or any Confidential Information pursuant to this Agreement, pursuant to provisions of § 504 of the Civil Code, and shall endeavor to remove any such personal data or Confidential Information that may be in the Agreement prior to its publication, including without limitation removal of the Protocol appended in Schedule B.

b) For the purpose of the publication of this Agreement within the intent of this section, the Site shall submit to UBC a version of the Agreement (in a machine-readable form) that the Site has revised in compliance with the legal regulations in paragraph (a) above at least 30 days prior to its publication. UBC retains the right to refuse the publication of such revised version of the Agreement if it deems that (i) the revisions have materially altered the terms of the Agreement, or (ii) there are Confidential Information or Information (as applicable) that has not yet been removed from the Agreement to the satisfaction of UBC.

c) The Site shall publish such version of the Agreement in the Register of Contracts and shall inform the Coordinating Institution about the publication in accordance to Section 14 (Notices).

[THE SIGNATURE PAGE FOLLOWS]

SIGNED BY THE PARTIES AS AN AGREEMENT and effective as of the Effective Date.

Signed for and on behalf of

THE UNIVERSITY OF BRITISH COLUMBIA

by its authorized signatory:

_____
Signature

Name: [redacted]
Title: Associate Director, UILO

Date

Signed for and on behalf of

PROVINCIAL HEALTH SERVICES AUTHORITY (on behalf of Children's & Women's Health Centre of British Columbia Branch, a public hospital)
by its authorized signatory:

_____
Signature

Name: [redacted]
Title: Interim Senior Executive Director
BC Children's Hospital Research Institute

Date

PRINCIPAL INVESTIGATOR

_____
Signature

Name: [redacted]
Title: Head, Division of Pediatric Oncology and Medical Director, BCCH Heart Centre

Date

Signed for and on behalf of
MOTOL UNIVERSITY HOSPITAL
by its authorized signatory:

_____
Signature

Name: [redacted]
Title: Deputy Director

Date

SITE INVESTIGATOR

_____

Name: [redacted]
Title:

Date

SCHEDULE “A”

DATA COLLECTION FORM

SCHEDULE “B”

PROTOCOL

SCHEDULE "C"

BUDGET AND PAYMENT SCHEDULE

The Study is investigator-driven and supported by the Heart and Stroke Foundation of Canada. All payments will be made in Canadian dollars.

Payment Schedule:

1. Payment will be made as follows:

[redacted]

1. The Coordinating Institution will provide payment for each Study participant within 90 days of receipt by the Principal Investigator or designate of all of the following:

    a) Study participant data entered into the REDCap database; and
    b) an invoice.

1. Invoices must be submitted to the Coordinating Institution within 90 days of each Study participant completing the Study. Maturity of the invoice shall be 30 days after the date of receipt of invoice by Coordinating Institution, and the Coordinating Institution shall pay such invoice on or before its maturity. The Site may include multiple subjects on each invoice. Invoices should be directed to:

[redacted]

1. No payment or partial payment will be made:

    a) for any Study participant entered in violation of the Protocol;
    b) for any Data Collection Form deemed to be non-evaluable;
    c) for any enrolment after a notice of termination has been sent by the Coordinating Institution;
    d) for any enrolment after the designated recruitment period, unless approved in writing by the Principal Investigator; or
    e) if the Site is in breach of the Agreement.

1. If at the date of Study termination the total amount that the Coordinating Institution has paid exceeds the amount to which the Site is entitled hereunder, the Site will return the overpayment to the Coordinating Institution within 30 days after the termination date. If at the date of Study termination the total amount that the Coordinating Institution has paid is less than the amount to which the Site is entitled hereunder, the Coordinating Institution will pay the amount due the Site.

THIS SECTION IS TO BE COMPLETED BY THE SITE

(A)	**Make Cheques Payable To:** *(Insert Name for Payment)*	**Fakultní nemocnice v Motole**
(B)	**Site Account Number:** *(Insert Bank name & address and account number)*	Czech National Bank, Na Příkopě 28, Prague 1 17937051/0710
(C)	**Mail Cheques To:** *(Insert Address)*	**V Úvalu 84, 150 06 Prague 5**
(D)	**Electronic Funds Transfer Details:** *(Insert Swift code and IBAN number)*	CZ42 0710 0000 0000 1793 7051
(E)	***Insert* GST** Registration number	
(F)	***Insert* QST** Registration number	
(G)	***Insert* HST** Registration number	

SCHEDULE "D"

Standard Contractual Clauses

SECTION I

Clause 1

Purpose and scope

(a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) for the transfer of personal data to a third country.

(b) The Parties:

(i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter 'entity/ies') transferring the personal data, as listed in Annex I.A (hereinafter each 'data exporter'), and

(ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A (hereinafter each 'data importer')

have agreed to these standard contractual clauses (hereinafter: 'Clauses').

(c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.

(d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

Clause 2

Effect and invariability of the Clauses

(a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46(2)(c) of Regulation (EU) 2016/679.. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.

(b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

Clause 3

Third-party beneficiaries

(a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:

(i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;

(ii) Clause 8 –Clause 8.5 (e) and Clause 8.9(b);

(iv) Clause 12 –Clause 12(a)

(v) Clause 13;

(vi) Clause 15.1(c), (d) and (e);

(vii) Clause 16(e);

(viii) Clause 18 –Clause 18(a) and (b);.

(b)Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

Clause 4

Interpretation

(a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.

(b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.

(c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

Clause 5

Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 6

Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

Clause 7 –Reserved

SECTION II – OBLIGATIONS OF THE PARTIES

Clause 8

Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

Transfer controller to controller

8.1 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B. It may only process the personal data for another purpose:

(i) where it has obtained the data subject's prior consent;

(ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or

(iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

8.2 Transparency

(a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:

(i) of its identity and contact details;

(ii) of the categories of personal data processed;

(iii) of the right to obtain a copy of these Clauses;

(iv) where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.

(b) Paragraph (a) shall not apply where the data subject already has the information, including

) when such information has already been provided by the data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.

(c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.

(d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.3 Accuracy and data minimisation

(a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.

(b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.

(c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

8.4 Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation of the data and all back-ups at the end of the retention period.

8.5 Security of processing

(a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter ‘personal data breach’). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse

to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.

(b) The Parties have agreed on the technical and organisational measures set out in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.

(c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

(d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.

(e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.

(f) In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.

(g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

8.6 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter 'sensitive data'), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature

of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

8.7 Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union (in the same country as the data importer or in another third country, hereinafter 'onward transfer') unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

(i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;

(ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;

(iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;

(iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;

(v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or

(vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.8 Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

8.9 Documentation and compliance

(a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.

(b) The data importer shall make such documentation available to the competent supervisory authority on request.

Clause 9- Reserved

Clause 10

Data subject rights

Transfer controller to controller

(a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. [10] The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

(b) In particular, upon request by the data subject the data importer shall, free of charge:

(i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);

(ii) rectify inaccurate or incomplete data concerning the data subject;

(iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.

(c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.

(d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter 'automated decision'), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary

in cooperation with the data exporter:

(i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and

(ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.

(e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.

(f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.

(g) If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.

Clause 11

Redress

(a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.

[OPTION: The data importer agrees that data subjects may also lodge a complaint with an independent dispute resolution body at no cost to the data subject. It shall inform the data subjects, in the manner set out in paragraph (a), of such redress mechanism and that they are not required to use it, or follow a particular sequence in seeking redress.]

MODULE ONE: Transfer controller to controller

(b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.

(c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:

(i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;

(ii) refer the dispute to the competent courts within the meaning of Clause 18.

(d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.

(e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.

(f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

Clause 12

Liability

Transfer controller to controller

(a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.

(b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.

(c) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.

(d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.

(e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

(a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.

(b) The data importer shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages the data importer or its sub-processor causes the data subject by breaching the third-party beneficiary rights under these Clauses.

(c) Notwithstanding paragraph (b), the data exporter shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material

damages the data exporter or the data importer (or its sub-processor) causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter and, where the data exporter is a processor acting on behalf of a controller, to the liability of the controller under Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable.

(d) The Parties agree that if the data exporter is held liable under paragraph (c) for damages caused by the data importer (or its sub-processor), it shall be entitled to claim back from the data importer that part of the compensation corresponding to the data importer's responsibility for the damage.

(e) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.

(f) The Parties agree that if one Party is held liable under paragraph (e), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.

(g) The data importer may not invoke the conduct of a sub-processor to avoid its own liability.

Clause 13

Supervision

Transfer controller to controller

(a) The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

(b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES

Clause 14

Local laws and practices affecting compliance with the Clauses

Transfer controller to controller

(a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.

(b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:

(i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;

(ii) the laws and practices of the third country of destination– including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards;

(iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.

(c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.

(d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.

(e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).

(f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason

) to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

Clause 15

Obligations of the data importer in case of access by public authorities

Transfer controller to controller

15.1 Notification

(a The data importer agrees to notify the data exporter and, where possible, the data subject) promptly (if necessary with the help of the data exporter) if it:

(i)receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or

(ii becomes aware of any direct access by public authorities to personal data transferred) pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.

(b If the data importer is prohibited from notifying the data exporter and/or the data subject) under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.

(c Where permissible under the laws of the country of destination, the data importer agrees to) provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).

(d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.

(e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

15.2 Review of legality and data minimisation

(a) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).

(b) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.

(c) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

SECTION IV – FINAL PROVISIONS

Clause 16

Non-compliance with the Clauses and termination

(a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.

(b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).

(c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the

) processing of personal data under these Clauses, where:

(i)the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;

(ii) the data importer is in substantial or persistent breach of these Clauses; or

(iii)the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

In these cases, it shall inform the competent supervisory authority

(d : Personal data that has been transferred prior to the termination of the contract pursuant to
) paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data.] [The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.

(e Either Party may revoke its agreement to be bound by these Clauses where (i) the European
) Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

Clause 17

Governing law

In the event of any dispute related hereto, the validity, construction and performance of the terms of this Agreement shall be governed by the law of the defending party, and any claims shall be submitted and subject to the determination of the courts of the defending party's domicile.

(3) The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union's internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purpose of these Clauses.

ANNEX II - TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA

MODULE ONE: Transfer controller to controller

De-identified Study data (Registry data, physical activity monitoring and questionnaire results) requested will be sent to the Coordinating Institution through secure electronic transfer mode, and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the BC Children's Hospital Research Institute. REDCap is a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for data entry, and audit trails for tracking data manipulation. Email addresses will be collected in REDCap to enable automated distribution of questionnaires; this is explicitly stated in the consent form. All data will be removed and destroyed five years after study completion.