**THE NEUROFIBROMATOSIS RESEARCH INITIATIVE (NFRI)**

**AT BOSTON CHILDREN’S HOSPITAL**

**GENOMICS OF MPNST (GEM) CONSORTIUM DATA USE AGREEMENT**

This **DATA USE AGREEMENT** (“Agreement”) is effective as of September 1, 2017 (the “Effective Date”), by and between (“Member”) and **THE NEUROFIBROMATOSIS RESEARCH INITIATIVE AT BOSTON CHILDREN’S HOSPITAL (“NFRI” or “Data User”).**

**RECITALS:**

**WHEREAS**, Participant is one of several institutions that have entered into an agreement to participate in the NFRI Genomics of MPNST Consortium (“GeM Consortium”); and

**WHEREAS**, NFRI is the coordinator and administrator of the GeM Consortium; and

**WHEREAS**, in accordance with the Master Participation Agreement for the GeM Consortium, NFRI may receive from Member, or create, receive, maintain or transmit on behalf of Member, de-identified data or protected health information (or “PHI”) in the form of a Limited Data Set, as defined under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and its regulations, as amended by the Health Information Technology for Economic and Clinical Health Act of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, Title XIII (2009) (the “HITECH Act”; any reference herein to HIPAA shall include the HITECH Act amendments and any other amendments), submitted by Participant; and

**WHEREAS**, certain Members may also be subject to the Personal Information Protection and Electronic Document Act (“PIPEDA”), the European Union Data Protection Directive 95/46/EC (“E.U. Directive”), the Personal Health Information Protection Act (Ontario) of 2004 (the “Ontario Act”), or other national equivalents, each as may be amended;

**WHEREAS**, certain Members have made assurances that transfer of de-identified data will be subject to Data Use Agreements with the receiving parties;

**WHEREAS**, Member is subject to HIPAA, as a Covered Entity, or other equivalent provisions as set forth above, and hereby agrees to specific terms that govern the use and disclosure of PHI disclosed by Participant to NFRI in conjunction with the Master Participation Agreement; and

**WHEREAS**, the parties wish to enter into this Agreement in order to comply with HIPAA or other equivalent provisions.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants set forth below, Member and NFRI agree as follows:

# **Definitions.** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, and that the terms set forth below shall be deemed to be modified to reflect any changes made hereafter to such terms by law or regulation.

## “*HIPAA Regulations*” means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164.

## “*Covered Entity*” means a health plan, a health care clearinghouse, or a health care provider (each as defined by HIPAA and the HIPAA Regulations) that transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.

## “*Individually Identifiable Health Information*” means information that is a subset of health information, including demographic information collected from an individual, that is;

### created or received by a health care provider, health plan, employer, or health care clearinghouse; **and**

### relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; **and**

#### that identifies the individual; or

#### with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

## “*Protected Health Information*”or“*PHI*” means Individually Identifiable Health Information, except that Protected Health Information excludes Individually Identifiable Health Information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g, records described at 20 U.S.C. § 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

# **Obligations of Member.**

Member agrees to share either or both of the following:

## *De-identified dataset.* Certain genomic and clinical data for inclusion in the GeM Consortium database pursuant to the Master Participation Agreement. Such de-identified datasets shall not include any of the following identifiers of the individual who is the subject of the genomic and clinical data or of relatives, employers, or household members of the individual: names, all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, all ages over 89, and all elements of dates (including year) indicative of age 89, except that such ages and elements may be aggregated into a single category of age 90 or older; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images; all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes; and any other unique identifying number, characteristic, or code.

### The initial three digits of a code may be used if, according to the current publicly available data from the Bureau of Census: (i) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (ii) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000. There are 17 zip codes with populations below 20,000 whose first 3 digits must be coded to ‘000’: 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893.

## *Limited Data Set.* Certain genomic and clinical outcomes data for inclusion in the GeM Consortium database pursuant to the Master Participation Agreement for the GeM Consortium, limited as required by HIPAA at 45 C.F.R. § 164.514(e) (the "Limited Data Set"). Such Limited Data Set shall not contain any of the following identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual: names; postal address information (other than town or city, state, and zip code); telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

# **Obligations of Data User.**

## *Performance of Activities.* Data User may use and disclose the De-Identified or Limited Data Sets received from Member only in connection with the performance of the research, public health, or health care operations activities described in the Master Participation Agreement (the “Activities”).

## *Permitted Access to De-Identified or* *Limited Data Sets.* Data User shall limit the use or receipt of the De-Identified or Limited Data Sets to the following individuals or classes of individuals who need the Limited Data Set for the performance of the Activities: Employees of NFRI involved in the GeM Consortium, and non-employee agents and subcontractors involved in the GeM Consortium, subject to the limitations of subparagraph c, below.

## *Assurances of Data User’s Non-Employee Agents.* Data User shall not disclose the De-Identified or Limited Data Sets to any non-employee agent or subcontractor of Data User except with the prior written consent of Member or as provided in the Master Participation Agreement. Data User shall ensure that any agents, including subcontractors, to whom it provides the De-Identified or Limited Data Sets agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such De-Identified or Limited Data Sets.

## *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the De-Identified or Limited Data Sets except as permitted or required by this Agreement.

## *Use Or Disclosure As If Covered Entity.* Data User may not use or disclose the De-Identified or Limited Data Sets in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if Data User were a Covered Entity.

## *Identification Of Individual.* Data User may not use the De-Identified or Limited Data Sets to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.

## *Disclosures Required By Law.* Data User shall not, without the prior written consent of Covered Entity, disclose the De-Identified or Limited Data Sets on the basis that such disclosure is required by law without notifying Member so that Member shall have an opportunity to object to the disclosure and to seek appropriate relief. If Member objects to such disclosure, Data User shall refrain from disclosing the De-Identified or Limited Data Sets until Member has exhausted all reasonably available alternatives for relief.

## *Safeguards.* Data User shall use appropriate safeguards to prevent use or disclosure of the De-Identified or Limited Data Sets other than as provided by this Agreement. Data User agrees to comply with requests from Member to assess NFRI’s compliance with this requirement, including complying with Participant’s information security assessment process.

## *Reporting.* Data User shall report to Participant within five (5) days of Data User becoming aware of any use or disclosure of the De-Identified or Limited Data Sets in violation of this Agreement or applicable law.

# **Material Breach, Enforcement, Term and Termination.**

## *Term.* This Agreement shall be effective as of the Master Participation Agreement Effective Date, and shall continue unless and until the Agreement is terminated in accordance with the provisions of Section 4.c. or the Master Participation Agreement terminates.

## *Rights of Access and Inspection.* Data User agrees to make its internal practices, books, and records relating to the use and disclosure of PHI under this Agreement available, as applicable, to the Member, the Secretary or other appropriate official of a foreign state, or his or her designee, for the limited purposes of determining Data User’s compliance with this Agreement or Member’s compliance with applicable law upon request. The fact that Member inspects, or fails to inspect, or has the right to inspect, Data User’s facilities, systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Member’s (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User’s remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Member’s enforcement or termination rights under this Agreement. The parties’ respective rights and obligations under this Section 4.b. shall survive termination of the Agreement.

## *Termination*. This section shall survive termination of this Agreement.

### Termination for Cause. Upon Member’sknowledge of a material breach by Data User, Participantshall either (i) provide an opportunity for Data User to cure the breach or end the violation and, if Data User does not cure the breach or end the violation within the cure period specified in the Agreement or if none is specified, then within thirty (30) days, terminate this Agreement and the Master Participation Agreement; (ii) immediately terminate this Agreement and the Master Participation Agreement if cure is not possible; or (iii) if neither termination nor cure are possible, Membershall report the violation to the Secretary.

### Participant may further terminate this Agreement pursuant to Section 5.b. of this Agreement.

### Effect of Termination.

#### Upon termination of the GeM Consortium, Data User shall confirm that all PHI received from Member has been destroyed, and Data User shall provide written confirmation of such destruction to Member.

#### In the event of termination of Member’s role in the GeM Consortium prior to the termination of the GeM Consortium, Data User shall be permitted to retain, use and disclose Member’s data already submitted as part of the GeM Consortium until termination of the GeM Consortium, provided that Data User shall extend the protections of this Agreement to such PHI for so long as Data User maintains such PHI.

## *Remedies*. If Member determines that Data User has breached or violated a material term of this Agreement, Member may, at its option, exercise any of its rights of access and inspection under Section 4.b. of this Agreement and/or terminate this Agreement in accordance with Section 4.c.

## *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations, or any equivalent regulations, automatically will be considered a breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.

## *Reporting to United States Department of Health and Human Services* or equivalent entity. If any breach or violation is not cured, and if termination of this Agreement is not feasible, Member shall report Data User’s breach or violation to the Secretary of the United States Department of Health and Human Services, and Data User agrees that it shall not have or make any claim(s), whether at law, in equity, or under this Agreement, against Member with respect to such report(s).

## *Indemnification.* Data User shall indemnify, hold harmless and defend Member from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the negligent acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. The parties’ respective rights and obligations under this Section 4.g. shall survive termination of the Agreement.

# **Miscellaneous Terms.**

## *Other Law*. In addition to HIPAA, the parties agree to comply with other applicable U.S. federal and state law, PIPEDA, the E.U. Directive, the Ontario Act and such other national equivalent with respect to the use and disclosure of Protected Health Information, including but not limited to obtaining the consent of an individual with respect to the disclosure of Protected Health Information and providing the individual with the rights of access, rectification, erasure and blocking of his or her disclosed Protected Health Information. In the event of a conflict between the requirements of such other law and the requirements stated herein, the applicable law under a conflict-of-law analysis, including the preemption analysis required under HIPAA, shall apply.

## *Amendment.* No amendment to this Agreement shall be effective unless it is in writing and signed and dated by the parties hereto or as required by law or regulations. The parties recognize that the Secretary may issue further amendments to the HIPAA Rules pursuant to the Secretary’s authority under law, and the parties agree that they shall promptly amend this Agreement as necessary

## to maintain compliance with HIPAA and any other privacy, security, or other applicable legal requirements. Member may terminate this Agreement upon thirty (30) days written notice in the event that Data User does not promptly enter into an amendment that Member, in its sole discretion, deems sufficient to ensure that Member will be able to comply with such laws and regulations.

## *No Third Party Beneficiaries.* Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Member, Data User and their respective successors and assigns, as permitted pursuant to the Agreement, any rights, obligations, remedies or liabilities.

## *Ambiguities.* The parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with applicable law protecting the privacy, security and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.

## *Primacy.* To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to Data User’s receipt, storage, use and disclosure of the De-Identified or Limited Data Sets received from Member for Data User’s performance of the Activities.

## *Waiver.* No failure to exercise and no delay in exercising any right, remedy or power hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right, remedy or power hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy or power provided herein or by law or in equity.

## *Notices*. Any notice, demand or communication required, permitted or desired to be given hereunder shall be deemed effectively given when personally delivered or mailed by prepaid certified mail, return receipt requested, or overnight courier service, addressed as follows:

|  |  |  |
| --- | --- | --- |
| If to Member: |  | If to Data User: |
|       |  | David Miller, MD, PhDDivision of Genetics and GenomicsBoston Children’s Hospital300 Longwood AvenueBoston, MA 02115 |

## *Entire Agreement*. This Agreement and the Master Participation Agreement constitute the entire agreement of the parties with respect to the subject matter hereof, and all prior and contemporaneous understandings, agreements and representations, whether oral or written, with respect to such matters are superseded.

## *Assignment*. No assignment of this Agreement or the rights and obligations hereunder shall be valid without the specific written consent of both parties hereto, provided, however, that this Agreement may be assigned by Memberto any successor entity operating Member, and such assignment shall forever release Member hereunder.

## *Binding Effect*. This Agreement shall be binding upon the parties hereto and their respective heirs, executors, administrators, successors and permitted assigns.

## *Non Exclusivity*. Nothing in this Agreement shall be construed as limiting the right of either party to affiliate or contract with any other person or entity on either a limited or general basis while this Agreement is in effect.

## *Signatures.* This Agreement may be executed in counterparts, each of which when so executed and delivered shall be deemed an original and all of which taken together shall constitute one instrument. This Agreement and any counterpart original may be executed and transmitted by facsimile or email. The facsimile or scanned email signature shall be valid and acceptable for all purposes as if it were an original.

**IN WITNESS WHEREOF**, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

(“Participant”) or ("Data User") **NF RESEARCH INITIATIVE**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_