

## **PARTICIPATION AGREEMENT**

This Participation Agreement (“Agreement”) is entered into as of \_\_\_\_\_, 2011 (“Effective Date”), by and between Children’s Hospital Boston, a Massachusetts non-profit corporation located at 300 Longwood Avenue, Boston, Massachusetts (“Children’s”) and \_\_\_\_\_, a \_\_\_\_\_ located at \_\_\_\_\_ (“Institution”).

Whereas, Children’s is a world-renowned acute care pediatric hospital conducting pediatric research, treatment and education; and

Whereas, Children’s, under the direction and leadership of Alan Beggs, Ph.D. (“Children’s Principal Investigator”) is conducting a research study entitled “Whole Genome Sequencing Challenge” (the “Study”); and

Whereas, the goals of the Study are to improve the ways that whole genome sequencing is performed and interpreted; and

Whereas, under the Study, Children’s wishes to challenge teams of researchers and companies from around the world to participate in a public competition; and

Whereas, Children’s Principal Investigator, in collaboration with Isaac Kohane, M.D. who will direct the Challenge, will provide the teams with de-identified whole genome sequence data and medical information from approximately three families which the teams will use to identify the best methods for analyzing the whole genome sequence in order to identify genetic alterations that are related to an individual’s genetic disease (the “Gene Partnership for Safety Challenge” or the “Challenge”); and

Whereas, Through the process identified in the Rules and Requirements, as defined herein, Children’s has identified the Institution as having the skills and expertise necessary to participate in the Challenge and has invited Institution to do so and Institution desires to participate.

Now Therefore, in consideration of the mutual promises made in this Agreement, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Institution and Children’s hereby agree as follows:

1. Responsibilities of Children’s. Children’s shall ensure that, under the direction of Children’s Principal Investigator:

- 1.1 the Study is approved by Children’s institutional review board (IRB) and remains in compliance, at all times during the Study, with requirements of the IRB, including but not limited to, obtaining informed consent from all subjects.
- 1.2 The Study is conducted as set forth in the Protocol, attached hereto as Exhibit A and incorporated herein (“Protocol”). In the event of any discrepancy between the Protocol and this Agreement, including the Exhibits hereto, the terms of the Protocol govern.
- 1.3 The Challenge is conducted according to the Challenge requirements and rules, attached hereto as Exhibit B and incorporated herein (“Rules and Requirements”).
- 1.4 The Data/Datasets, as defined in the Data Use Agreement, attached hereto as Exhibit C and incorporated herein, are provided to the Institution under the terms of the Data Use Agreement and for the sole purpose of Institution participating in the Challenge.
2. Responsibilities of Institution. Institution shall ensure that:
  - 2.1 It assigns a principal researcher with the expertise and knowledge to complete the Challenge and lead the team of researchers (“Institution Principal Investigator”). If for any reason, the Institution Principal Investigator is unwilling or unable to continue to serve as Institution Principal Investigator, Institution shall appoint a successor acceptable to Children’s.
  - 2.2 The Study is conducted by individuals identified by the Institution with the skills necessary to complete the Challenge under the direction of the Institution Principal Investigator (“Institution Team Members”).
  - 2.3 Institution, Institution Principal Investigator and Institution Team Members do not have any conflicts of interest related to the Challenge.
  - 2.4 The Study shall have the prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all applicable federal, state and local laws and regulations.
  - 2.5 The Institution Principal Investigator shall be responsible for the direction of the Study and shall ensure the Study is conducted in full compliance with the Protocol, as such relates to Institution.
  - 2.6 The Institution and the Institution Principal Investigator shall ensure the Challenge is conducted in full compliance with the Rules and Requirements, as such relates to the Institution.
  - 2.7 The Institution hereby certified that it meets the Requirements to Participate, as set forth in the Rules and Requirements.
  - 2.8 The Institution and the Institution Principal Investigator shall abide by the Data Use Agreement.
  - 2.9 The Institution hereby represents and warrants that (i) the Institution has the resources to complete the Challenge; (ii) the Institution has the authority to enter into this Agreement

on behalf of itself and the Institution Principal Investigator; (iii) once executed and delivered, this Agreement is enforceable according to its terms; and (iv) the execution and delivery of this Agreement and the performance of its obligations set forth herein do not and will not conflict with, or result in a breach of, any of the terms or provisions of, or constitute a default under, the organizational documents of Institution or any other agreement or instrument to which Institution is a party or by which it may be bound or to which any of its property or assets are subject, including but not limited to, any patents, patent application or agreements regarding Institution Intellectual Property, as defined herein.

3. Term. This Agreement will commence on the Effective Date and continue until the completion of the Challenge, unless terminated as set forth below:

- (i) Either party may terminate this Agreement upon fifteen days notice to the other party.
- (ii) Children's may terminate this Agreement immediately upon notice if the Institution defaults in the performance of any material obligation hereunder including but not limited to any provision in the Exhibits to this Agreement.
- (iii) Children's may terminate this Agreement immediately upon notice that the Institution Principal Investigator is no longer involved in the Challenge and the parties have not agreed to an acceptable alternative.
- (iv) Either party may terminate this Agreement immediately upon notice to the other party if the terminating party has received information regarding the debarment, ineligibility, conviction, threat or indictment of either the party or that party's principal investigator.
- (v) Either party may terminate this Agreement immediately upon notice if the other party files a petition in bankruptcy, or is adjudicated bankrupt, or makes a general assignment for the benefit of creditors, or becomes insolvent, or is otherwise unable to meet its business obligations for a period of three (3) consecutive months.

Upon termination of this Agreement, Institution shall return to Children's all Data/Datasets and other information as set forth in the Rules and Requirements.

4. Publication.

4.1 Institution acknowledges and agrees that Children's will publish the results of the Challenge and the Study. Children's may publish at any time during the Study. Institution acknowledges that Children's may identify Institution and Institution Team Members as participants in the Challenge. Children's may identify the winner(s) of the Challenge by name and in such publication will describe the methods disclosed by the Institution in the Institution Results. Further, although Children's will not disclose the source of the methods, Children's may describe methods disclosed by any participating Institution, winner or not, described in Institution Results. In the event that Institution, in its Institution Results has identified Institution

Intellectual Property, which it indicates it intends to protect by filing a patent application, Children's shall furnish Institution Principal Investigator a copy of any proposed publication for review and comment prior to submission for publication, at least thirty (30) days prior to submission for manuscripts and at least fourteen (14) days prior to submission for abstracts for the sole purpose of allowing Institution to ensure that it has filed the patent application prior to Children's publishing the Institution Intellectual Property. At the expiration of such thirty (30) day or fourteen (14) day period, Children's may proceed with submission for publication.

4.2 Children's acknowledges and agrees that, subject to this Section 4, Institution may publish its activities as a participant in the Challenge. Without the consent of Children's, no presentation or publication of the results obtained from the Data/Datasets shall be made prior to the presentation or publication by Children's based on the completion of the Challenge. Thereafter, should results obtained from the Data/Datasets be presented or published, adequate reference shall be made to Children's primary presentation or publication. In no event shall the Institution or the Institution Principal Investigator be restricted from presenting or publishing independently after the expiration of eighteen (18) months from the completion of the Challenge (completion of Challenge being defined as notification from Children's that the Challenge is complete), provided that all other provisions of this Section have been satisfied and provided that the presentation or publication adequately describes the results as obtained from the Data/Dataset.

4.3 Institution Principal Investigator shall furnish Children's Principal Investigator with a copy of any proposed publication for review and comment prior to submission for publication, at least thirty (30) days prior to submission for manuscripts and at least fourteen (14) days prior to submission for abstracts. Such review may include a review by the Children's IRB to ensure the publication does not violate the terms of the IRB protocol governing use of the Data/Dataset. At the expiration of such thirty (30) day or fourteen (14) day period, Institution Principal Investigator may proceed with submission for publication. Institution Principal Investigator agrees to acknowledge Children's as the source of the Protocol and the Data/Dataset in all published and oral communications describing the Institution's participation in the Challenge, and Principal Investigator shall include Dr. Isaac Kohane and other Children's investigators, as appropriate, as co-authors on any such publications or presentations.

## 5. Confidentiality.

5.1 Institution. During the term of this Agreement, Institution or its employees, agents and consultants may receive, be given access to or become familiar with certain information or trade secrets of Children's, including protocols, compensation and personnel policies, operating systems, marketing data, reports, materials and managed care contracting information, including but not limited to the Protocol and the Data/Datasets (the "Children's Information"), all developed by, relating to or useful in the business of Children's, and all of which Children's considers proprietary and desires to maintain as confidential. Except as set forth below, Institution agrees that it, directly and through its agents and consultants, will take all reasonable efforts to hold the Children's Information confidential, and will not disclose or use the Children's Information for its own purposes, or any purpose other than the performance of its obligations under this Agreement, without the prior consent of Children's. Notwithstanding the

foregoing, nothing in this Agreement will be interpreted as placing any obligation of confidence and non-use on Institution with respect to any Children's Information that can be demonstrated to have been independently developed by Institution, or in the public domain or that comes into the public domain during the term of this Agreement through no fault of Institution.

5.2 Children's. During the term of this Agreement, Children's or its respective employees, agents and consultants, may receive, be given access to, or become familiar with certain information or trade secrets of Institution, including financial data and reports, patient and employee information, documents, memoranda, reports, records, files, correspondence, lists, operating or management systems or protocols (the "Institution Information"), all developed by or relating to Institution and all of which Institution considers proprietary and desires to maintain as confidential. Except as set forth below, Children's agrees that it, directly and through its employees, agents and consultants, will take all reasonable efforts to hold Institution Information confidential, and will not disclose or use Institution Information for its own purposes, or any purpose other than the performance of its obligations under this Agreement, without the prior consent of Institution. Notwithstanding the foregoing, nothing in this Agreement will be interpreted as placing any obligation of confidence and non-use on Children's with respect to any Institution Information that can be demonstrated to have been independently developed by Children's, or in the public domain or that comes into the public domain during the term of this Agreement through no fault of Children's.

5.3 Ownership of Information. The party furnishing Children's Information or Institution Information (collectively the "Information") referred to in this Section 5 will retain all ownership interests in such Information. Upon the termination of this Agreement, each party will return all such Information provided to it by the disclosing party, together with any copies that may have been made of it, or a party will certify to the disclosing party in writing that all such copies have been destroyed, and the parties will maintain as confidential (in accordance with this Agreement) any information or materials, such as summaries and analyses, that may have been derived from such Information.

5.4 Forced Disclosure. Notwithstanding the foregoing, a party may divulge the Information referred to in this Section 5 to the extent a party is advised in writing by legal counsel that such party is legally compelled to do so, as long as such party first gives written notice of its intention to do so to the other party, and a reasonable opportunity, under the circumstances, for the other party to seek a court order protecting the Information.

5.5 Breach. Institution and Children's agree that a breach of any of the provisions contained in this Section 5 will constitute a substantial and material breach of this Agreement, whenever occurring, from which the parties are likely to suffer financial and economic loss and loss of goodwill. In the event of such a breach, or a threatened breach by either party of these provisions, without limiting other available remedies, the non-breaching party will be entitled to injunctive or equitable relief restraining the breaching party from disclosing or using the Information, such relief to be without the necessity of posting bond and including the expenses of litigation, including but not limited to reasonable attorneys' fees and costs upon trial and appeal. Should any covenant, term or condition of this Section 5 become or be declared invalid or unenforceable by a court of competent jurisdiction, then the parties will request that such court

judicially modify such unenforceable provision consistent with the intent of this Section so that it will be enforceable as modified.

## 6. Intellectual Property

6.1 Pre-existing Intellectual Property. Except as otherwise provided in this Agreement, each party shall continue to own and retain all ownership rights and interests associated with any and all pre-existing and independently developed intellectual property of that party (“Separate Intellectual Property”), including but not limited to patents, software, copyrights, trademarks, service marks, trade names, trade secrets, and other intellectual property rights relating thereto (including, but not limited to techniques, methodologies, procedures, processes, management tools, workshops, manuals and writings whether published or not, documentation, report formats, report templates, software, algorithms, data files, data, concepts, ideas, discoveries, inventions, and know-how, the components thereof, in whole and in part) together with any editorial revisions, annotations, elaborations, improvements, derivative works, or other modifications (“Intellectual Property”) made to such Separate Intellectual Property during the Term hereof. Except as expressly stated herein, neither party shall acquire any ownership, license, or other right in the other party’s Separate Intellectual Property by virtue of any work done or material produced under this Agreement. Attached hereto and incorporated herein as Exhibit D is a list of pre-existing Institution Separate Intellectual Property. The Data/Data Sets and all information provided to Institution in any format is Children’s Separate Intellectual Property. The parties acknowledge that any methods innovations made by Institution during participation of the Challenge will be Institution Separate Intellectual Property. Each party is solely responsible for the costs related to protecting its own Separate Intellectual Property.

6.2 Joint Ownership. Ownership to Intellectual Property developed jointly by the parties hereto shall be determined according to U.S. patent law and the contributions of the parties thereto (“Joint Intellectual Property”). Institution understands and agrees that such Joint Intellectual Property may be published by Children’s at any time without permission of Institution. Joint Intellectual Property may include, but is not limited to, molecular data and molecular or biological results or discoveries arising from the analysis of the provided whole gene sequence data and associated medical information.

6.3 Institution agrees that it will not own, nor will it file any patent applications covering, any discovered genetic associations or any specific genes or their functions as elucidated through this Challenge.

## 7. Indemnification, Insurance, No Warranty, and Debarment.

7.1 Institution shall indemnify, defend, and hold harmless Children’s and Children’s trustees, officers, employees, agents, staff and affiliates from and against any and all debts, demands, actions, causes of action, suits, accounts, costs, including attorney’s fees, covenants, contracts, agreements, damages and any and all claims, demands and liabilities whatsoever of every name, nature and description, direct or indirect, matured or unmatured, absolute or contingent, both in law and equity, incurred as a result of any act or omission of the Institution in

performing the Study hereunder, or the breach of this Agreement by the Institution, its employees or agents, except to the extent caused by the negligence or willful misconduct of Children's.

7.2 Institution shall, at its own cost and expense procure and maintain Commercial General Liability (CGL) insurance, worker's compensation insurance and medical professional insurance or other coverage sufficient to cover its potential liabilities and responsibilities hereunder, but no less than a limit of \$2,000,000 per person/occurrence and \$3,000,000 in the aggregate.

7.3 EXCEPT AS PROVIDED HEREIN, CHILDREN'S MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, TRADE SECRET, TANGIBLE RESEARCH PROPERTY, INFORMATION OR DATA/DATASET PROVIDED TO INSTITUTION HEREUNDER AND HEREBY DISCLAIMS THE SAME. CHILDREN'S SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL OR OTHER DAMAGES SUFFERED BY INSTITUTION RESULTING FROM INSTITUTION'S USE OF ANY PATENT, TRADEMARK, SOFTWARE, TRADE SECRET, TANGIBLE RESEARCH PROPERTY, INFORMATION OR DATA/DATASET PROVIDED TO INSTITUTION HEREUNDER.

7.4 The Institution hereby certifies that (i) it has not been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC 335a) and no person who has been debarred under Subsection (a) or (b) of Section 306 of said Act will participate in the performance of the Challenge, and (ii) no person on any of the following FDA Clinical Investigator Restriction Lists - Disqualified/Totally Restricted List, Restricted List and Adequate Assurances List - will participate in the performance of the Challenge. The Institution further certifies that if, at any time after execution of this Agreement, it becomes aware that it or any person who participated, or is participating, in the performance of the Challenge, or is being added to, the FDA Debarment List or any of the three (3) FDA Clinical Investigator Restriction Lists, it will provide notice of this to Children's within forty-eight (48) hours of its becoming aware of this.

## 8. Miscellaneous

8.1. Complete Understanding. This Agreement supersedes any prior contracts, understandings, discussions and agreements between the parties and constitutes the complete understanding between them with respect to the subject matter hereof.

8.2. Use of Name. Institution agrees not to use the name or logo of Children's or any of its affiliates or any of their respective trustees, directors, officers, staff members, employees, students or agents, including the name of Children's Principal Investigator, for any purpose without Children's prior written approval excepting in the course of presentation and or publication deriving from the Challenge wherein the Data/Dataset source is acknowledged.

8.3 Modification; Waiver. This Agreement may be amended or waived if, and only if such amendment or waiver is in writing and signed, in the case of an amendment, by Institution and Children's, or in the case of a waiver, by the party against whom the waiver is to be effective. No failure or delay by any party in exercising any right, power or privilege hereunder will operate as a waiver thereof nor will any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided will be cumulative and will not be exclusive of any rights or remedies provided by law or at equity.

8.4 Joint Effort. The parties hereto acknowledge and agree that: (i) each party has reviewed and negotiated the terms and provisions of this Agreement and has contributed to its revision, (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party will not be employed in the interpretation of this Agreement and (iii) the terms and provisions of this Agreement will be construed fairly as to all parties hereto and not in favor of or against any party, regardless of which party was generally responsible for the preparation of this Agreement.

8.5 Notices. All notice and other communications necessary or contemplated under this Agreement will be deemed to have been duly given when delivered by hand or one business day after sending by overnight delivery service, or three business days after sending by certified mail, postage prepaid, return receipt requested, to the respective addresses of the parties set forth below:

(a) for notices and communications to Children's:

Children's Hospital Boston  
300 Longwood Avenue  
Boston, MA 02115  
Attn: Isaac Kohane, M.D

with a copy to:  
General Counsel  
300 Longwood Avenue  
Boston, MA 02215

(b) for notices and communications to Institution:

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By notice complying with the foregoing provisions of this Section 8.5, each party has the right to change its mailing address for future notices and communications.

8.6 Governing Law. This Agreement will be construed in accordance with and governed by the substantive laws of The Commonwealth of Massachusetts without regard to the choice of law rules thereof. Each of the parties hereto agrees to submit to the jurisdiction of

the courts of Massachusetts in any action or proceeding arising out of or relating to this Agreement.

8.7 Counterparts. This Agreement may be signed in any number of counterparts, each of which will be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

8.8 Survival. The provisions of Sections 5, 6, 7 and 8 of this Agreement and the provisions of the Data Use Agreement will survive the termination or expiration of this Agreement.

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**Exhibit A**

**Protocol**

## **Exhibit B**

### **GENOME PARTNERSHIP FOR SAFETY CHALLENGE CHALLENGE RULES AND REQUIREMENTS**

#### **I. Study Goals**

- a. The purpose of the Genome Partnership For Safety Challenge is to spur development of better methods to interpret and report the results of clinical whole genome DNA sequencing.
- b. The goal of the Challenge is to discover the best and most efficient methods for analyzing whole genome sequence data, identifying potential genetic alterations associated with the phenotype in the proband, and correlating the phenotype one sees in a patient with the mutation detected.
- c. The Study will also seek to determine key components for reporting the results of whole genome sequencing, including which results to report and how to characterize them.

#### **II. Subject Selection Process**

- a. The subject selection process will occur at Children's under the direction of the Children's Principal Investigator.
- b. The samples used in this Study will be derived from individuals with a suspected genetic disease and their biological parents.
- c. Three family triads (one child, two biological parents) will be chosen to participate in the Study, either from ongoing genetic research studies at Children's, or directly by one of the Study investigators.
- d. Each family member from all three triads will give their informed consent/assent to participate in the Challenge.
- e. The affected child and their two (2) biological parents will submit to Children's his or her genetic material by way of a saliva, blood, or other sample.
- f. Each family will give to the Children's Investigator a verbal medical history of the entire family, including current abilities with a focus on the chief complaint, and access to relevant medical records.

#### **III. Institution Selection Process**

- a. Children's will issue a call for Challenge applicants and will, in its sole discretion, choose those applicants who will be invited to participate in the Challenge.
- b. Suitable applicants will:
  - i. Have documented that they or team members have competence in each of the essential steps of the Challenge, specifically including sequence assembly, identification of genetic variation, and clinical characterization of genetic variant.
  - ii. Have documented that they have or can readily obtain data storage facilities which meet accepted standards of data protection and prevention of unauthorized disclosure, including disk-level encryption.

- iii. Have sufficient resources in personnel, services or hardware to complete the Challenge without requiring support beyond what is available within their team.
- c. Invited researchers and commercial laboratories from around the world may assemble teams of individual researchers to complete the Challenge (“Institution Team Members”),
- d. Each team will have a designated Challenge Lead Applicant (CLA). The CLA may or may not be the Institution Principal Investigator. The CLA will be responsible for representing the Institution Team Members to the organizers of the Challenge, defining their role and the roles of the Institution Team Members within the Challenge, responsible for organizing communications between the Institution Team Members and Challenge organizers and interested observers (e.g. reporters). The CLA will sign the Participation Agreement and also ensure that all Institution Team Members sign the Participation Agreement.
- e. By accepting the Data/Data Set and signing the Participation Agreement, Institution and Institution Team members represent and warrant that they have the resources to complete the Challenge

#### **IV. Challenge Parameters**

- a. Each Institution and Institution Team Members agree that they individually and collectively:
  - i. Will not contact the subjects or their family members;
  - ii. Will not do or attempt to do anything to jeopardize the family’s privacy or confidentiality;
  - iii. Will not use any data pertaining to the subjects and their family members in conducting the Challenge other than the Data/Dataset provided by Children’s. All other types of data, whether the sources are proprietary or public, may be used;
  - iv. Will not release Study Data/Datasets to those outside of their own Institution Team Members in any form or manner;
  - v. Will adhere to all applicable laws, specifically the Health Insurance Portability and Accountability Act (HIPAA), ensuring the privacy of all Study information; and
  - vi. Will adhere to all Rules and Requirements for the duration of the Challenge and the necessary time after the Challenge’s end to ensure compliance with all provisions.
- b. Institutions agree to limit their reported and published findings to only those listed in the Protocol. Institutions further agree that they will take all reasonable and necessary steps to prevent instances of incidental findings, taking a narrow view of the Data/Datasets and focusing solely on that which is required for completion of the Challenge. Only variants/findings with a reasonable association with patient phenotype will be reported and published.
- c. Each Institution will be provided with de-identified genetic sequence data processed by a CLIA-certified commercial laboratory, and relevant medical information from the same three Study families by way of a secure, password-protected website and/or an encrypted disc/hard drive.

- d. Institutions will have six (6) months from the date of receipt of the Data/Datasets to complete the Challenge.
- e. Institutions may use any method to complete the Challenge, so long as they contain all Data/Datasets within their own research team or entity, where applicable.
- f. At the end of the Challenge, Institutions will submit to Children's the following for judgment (collectively "Institution Results"):
  - i. Methods for analysis and interpretation  
These will include sufficient detail (whether presented as a paper or electronic/web document) so that a medical genetics expert will be able to follow the provenance of any clinical interpretation from the original sequence data, including any intermediate steps, so that they fully understand and can independently judge the validity of the interpretation.
  - ii. Molecular results  
These will include any genetic variants/characterizations that the Institutions deem relevant for communication to the medical personnel caring for the patient/subject and/or to the patients and their families.
  - iii. Presentations/reporting of results.  
These will include reports for the medical personnel caring for the patient and optionally reports for the family and patient, which describe the relevant genetic variation of each individual and what the clinical interpretation of the variation is, if any is available.
- g. Institution Results will be submitted to Children's in the manner and method communicated to Institution by Children's.
- h. As set forth in the Participation Agreement, Children's may in Children's sole discretion, publish Institution Results.
- i. Institutions will return all hard copies of the Data/Datasets, and certify through signature that any and all copies of Data/Datasets, as well as any and all information rightfully owned by Children's as set out in the Participation Agreement have been returned or destroyed ("Destruction Certification"). If an Institution fails to return the Data/Datasets, or fails to submit the signed Destruction Certification at that time, their entries will not be judged and they will be disqualified from the Challenge.

**V. Judging Process**

- a. Children's will assemble a panel of judges ("Panel") to complete the judging process for the Challenge.
- b. Members of the Panel will be chosen in Children's sole discretion.
- c. The Panel will consist of experts in genetics, genomics, and communications.
- d. Members of the Panel will have no known financial conflicts with respect to the Challenge Institutions and will not be compensated for their participation in the Challenge.
- e. The Panel will review all submissions from Institutions that have adhered to both the Participation Agreement, all Exhibits thereto, and the Destruction Certification.

- f. Judging criteria, to be determined in Children’s sole discretion, may include but are not limited to:
  - i. Accuracy and completeness of sequence analysis.
  - ii. Documentation of dependencies of any clinical interpretation through all the steps of analysis from the original sequence data. This includes identification of relevant quality control/accuracy problems or challenge.
  - iii. Plausibility of the clinical interpretation in the context of the sequence data.
  - iv. Relevance of the clinical interpretation to the chief complaint of the patient/family.
  - v. Intelligibility of the report to the healthcare provider and (optionally) to the families and/or patient.
- g. The results of the Challenge may also be analyzed by members of the Informed Cohort Oversight Board (“ICOB”) at Children’s.
- h. The ICOB’s main purpose is to determine appropriate messaging and communication of results, subject to IRB review<sup>1</sup>. It may assist the Panel in deciding whether to release certain Challenge results by considering the accuracy and health importance of the research findings, determining what research results are appropriate to return to subjects, and what is the best method of releasing the information.
- i. The judging process will take an estimated six to nine months.
- j. At the end of the judging process, the Panel will award a monetary prize in the amount of \$20,000 to the winning Institution/s.

**VI. Privacy Measures**

- a. In order to ensure the privacy of all subjects, Institutions will adhere to all applicable HIPAA guidelines through the course of this Challenge.
- b. In accordance with the Participation Agreement, Institutions will also ensure that any password or other encryption information will be kept in strict confidence, and that no unauthorized person or entity will be permitted to access the Challenge Data/Datasets.

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<sup>1</sup> I.S. Kohane, et al, Reestablishing the Researcher-Patient Compact. *Science* **316**, 836-837 (2007); I.S Kohane, P.L. Taylor, Multidimensional Results Reporting to Participants in Genomic Studies: Getting it Right. *Sci.Transl.Med.* **2**, 37cm19 (2010).

## Exhibit C

### Children's Hospital Boston

#### **DATA USE AGREEMENT for access to data and DNA**

Children's and Institution have entered into that certain Participation Agreement (the "Agreement") under which Institution agrees to participate in the Challenge under the terms and conditions set forth in the Agreement. Children's controls certain patient-level data, in the form of DNA sequence and medical information, which data have been de-identified within the meaning of the HIPAA Privacy Rule (the "**Data**"). Children's wishes to make the Data, in the form of one or more "**Datasets**," available to Institution as a byproduct of the Challenge. Children's is making Data available solely for the purpose of enabling Institution to participate in the Study and the Challenge (the "**Purpose**").

Capitalized terms used herein and not defined shall have the meaning ascribed to them in the Agreement.

This Data Use Agreement explains the terms and conditions of access to the Data by Institution. **ANY INSTITUTION WHO WISHES TO ACCESS THE DATA MUST READ THE FOLLOWING TERMS AND AGREE TO THEM BY ENTERING THE INFORMATION REQUESTED BELOW AND BY PRINTING, SIGNING, AND RETURNING THE AGREEMENT TO CHILDREN'S AS DIRECTED BELOW.**

1. Institution understands and agrees that any Data / Datasets that Children's provides to Institution are proprietary and confidential to Children's and are Children's Information subject to the confidentiality obligations under the Agreement.
2. Institution agrees that Institution will use the Data / Datasets solely for participating in the Challenge and the Study for no other purpose.
3. Institution agrees that Institution will not attempt to identify or re-identify any individual patient or group of patients from the Data / Datasets.
4. Institution agrees that Institution will not disclose, disseminate, or otherwise share the Data / Datasets to or with any other person or entity except with Institution Team Members as identified on the signature page of the Agreement. Institution shall inform each Institution Team Member of their obligations with respect to use and confidentiality of the Data under this Data Use Agreement. Institution shall be responsible for compliance by Institution Team Members with the terms of this Data Use Agreement and any breach thereof.
5. All Data / Datasets disclosed pursuant to this Data Use Agreement, including without limitation all written and tangible forms thereof, shall be and remain the property of Children's. Upon termination of this Data Use Agreement as provided in Section 6 below, Institution shall cease using the Data / Datasets.
6. Children's may terminate Institution's access to Data / Datasets under this Data Use Agreement for any reason upon written notice to Institution.
7. Institution's obligations under this Date Use Agreement shall survive the expiration or termination of the Agreement.
8. This Data Use Agreement may be modified or amended only in a writing signed by duly authorized representatives of both Institution and Children's. This Data Use Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. Any claim or action brought under this Agreement shall be brought in the federal or state courts of Massachusetts.