

AMENDMENT # 2
INSTITUTIONAL DATA USE AGREEMENT

This Amendment #2 to the Institutional Data Use Agreement ("Amendment") is made and entered into as of the date of latest signature below, but by express agreement of the parties, shall be effective as of August 31, 2017 (the "Effective Date"), by and among the following Institutions: Emory University ("Emory"), Morehouse School of Medicine ("MSM"), Board of Regents of the University System of Georgia by and on behalf of the Georgia Institute of Technology ("GT"), Children's Healthcare of Atlanta, Inc. ("Children's"), and the Board of Regents of the University System of Georgia by and on behalf of the University of Georgia ("UGA"), each of which is a member of the Georgia Clinical & Translational Science Alliance ("Georgia CTSA"), previously known as the Atlanta Clinical & Translational Science Institute ("ACTSI"). Emory, MSM, GT, Children's, and UGA are hereby collectively referred to as the "Parties," and each individually, a "Party."

WHEREAS, Emory, MSM, GT, and Children's are members of the collaborative organization Georgia CTSA, which seeks among other things, to foster the translation of basic scientific discoveries into clinical improvements; and

WHEREAS, on or about August 31, 2012, Emory, MSM, GT, and Children's entered into an ACTSI Institutional Data Use Agreement to permit the exchange of de-identified health information, as defined in 45CFR §160.103 between them in order to further the ACTSI research; and

WHEREAS, on or about July 18, 2017, Emory, MSM, GT, and Children's entered into an Amendment #1 to the DUA ("Amendment #1"), extending the term through August 31, 2017 (the ACTSI Institutional Data Use Agreement and the Amendment #1 are hereinafter collectively referred to as the "DUA"); and

WHEREAS, ACTSI changed its name to the Georgia Clinical & Translational Science Alliance in connection with the September 22, 2017 Notice of Award; and

WHEREAS, the University of Georgia was added as a member of the Georgia CTSA as of the date of such Notice of Award; and

WHEREAS, the Georgia CTSA has received continued funding through June 30, 2022.

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein, the Parties agree to amend and supplement the DUA as follows:

1. The Parties agree to hereby add the Board of Regents of the University System of Georgia by and on behalf of the University of Georgia as a party to the DUA.
2. Emory, MSM, GT, and Children's hereby ratify and confirm their respective obligations under the DUA and represent that they have continued to operate under the terms and conditions of the DUA.
3. The Parties hereby agree to extend the term of the DUA to June 30, 2022.

4. The Parties hereby agree that, beginning on the Effective Date of this Amendment, references in the DUA to the "Atlanta Clinical and Translational Science Institute" are changed to the "Georgia Clinical & Translational Science Alliance" and references in the DUA to "ACTSI" are changed to "Georgia CTSA".

Subject to the alterations and amendments contained herein, the Parties acknowledge, ratify and confirm the DUA in all other respects.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed as of the dates set forth below.

EMORY UNIVERSITY

By: *David L. Wyles*

Name: DAVID L. WYLES

Title: VICE PRESIDENT FOR RESEARCH ADMIN.

Date: NOVEMBER 8, 2017

MOREHOUSE SCHOOL OF MEDICINE

By: *Sandra Harris-Hooker*

Name: Sandra Harris-Hooker, Ph.D.

Title: Vice President, Executive Vice Dean

Date: 11/13/17

BOARD OF REGENTS OF THE UNIVERSITY SYSTEM OF GEORGIA BY AND ON BEHALF OF GEORGIA INSTITUTE OF TECHNOLOGY

By: _____

Name: _____

Title: _____

Date: _____

CHILDREN'S HEALTHCARE OF ATLANTA INC.

By: *Kristine Rogers*

Name: Kristine Rogers

Title: VP, Research + Academic Admin

Date: 11/8/2017

BOARD OF REGENTS OF THE UNIVERSITY SYSTEM OF GEORGIA BY AND ON BEHALF OF THE UNIVERSITY OF GEORGIA

By: *David Lee*

Name: DAVID LEE

Title: VICE PRESIDENT FOR RESEARCH

Date: NOVEMBER 2, 2017

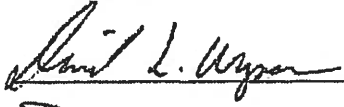
4. The Parties hereby agree that, beginning on the Effective Date of this Amendment, references in the DUA to the "Atlanta Clinical and Translational Science Institute" are changed to the "Georgia Clinical & Translational Science Alliance" and references in the DUA to "ACTSI" are changed to "Georgia CTSA".

Subject to the alterations and amendments contained herein, the Parties acknowledge, ratify and confirm the DUA in all other respects.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed as of the dates set forth below.

EMORY UNIVERSITY


MOREHOUSE SCHOOL OF MEDICINE

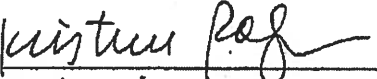
By: 
Name: DAVID L WYDES
Title: VICE PRESIDENT FOR RESEARCH ADMIN.
Date: NOVEMBER 8, 2017

By: _____
Name: _____
Title: _____
Date: _____

BOARD OF REGENTS OF THE UNIVERSITY SYSTEM OF GEORGIA BY AND ON BEHALF OF GEORGIA INSTITUTE OF TECHNOLOGY


CHILDREN'S HEALTHCARE OF ATLANTA INC.

By: 
Name: JILDA DIEHL GARTON
Vice President for Research
Title: _____
Date: 10 NOV 2017

By: 
Name: Kristine Rogers
Title: VP, Research & Academic Admin
Date: 11/8/2017

REVIEWED BY GT LEGAL AFFAIRS AL
for Susann D. Estroff w/expressed permission

BOARD OF REGENTS OF THE UNIVERSITY SYSTEM OF GEORGIA BY AND ON BEHALF OF THE UNIVERSITY OF GEORGIA

By: 
Name: DAVID LEE
Title: VICE PRESIDENT FOR RESEARCH
Date: NOVEMBER 2, 2017

AMENDMENT # 1
INSTITUTIONAL DATA USE AGREEMENT

This Amendment #1 to the Institutional Data Use Agreement (“Amendment”) is made and entered into June 1, 2017 (the “Effective Date”), by and among the following institutions: Emory University (“Emory”), Morehouse School of Medicine (“MSM”), the Board of Regents of the University System of Georgia by an on behalf of the Georgia Institute of Technology (“GT”), and Children’s Healthcare of Atlanta, Inc. (“Children’s”), each of which is a party to the Atlanta Clinical and Translational Science Institute (“ACTSI”).

WHEREAS, Emory, MSM, GT, and Children’s are parties to the collaborative organization ACTSI, which seeks among other things, to foster the translation of basic scientific discoveries into clinical improvements,

WHEREAS, on or about August 31, 2012, Emory, MSM, GT, and Children’s entered into an Institutional Data Use Agreement (the “ACTSI DUA”) to permit the exchange of de-identified health information, as defined in 45CFR §160.103 between them in order to further the ACTSI research;

WHEREAS, the ACTSI DUA was scheduled to automatically renew on May 31, 2017 for an additional five (5) year term if funding for ACTSI was renewed;

WHEREAS, ACTSI was granted a no cost extension through May 31, 2018, and Emory, MSM, GT, and Children’s expect the funding to renew and have continued to operate under the terms of the ACTSI DUA;

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein, the parties agree to revive, amend and supplement the ACTSI DUA as follows:

1. The Parties hereby agree to extend the term of the ACTSI DUA for an additional three (3) months to August 31, 2017.

Subject to the alterations and amendments contained herein, the parties ratify and confirm the ACTSI DUA in all other respects.

[signatures on next page]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed as of the Effective Date.

EMORY UNIVERSITY

By: J. Cale Lennon III

Name: J. Cale Lennon, III

Title: Director, Licensing

Date: 7/10/17

MOREHOUSE SCHOOL OF MEDICINE

By: Sandra Harris-Hooker

Name: Sandra Harris-Hooker, PhD

Title: Vice President, Executive Vice Dean

Date: 7/11/2017

**BOARD OF REGENTS OF THE
UNIVERSITY SYSTEM OF GEORGIA
BY AND ON BEHALF OF
GEORGIA INSTITUTE OF TECHNOLOGY**

By: J. Dale Garton

Name: J. DALE GARTON
Vice President for Research

Title: _____

Date: 6/21/17

CHILDREN'S HEALTHCARE OF ATLANTA, INC.

By: Kristine Rogers

Name: Kristine Rogers

Title: Intzm NP, Research Academic Administration

Date: 7/10/17

REVIEWED BY GT LEGAL AFFAIRS: SDE
20 JUNE
2017

Atlanta Clinical and Translational Science Institute
Institutional Data Use Agreement

This Institutional Data Use Agreement (the "Agreement") is entered into as of the date of the last signature below by and among the following institutions: Emory University ("Emory"), Morehouse School of Medicine (MSM), Board of Regents of the University System of Georgia by and on behalf of the Georgia Institute of Technology (GT), and Children's Healthcare of Atlanta, Inc. (Children's), each of which is a party to the Atlanta Clinical and Translational Science Institute (ACTSI).

WITNESSETH:

WHEREAS, Emory, MSM, GT, and Children's are parties to the collaborative organization ACTSI, which seeks, among other things, to foster the translation of basic scientific discoveries into clinical improvements, and

WHEREAS, in order to promote ACTSI's goal of translational science, Emory, MSM, GT, and Children's (hereinafter collectively referred to as "ACTSI Parties" or the "Parties") desire to enter into this Institutional Data Use Agreement to permit the exchange of de-identified health information, as defined in 45 CFR §160.103, among the ACTSI Parties in order to further ACTSI research.

NOW THEREFORE, in consideration of the premises and other good and lawful consideration, the ACTSI Parties agree as follows:

1. **Recitals.** The foregoing recitals are restated here and agreed upon by the Parties hereto.
2. **Data to be Shared.** The health information (data) that will be subject to this Agreement consists of data generated by each ACTSI Party as a part of its research or clinical operation that meets the following requirements:
 - a. The data is de-identified in accordance with the de-identification standards set forth under the Health Insurance Portability and Accountability Act (HIPAA) and all implementing regulations, including, but not limited to 45 CFR Section 164.514(a)-(c) and Section 164.502(d); or
 - b. The data is part of a Limited Data Set created in accordance with the requirements of 45 CFR Section 164.514(e). Data provided in the form of a limited data set will be subject to an agreement for Use of Limited Data sets signed by both the ACTSI Party who provides the data ("Providing Party") and the ACTSI Party who receives the data ("Receiving Party") under this Agreement and by the individual requesting the data. (A copy of the template for the Agreement for Use of Limited Data Sets is attached hereto as Exhibit "A" to this Agreement); and
 - c. The de-identified data may be coded in a way that permits re-identification by the ACTSI Party that generated the data; provided, however, that any code associated with the data that permits re-identification shall not be disclosed to the ACTSI Party receiving the data pursuant to this Agreement. Any such re-identification code must be maintained by a unit within the ACTSI Party providing the data, and this unit shall function as an honest broker that de-identifies the

data and prohibits release of any codes associated with such data that permit re-identification by the Receiving Party; and

- d. The data must not be subject to any proprietary or contractual restrictions that would limit its disclosure. Data that is subject to such restrictions shall not be shared pursuant to this Agreement, and
 - e. The data will be used under a protocol for which at least one investigator is a faculty member at one of the ACTSI Party institutions.
3. **Use of Data.** The Parties agree that any data shared pursuant to this Agreement may be used for research purposes only. In the case of "research involving human subjects," as defined under the "Common Rule" at 45 CFR Part 46 and associated guidance issued by the Office of Human Research Protections (OHRP), appropriate Institutional Review Board (IRB) review and approval must be obtained (including, but not limited to, obtaining an IRB determination that the research is exempt per 45 CFR Part 46.102(d), 102(f), and applicable OHRP Guidance) prior to release of the data.
 4. **No Commercial Use.** Data provided pursuant to this agreement shall not be sold, used for marketing purposes, or used in any other manner that shall constitute a commercial use.
 5. **No Re-identification or Subject Contact.** Notwithstanding the coding and honest broker obligations required under Paragraph 2.c. herein, the Parties agree that no Party receiving data pursuant to this agreement shall attempt to re-identify the data or attempt to contact any subject whose data was received under this agreement.
 6. **Security Requirements.** The Parties agree that a Party receiving data pursuant to this agreement shall store and use the de-identified data and/or limited data set in accordance with the Providing Party's administrative and technical requirements for information security. The Party who provides the data shall provide the Party receiving the data with access to its administrative and technical security standards that shall be maintained on a secure website.
 7. **Adherence to Agreement.** Each ACTSI Party is responsible for ensuring that its investigators and/or other individuals who obtain data pursuant to this Agreement are aware of the requirements for use of the data under this Agreement and for ensuring adherence to its terms.
 8. **Notification of Information Privacy or Security Breach.** The ACTSI Party who receives de-identified data from another ACTSI Party agrees to notify the Providing Party of any breach of security or privacy involving the data. Such notification must occur within five (5) business days of discovery of the breach.
 9. **Ownership of Data.** The ACTSI Party who de-identifies and provides the data to the Receiving Party shall continue to hold all right, title and interest in and to the data, and the Receiving Party will not hold, and will not acquire by virtue of this Agreement, any right, title or interest in or to any data provided pursuant to this Agreement.
 10. **Right to Injunctive Relief.** The ACTSI Parties expressly acknowledge and agree that the breach, or threatened breach, of any provision of this Agreement by an ACTSI Party who receives data under

this agreement may cause the ACTSI Party who provided the data to be irreparably harmed and that the Providing Party may not have an adequate remedy at law. Therefore, the Receiving Party agrees that upon such breach, or threatened breach, the Providing Party may be entitled to seek injunctive relief. Nothing in this paragraph will be deemed to limit or abridge any other remedy available to the Providing Party at law or in equity.

11. Miscellaneous.

- a. This Agreement shall be effective until May 31, 2017, at which time the Agreement shall automatically renew for an additional five year term if funding for ACTSI is renewed.
- b. This Agreement is not exclusive and does not prohibit or restrict the Parties from participating in activities similar to those described herein with any other private or public entities or individuals.
- c. In the event of changes to state or federal laws and regulations applicable to the use, maintenance, and/or storage of data shared under this Agreement, the Parties will work to effect an amendment to this Agreement that shall reflect any necessary legal and/or regulatory changes. Failure by any ACTSI Party to execute the necessary amendment shall be a basis for terminating use of any data previously received pursuant to this Agreement.
- d. Any modification of or addition to this Agreement must be in writing and be signed by the Parties hereto in order to be effective.
- e. This Agreement may not be transferred or assigned, in whole or in part, without the advance written consent of the parties hereto, and any attempted transfer or assignment without such written consent shall be null and void.
- f. This Agreement may be terminated by any Party hereto, with respect to that Party's participation, for any or no reason upon sixty (60) days written notice to the other Parties at the addresses set forth in the notices section below. Except as provided in Paragraph 12.a., herein, the termination of the Agreement by one Party shall not affect the operation of the Agreement as to all remaining Parties.
- g. In the event that a Party breaches this Agreement, the non-breaching Party or Parties shall give the breaching Party written notice describing the breach. The breaching Party shall have ten (10) days from the receipt of the notice of the breach in which to cure the breach. If the breach is incapable of being cured, or if the breaching Party fails to cure the breach within the aforesaid 10-day period, then the non-breaching Party or Parties may terminate this Agreement with respect to the breaching Party by written notice to the breaching Party, effective immediately upon receipt.
- h. In the event of any termination, whether for breach or convenience, the Party or Parties as to whom termination has occurred must return or destroy any data previously provided pursuant to this Agreement, and may not make any further new use of said data or receive any future data under this Agreement.
- i. The persons signing this Agreement on behalf of the Parties each warrant and represent that they have all right and authority to do so and to bind the parties to the terms and conditions of this MOU.
- j. This Agreement may be executed in multiple counterparts, each of which will have the same force and effect.
- k. Notices -- In order to be effective, all notices required or permitted under this Agreement must be in writing and be sent by Federal Express or other commercial courier service with evidence of delivery or refusal to the parties at the addresses set forth below:

TO EMORY:
Kristin West, J.D.
Assoc. VP for Research Affairs
Director, Office of Research Compliance
1599 Clifton Road
Atlanta, GA 30322
kwest02@emory.edu

TO MSM:
Sandra Harris-Hooker, Ph.D.
Vice President and Senior Associate Dean
for Research Affairs
720 Westview Drive, SW
Atlanta, GA 30310
(404) 752-1725
sharris-hooker@msm.edu

TO GT:
Barbara Henry, Director
Office of Research Integrity Assurance
Georgia Institute of Technology
505 Tenth Street
Atlanta, GA 30332-0415
(404) 894-6949
irb@gatech.edu

TO CHILDREN'S:
Kristine Rogers
Director Academic Administration

With copy to:
Pamela Brooks, Contracting Officer
Office of Sponsored Programs
505 Tenth Street
Atlanta, GA 30332-0415

Notices are deemed effective upon receipt or refusal.

- i. This Agreement constitutes the entire agreement concerning the subject matter hereof, and it shall not be modified or added to except by a written agreement signed by all Parties hereto.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

Emory University

By: David Wynes

Print Name: David L. Wynes, Ph.D.
Vice President for Research Administration
Print Title: _____

Date: 8/10/12

Morehouse School of Medicine

By: Sandra Harris-Hooker

Print Name: Sandra Harris-Hooker
Print Title: Vice President + Sr. Assoc.
Dean for Research Affairs

Date: _____

Georgia Institute of Technology

By: G. Duane Hutchison

Print Name: G. DUANE HUTCHISON
DIRECTOR, OSP

Print Title: _____

Date: 8.9.12

Children's Healthcare of Atlanta, Inc.

By: Kristine Rogers

Print Name: Kristine Rogers
Print Title: Director Academic
Administration

Date: 8/21/12

**GEORGIA CLINICAL AND TRANSLATIONAL SCIENCE ALLIANCE (GEORGIA CTSA)
AGREEMENT FOR USE OF LIMITED DATA SETS**

Emory University (Emory), Morehouse School of Medicine (MSM), Board of Regents of the University System of Georgia by and on behalf of the Georgia Institute of Technology (GT), Children's Healthcare of Atlanta, Inc. (Children's), and the Board of Regents of the University system of Georgia by and on behalf of the University of Georgia ("UGA"), each of which is a member of the Georgia Clinical Translational Science Alliance (Georgia CTSA), have all entered into an Institutional Data Use Agreement (the "Institutional Agreement") outlining the requirements and conditions for the sharing among members of data generated by a Georgia CTSA member. The terms and conditions of the Institutional Agreement are hereby fully incorporated by reference into this Agreement for Use of Limited Data Sets ("LDS Agreement").

In accordance with the terms of the Institutional Agreement and the requirements of the Health Insurance Portability and Accountability Act, 42 USC§ 1320d-2 ("HIPAA") and its implementing regulations at 45 CFR §162.514, a researcher or other appropriate party who requests a limited data set from a Georgia CTSA member must agree to the terms of this LDS Agreement by completing, signing, and dating this document.

Name of Georgia CTSA Member from Which Limited Data Set is Requested ("Providing Member"):

Name of Georgia CTSA Member Requesting Limited Data Set ("Requesting Member"):

Name of Individual Requestor ("Requestor"):

Contact Information for Individual Requestor:

Address: _____

Telephone Number: _____

E-mail Address: _____

The undersigned authorized Requester hereby requests that the Providing Member, identified above, provide it with the Limited Data Set described below for the uses and purposes described below. The Requester agrees and affirms that all information requested to be provided in the Limited Data Set, and all uses and purposes for which the Limited Data Set is requested, are permitted by and are in accordance with the Institutional Agreement and the requirements for use of a Limited Data Set as set forth in 45 CFR §162.514.

(1) Description of Limited Data Set Requested: _____

Exhibit "A"

(2) The Limited Data Set is being requested for the following purpose(s):

_____ **Research.** Briefly describe: _____

_____ **Public Health Purpose(s).** Briefly describe: _____

_____ **Health care operations.** Briefly describe: _____

(3) Description of Persons who will be Permitted to Use or Receive the Limited Data Set (e.g., PI and research staff; specific study sponsor, etc.): _____

(4) By signing below, the Requestor agrees and will ensure that Requestor and his or her staff:

(a) Will not, use or further disclose the information contained in the Limited Data Set other than as permitted in the Institutional Agreement, this LDS Agreement, or as required by law;

(b) Will use appropriate safeguards to prevent the use or disclosure of the information contained in the Limited Data Set other than as permitted in this Data Use Agreement;

(c) Will not attempt to re-identify the information or contact the individuals who are the subject of the information.

(d) Will ensure that any of its agents or subcontractors to whom it provides the Limited Data Set agrees in writing to the same restrictions and conditions, including information security and privacy requirements, that apply to the Requestor and Requesting Member. The Requestor and/or Requesting Member may do this by providing its agents and subcontractors with a copy of the Institutional Agreement and this Agreement for Use of Limited Data Sets and having them agree in writing that they have received and reviewed the Agreements and agree to abide by their terms (see Subcontractor/Agent Signature Block below).

Exhibit "A"

(e) Will notify the Providing Member, within five (5) business days, of any use or disclosure of the information contained in the Limited Data Set of which it becomes aware that is not permitted by this Data Use Agreement. Such notification should be made in writing to the following:

Georgia CTSA Member Institution: _____

Requestor Name: _____

Requestor Title: _____

Requester Address: _____

Requester Telephone: _____

Requester E-mail: _____

Requestor:

Signature: _____

Title: _____

Date: _____

Approved by Providing Member:

Signature: _____

Title: _____

Date: _____

Acknowledgement and Agreement of Requestor's Agents & Subcontractors:

The undersigned subcontractor/agent of the Requestor and/or Requesting Member who will be receiving access to the Limited Data Set described herein agrees that it has received a copy of and reviewed this LDS Agreement governing its use of the Limited Data Set and that it will ensure that it and its employees and agents abide by its terms.

Name of Subcontractor/Agent: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Authorized Signature: _____

Date: _____