**Research Associate Agreement**

This Research Associate Agreement (“Agreement"} is made and entered into on this date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (“Effective Date”) by and between Children's Hospital Colorado, a Colorado non-profit corporation with an address of 13123 East 16th Avenue, Aurora, CO 80045 (“Covered Entity"), and Click here to enter name of individual who is the data recipient with research at Children’s Colorado, with an address of Click here to enter the Non-Employee’s home address and phone number ("Data Recipient").

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will disclose certain protected health information (“PHI”) to the Data Recipient for purposes of the research described herein.
2. Data Recipient shall maintain confidentiality of all information received in accordance with the Covered Entity’s Security User Agreement (“SUA”). The SUA must be completed prior to accessing any electronic system. The provisions for confidentiality and protection of PHI contained in this MOU and the SUA survive termination and expiration of this Agreement.
3. Data Recipient will submit all certifications including Research Compliance Training Module (Cornerstone), Human Subjects Protection (CITI) (if applicable), and HIPAA (HIPS) prior to participating in research at Children’s Colorado. If participating in human subjects research, and if required by the rules of the IRB of record, the Children’s Colorado Principal Investigator will add the Data Recipient to the IRB application under the category of Additional Research Personnel.
4. Except as otherwise specified herein, Data Recipient may make all uses and disclosures of the PHI necessary only for the research described herein entitled:

COMIRB Approved Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Email Address:

Onsite (Department) Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Children’s Colorado Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Description of research study (include title of project, a brief description of the research and provide the Institutional Review Board number):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

1. Data Recipient agrees to only access and not Use or Disclose the PHI for any purpose other than the Research Project or as required by law.
2. If Data Recipient is granted remote access, Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the PHI including, but not limited to, the following:

a. Storing PHI on a password protected computer or server and protecting the confidentiality of passwords.

b. Limiting access to Children's Hospital Colorado system's patient protected health information to persons or entities that are authorized under this Agreement.

c. Not emailing PHI or transmitting PHI over the internet in unencrypted form.

d. Restricting access to any PHI stored on a network such that only individuals directly associated with Research Project and aware of this Agreement have access to the data.

e. Ensuring that PHI is encrypted if it is stored on or accessed from any portable media or device, including, but *not* limited to, laptops, CD's/DVD's, USB drives, tablets or smartphones/PDA's.

f. Ensuring that PHI is encrypted using a FIPS 140-2 compliant algorithm if it is transported across a public network such as the Internet.

g. Maintaining appropriate anti-virus protection on all systems handling or accessing data.

h. Maintain all record retention policies and destroy all copies of data at the conclusion of the Research Project, per any applicable regulatory requirements or as set forth in the Institutional Review Board approved protocol or protocol application.

1. Data Recipient agrees to immediately report to the Covered Entity any Use or Disclosure of the PHI not provided for by this Agreement, including without limitation, any Disclosure of the PHI to an unauthorized person or entity.
2. Data Recipient agrees that if disclosure of the PHI to any person or entity is authorized in paragraph 9 below, Data Recipient will ensure that such person or entity agrees to the same restrictions and conditions with respect to the PHI that apply to the Data Recipient under the terms of this Agreement.
3. Data Recipient may only disclose the PHI to the following persons or entities (if applicable).

No person or entity may be listed unless there is prior authorization by Covered Entity's Privacy Officer. Please list those persons or entities to whom Data Recipient will be disclosing PHI:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Data Recipient further agrees not to disclose to any other person or entity any proprietary or confidential information contained in the records of Covered Entity.
2. This Agreement does not create an employment relationship, partnership, joint venture, or independent contractor relationship. Data Recipient acknowledges that research activities that he/she engages in at Children’s Colorado are for his/her vocational or academic benefit, that no promise of future employment at Children’s Colorado has been made to Data Recipient. Data Recipient is a(n) 🞏 Employee of; or 🞏 Student at Click here to enter parent organization (i.e., employer or university).

IN WITNESS THEREOF, the parties have executed this Agreement on the dates shown below.

|  |  |
| --- | --- |
| **CHILDREN'S HOSPITAL COLORADO**  **Covered Entity**  Authorized Children’s Colorado employee  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Print Name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Data Recipient**  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |