[redacted]

[redacted] 2021

Colorado Department of Public Health and Environment ("Recipient")
4300 Cherry Creek Drive S
Denver, CO 80246-1530

RE: Letter Agreement - [redacted] ("Protocol")

To Whom It May Concern:

Children's Hospital Colorado ("CHCO") is engaged in the study named above [redacted], and seeks to provide sufficient data to the Recipient to obtain selected data elements from death records, as registered with Colorado's vital statistics system (the "Data") and as described in ATTACHMENT A.

Recipient acknowledges that the Data contains "protected health information" or "PHI" (as that term is defined by the Health Insurance Portability and Accountability Act of 1996, or "HIPAA").

Pursuant to applicable federal regulations and regulatory guidance, the performance of the Protocol (ATTACHMENT B) and disclosure of the Data by CHCO to Recipient is required to be reviewed and approved by an appropriately constituted Institutional Review Board ("IRB") (ATTACHMENT C). Colorado Multiple IRB ("COMIRB") is the relevant IRB with respect to CHCO's performance of the Protocol. Based upon the nature of the Protocol and the Data to be disclosed, CHCO has sought, or intends to seek, to obtain from its IRB a waiver of the requirements for patient authorization, as permitted by 45 CFR 164.512(i)(1)(i). Recipient acknowledges that pursuant to applicable federal regulations and regulatory guidance, a waiver of patient authorization may be granted by an IRB only in the event that certain criteria are met.

Accordingly, Recipient represents and certifies as follows:

1. Recipient will not use or disclose the Data for any purpose other than the performance of the Protocol, or as otherwise required by law;

2. Recipient has in place an adequate plan to protect the Data from improper use and disclosure;

3. Recipient will destroy any identifiers contained in the Data at the earliest opportunity consistent with conduct of the Protocol, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

4. Recipient will ensure that any PHI contained in the Data will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the performance of the Protocol, or for other research for which the use or disclosure of such PHI would be permitted by applicable regulations.

[redacted]

Recipient agrees to promptly inform CHCO in the event any of the foregoing representations are no longer true and accurate. Recipient acknowledges that the foregoing representations may be relied upon by the IRB. In no event shall Recipient attempt to use the Data to identify or contact any patient.

Prior to disclosure of the Data to any agent, contractor, or service provider, Recipient shall obtain CHCO consent for such disclosure and ensure that such third party is bound by written obligations of confidentiality at least as strict as those contained herein. Recipient shall be responsible for any use or disclosure of Data by such third parties.

The foregoing restrictions shall not apply with respect to Data to the extent that the Data has been fully de-identified (as that term is used in 45 CFR 164.502(d)(2)).

The term of this Agreement shall commence as of the date of signature below, and shall remain valid as long as the Data is retained by Recipient.

Children's Hospital Colorado,
a non-profit corporation
(Authorized Signatory)

By: [redacted]

Name: [redacted]

Title: [redacted]

Date: [redacted]2021

Colorado Department of Public Health and Environment
(Authorized Signatory)

By: [redacted]

Name: Joni Koenig, MSPH, CIP

Title: Privacy Officer

Date: [redacted] 2021

Read and acknowledged by:
CHCO Principal Investigator

[redacted]

[redacted]2021
Date:

[redacted]

ATTACHMENT A – STATEMENT OF WORK

Project Type:	Human Subjects Research
Project Name:	[redacted]
Project Objective(s):	[redacted]
CHCO Deliverables:	Children's Hospital Colorado (CHCO) requests that Colorado Department of Public Health and Environment (CDPHE) Vital Statistics Program conduct a linkage of patients to Colorado death certificates. CHCO will provide the Vital Statistics Program a data file containing [redacted]
CDPHE Deliverables:	For records for which a matching death certificate if found, the Vital Statistics Program at CDPHE will return to CHCO matching patients': • Fact of death, • Date of death, • Underlying and/or multiple causes of death, • Race, and • Ethnicity

Tasks to Support Deliverables:	The role of CDPHE Vital Statistics Program in support of this research will be limited to conducting the requested linkage to Colorado birth certificates; returning the approved data files resulting from the matching births certificates; and providing any necessary technical assistance in understanding the data elements returned.
Additional Resources to Support Deliverables:	CHCO will provide to Vital Statistics Program a minimal dataset containing only sufficient patient identifiers to conduct the requested linkage to death certificates, as outlined above.
Timeline for Completion of Work:	Upon execution of a formal Agreement, receipt of study protocol and relevant IRB approvals, and receipt of study identifiers from CHCO, the linkage to Colorado death certificates and return of data elements described above will be complete within three weeks.
Payment Costs/Terms:	This Agreement is non-financial.
Additional Information:	CDPHE Vital Statistics Program will destroy the dataset provided by CHCO for purposes of linking to death certificates upon completion of the match and return of results to CHCO. The Vital Statistics Program will retain de-identified results that are returned to CHCO for a period of six (6) months after the close of the study in order to facilitate responses to questions or inquiries by CHCO investigators concerning the matching process or results.

[redacted]

ATTACHMENT B – STUDY PROTOCOL

ATTACHMENT C – IRB APPROVAL DOCUMENTATION