Agreement to Prohibit CDC from Receiving Identifying Key

This agreement allows a non-CDC party that holds coded private information or human biological specimens to release the information or specimens to a receiving CDC investigator without CDC's becoming engaged in research involving human subjects. For basic instructions on using this form, see the next page.

1 Scope of agreement

A non-CDC party holds a key enabling linkage of identifying information to private information or specimens, and this key will not be released to the signing CDC investigator while the identifiable humans are alive.

The releasing non-CDC party attests that this release and the purposes of the planned research do not contradict the terms of consent under which the information or specimens were collected, whether that consent was documented or not documented. If the receiving CDC investigator learns the identity of one or more living individuals or, for previously unforeseen reasons, comes to believe that it is important to identify the individual(s), then this project might become research involving human subjects, and additional procedures must be followed to determine if the activity requires IRB approval under criteria at 45 CFR 46.111.

Brief description of information or specimens, such as protocol title(s) and reference number(s)

Poison Center Collaborations for Public Health Emergencies (OMB Control No. 0920-1166). The Centers for Disease Control and Prevention's (CDCs) National Center for Environmental Health's (NCEH) partner, America's

Additional comments

2 Signatures

Releasing non-CDC signatory

Richard Fogelson Digitally signed by Richard Fogelson Date: 2022.10.13 17:03:40 -04'00'

Signature Date

Richard J. Fogelson 10-13-22

Printed name

(address) 4601 Fairfax Dr., Suite 630, Arlington, VA 222(
(voice) 7038941871 (fax)
(e-mail) fogelson@poisoncenters.org

Receiving CDC investigator

Amy H. Schnall -S Digitally signed by Amy H. Schnall -S Date: 2022.11.09 13:26:29 -05'00'

Signature Date

Amy Helene Schnall 11-09-2022

Printed name

(address) 4770 Buford Highway, NE
(voice) 770-488-3422 (fax)
(e-mail) ghu5@cdc.gov

Secondary non-CDC signatory (optional)

Signature Date

Printed name

Title

CDC science official

Stephanie I. Davis -S Digitally signed by Stephanie I. Davis -S Date: 2022.11.09 13:32:39 -05'00'

Signature (on behalf of) Date

G. David Williamson, PhD

Printed name

NCEH/ATSDR Associate Director for Science

Title

Basic instructions

Use this form to establish an agreement between a party that holds coded private information or human biological specimens and a receiving CDC investigator without CDC's becoming engaged in research involving human subjects. Under this agreement, research at CDC does not require human research review under federal regulations at 45 CFR part 46[*].

This agreement precludes a receiving CDC investigator from having access to identifiable private information, including, for example, access during a site visit or on-site audit or access to an identifying key for the purpose of repairing corrupted data. If, after executing this agreement, it becomes necessary for a receiving CDC investigator to have access to identifiable private information, the agreement is voided and the CDC investigator must arrange for approval by a CDC or non-CDC IRB before gaining access to identifiable private information.

For the purposes of this agreement, the following definitions apply:

Investigator means anyone involved in conducting research.

Individually identifiable information is information in which the identity of the subject is or may readily be ascertained by the investigator or in which the identity is associated with the information.

Coded means that:

1. identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
2. a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

This agreement may be used only at the discretion of the CDC investigator's National Center (NC) Associate Director for Science (ADS) or designee. Investigators should consult with their NC ADS or human subjects contact before entering into such an agreement. The agreement does not require review by HRPO or by the CDC IRB.

The CDC investigator should complete all information on the requested form except for the non-CDC signature and have the form signed by the appropriate parties. The releasing and receiving parties should keep the signed form for three years after completion of the proposed research. The signed form should be made available to HRPO or OHRP on request.

[*] See OHRP guidance at http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm and http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html.