

# This is a packet of information and instructions for reference as you prepare your application for a **new** contract for the Add Health Restricted-Use data.

#### Contact us

• Add Health Contracts email: addhealth\_contracts@unc.edu

#### Sending the application

- The application can be submitted in pieces or the whole application at once.
- If you send the PI Information page and the Security Plan, we can start the SP review process immediately.

#### Investigator Information Page

• Please fill out completely.

## Investigator and Institutional Signatures (last page of DUA)

- The PI fills out and signs their portion.
- The Institutional Representative fills out and signs their portion.
  - The "Institutional Representative" must be someone who is legally authorized to enter into contractual agreements on behalf of the University.
  - This is often not someone within the department; however, this role varies by institution.

**Note**: Some institutions will not sign and/or will not allow the PI to sign until UNC has approved the contract. If this is so for your institution:

- Please submit the Signature Page with the "Investigator" section filled in with your information (we must have it to collect UNC's signatures).
- We will send you a partially-executed contract once it has been approved and UNC has signed. You will return the contract to us signed by your institution.

# Sensitive Data Security Plan (Attachment A)

There are three configuration options, described on the information sheet.

- Download the information sheet from the Portal.
- The information sheet contains links to the three different forms.

The following points apply to all three Security Plan options:

- In the box labeled "List below the name(s) and responsibilities of the investigator(s) and the research staff..."
  - List specific names and a brief description of what they will do (e.g., programmer, mentor, researcher).
- System Administrator
  - The Add Health security administrator requires that you consult an IT professional.
  - $\circ$   $\;$  Please list the name and contact information of the IT staff who is assisting you.
  - Security Pledges -- Required for PI, other Researchers, Collaborators, IT staff.
- Strong passwords
  - Add Health recommends the password be at least 16 characters long
  - A password of 16 or more characters should be changed annually.

## Data Request

- <u>Requesting</u> additional data beyond what you have already requested?
  - See the button on your Portal application "Request More Data."
  - Add any additional datasets, click Cart in the blue bar at the top of the page, click "Proceed to checkout," then click "Submit."

## Data Details and Justification (Attachment B)

- <u>This form is required</u>, whether or not you are requesting data beyond the Core Files.
  - If you have requested data beyond the Core Files:
    - Download the form from the Data Details and Justification requirement.
    - Fill out all parts of the form.
    - Upload the completed form.
- If you have *not* requested data beyond the Core Files:
  - Add Health will email a copy of the form to you.
  - Fill out the top (the Justification statement is not required in this case).
  - Submit by emailing the form to addhealth\_contracts@unc.edu.

#### Supplemental Agreement (Attachment C)

- All researchers except the PI should be listed on the form and should sign it.
  - In Add Health terms, a "Researcher" is anyone accessing the Add Health data directly.
  - Up to five researchers can be listed on one form, or you can submit a form for each.
- PI marks whether authorizing additional researchers.
- PI signs and dates each Attachment C at the bottom of the form.

#### Security Pledge (Attachment D)

- Each person listed on the contract (including the PI), as well as IT staff and officemates, must sign a Security Pledge.
- There are four versions of the Security Pledge:
  - Researcher
    - PI signs this version
    - Anyone accessing the Add Health data directly signs this version.
    - "Location" is <u>required</u>. This is the specific location (e.g., building and office #) where the Researcher will be working when accessing the Add Health data.
    - IT staff
  - Collaborator
    - Anyone working with the contract's researcher(s) in a way that does not involve direct access to the Add Health data on the contract
  - Officemate
- Please copy as needed.

# Payment

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- Once you have created your Portal application and submitted your Investigator Information Page, Add Health will upload an invoice.
- Payment can be made at any time.
  - It must be received before data can be sent.
  - Processing of your application can continue before payment is received.
  - Payment can be by check, money order (personal check or from your institution) or credit card.
    - Add Health cannot accept payment by Electronic Funds Transfer (direct deposit).
- To pay by check:
  - Check must be made payable to University of North Carolina at Chapel Hill.
  - Mail check to the address as shown on the invoice.
- To pay by credit card
  - Email your request to addhealth\_contracts@unc.edu.
  - Please do not send credit card information to Add Health.

#### **IRB Approval Letter**

- Must have an expiration date and/or specification of EXEMPT.
- Only one is required (not for every researcher); the PI for the Add Health contract must appear in this letter, though not necessarily as the primary investigator of the IRB-approved project.
- Add Health does not require annual review by your IRB; the requirement is for a current approval letter.
- For institutions without an IRB:
  - Your letter may come from one of the following:
    - An ethics council
    - A Research Governance Board or Manager
    - Executive Board of the Institution
    - Office of the President of the Institution
    - a similar office
  - Your letter should contain:
    - Date of the letter
    - The PI's name
    - The title of the project
    - Name and title of the writer
    - Language similar to:

"The above-named project has been approved for meeting our institution's standards of ethics because it uses data which is recorded in such a manner that subjects cannot be identified, and the methods and purposes of the project follow a standard academic manner."

# Designated Downloader Form

- This form is required and due before data is provided.
- Add Health is no longer shipping data CDs.
  - Instead, we will make your data available for download from your Portal application (to be unencrypted and copied to your approved storage device).