APPENDIX R

# Collaborative research Adding an Unaffiliated independent individual

**INSTRUCTIONS**: Complete this form if requesting that an Unaffiliated Independent Individual be added to a DU IRB-approved human subjects project. An **unaffiliated independent individual** is an individual whose organization (i.e., community agency) is not registered with the Office of Human Research Protections (OHRP) to obtain a Federal Wide Assurance (FWA). When a request is submitted to involve a non-affiliated independent investigator in human subjects research at DU, this request will be evaluated to determine whether the individual’s involvement in the proposed research meets the criteria for DU to cover this individual.

Please Note: If the unaffiliated independent individual will only be working with deidentified data or biospecimens and does not have access to the identification key code, then this form does not need to be completed. This individual does not need to be included in the IRB Application (Section A, Table 3.1) or complete the CITI Training.

In order to evaluate and assess whether an unaffiliated independent individual may be added to a DU research project, the following documents are required:

* Complete this Appendix R: Adding an Unaffiliated Independent Individual form
* [Individual Investigator Agreement (IIA)](https://www.du.edu/sites/default/files/2021-10/Individual%20Investigator%20Agreement%20%28IIA%29.docx)
* Evidence of the mandatory human subjects’ protection training (CITI) completed by the unaffiliated independent individual

Attach this form (Appendix R), along with the other required documents to your IRBNet package.

If the unaffiliated independent individual is granted approval to be on a DU research project, the DU PI must add this individual to the IRB Application (Section A, Table 3.1) initially as a New Project application or as an amendment after the project has been issued full approval.

## Section A: Investigator information

A.1 **DU investigator:** Click here to enter text. Credentials: Click here to enter text.

#####

DU Dept./college: Click here to enter text.

#####

DU Investigator email: Click here to enter text.

A.2 **Unaffiliated Independent Individual**: Click here to enter text. Credentials: Click here to enter text.

Unaffiliated Independent Individual’s Organization: Click here to enter text.

Unaffiliated Independent Individual email: Click here to enter text.

A.3 **Financial Conflict of Interest**. Does the Unaffiliated Independent Individual have ownership of any Significant Financial Interest (SRI) with this research?

[ ]  No

[ ]  Yes; If yes, is there a management plan regarding this SFI as it pertains to this proposed research?

 [ ]  Yes

[ ]  No; If no, contact the Office of Research Integrity (303-871-2121)

## Section B: Funding

B.1. Study sponsor name: Click here to enter text.

*(if none, put “n/a”)*

B.2 Sponsor protocol number or grant number: Click here to enter text.

*(if none, put “n/a”)*

B.3 Name of awardee on the funding source.

Click here to enter text.

B.4 Institution that is receiving the funds:

Click here to enter text.

B .5 Will the Unaffiliated Independent Individual’s organization or institution be a sub-recipient of the grant or funding source?

[ ]  Yes [ ]  No

##  Section C: Study Activities Conducted by the Unaffiliated Independent Individual

C. 1 Which of the following activities will be conducted by the **Unaffiliated Independent Individual**? Check all that apply:

[ ]  Obtain consent and/or assent

[ ]  Perform research procedures

[ ]  Administer study interventions

[ ]  Obtain, use, or analyze identifiable data and/or specimens

[ ]  Obtain, use, or analyze de-identifiable data and/or specimens

[ ]  Other participant contact

[ ]  Other responsibilities or roles

 If other, please briefly explain: Click here to enter text.

## Section D: Transferring Data

**Data Transfer/Use Agreement**
A data transfer agreement is a contract governing the transfer of data, including human subject data, between institutions for the purposes of research.

D.1 Will this project involve receiving or sending data from the **Unaffiliated Independent Individual’s organization or institution**?

[ ]  No [ ]  Yes

If **yes**, a Data Agreement Request Form is needed to determine the type and scope of data to be used or transferred.

[ ]  **I will receive data**: When data will be transferred to DU from an outside entity, the Data Agreement Request Form for **RECEIVING** data is required.

* + [**Data Agreement Request Form Receiving Data**](https://tinyurl.com/3cme62am)

[ ]  **I will send data:** When data will be transferred from DU to an outside entity, the Data Agreement Request Form for **SENDING** data is required.

* + **[Data Agreement Request Form Sending Data](https://tinyurl.com/3cme62am%22%20%5Ct%20%22_blank)**

Please complete and submit the appropriate Data Agreement Request Form to **datacontract@du.edu**