APPENDIX P

# Collaborative research Request the DU IRB to serve as the IRB of Record

**DU IRB may serve as the IRB of record if one of the following criteria is met**:

* Meets a sponsor requirement
* DU is the award recipient
* The Principal Investigator is affiliated with DU (e.g., faculty, student, staff)
* The DU-affiliated investigator(s) is assuming more of the responsibilities/risk of the research

**Ceding will NOT be approved by DU if any of the following criteria are met**:

* The research is a collaboration with an international entity (each IRB must review)
* The research project has been determined or qualifies for exempt level review (each IRB must review)
* The research is a collaboration with an entity that does not have an IRB (each IRB must review)
* The external investigator is not ‘engaged’ in the research (e.g., recruitment that involves talking with potential participants about the study, obtaining consent/assent, interaction with participants during their participation, access to or use of identifiable data, etc.)

**INSTRUCTIONS**:

* **If the above criteria are met** for **DU to serve as the IRB of Record** for a collaborative project, provide the following documents:
* Evidence of human subjects’ protection training for all external study personnel
* If PHS-funded project, provide a copy of the external investigator’s “Financial Conflict of Interest” Policy
* Attach this form (Appendix P), along with the other required documents to your IRBNet package.

If ceding is allowed, the DU PI must add the external investigator(s) to the Part I: Human Research Application (Section A.2.4) 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 **External non-DU investigator**: Click here to enter text. Credentials: Click here to enter text.

Non-DU investigator Institution: Click here to enter text.

Non-DU Investigator email: Click here to enter text.

 Name of external IRB: Click here to enter text.

External Federalwide Assurance (FWA) #: Click here to enter text.

External IRB Registration #: Click here to enter text.

External IRB Administrator Contact: Click here to enter text.

Email for external IRB Contact (if different than Administrator Contact): Click here to enter text.

A.3 **Financial Conflict of Interest**. Does the external investigator have ownership of other Significant Financial Interest (SRI) with this collaborative research?

[ ]  No

[ ]  Yes

If yes, does the external investigator have a management plan regarding this SFI as it pertains to this proposed research?

 [ ]  Yes, provide a copy of the management plan that has been implemented to address the SFI

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

A.4 **Performance Sites:** Click here to enter text.

## Section B: IRB Reliance Information

B.1 Why is the external IRB requesting to cede to the DU IRB? Check all that apply.

[ ]  In order to comply with the NIH single IRB (sIRB) policy

[ ]  In order to meet another, non-NIH, sponsor’s requirement

[ ]  It is required by another institution engaged in the research

[ ]  DU is conducting most of the research

[ ]  Other: Click here to enter text.

B.2 Is this study related to an existing application and/or study or series of studies reviewed by either the DU IRB or an external IRB?

[ ]  No

[ ]  Yes; If yes, briefly describe the relationship of those studies to this one and list the DU study PI and IRBNet number. Click here to enter text.

*For example, a new sub-study for a study currently reviewed by an external IRB or a study currently under review by the DU IRB that you are requesting be transferred to an external IRB. If you are requesting a transfer from one IRB to another contact the DU IRB Office before submitting this form.*

## Section C: Funding

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

*(if none, put “n/a”)*

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

*(if none, put “n/a”)*

C.3 Name of awardee on the funding source.

Click here to enter text.

C.4 Institution that is receiving the funds:

Click here to enter text.

C.5 Does this study involve more than one organization or institution, meaning that more than one organization or institution is engaged in the research?

[ ]  Yes [ ]  No

*The DU IRB can only provide authorization for the external IRB to review on behalf of DU. If other organizations are involved in the research, those organizations must also authorize any external IRB to conduct review on their behalf. Contact the IRB at the involved institutions for guidance.*

C.6 If funded, will the external institution or organization be a sub-recipient on this grant or funding?

[ ]  Yes [ ]  No

##  Section D: Study Activities to be Conducted by External Investigator

D. 1 Which of the following activities will be conducted by the **external investigator**? 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.

D. 2 Identify any of these populations that will be recruited in this collaborative project:

[ ]  Children

[ ]  Pregnant women/fetuses

[ ]  Prisoners

[ ]  Native Americans/Alaska Natives

[ ]  Cognitively-impaired adults

[ ]  Other unique populations

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

## Section E: 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.

E.1 Will this collaborative project involve receiving or sending data?

[ ]  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://www.du.edu/techtransfer/media/documents/data-agreement-request-form-receiving-data.pdf)

[ ]  **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://www.du.edu/techtransfer/media/documents/data-agreement-request-form-sending-data.pdf)

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