**IRB Application**

#### Proposed IRB Review Type:

**Select the type of IRB review requested for your proposed research. The IRB will make the final determination on the type of review for this IRB submission based on the federal research regulations. Click on the options below for more information about the criteria required for each type of IRB review.**

[**Exempt Review**](https://www.du.edu/orsp/research-compliance/human-subjects/2020/levels-of-review.html)

[**Expedited Review**](https://www.du.edu/orsp/research-compliance/human-subjects/2020/levels-of-review.html)

[**Full Board Review**](https://www.du.edu/orsp/research-compliance/human-subjects/2020/levels-of-review.html)

# Protocol title

CLICK HERE TO ENTER TEXT

# SECTION A: Research personnel

## A.1 Principal Investigator

### Principal Investigator (Faculty, Staff, or Student)

Principal Investigator Name: Click here to enter text DU ID#: Click here to enter text

Position/Title:  faculty  staff  Grad-Doc  Grad-Masters  Undergrad

Department/College/Division: Click here to enter text

Office/Cell Phone #: Click here to enter text

Email Address: Click here to enter text

### Faculty Sponsor, If Student Investigator

Faculty Sponsor Name: Click here to enter text

Credentials/Title: Click here to enter text

**Position**:  Professor  Assistant Professor  Associate Professor  Staff  Other:

Department/College/Division: Click here to enter text

Office/Cell Phone #: Click here to enter text

Email Address: Click here to enter text

Student Project:  thesis  dissertation  capstone  other: explain below

If ‘OTHER’ explain here: Click here to enter text

## A.2 KEY DU Research Study Personnel

**NEW REQUIREMENT: All research team members must create an IRBNet account and link their CITI training account to it. Please follow these instructions to share project access for all team members and link training:**

* [Sharing Access to Your Projects in IRBNet](https://www.du.edu/node/66610)
* [Linking Your CITI Account to IRBNet](https://www.du.edu/node/66556)

All research study personnel are required to complete & maintain valid human subjects protection training through the Collaborative Institutional Training Initiative (CITI) Program. IRB-approved courses include Human Subjects Research -- Social Behavioral Educational Research (SBER) or Biomedical Research. Certificates are valid for four (4) years after the date of completion.

*Please note:**Responsible Conduct of Research (RCR), Conflict of Interest (COI), and Good Clinical Practice (GCP) courses are separate from the human subjects research course requirement and may not be used as a substitute.*

List all key personnel, including yourself as the PI, who are affiliated with DU and will have interaction or intervention with participants or have access to any identifiable, private data, or biospecimens during the research (e.g., administering consent, collecting data, conducting interviews or tests, analyzing identifiable data, etc.). Video and audio recordings are considered identifiable data.

**TABLE A.2.1**

To add additional personnel, click on the **+** at the end of each box.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NAME | DEGREE(S) | DEPARTMENT | POSITION/TITLE | RESEARCH ROLE |
| Click here to enter text | Click here to enter text | Click here to enter text | Choose an item | Click here to enter text |

### A.3 Unaffiliated Investigators and Individuals

**A.3.1 Will the proposed research project involve other investigators who are not affiliated with DU, or individuals from an external organization or institution?**  Yes  No

If **NO**, continue to **Section B: Funding and Financial Conflict of Interest**

If **YES**, list all unaffiliated investigators and individuals in **TABLE 3.1** who will be directly involved in interacting with potential participants (e.g., administering consent, conducting interviews, etc.) or viewing identifiable data. **Individuals only involved in distributing recruitment materials, on behalf of the PI, and will not consent or participate in any study activities, should not be listed as unaffiliated individuals below in section A.3.2.**

**A.3.2 Has a request been issued for an external institution or organization to serve as the IRB of Record for this project and enter into a reliance agreement?**  Yes  No

If **YES**, **STOP. Do not complete this form.** Instead, complete [**Appendix Q: Ceding to an External IRB**](https://www.du.edu/sites/default/files/2024-01/appendix_q_-_unaffiliated_investigator_agreement_approval_request_form%20v5%201-12-2024.docx) and follow the instructions for requesting DU to cede to an external IRB to serve as the IRB of Record for a collaborative project.

If **NO**, you will need to complete **Section L: Multi-Site/Collaborative Research with External Institutions or Organizations & Unaffiliated Investigators** of this application and complete[**Appendix P.**](https://www.du.edu/sites/default/files/2024-01/appendix_p_-_collaborative_research_with_ceding_form%20v5%201-12-2024.docx)

**TABLE 3.1 – Unaffiliated Investigators/Individuals**

To add non-affiliated individuals, click on the **+** at the end of each box.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NAME | CREDENTIALS | INSTITUTION/AGENCY | EMAIL ADDRESS | ROLE |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text |

**NOTE**: All unaffiliated investigators/individuals added to this research project are required to complete & maintain valid human subjects protection training through the Collaborative Institutional Training Initiative (CITI) Program or equivalent training offered by their institution.

# SECTION B: Funding and Conflict of Interest (COI)

## B.1 Funding

**B.1.1** **Will the proposed research be funded?**   Yes  No (if “no”, [proceed to **B.2 Conflict of Interest**)](#__A.5_Timeline)

If **YES**, please select the funding source(s) for the proposed research:

Federally-funded (i.e., NIH, NSF, DoD, etc.): (provide name of funder: Click here to enter text )

State or Local Government Grant: (provide name of funder: Click here to enter text )

Contract (i.e., private industry) (provide name of funder: Click here to enter text )

DU Internal Awards (i.e., PinS, Summer Research Grant, etc.)

Faculty Research Fund

PROF

PinS

Summer Research Grant

Other: Click here to enter text

Private Foundation (provide name of funder: Click here to enter text )

Scholarship/Fellowship (provide name of funder: Click here to enter text )

Gift (provide name of funder: Click here to enter text )

Other: Click here to enter text

**B.1.2 IF FUNDED PROJECT:**

Grant Proposal Title: Click here to enter text

PI on Grant: Click here to enter text

**If this project is externally-funded, you must have a FCOI Disclosure on file in InfoEd.**

## B.2 Conflict of Interest (COI)

**The term “conflict of interest (COI) in research” refers to situations in which financial or other personal considerations may compromise — or have the appearance of compromising — an investigator’s professional judgment in conducting or reporting research. A COI depends on the situation and not on the actions or character of an individual investigator.**

**It is important that researchers involved in human research do not have or appear to have a COI —including a financial interest—related to any of the studies in which they participate.**

**Federal regulations, state laws and University policies require that faculty members submit financial disclosure forms at the time that a proposal is submitted for funding.**

**For more information regarding COI in research, please refer to our** [**website.**](https://www.du.edu/orsp/research-compliance/conflict-interest/training-resources)

**B.2.1 If this project is externally funded, has the Principal Investigator and any other individuals responsible for the design, conduct, or reporting of research completed the** [**Research Financial Conflict of Interest Disclosure Form**](https://pioneerera.du.edu/) **within the last 12 months?**  Yes  No

**If no, please proceed to** [**InfoEd**](https://pioneerera.du.edu/) **to complete this disclosure.**

**B.2.2**   **Does the DU Principal Investigator or any of the individuals listed on the research protocol have any financial or non-financial conflicts of interest that reasonably appears to be related to the research?**  *Examples of non-financial conflicts of interest include things such as personal and professional relationships, affiliations, etc.*

 ☐Yes    ☐ No

If **NO**, there are no individuals who have potential COI related to this Research Project. Proceed to **B.2.3**

If **YES**, please describe the nature of the COI.

Click here to enter text

**B.2.3** **If this research is or may be federally-funded, has the Principal Investigator and all of individuals responsible for the design, conduct, or reporting of the research completed the Research Conflict of Interest training curriculum through the CITI Program?**

☐ Yes    ☐ No  ☐ N/A

If **YES,** proceed to **Section C: Research Purpose**

**If NO,** this training must be completed through the CITI Program curriculum affiliated with DU at: [**citiprogram.org**](https://www.citiprogram.org/Shibboleth.sso/Login?target=https%3A%2F%2Fwww.citiprogram.org%2FSecure%2FWelcome.cfm%3finst%3d1294&entityID=https%3A%2F%2Flogin.du.edu%2Fidp) prior to the expenditure of federal funds and issuing IRB approval.

# SECTION C: RESEARCH PURPOSE

## C.1 Project Summary

Provide a **brief, concise summary** of the purpose of your research project.

Click here to enter text

## C.2 Project Results

**C.2.1 Specify what you plan to do with the results of your research**

Publish in a professional journal

Poster Presentation

Conference Presentation

Fulfill a dissertation, thesis or capstone project requirement

Secondary data/biospecimens for future research

Validate a new intervention, product, or test

Other:

## C.3 Location of Research

**PLEASE NOTE:** Students engaging in research abroad should register at abroad.du.edu. Faculty and staff are registered by virtue of their required booking in Concur. For more information about DU’s [international travel policy](https://www.du.edu/sites/default/files/2023-02/RISK%202.50.070%20International%20Travel.pdf), please visit: <https://www.du.edu/risk/international-travel>

**C.3.1** **List the site(s) or location(s) where the research team will conduct the research (e.g., DU campus locations, clinic, school, community group/agency, village, lab, etc.)**

Click here to enter text

**C.3.2 If this is a multicenter study, provide the total number of subjects to be enrolled at each participating location or site.**

Click here to enter text

**C.3.3 If the research will physically be conducted outside of the United States, please complete and submit:**  [Appendix G: International Research.](https://www.du.edu/sites/default/files/2023-12/irb-appendix%20g%209_0.docx)

# SECTION D: RESEARCH PROCEDURES

## D.1 Categories of research

The research will involve the following (check all that apply):

Activity Observations

Analysis of Existing Data/ Secondary Data

Analysis of Biological Specimens

Audio/Video Recording

Classroom Observations

Clinical Procedures

venipuncture/finger stick

blood pressure

saliva or hair sampling

other: Click here to enter text

Collection/Handling of Biospecimens - any protocol involving handling of human tissue/fluids (not including hair or saliva) must obtain Institutional Biosafety Committee (IBC) approval **PRIOR TO** obtaining IRB approval. The IBC approval letter must be attached to the IRB application in IRBNet.

Cognitive & Perceptional Experiments

Education Records

EKG/EEG/fMRI/Chest X-Ray

Epidemiological Studies

Ethnographic

Field Research (complete [Appendix B](https://www.du.edu/sites/default/files/2021-10/appendix_b_-_field_work.docx))

Evaluation of social or educational programs

Focus Groups

International Research

Internet-based Research

Interviews

Investigational Devices

Investigational Drugs/Biologics

Journaling/Diaries

Medical Chart/Records Review (HIPAA may apply)

Online Surveys

Photography

Questionnaires/Surveys

Use of previously collected tissues (e.g. BioBank)

Other: Click here to enter text

## D.2 Step-by-Step Description of Research Procedures

**D.2.1 Provide a step-by-step description of what each participant will be asked to do, the duration, and state the where, when, and by whom the research will be conducted.**

Click here to enter text

# SECTION E: Recruitment - PARTICIPANT and POPULATION SELECTION

In determining whether selection of subjects for this project is fair and equitable, the IRB will consider the purpose of the research, the setting in which the research will be conducted as well as additional safeguards to protect vulnerable populations, such as children, prisoners, pregnant women, individuals with diminished decision-making capacity, or economically or educationally disadvantaged persons.

## E.1 Resources for Identifying and Recruiting Participants

**E.1.1 Identify the resources or individual contacts that will be utilized to identify eligible participants.** (check all that apply):

Requesting potential contacts from outside source (may require Data Use Agreement)

Requesting student email addresses from a DU department or Registrar’s Office

Requesting others to send recruitment email on PI’s behalf

Snowball sampling

Referrals from professional contacts/organizations

Participant pools

IRB-approved screening and/or recruitment protocol and/or recruitment database

Review of publicly available records

Recruitment in classrooms

Recruiting researchers’ students or staff

Review of student records (requires FERPA authorization)

Review of medical or counseling/therapy records (requires HIPAA authorization)

Recruiting individuals from the European Union (EU)

Other: Click here to enter text

## E.2 Targeted participants and populations

**E.2.1 Select the following participants and populations that will be targeted for this research** (check all that apply):

Children or Minors, (complete [**Appendix F**](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-appendix_f.docx))

Children who are Wards of the State (complete **Appendix F**)

Individuals with Diminished Decision-Making Capacity (complete [**Appendix C**](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_appendix_c.docx))

DU Students**\*\*** (complete **Appendix M**)

Indigenous Peoples

Employees, Specify Employer: Click here to enter text

Healthy Participants

Individuals from the European Union (EU)

Institutionalized Individuals (not prisoners) (complete [**Appendix C**](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_appendix_c.docx))

Non-English Speaking Subjects (complete **Appendix K**)

Pregnant Women, Fetuses, Neonates

Adolescents detained in juvenile detention facility (complete **Appendix D**)

Prisoners (complete [**Appendix D**](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_appendix_d.docx))

Students (Pre-school, K-12 public/private school) (complete [**Appendix M**](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_appendix_m.docx))

**\*\***If a DU student investigator plans to recruit only DU students in their research, Appendix M does not need to be completed. DU faculty and staff investigators recruiting DU students are still required to submit Appendix M to their IRBNet package.

**E.2.2 Explain how the subject selection process will ensure that the recruitment process does not violate the privacy of the potential participants.** The inclusion and exclusion criteria in **E.4.1** must include the participants and populations selected above.

Click here to enter text

## E.3 Vulnerable Populations

**E.3.1 Identify any of the following individuals or populations that may be vulnerable to coercions or undue influence in this research** (check all that apply):

Children or Minors

Individuals with diminished decision-making capacity

Elderly

Institutionalized Individuals (not prisoners)

Non-English Speaking Individuals

Educationally Disadvantaged Individuals

Low-income and/or Homeless Individuals

Prisoners

Adolescents detained in juvenile detention facility

Undocumented Immigrants

Veterans

Students (Pre-school, K-12 public/private school,)

DU students

If any individuals or target populations were identified in **E.3.1**, you are required to complete **Appendix C: Populations Requiring Additional Safeguards.**

**E.3.2 Describe the additional safeguards that will be incorporated in the research to protect any vulnerable populations that were identified in E.3.1.** Additional safeguards must be included to protect their rights and welfare (i.e., ensuring that consent documents are written at an appropriate reading level for the targeted population).

Click here to enter text

## E.4 Inclusion and Exclusion Criteria

Research that has the potential to benefit a variety of individuals should target a population of subjects that is diverse enough to distinguish differing effects, risks, and benefits. No group or individual subject should be excluded without a scientifically sound reason or a requirement of the regulations to do so.

**E.4.1** **Describe the criteria that defines who will be included or excluded in your proposed study sample.**

Indicate specifically whether you will include or exclude any special populations. ***You may not include members identified in section E.2 as subjects in your research unless you indicate this in your inclusion criteria.***

|  |  |
| --- | --- |
| **Inclusion Criteria:**  Inclusion criteria are defined as the key features of the target population that the investigators will use to answer their research question. Typical inclusion criteria include demographic, clinical, and geographic characteristics. | Click here to enter text |
| **Exclusion Criteria:**  Exclusion criteria are defined as features of the potential study participants who meet the inclusion criteria but present with additional characteristics that could interfere with the success of the study or increase their risk for an unfavorable outcome. | Click here to enter text |

**E.4.2 Describe the process for assessing and documenting a participant's qualifications based on the inclusion and exclusion criteria identified in E.4.1 above.**

Click here to enter text

## E.5 Enrollment of Participants

**E.5.1 Indicate the total number of subjects to be recruited/enrolled in this research.**

Click here to enter text

**E.5.2 If this study will be conducted in multiple locations, indicate the total number of subjects to be enrolled in each participating site.**

Click here to enter text

# SECTION F: PARTICIPANT RECRUITMENT PROCEDURES

## F.1 Recruitment Plan

**F.1.1** **Identify where the research team will identify and recruit potential participants. If specific individuals or organizations will be used for recruiting purposes only, explain how information will be provided to them and how potential participants will contact the researcher.** Include all emails, recruitment scripts, flyers, social media postings, and other communication methods that will be utilized in your research project.

Click here to enter text

**F.1.2** **Will you be screening for eligibility before consenting potential subjects into the study?**

**No.** **Proceed to section F.2.**

**Yes**. **Complete the information below.**

Indicate what you will use to screen potential subjects:

Survey/Questionnaire

Other: Click here to enter text

You do not need to obtain informed consent to screen for eligibility. Potential subjects should not be asked to consent to participating if they are not eligible for the study in the first place.

Screening instruments should only include items or questions based on the inclusion and exclusion criteria listed in item E.4.1, unless you can provide justification for additional items.

Provide justification for additional screening items:

Click here to enter text

**The screening instrument must include an introduction and the following statements (edit appropriately):**

* You will be notified if you are eligible for this study. The information you provide below will/will not be used in the study.
* If you are not eligible for this study, you will/will not be notified, and any information you provide below will be destroyed.

## F.2 Recruitment Materials

**F.2.1 Check all recruitment materials that will be used in the research. Copies of all recruitment materials must be included in the IRBNet package for IRB approval prior to distribution and use (check all that apply):**

Advertisements/Public Service Announcements

Emails for recruitment - if selected, describe how email addresses will be obtained: Click here to enter text

Recruitment Flyer (hard copy and/or electronic)

Letters or information sheets for participants

Scripts or guides that will be used for in-person or telephone recruitment interviews

Social Media Postings

Printouts of web postings or pages used for direct recruitment

Other – describe: Click here to enter text

## F.3 Obtaining Approval From External Sites

**F.3.1** **Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, DU biosafety committee, community leader, Dept of Corrections, etc.) as identified in C.3 – Location of Research.**

Click here to enter text

If research is conducted at an off-campus site (i.e., community center, school, etc.) or if recruiting potential study participants from that site (i.e., employees, students, etc.) a signed **letter of support** must be obtained from the external site confirming their support of the proposed research and their approval to have the research be conducted at their site.

All letters of support from external sites must be signed and include the title of the signing party posted in the IRBNet project submission. Letters of support must be obtained and reviewed before final IRB approval will be issued.

## F.4 Obtaining Records and Data for Recruitment

**F.4.1 Will participants be recruited by obtaining records (e.g., educational records, medical or counseling/therapy records, databases, etc.)?**

**☐ Yes     ☐ No**

If **NO**, proceed to **F.5 – Subject Compensation**

If **YES**, will this include paper files?  Yes  No

1. If **YES**, will this include electronic files?  Yes  No
2. Who is responsible for and how will the files will be maintained and properly secured:

Click here to enter text

**F.4.2**  Will **student educational records** be requested or reviewed for research purposes?  Yes  No

If **NO**, proceed to **F.4.3**

If **YES**, obtaining **Family Educational Rights and Privacy Act** (**FERPA) authorization is required**. FERPA authorization language should be included in the consent (refer to **Informed Consent Template** for appropriate language) and the [Student Records Request Form](https://www.du.edu/sites/default/files/2023-09/Student%20Records%20Request%20Form.docx) must be completed and sent to the Office of Institutional Research. For further guidance on FERPA regulations and procedures, please see the [FERPA Guidance](https://www.du.edu/sites/default/files/2023-09/FERPA%20Guidance.docx) document.

**NOTE*:*** *If a researcher has access to student records as part of their professional or academic position, they are not allowed to access those records for research purposes without obtaining proper written authorization from the student.*

**F.4.3** Will an **individuals’ medical or counseling/therapy records** be reviewed or requested for research recruitment purposes? ☐ Yes     ☐ No

If **NO**, proceed to **F.4.4**

If **YES**, obtaining **Health Insurance Portability and Accountability Act** (**HIPAA) authorization is required**. HIPAA authorization must be provided by the healthcare provider or individual patient or client. Refer to the **Informed Consent Template** for appropriate language) or be obtained as a separate document.

**NOTE:** *If a researcher has access to an individuals’ medical or counseling/therapy records as part of their professional or clinical position, they are not allowed to access those records for research purposes without obtaining proper authorization from the individual.*

**F.4.4** Will **identifiable data** be requested and provided by an outside entity for research purposes?  Yes  No

If **NO**, proceed to **F.5** **– Subject Compensation**

If **YES**, complete the Office of Intellectual Property and Technology Transfer (OIPTT) intake form [here](https://tinyurl.com/3cme62am). The DUA process and review is conducted separately from the IRB. After the DUA form and agreement has been reviewed and approved, a copy will be issued to the PI. The PI is responsible for attaching the fully executed DUA document to their approved IRBNet project as a new package labeled “Other.”

If **de-identifiable data** is requested from an outside entity, without any codes or access to the key to the codes, it is at the discretion of the outside entity whether they will require a DUA.

## F.5 Subject Compensation

**F.5.1** **Will subjects be offered compensation for participating in the research?**  Yes  No

If **NO**, proceed to **Section G: Consent Procedures**

If **YES**, check all that apply:

Gift card

Monetary cash payment

Check

Class credit (**If selected, complete F.5.4** below)

SONA chit

Gift

Drawing/Lottery for gift card or cash

Other: Click here to enter text

**F.5.2 Describe the amount and the schedule for issuing payments as well as any conditions for participant receiving the compensation (e.g..** **prorating payment, timing of the drawing or payment).**

If payment by check, gift card, or cash will be used, please refer to the [**Human Subjects Payment Policy**](https://my.du.edu/#human-subject-research)found on the myDU portal under “Administrative Resources and Processes.”

Click here to enter text

**F.5.3 Will an individual participant receive more than $600 per calendar year for participating in this research project?**  Yes  No

If **YES**, additional information must be included in the consent document regarding the IRS reporting requirement and 1099 language (refer to the **Informed Consent Template** for specific language).

**F.5.4 If students will receive extra credit or course credit (i.e., SONA chits), state the alternative method(s) that will be available for earning credit for those who do not wish to participate. The alternative method for earning extra credit must be provided in the recruitment materials and included in the consent or information sheet.**

Click here to enter text

# SECTION G: CONSENT PROCEDURES

## G.1 Consent Options

**G.1.1 Select the consent document(s) that will be utilized in your research (please be sure to only select the option from the review category for your research project). All consent templates are located on the** [**IRB Forms webpage**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)**.**

**Options** **for *Exempt Review Projects***

[**Exempt Research Information Sheet**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) **–** Complete and upload to IRBNet package for review. You will need to offer a copy to the participants.

[**Consent for Online Surveys**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) **–** Consent language to be used with online surveys or questionnaires. Complete and upload to IRBNet for review.

**Non-English Reading/Speaking Participants -**  Complete the [Exempt Research Information Sheet](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) in both English and the translated language. Upload to IRBNet for review along with [Appendix K](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates).

**Options for *Expedited & Full Board* Review Projects**

**Written Informed Consent** (physical, hand-written signature) **-**  (complete [**Expedited/Full Board Consent template**).](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)  A hard copy of the consent form must be provided unless providing a copy increases potential risk to the participant.

**Electronic Consent** - no written hardcopy signature, but consent obtained and completed using a secure electronic signature platform (i.e., DocuSign or REDCap. **Note:** Qualtrics may not be used to obtain electronic signatures.) (Complete [**Expedited/Full Board Consent template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and remove signature/date line). **Note:** Research participants must be offered a hard copy or electronic version of the consent form they can retain for their records.

**Waiver of Written Documentation**, no written or electronic signature (complete [**Appendix A**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and [**Expedited/Full Board Consent template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and remove signature/date line). Note: Research participants must be offered a hard copy or electronic version of the consent form they can retain for their records.

**Verbal Consent** – **Waiver of Written Documentation**, recommended that an information sheet is provided to participants (complete [**Appendix A**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)**,** and [**Verbal Consent Script template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)). Provide a copy of the information sheet if utilized. To confirm a participant’s understanding of the research, a set of questions should be included to test their comprehension.

**Consent Form (Non-English language),** (complete[**Appendix K**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)and the [**Informed Consent Document template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)formatted in the English language). Provide a copy of the **Short Form Consent** in Non-English language unless providing a document increases a potential risk to the participant. To confirm a participant’s understanding of the research, a set of questions should be included to test their comprehension.

**Verbal Consent (Non-English language),** (complete[**Appendix K**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)and[**Verbal Consent Script template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)formatted in English language). Provide a copy of the Short Form Consent in Non-English language unless providing a document increases a potential risk to the participant. To confirm a participant’s understanding of the research, a set of questions should be included to test their comprehension.

**Short Form Consent,** required if consenting non-English speaking potential participants and an interpreter is used. Complete the [**Short Form Consent template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates). Provide a copy of the Short Form Consent in the English-version for IRB review. Provide a copy of the non-English version to the participant unless providing a document increases a potential risk to the participant. To confirm a participant’s understanding of the research, a set of questions should be included to test their comprehension.

**Full Waiver or Alteration of Consent Elements -** (complete [**Appendix A**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)**,** and if alteration of consent requested, complete[**Informed Consent Document template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)). An alteration of consent is requested if any of the required elements of an informed consent are altered or removed.

**Written** **Assent Document** (aged 7-12 years old participants) - (complete [**Assent Document template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates))

**Written** **Assent Document** (aged 13 – 17 years old participants) – (complete [**Assent Document template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates))

**Written** **Assent Document** ( for individuals with diminished decision-making capacity) – (complete [**Assent Document (individuals with diminished decision-making capacity) template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)and[**Parental, Guardian or LAR Permission Form**)](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)

**Verbal Assent** (for young children or individuals with diminished decision-making capacity who may not be able to sign an assent document but are mature enough to have the study information verbally explained) – (complete [**Appendix A**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and [**Parental, Guardian or LAR Permission Form**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and provide a copy of the [**Verbal Assent Script**)](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)

**Waiver of Assent** (newborn – 6 years old participants**)** – (complete [**Appendix A**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and [**Parental Permission Form template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates))

**Written** **Parental Permission Form** (hardcopy signature obtained) – (complete [**Parental Permission Document template**)](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) Parents or guardians must be provided with a hard copy or electronic version of the parental permission form they can retain for their records.

**Parental Permission Form – Electronic Documentation** – no written hardcopy signature but permission is obtained and completed on a secure electronic signature platform (i.e., DocuSign or REDCap. **Note:** Qualtrics may not be used to obtain electronic signatures.) **Note:** Parents or guardians must be provided with a hard copy or electronic version of the consent form that they can retain for their records. (complete [**Parental Permission Document template**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates) and provide copy of Investigator Letter to be distributed to parent/guardian)

**Full** **Waiver of Parental Permission Form** – (complete [**Appendix A**](https://www.du.edu/orsp/research-compliance/human-subject-research/forms-templates)) , this type of waiver may only be granted by the IRB for minimal risk studies.

## G.2 Obtaining Signed (hardcopy or Electronic signature) Informed Consent, Assent, or Parental Permission

**G.2.1.1** **Specify where the informed consent, assent, and/or parental permission process will take place.**

Click here to enter text

**G.2.1.2** **Specify who on the research team will administer the consent, assent or parental permission.**

Click here to enter text

**G.2.1.3** **Describe how hard copies or electronic signed consents, assents or parental permission forms will be collected, stored and managed. If research will be conducted outside or away from the DU campus, explain how the documents will be securely transferred back to the secure storage site.**

Click here to enter text

## g.3 Using Translators and Interpreters

**G.3.1** **Will this research project target non-English speaking persons?**  Yes  No

If **NO**, proceed to **G.3.2**

If **YES**, complete **Appendix C – Populations Requiring Additional Safeguards**

**G.3.2** **Will this research project use translators to communicate with non-English speaking persons?**

Yes  No

If **NO**, proceed to G.4

If **YES**, complete **Appendix K: Certificate of Translation & Use of Interpreters**

## G.4 Verifying Comprehension and Documentation of Consent

**G.4.1 If obtaining written consent or providing information in hard copy format about the study could potentially increase risk to the study participant, describe how comprehension about the research will be verified.**

Click here to enter text

**G.4.2** **If written consent is not obtained, explain how researchers will document a participant’s voluntarily agreement to participate in the research?**

Click here to enter text

## G.5 Research Involving Deception

**G.5.1** **Does the proposed research involve deception, e.g., through provision of misinformation, withholding information, etc.?**  Yes  No

If **NO**, proceed to **Section H: Risks and Benefits to Subjects**

If **YES**, complete [**Appendix L**](https://www.du.edu/orsp/media/documents/new_irb_forms/appendix_l.docx)**: Research Involving the Use of Deception**

# SECTION h: RISKS and Benefits TO SUBJECTS (beneficence)

## H.1 Risk Classification

**H.1.1 What is the overall risk classification for the proposed research?**

**NOTE:** According to HHS regulations, minimal risk means, “*The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*”.

Minimal risk  More than minimal risk

## H.2 Anticipated Risks and Discomforts

**H.2.1** **What are the possible anticipated risks and discomforts to the participants? Describe all possible risks including psychological, physical, sociological or economic harm (e.g., risk of criminal or civil liability, damage to their financial standing, employability, insurability, reputation, or stigmatization, etc.) Check all that apply and provide a description for each:**

**Physical Harms**: Medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs and devices. Procedures commonly used in research may result in no more that minor discomfort (e.g., temporary dizziness, the pain associated with venipuncture).

**Describe all possible physical harms that are anticipated during the research:**

Click here to enter text

**Psychological Harms**: Participation in research may result in undesired changes in thought processes and emotion (e.g., episodes of depression, confusion, feelings of stress, guilt, and loss of self-esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but some research has the potential for causing serious psychological harm.

Stress and emotional discomfort such as feelings of guilt or embarrassment may arise simply for thinking or talking about one’s own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence. These feelings may be aroused when the subject is being interviewed or filling out a questionnaire. Stress may also be induced when a researcher manipulates the subjects’ environment – as when “emergencies” or fake “assaults” are staged to observe how passer bys respond. The possibility of psychological harm can increase when behavioral research involves an element of deception.

**Describe all possible psychological harms that might occur during the research:**

Click here to enter text

**Invasion of Privacy**: Invasion of privacy is a risk of a somewhat different character. In the research context, it usually involves either covert observation or “participant” observation of behavior that the subjects consider private.

* Is the invasion of privacy involved acceptable considering the subjects’ reasonable expectations of private in the situation under study?
* Are the research questions of sufficient importance to justify the intrusion?
* Will the research involve the use of a subject’s medical, school, or employment records? Access to such records for legitimate research purposes is generally acceptable, if the researcher protects the confidentiality of that information and obtains appropriate authorization from the individual. It is important to recognize that a breach of confidentiality may result in psychological harm to individuals (in the form of embarrassment, guilt, stress, and so forth).

**Describe any possible situations that may be perceived as an invasion of privacy:**

Click here to enter text

**Social and/or Economic Harms:** Some invasions of privacy and breaches of confidentiality may result in embarrassment within one’s business or social group, loss of employment, or criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Confidentiality safeguards must be strong in these instances. Any anticipated costs to research participants should be described to prospective subjects during the consent process.

**Describe any possible situations that may result in any social or economic harms:**

Click here to enter text

**H.2.2** **Describe any additional risks to participants or others:**

Click here to enter text

**H.2.3** **How will risks be minimized and their potential impact to the participants or others be reduced?**

* Does the research team have sufficient expertise and experience to conduct the research?
* Is the projected sample size sufficient to yield useful results?
* Is the data collected from standard-of-care procedures to avoid unnecessary risk, particularly for invasive procedures?
* Are adequate safeguards incorporated into the research design such as the presence of trained personnel and/or resources to respond to emergencies, and procedures to protect the confidentiality of the data (e.g., IT-approved databases for management and storage, adequate encryption, codes, and passwords).

Click here to enter text

## H.3 Direct Benefits

In order to justify the use of participants in a research study, the potential benefits of the study must be evaluated and weighed against the risk in the study. The benefit of a study can be to the participant in the study and/or the general community.

**Therapeutic studies**, such as behavioral interventions, are conducted with the intent to study alternative procedures for patient or client care. For a therapeutic study to be justified the study procedure must offer care that is consistent with other therapeutic options, there are multiple options for treatment none of which are clearly preferred, and the risks are reasonable in relation to the potential benefit to participants.

**Non-therapeutic studies** seek to answer a scientific question without providing any treatment or direct benefit to a participant. For a non-therapeutic study to be approved, the risks in the study must be minimized according to sound scientific design and the risks are reasonable in relation to the knowledge gained by the study. Although the participant may not directly benefit from the study the study may provide valuable information for a community or the general population.

**The DU IRB does not consider payment to be a benefit. Payments are used to encourage participation and should not be advertised as a benefit to participating in the study.**

**H.3.1.** **Describe the direct benefits to the research participants for participating in this research (i.e., to contribute to science, society, or to study alternative therapeutic methods)?**

Click here to enter text

# SECTION I: CONFIDENTIALITY & Privacy

## I.1 Confidentiality

**Confidentiality refers to the researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed, and disseminated, including the research participants’ authorization for the PI to view, share, and use their private information.** Confidentiality means that the participants can be identified, but their identities are not revealed to anyone outside of the study, only the researcher knows the identities of the participants.

**Anonymity** **means that there is no way for anyone (including the researcher) to personally identify participants in the study at any time.** This means no personally identifying information can be collected in an anonymous study. Personally identifying information includes, but is not limited to, names, addresses, e-mail addresses, phone numbers, and IP addresses. Any study conducting face-to-face interaction, through in-person contact, using video technology (i.e., Zoom), or conducting any part of the study interventions via phone is NOT considered anonymous; this rules out virtually all qualitative research that involves collecting and analyzing non-numerical data (e.g., texts, video, or audio) to understand concepts, opinions, or experiences.

**I.1.1 Will any demographic data or direct participant identifiers (data that contains any of the 18 elements defined by HIPAA) be collected or recorded, at any time, in your research?**   Yes  No

If **YES**, indicate the type of data that will be recorded:

Names/initials

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89

Telephone numbers

Email addresses

Social security numbers

Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Web Universal Resource Locators (URLs)Other: Click here to enter text

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full-face photographic images and any comparable images

Any other unique identifying number, characteristic, or code (e.g. student ID numbers);

Any information if used alone or in combination with other information could identify an individual who is a subject of the information

**If NO**, proceed to **section I.3 - Privacy**

Click here to enter text

**I.1.2 Does the consent and other information presented to potential research participants adequately and clearly describe confidentiality risks?**

Yes  No

Click here to enter text

**I.1.3 Does the consent process and the informed consent document clearly delineate who will have access to the subject’s information and under what circumstances data may be shared?**

Yes  No

**I.1.4 Will an individual study participant’s data be shared with that participant?**

Yes  No

**If YES, are there circumstances or limitations on what data will be shared or how it will be shared with the participant? Please explain below.**

Click here to enter text

## I.2 Certificate of confidentiality (CoC)

**Certificates of Confidentiality (CoCs)** protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are issued automatically for any NIH-funded projects using identifiable, sensitive information. Receiving a CoC for research that is funded by other HHS-agencies, by non-HHS federal agencies, and for research supported by non-federal funders.

To obtain a Certificate of Confidentiality, access [**NIH Website: Certificates of Confidentiality**](https://grants.nih.gov/policy/humansubjects/coc.htm).

**I.2.1** **If your project is NIH-funded, and involves identifiable, sensitive information has information been included in the informed consent document?**  Yes  No (refer to the **consent template for wording**)

**I.2.2** **If your project is funded by non-HHS agencies and involves identifiable, sensitive information, will a CoC be obtained?**  Yes  No

If **YES**, has CoC information been included in the informed consent document?  Yes  No

If **NO**, please refer to the **NIH Certificate of Confidentiality** website for information.

## I.3 Privacy

**Privacy** is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. For example, potential participants may not want to be seen entering a place or talking to an outsider (e.g., researcher) that may stigmatize them or increase potential risks by doing so. The evaluation of privacy also involves consideration of how the researcher accesses information from or about potential participants (e.g., recruitment process).

**I.3.1 Describe the methods used to identify and obtain information about potential study participants who may meet the inclusion criteria for this study and maintain their privacy.**

Click here to enter text

**I.3.2 Describe the methods and process to contact and recruit potential participants who meet the inclusion criteria while ensuring their privacy is respected.**

Click here to enter text

**I.3.3 Describe the settings in which an individual will be interacting with the investigator or research team member that provides adequate privacy.**

**Note: If any study intervention will occur remotely, describe what information or safeguards will be implemented to ensure the study participant’s privacy is protected during the remote study intervention.**

Click here to enter text

**I.3.3 If information be obtained about individuals other than the “target participants,” (e.g., a subject provides information about a family member for a survey), describe the process for obtaining this individual’s information and how their privacy will be protected and respected. If not applicable to this study, enter “N/A”.**

Click here to enter text

**I.3.5 Outline any privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology) that will be applied to this research. If none, enter “N/A”.**

Click here to enter text

# SECTION J: Research Data management

The retention of recorded and retrievable research data is of utmost importance for the progress of scientific integrity. The investigator is responsible for accurately recording, retaining, and storing research data as well as ensuring the rights and privacy of the research participants and their identifiable information is protected. Research records should include sufficient detail to permit examination for the purpose replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions as well as maintained to preserve the confidentiality of a participant’s private data.

## J.1 Identifiers and Coding

**Research involving *the initial collection of private data from living individuals* will always require IRB approval whether or not the data are “coded” or “de-identified” subsequently.** Researchers who will use coded or de-identified private information or specimens must provide adequate information about how the proposed research data will be or was coded or de-identified. As an investigator who proposes to obtain and use “de-identified data”, certain conditions must be met to ensure that the identities of research subjects cannot be ascertained with the data. If the conditions for de-identification are not met and the data may simply be “coded “, **and** the key to the code exists somewhere, additional information must be provided to describe how the coded or de-identified private information or biospecimens will be secured. To further define the terms used with identifying and coding data, please refer to the following terms and definitions:

**A direct identifier** is a specific element of data, such as a name, social security number, or address, which directly connects a participant and their data.

**An indirect identifier** is any element or condition of data which potentially allows someone to connect a research participant and their data.

**Coded Data:** Coded data has identifying information (such as name or social security number) that would enable a research team to ascertain the identity of the individual to whom the private information or specimens pertain and is replaced with a “code” (number, letter, symbol, or combination). **Note that simply coding the data does not make that data anonymous or de-identified.** In most studies involving coded data, a key to decipher the code typically exists, and the key enables linkage of the private information or specimens to individuals.

**Anonymous Data:** Data are anonymous if no one, not even the researcher, can connect the data to the individual who provided it. If no identifying information is ever collected from individuals (including direct identifiers as listed in **section I.1.1**), the data might be anonymous. However, researchers should be aware that collection of indirect identifiers, (e.g., information regarding other unique individual characteristics) might make it possible to identify an individual from a pool of subjects. For example, a study participant whose data may identify them as a member of a minority ethnic group and a particular sex might be identifiable from even a large data pool.

**Data De-identified**: Data are considered de-identified when all direct or indirect identifiers or codes linking the data to the individual subject’s identity are destroyed. This means that any of the 18 identifiers listing in **section I.1.5**, of the individual or of relative,s, employers, or household members of the individual are removed.

**J.1.1 Will this study collect or obtain any identifiable data about the study participants?**  Yes  No

If **NO,** proceed to section J.2– **Research Data Collection**

If **YES,** continue to **section J.1.2**

**J.1.2 Describe the data security measures that will be implemented to protect the identity of and/or confidential information obtained about individuals who participate as subjects in research. Explain why it is necessary to maintain such identifiers and describe the coding system you will use to protect the subject’s privacy against disclosure.**

Click here to enter text

## J.2 Research Data Collection

**J.2.1** **Specify how information will be obtained? (check all that apply)**

**Information is publicly available** (e.g., Public Use Database) Specify source: Click here to enter text

**De-identified data** is collected by the investigator, with no direct or indirect identifiers and all data is anonymous

**De-identified data** is obtained from an outside entity. Specify source:Click here to enter text

**De-identifiable data** obtained from a DU-affiliated investigator, without codes or any direct or indirect identifiers. Specify DU-affiliated investigator and IRBNet Project number (if applicable): Click here to enter text

**Identifiable data** collected and coded as part of the study, with the key to the codes maintained only by the investigator.

**Identifiable data** collected and then de-identified by the study investigator, with no codes or any direct or indirect identifiers,

**Identifiable data** collected and then de-identified (all identifiers stripped) by an independent individual not associated with the study, with no codes or any direct or indirect identifiers (e.g., obtaining student data from a DU department or client data from a DU clinic). Specify responsible individual and the source of data: Click here to enter text

**Storage or maintenance of existing or prospectively collected identifiable private information or identifiable biospecimens** obtained through an outside entity. Specify source: Click here to enter text **Data Use Agreement (DUA) or Materials Transfer Agreement (MTA) may be required**

**Secondary research using identifiable private information or identifiable biospecimens** will be conducted. Provide source of data: Click here to enter text **Data Use Agreement (DUA) or Materials Transfer Agreement (MTA) may be required**

## J.3 Data Management

**Ownership of Data**

**J.3.1 If your research plans include the collection or study of existing data, pathological or diagnostic specimens, please specify whether data will be restricted and if an agreement is in place prohibiting release of private identifiable information or if you will be provided the key to coded information and provide such documentation.** If not applicable, please indicate “N/A”.

Click here to enter text

**Retaining and Securing Data**

**J.3.2 How will the research data and/or specimens be protected against inappropriate use or disclosure?**

A study participants’ personally-identifying information can be linked to their data using ID numbers (quantitative research ) or pseudonyms (qualitiative research); this allows personally-identifying information to be stored separately from the data. In terms of data security, researchers should follow all security measures, such as keeping paper and pencil data in locked file cabinets, password-protecting electronic data, and securely destroying the data after the research is complete.Confidentiality is best ensured through proper data management and security. **It is strongly recommended that all researchers consult with DU IT to confirm that their proposed data security system meets the appropriate requirements to protect the research data.**

**(Check ALL that apply)**

Locked office on campus

Locked storage unit on campus

Restricted access to authorized study personnel

Secure computer/laptop

Individual ID plus password protection

Encryption of digital data

Network Restrictions

Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study

Restrictions on copying study related materials

Destruction of source data immediately after data collection (to preserve anonymity of participants)

Audio and/or video recordings will be transcribed and then will be destroyed

Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified

Photos or images will be modified to eliminate the possibility that study participants could be identified

Study personnel will sign statements agreeing to protect security and confidentiality of study information

Access rights are terminated within authorized study personnel leave the study

Not Applicable

Other (specify below)

Click here to enter text

**Storage of Data**

**J.3.3** **If a secure DU data management system will be utilized to store research data, identify the system(s) below**.

OneDrive

RedCAP

Google Drive

Other: Click here to enter text

N/A

**J.3.4** **What will happen to the research data and/or specimens at the conclusion of the study?** Include paper records, audio and video recordings, field notes, transcriptions, etc. in your response. If study materials are to be retained for at least three years after at the conclusion of the research, describe how secure storage of those materials will be maintained.

Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased

Retain for study recordkeeping purposes per institutional policy

Retained by the investigator for future research use.

Retained for future research use (create data or tissue repository/bank).

Restricted use of data will be destroyed or returned to the source.

No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator.

This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor in accordance with FDA regulations.

Other (specify below)

Click here to enter text

**NOTE:** Per DU IRB Policy, documentation of the signed informed consent of the subjects, written protocol, and other records related to conducting research that are typically held by investigators must be retained for at least three years after completion of the research.

**J.3.5**  **If identifiable study data, direct or indirect identifiers, are stored on a networked computer or device, either on campus or off-campus, transmitted over a network, and/or stored on a removable medium, what security measures will be implemented AFTER the research has been completed.**  If not applicable, please indicate “N/A”.

Click here to enter text

**Transfer of Data**

**J.3.6** **In the event that outside organizations are involved (in data gathering, processing, and storage), what safeguards or procedures will be incorporated to ensure the rights of the subjects will be guaranteed by that agency?** If not applicable, please indicate “N/A”.

Click here to enter text

**Future Use of Data**

**J.3.7 Will *deidentified* data be used for future research?**

Yes - Please submit [Appendix I](https://www.du.edu/sites/default/files/2021-10/appendix_i_-_stored_data_for_future_use.docx) and include the following statement in the consent form: Information you provided for this study may be deidentified and used for future research or shared with another researcher for future studies without additional consent.

No

*\*Please note: The use of identifiable data in future research will require additional informed consent.*

# SECTION K: Data Use Agreements/Material Transfer Agreements

## K.1 Data Use Agreements

A data use agreement (DUA) is a written contract governing the transfer of data, including human subject data, between entities for the purposes of research. These agreements can be set up between academic institutions, non-profits, government agencies, and/or corporate entities. The Data Agreement will govern data ownership, permitted uses of the data, publication of results, development of inventions, disposal of the data, and liability.

If **de-identifiable data** is requested from an outside entity, without any codes or access to the key to the codes, it is at the discretion of the outside entity whether they will require a DUA.

**K.1.1 Will this research involving RECEIVING data from or TRANSFERRING data to an outside entity?**

Yes  No

If **NO**, proceed to **K.2.**

If **YES**, complete the Office of Intellectual Property and Technology Transfer (OIPTT) intake form [here](https://tinyurl.com/3cme62am). The DUA process and review is conducted separately from the IRB. After the DUA form and agreement has been reviewed and approved, a copy will be issued to the PI. The PI is responsible for attaching the fully executed DUA document to their approved IRBNet project as a new package labeled “Other.”

## K.2 Material Transfer Agreements

A material transfer agreement is a contract governing the transfer of tangible research materials (biological materials) between institutions for the purposes of research.

**K.2.1 Will this research involve RECEIVING or TRANSFERRING tangible research materials?**  Yes  No

If **YES**, complete the Office of Intellectual Property and Technology Transfer (OIPTT) intake form [here](https://tinyurl.com/3cme62am).

# SECTION L: Multi-Site/ Collaborative Research with External Institution or organizations & unaffiliated investigators

**If you are not collaborating with another institution or organization, please leave Section L blank.**

**L.1.1. Are you requesting that DU IRB serve as the IRB of record for this study?**  Yes  No

If **YES**, is this external/unaffiliated individual(s)associated with another institution or organization that has a Federalwide Assurance (FWA)?  Yes  No  Unsure If unsure, contact the IRB Office.

If **YES**, complete and attach [**Appendix P: Request the DU IRB to Serve as the IRB of Record**](https://www.du.edu/sites/default/files/2024-01/appendix_p_-_collaborative_research_with_ceding_form%20v5%201-12-2024.docx) to your IRBNet package submission

If **NO, DU is unable able to execute a reliance agreement with another institution or organization that does not maintain a Federalwide Assurance (FWA).** Proceed to **L.2.**

**NOTE:** The DU IRB will evaluate the ceding request and make a determination whether a reliance agreement can be executed between DU and the other institution or organization.

**L.1.2 Is the external organization or institution that requests a ceding arrangement with DU an international entity?**

Yes  No

If **YES**, **no ceding arrangement may be executed between DU and a foreign country** and each investigator must obtain their own IRB or research ethics committee review.

If **NO**, proceed to **L.1.3**

**L.1.3 Does the external/unaffiliated individual(s) institution or organization have an internal Institutional Review Board (IRB)?**  Yes  No

If **YES**, the external/unaffiliated individual(s) must obtain approval from their own institution’s IRB to allowa formal ceding arrangement to occur between DU and the unaffiliated individual’s own institution.

* If a ceding arrangement is requested to have DU serve as the IRB of Record, [**Appendix P: Request the DU IRB to Serve as the IRB of Record**](https://www.du.edu/sites/default/files/2024-01/appendix_p_-_collaborative_research_with_ceding_form%20v5%201-12-2024.docx) must be completed and attached to the DU IRB application. If the ceding request is approved, the DU IRB will coordinate with the external institution and facilitate the completion of the necessary ceding documents, including the required institutional official signatures on the reliance agreement (e.g., IRB Authorization Agreement (IAA)).

If **NO**, the external/unaffiliated individual(s) individual(s) must be listed in **Section A.3 -** **Table 3.1**. The IRB will need to evaluate whether the individual(s) are qualified to be added as a unaffiliated investigator on the research project. If approved, each external individual must complete the mandatory human subjects protection training for unaffiliated investigators through the DU CITI Program. **COMPLETE SECTION L.2**

## L.2 Adding an Unaffiliated Independent Investigator or Individual

* To add an unaffiliated independent investigator/individual who is **not eligible for ceding**, the [**Individual Investigator Agreement (IIA)**](https://www.du.edu/orsp/media/documents/new_irb_forms/iia_agreement_form.docx) and the[**APPENDIX R: Adding an Unaffiliated Independent Individual**](https://www.du.edu/sites/default/files/2024-01/appendix_r_-_adding_an_unaffiliated_independent_individual_form%201-24.docx)must be completed and attachedto this IRBNet package for review. All individuals listed in Section A.3, **Table 3.1 – Unaffiliated Investigators/Individuals** must complete the mandatory DU human subjects protection training curriculum created for unaffiliated investigators offered through the DU CITI Program.

## L.3 Collaborative Research with an external Organization/school/institution

**L.3..1** **Will any recruitment or research interventions occur at any off-campus site or sites?**

Yes  No

If **YES**, provide a complete list of the external organizations, schools, or institutions that will be involved in the recruitment or participating in any of the research interventions and attach a letter of support as part of your IRBNet package.

Click here to enter text

If research is conducted at an off campus site (i.e., community center, school, etc.) or is recruiting potential study participants from that site (i.e., employees, students, etc.), a signed **letter of support** must be obtained from the external site confirming their support of the proposed research and their approval to have the research be conducted at their site. Post the letters of support from all off-campus sites in the IRBNet project submission. Letters of support must be obtained and reviewed before final IRB approval will be issued.

## FINAL INSTRUCTIONS

Before submitting your IRBNet Application, please make sure that the PI has electronically signed the package. If the PI is a student, then the PI and Faculty Sponsor must electronically sign the package.

Research staff may not sign on behalf of the PI or Faculty Sponsor.