APPENDIX o

# SECONDARY DATA USE FORM

Complete this form if research involves use of existing data or data being collected for non-research purposes.

Use this form if your study is limited to analysis of existing data, documents, records, or specimens.

**NOTE:**

* Please make sure that the information provided on this form is consistent with the information included on [Human Subject Application – Part 1](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_part_one.docx), which you must also complete as part of your IRBNet submission.

## 1. RESEARCH PURPOSE

1.1. Briefly explain the purpose of research, the research questions, and the potential value.

Click here to enter text.

1.2. What are the study aim(s) question(s) or hypotheses this activity is designed to answer.

Click here to enter text.

## 2. RESEARCH PROCEDURES INVOLVED IN THE SECONDARY DATA ANALYSIS

2.1. Provide a complete description of your study design and all the study procedures that you will perform.

 For example:

* How will data be obtained?
* Are the data identifiable?
* Will any member of the study team have access to the code that links identifiers to subjects?
* Did subjects provide consent for original data?
* If a HIPAA waiver is needed to access existing private data, make this clear.

Click here to enter text.

## 3. EXISTING DATASET

3.1. Are the data existing at the current time?

[ ]  Yes

[ ]  No

Who/what is the source from which the data set will be obtained?

(Data should not be obtained prior to IRB approval or exemption)

Click here to enter text.

3.2. Describe the process for gaining permission to use the data set, including any requirements, agreements, or credentials necessary to access the data. Attach a letter of cooperation or agreement for the data access.

Click here to enter text.

3.3. Does the original file contain direct or indirect personal identifiers?

[ ]  Yes

[ ]  No

**Direct personal identifiers** include information such as: name, address, telephone number, social security number, identification number, medical record number, license number, photographs, biometric information, etc.

[ ]  Yes

[ ]  No

**Indirect personal identifiers** include information such as: race, gender, age, zip code, IP address, major, etc.

[ ]  Yes

[ ]  No

3.4. If you answered ‘YES’ to either in 3.3., please respond to the following:

1. Please list the personal identifiers (direct and indirect) that will be included in the data set:

Click here to enter text.

1. Will you remove the identifiers from the data set or otherwise maintain and analyze the data in such a manner that individuals cannot be identified either directly or indirectly through identifiers linked to participants? (A de-identified data set refers to original data that has been stripped of all elements that might enable a reasonably informed and determined person to deduce the identity of the participant.)

[ ]  Yes

[ ]  No

 If answered ‘NO’, please provide brief justification:

Click here to enter text.

3.5. Please clarify the following regarding the consent process (Choose 1 below):

[ ]  Consent for use of the data for this purpose was obtained at the time of the data were originally collected. Attach the original consent document.

[ ]  Consent will be obtained from each participant group.

If you plan to obtain consent from the participants, you must complete and attach either the informed consent form (using the DU IRB Template online) or the exempt information sheet (if research is exempt).

[ ]  Waiver of consent is requested.

Please complete the [Appendix A](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-appendix_a.docx). Be sure to select the option for a “Waiver or Alteration of Consent” and to provide sufficient justification in each of the boxes provided.

Please describe briefly how consent will be obtained, or if applicable, why consent will not be obtained.

Click here to enter text.

3.6. Explain how researchers will maintain confidentiality of the data.

Describe how researchers will protect data against disclosure to the public or to other researchers or non-researchers. Other than members of the research team, explain who will have access to the data (e.g., sponsors, advisors, government agencies), and how long identifiable data will be kept.

Click here to enter text.

3.7. Do you anticipate using these data for other studies in the future?

[ ]  Yes

[ ]  No

If answered ‘YES’ please explain.

Click here to enter text.