**Colorado College IRB Secondary Research Exemption Determination Form**

**[45 CFR 46.104(d)(4)]**

The federal government defines secondary research as “research [using] identifiable private information or identifiable biospecimens” in which the information or biospecimens in question were initially collected for a different research study or for a non-research activity such as an institutional improvement project. (Information or biospecimens collected specifically for the research project at hand are not considered “secondary use;” also note that use of de-identified private information or biospecimens for secondary research is not considered research by the federal government’s definition and so is not regulated by the IRB. No IRB contact is required for such research.)

A secondary research exemption is available when the research meets one or both of the following criteria:

* The identifiable private information or identifiable biospecimens are publicly available
* Identifiable information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained directly or through identifiers linked to the participants. (Note that the researcher may know the identity of participants as long as the information recorded does not provide any way to identify the participants and as long as no others involved in the research know the identities.)

In the second of the above two cases, the following criteria also hold:

* The investigator does not contact the participants.
* The investigator will not re-identify participants.

The secondary research exemption does not require consent of participants whose information or biospecimens are used, and as noted above, contacting any of the participants would void the criteria for the exemption.

Finally, this exemption may hold for “prospective information” as well as currently existing information.

To have your secondary research considered for exempt status, please complete the following form.

1. SAVE this blank form onto your computer.

2. COMPLETE the following form. Since this is a Word document, you can add additional lines as necessary to provide the required information.

3. EMAIL the completed form as an attachment to: [audiskessler@coloradocollege.edu](mailto:audiskessler@coloradocollege.edu) (Amanda Udis-Kessler, IRB Chair).

1. Provide a brief description of your secondary research in one to two paragraphs, including the nature of the project, the source of the information or biospecimens, and key variables with which you will be working.

2. Is the private information or are the biospecimens with which you are working identifiable?

\_\_ Yes \_\_\_ No

If you answered no, your project is not research as defined by the federal government and you do not need to interact with the IRB.

3. Is the identifiable private information or are the identifiable biospecimens with which you are working publicly available?

\_\_ Yes \_\_\_ No

If you answered yes, you are eligible for the exemption and do not need to continue filling out the form. If you answered no, you may still be eligible for the exemption. Please fill out the rest of the form.

4. Are you able to record the information (including information about biospecimens if relevant) in such a way that the identity of the participants cannot readily be ascertained directly or through identifiers linked to the participants?

\_\_ Yes \_\_\_ No \_\_\_ Unsure

If you answered no or unsure, you are not eligible for this exemption. If you answered yes, please answer the remaining questions.

5. Can you guarantee that you will not contact the participants whose information or biospecimens you are using?

\_\_ Yes \_\_\_ No \_\_\_ Unsure

If you answered no or unsure, you are not eligible for this exemption. If you answered yes, please answer the final question.

6. Can you guarantee that you will not re-identify participants?

\_\_ Yes \_\_\_ No \_\_\_ Unsure

If you answered no or unsure, you are not eligible for this exemption. If you answered yes, you are eligible for the exemption.

Please contact Amanda Udis-Kessler ([audiskessler@coloradocollege.edu](mailto:audiskessler@coloradocollege.edu)) with questions.