**Exempt Category 4
SECONDARY RESEARCH FOR WHICH
CONSENT IS NOT REQUIRED**

|  |
| --- |
| * 1. Does the research involve secondary research use of identifiable private information or identifiable biospecimens?
 |
| [ ]  Yes | Describe the source of the information and/or biospecimens:      |
|  |  |
|  | Is an agreement required to access the information and/or biospecimens (i.e., data use agreement, materials transfer agreement, contract, etc.):  |
|  | [ ]  Yes | Explain:      |
|  |  |  |
|  | [ ]  No |
| [ ]  No | This research is not exempt under this category. |
| * 1. Select any of the following criteria that is/are applicable to this research:
 |
| [ ]  | The identifiable private information or identifiable biospecimens are publicly available. |
|  | Describe how these are *publicly available*:       |
| [ ]  | The information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator will not contact the subjects, and the investigator will not re-identify subjects. |
|  | Describe how these are *recorded*:       |
| [ ]  | The research involves ONLY information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b).  |
| **—AND/OR—** |
| [ ]  | The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. |
| [ ]  | None of the above statements applies. |
| * If you answered ‘yes’ to Questions 1 and were able to select an applicable statement for Question 2, your project likely qualifies for exemption:
	+ Complete any additional category worksheets applicable to your research;
	+ Proceed with completing Parts III-VI of the Exempt Application Form;
	+ Submit the items noted in the Submission Checklist at the end of the form to Research Compliance Services (RCS). RCS will review and verify the exempt determination;
	+ If RCS determines the study does not qualify for exemption, you will need to prepare and submit a protocol using the Initial Review Application.
* If you answered ‘No’ to Question 1 and/or were unable to select an applicable statement for Question 2, this research is not exempt under this category. Return to the screening form to identify alternative categories for exemption. If you conclude that no categories are applicable to your research, your study is not eligible for exemption. Proceed with preparing an Initial Review Application.
 |