

Exemption Category 4

Secondary research for which consent is not required. Secondary research uses of identifiable private information and identifiable biospecimens if at least one of the following criteria is met:

Publicly Available	Identifiers Removed/No Linkage/No Contact
(i) The identifiable private information or identifiable biospecimens are publicly available	(ii) 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 does not contact the subjects, and the Investigator will not re-identify the subjects
HIPAA Regulated	Federal agency directed/Federal privacy protections
(iii) 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" or "public health activities and purposes"	(iv) The research is conducted by or on behalf of a Federal department or agency using government-collected information obtained for non-research activities, if the research generates identifiable private information it is or will be maintained on information technology that is subject to specific Federal privacy protections
Studies <i>not</i> eligible for Exempt #4 include:	Additional definitions/notes:
<ul style="list-style-type: none"> ◆ Primary data collection, whether information or biospecimens. ◆ Contact with participants. ◆ Maintaining a linking ID/code that allows participants to be identified/re-identified. ◆ Using data sets that are only available with conditions. ◆ Research utilizing multiple datasets is not generally eligible for Exemption 4, since the researchers maintain identifiers temporarily to collate the data. 	<ul style="list-style-type: none"> ◆ HIPAA regulations still apply; including authorization or waiver of authorization. ◆ HIPAA does not apply to biospecimens. This category applies only to secondary use of identifiable private health information. ◆ Student records covered by the Family Educational Rights and Privacy Act (FERPA) are not publicly available. FERPA requires written permission from students unless certain exceptions are applicable.
Examples: May be eligible for Exempt #2:	Examples: May <i>not</i> be eligible for Exempt #2:
<ul style="list-style-type: none"> ◆ Researcher has access to identifiable medical chart data, and extracts information without identifiers and does not assign a study ID/code that can be used to link the data back to the individual subjects. 	<ul style="list-style-type: none"> ◆ Researcher has access to identifiable medical chart data, and extracts information without identifiers but does assign a study ID/code that can be used to link the data back to the individual subjects.