Understanding the common rule

Exempt Category 4

See Introduction to Exempt and Exempt and Vulnerable Populations for Additional Details

Exempt Category 4 (to be effective January 21, 2019)	The New Rule makes a lot of changes to the exempt categories. This document discusses the change to exempt category 4. **What is the current Exempt Category 4?** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **What are the key changes?** • This category will allow secondary uses of information and biospecimens that are not pre-existing at the time that the investigator begins a particular research study. • Recording of identifiers will now be allowed if certain requirements are met. **Why was it changed?** As an example, medical records are already protected by HIPAA. The HIPAA standards, correctly applied, minimize the risk of loss of confidentiality. **What is the New Rule Exempt Category 4?** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: 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 subjects; 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 [HIPAA], 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); or iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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. Some caveats: - HIPAA applies! The IRB would still be acting as the Privacy Board.
Implications for Researchers:	• HIPAA would still apply to certain studies, as before, and it is likely that studies using the new pathway would still require a HIPAA waiver. • There are likely to be some complicating issues, such as consideration of covered entities. • The IRB is working with the ETSU HIPAA Compliance Officer to establish guidance about this category.
Examples:	1. An investigator wants to look at medical records, and then call the participants for a follow-up survey. Would that be covered by this exemption? Answer: No, this category only allows secondary research.