Converting expedited category 5 (1998) to the 2018 Common Rule Exempt category 4 (i-iv)

**START**

Was the study originally approved under expedited cat 5?

**NO**

STOP

**YES**

*HIPAA Rules apply and study must meet the requirements for HIPAA waiver.*

Does the study as approved contain at least one of the following elements

YES

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.

**AND/OR**

Data is from a federal department or agency collected for non research purposes?

**YES**

Qualifies as exempt under Category 4. Close study with the IRB per local procedures.

**AND/OR**

Identified data/specimens to be deidentified?

**YES**

Qualifies as exempt under Category 4. Close study with the IRB per local procedures.

**AND/OR**

The data/specimens are publicly available?

**YES**

Qualifies as exempt under Category 4. Close study with the IRB per local procedures.

**AND/OR**

The data/specimens are federally controlled?

**YES**

Qualifies as exempt under Category 4. Close study with the IRB per local procedures.

**STOP. Cannot be converted to Exempt Category 4.**

**WHAT IS NEW IS THAT THE USE OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS IS EXEMPT FROM IRB OVERSIGHT IN CERTAIN CASES. HIPAA AUTHORIZATION OR WAIVER IS STILL REQUIRED.**

Deidentified: The information is recorded in a way that there is no possible way to link the data to the subjects’ identities, the researcher does not have any contact with the subjects, and will not re-identify the data; HIPAA authorization or waiver is still required.

**V4 22 Jul 2018 mmk**