2018 Exempt Category 4:
Secondary Use of Identifiable Data or Specimens
After 21 Jan 2019

What is new is that the private information and/or biospecimens can be identifiable and can be prospectively collected. HIPAA authorization or waiver is still required.

START

**YES**

The data/specimens are publicly available?

**YES 4(i)**

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;

Qualifies as exempt under Category 4.

**YES 4(ii)**

Identified data or specimens to be deidentified?

**YES 4(iii)**

All study data and use is covered by HIPAA*?

**YES 4(iv)**

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

**YES 4(v)**

Does not meet exempt Cat 4

**NO**

Study meets the definition of research?

**NO**

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

NO