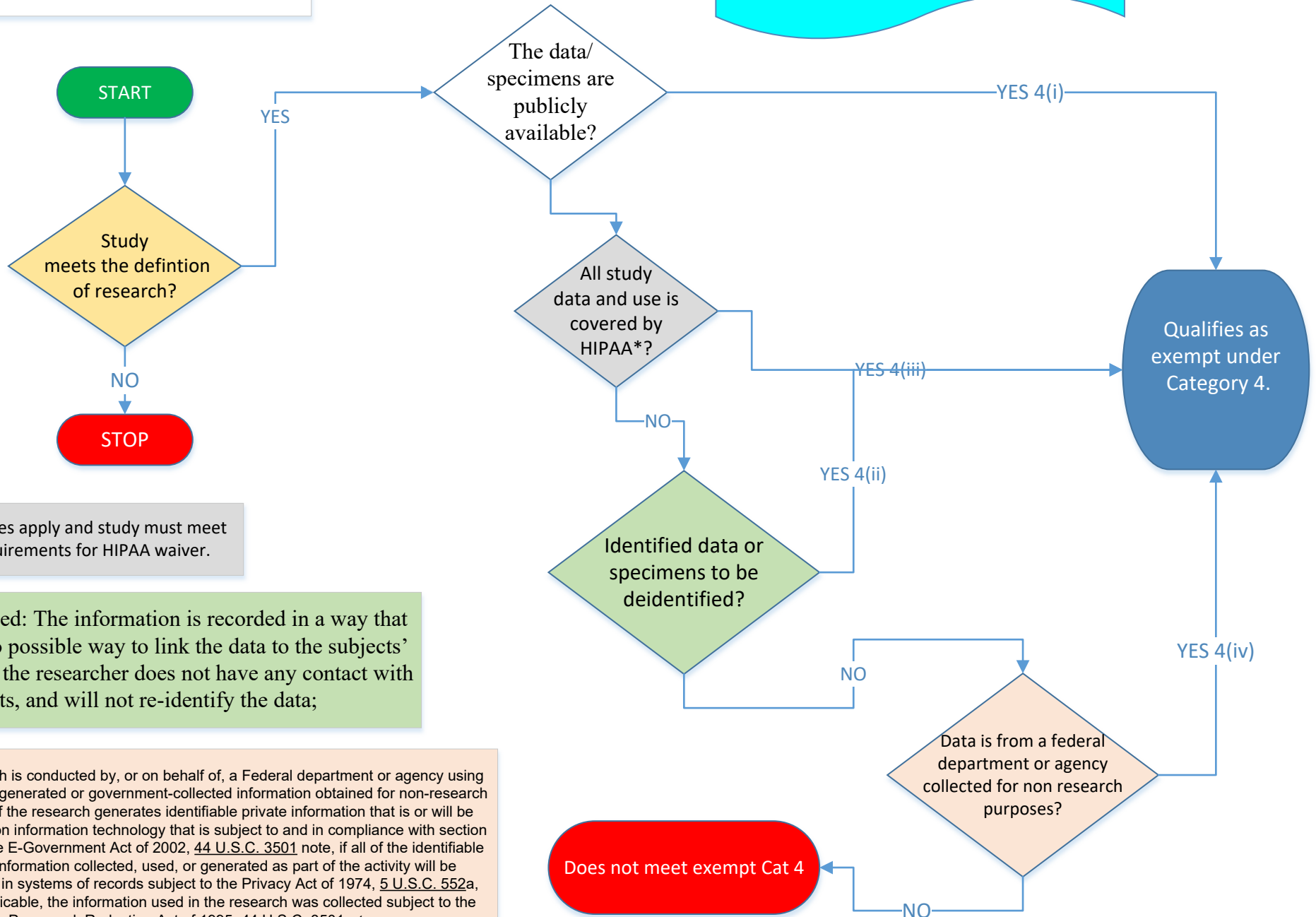


2018 Exempt Category 4:
Secondary Use of Identifiable Data or
Specimens
After 21 Jan 2019

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.

V3 24 Jul 2018
mmk



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

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;

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.