The 2018 Revised Common Rule:

Breaking down the exempt categories 2 and 4 (45 CFR 46.104)

Exempt Research Category 2
(Educational tests, surveys, interviews, observation of public behavior)

The 2018 changes to the Common Rule provide additional flexibility with regard to the kind of information that can be collected in survey/questionnaire research under exempt review.

NOTE: The only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the Principal Investigators do not participate in the activity being observed.

The regulation:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained 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;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

If this sub-category applies and health information is to be collected, application should include a request for a HIPAA waiver of authorization.

Exempt Research Category 4
(Secondary research)

Perhaps the most impactful procedural change as a result of the Revised Rule relates to secondary research, i.e. retrospective chart review studies. Many of these were previously reviewed as expedited and may now be eligible for exempt review under Category 4.

Two things now allowable under exempt review which were not included previously:

- Recording of HIPAA identifiers or links to identifiers for information collection studies
- Use of not yet existing or not currently "on the shelf" data

Note that secondary use of identifiable biospecimens in which the researcher would like to document/retain a link between the identifiers and the specimen is still not allowed under Category 4 –those must still be reviewed via expedited review.

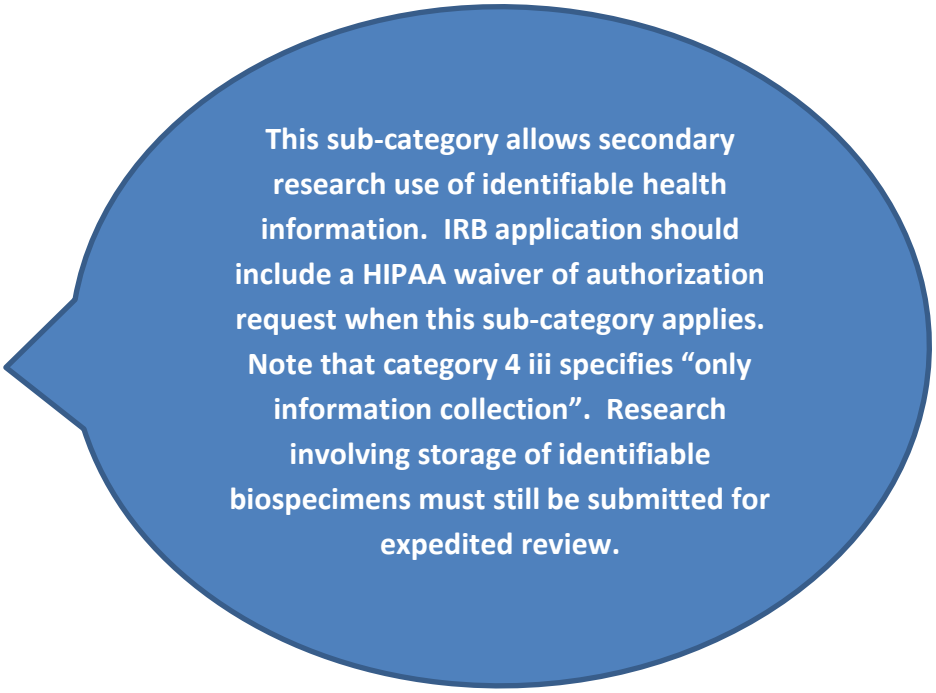
The regulation:

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;

Secondary research under this sub-category must be recorded in a non-identifiable manner.

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, 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.