

An established educational setting may vary based on the type of institution. Your institutional HRPP should be consulted.

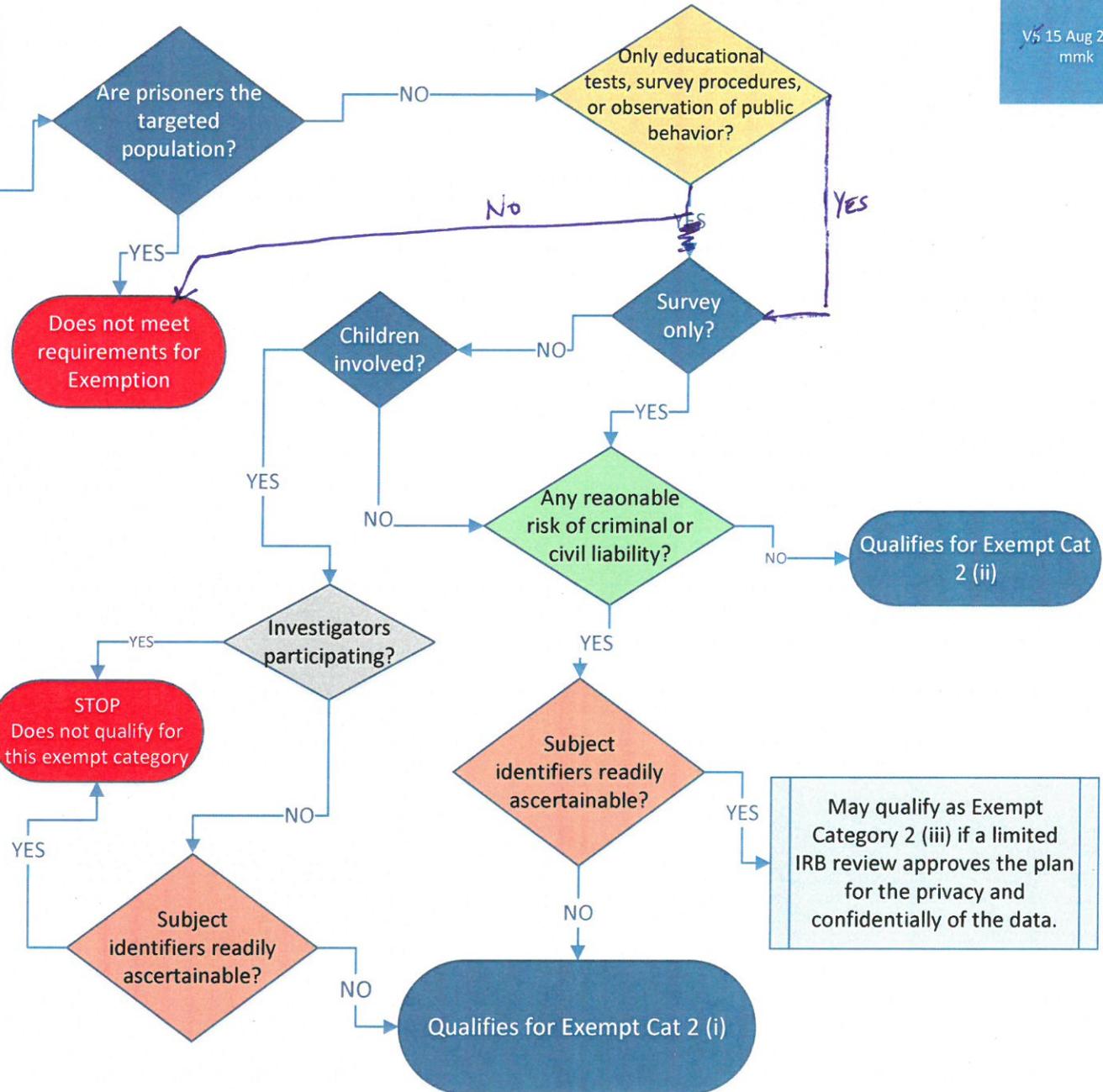
This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, or classroom management methods.

Not likely to impact the student's opportunity to learn required educational content or the assessment of educators who provide instruction.

Vb 20 Dec 18
 VS 15 Aug 2018
 mmk

2018 Exempt Category 2:
 Educational Tests, Surveys,
 Observations of Public Behavior
 Use after 21 Jan 2019

START
 Meets the definition of
 research



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)

Identifiers: 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,

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

The exempt category does not apply if the investigator participates in the activities involved in the educational test or the public behavior being observed

A protocol need only meet ONE of the requirements to meet the exemption.

2018 Exempt Category 3:
Benign Behavioral Interventions
Use after 21 Jan 2019

V3 25 Jul 2018
mmk

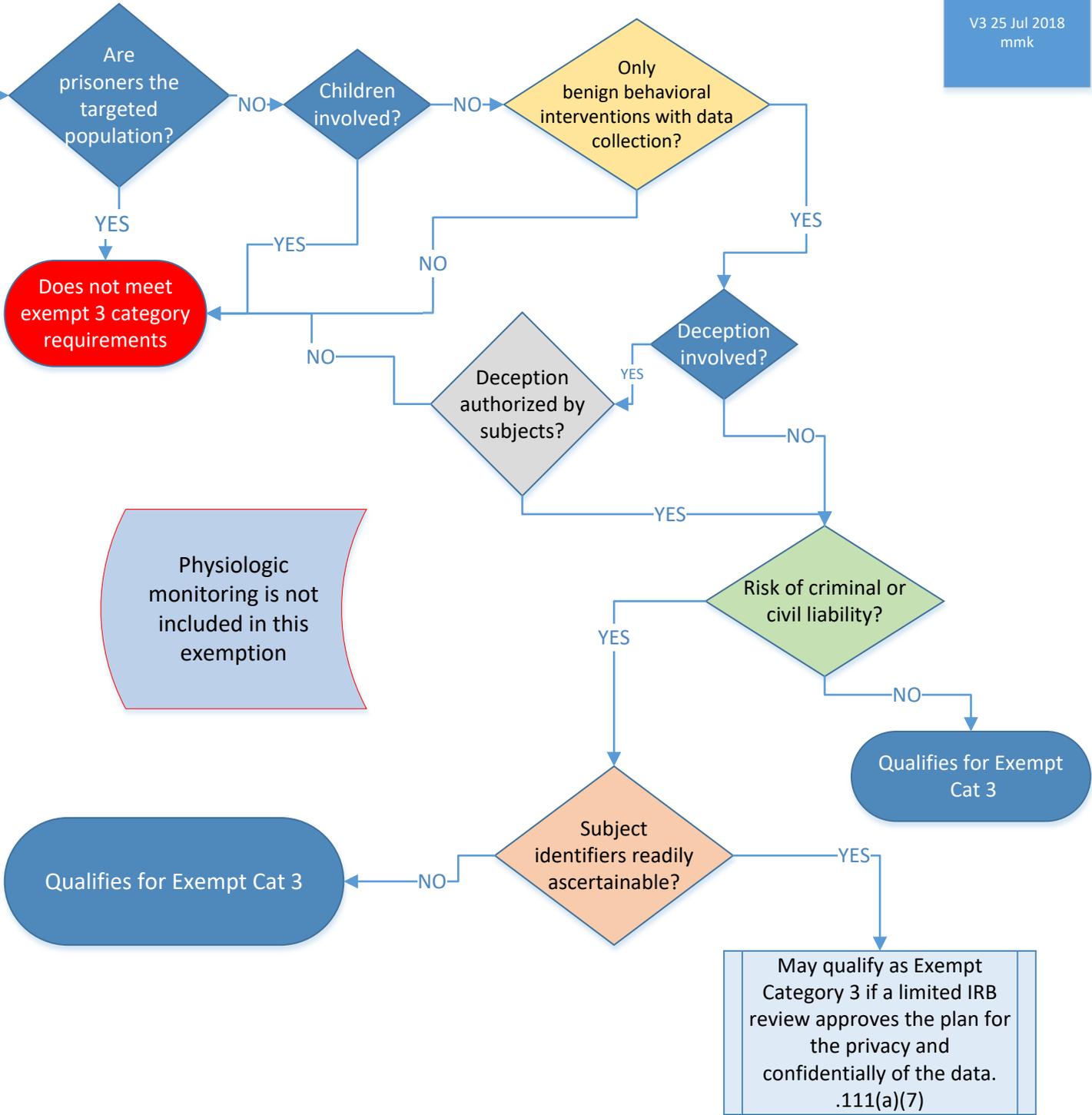
START
Meets the definition of
research

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Identifiers: 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,

104.(d)(2)(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

The subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research



Physiologic
monitoring is not
included in this
exemption

Qualifies for Exempt Cat 3

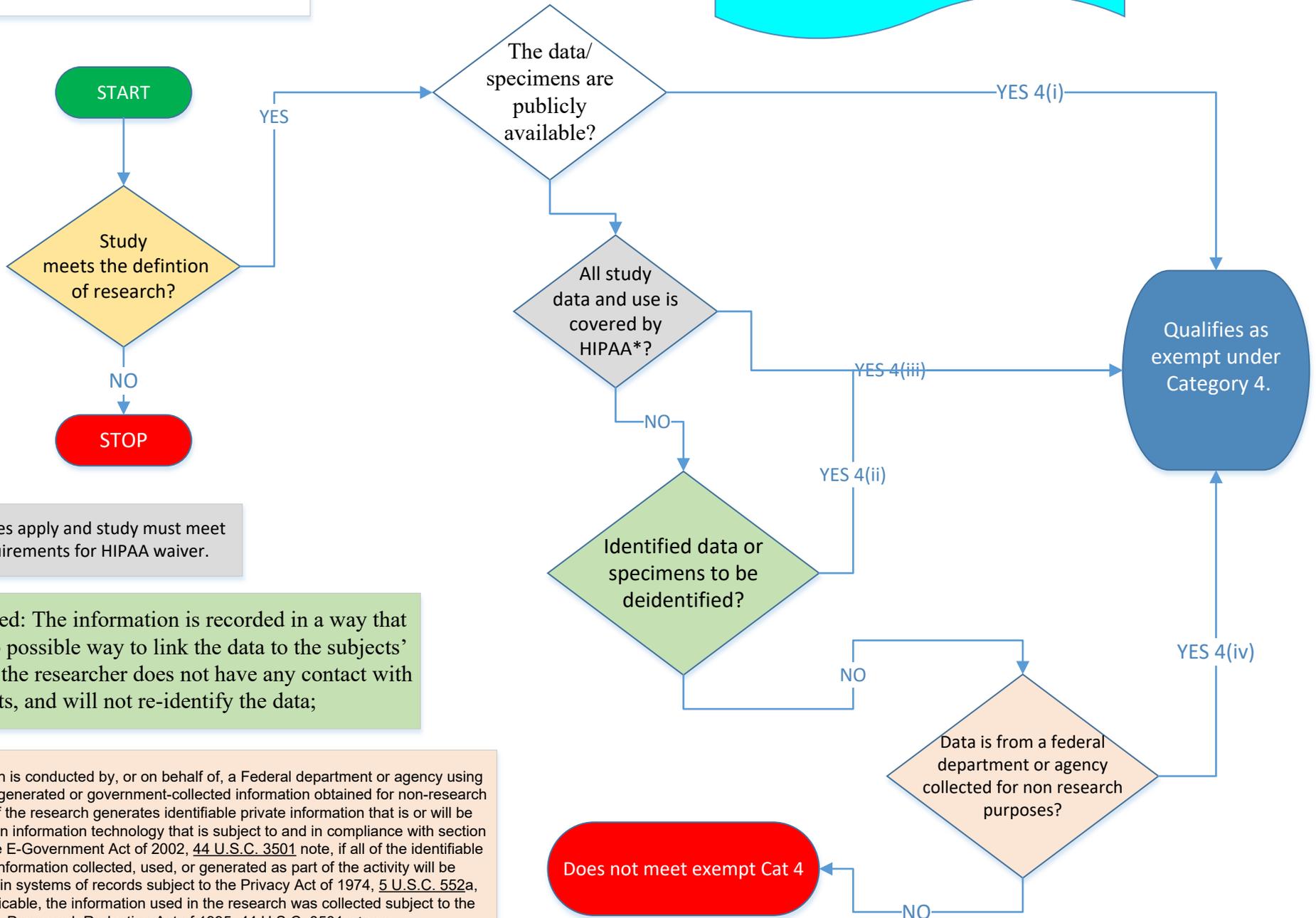
Qualifies for Exempt
Cat 3

May qualify as Exempt
Category 3 if a limited IRB
review approves the plan for
the privacy and
confidentiality of the data.
.111(a)(7)

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.