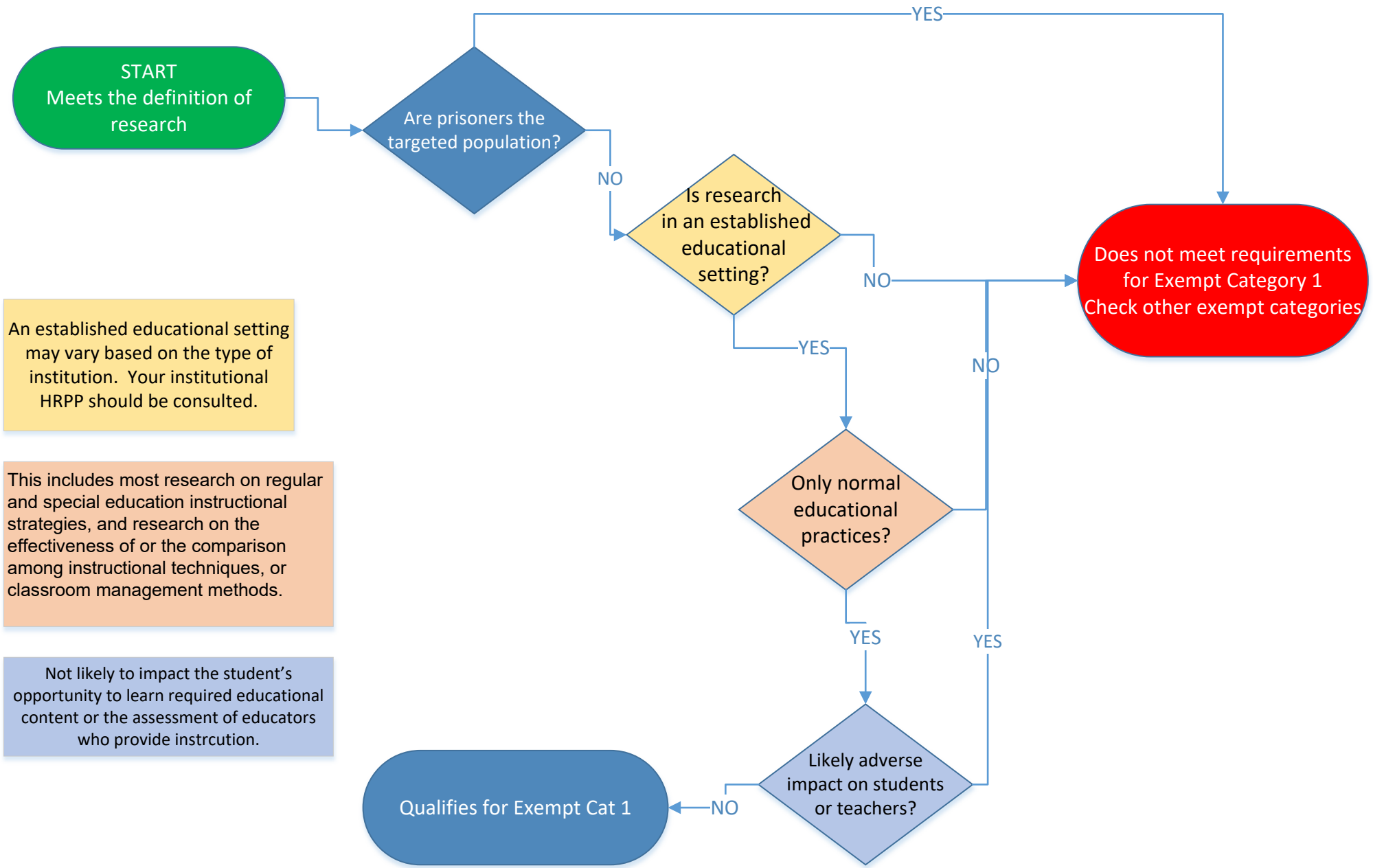
2018 Exempt Category 1
Educational Setting
Use after 21 Jan 2019

V2 25 Jul 2018
mmk



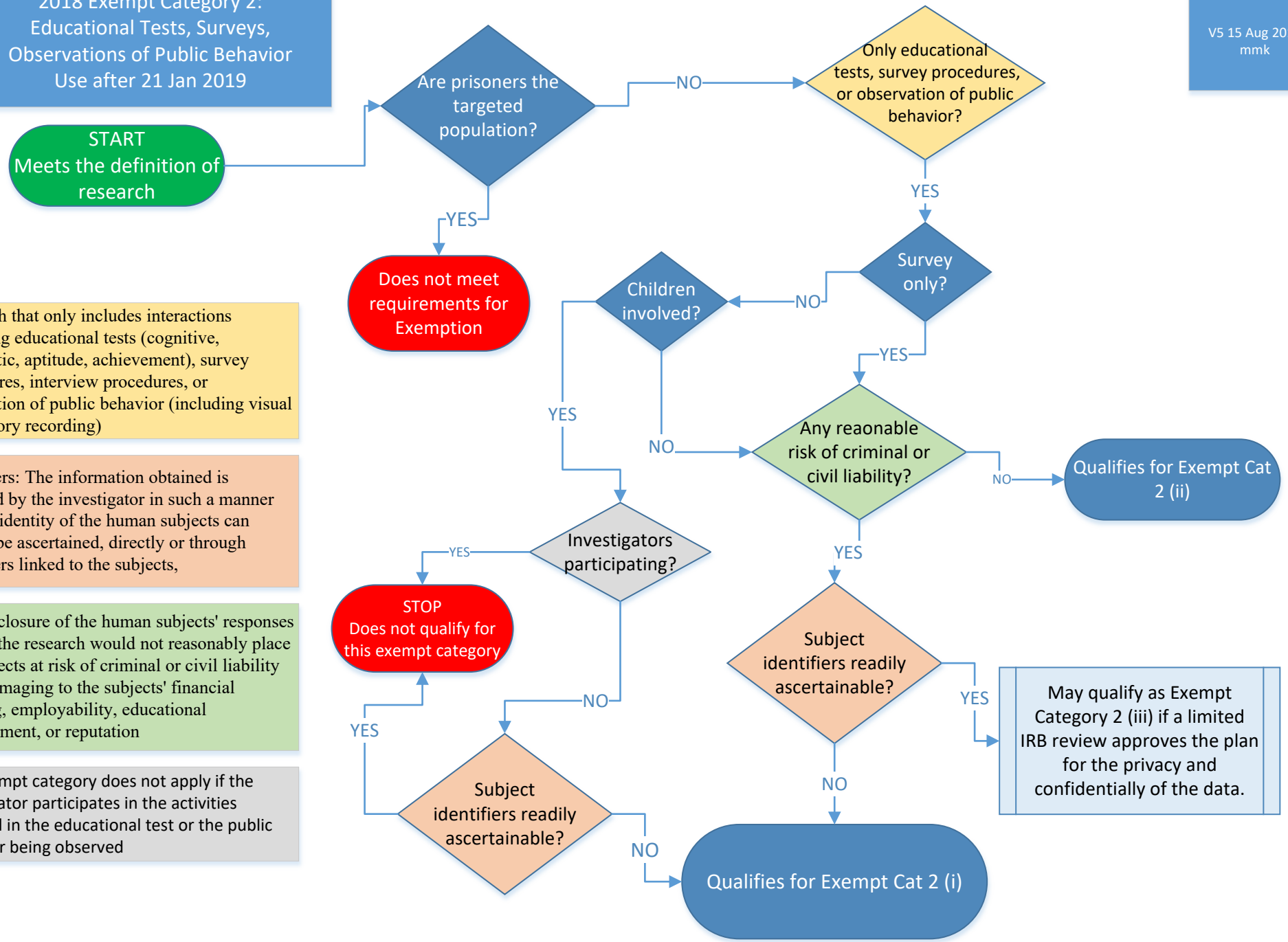
An established educational setting may vary based on the type of institution. Your institutional HRPP should be consulted.

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 instrcution.

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

V5 15 Aug 2018 mmk



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

Are prisoners the targeted population?

NO

Children involved?

NO

Only benign behavioral interventions with data collection?

YES

Does not meet exempt 3 category requirements

YES

NO

NO

Deception involved?

YES

Deception authorized by subjects?

NO

YES

Physiologic monitoring is not included in this exemption

Risk of criminal or civil liability?

YES

NO

Qualifies for Exempt Cat 3

Subject identifiers readily ascertainable?

NO

Qualifies for Exempt Cat 3

YES

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

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

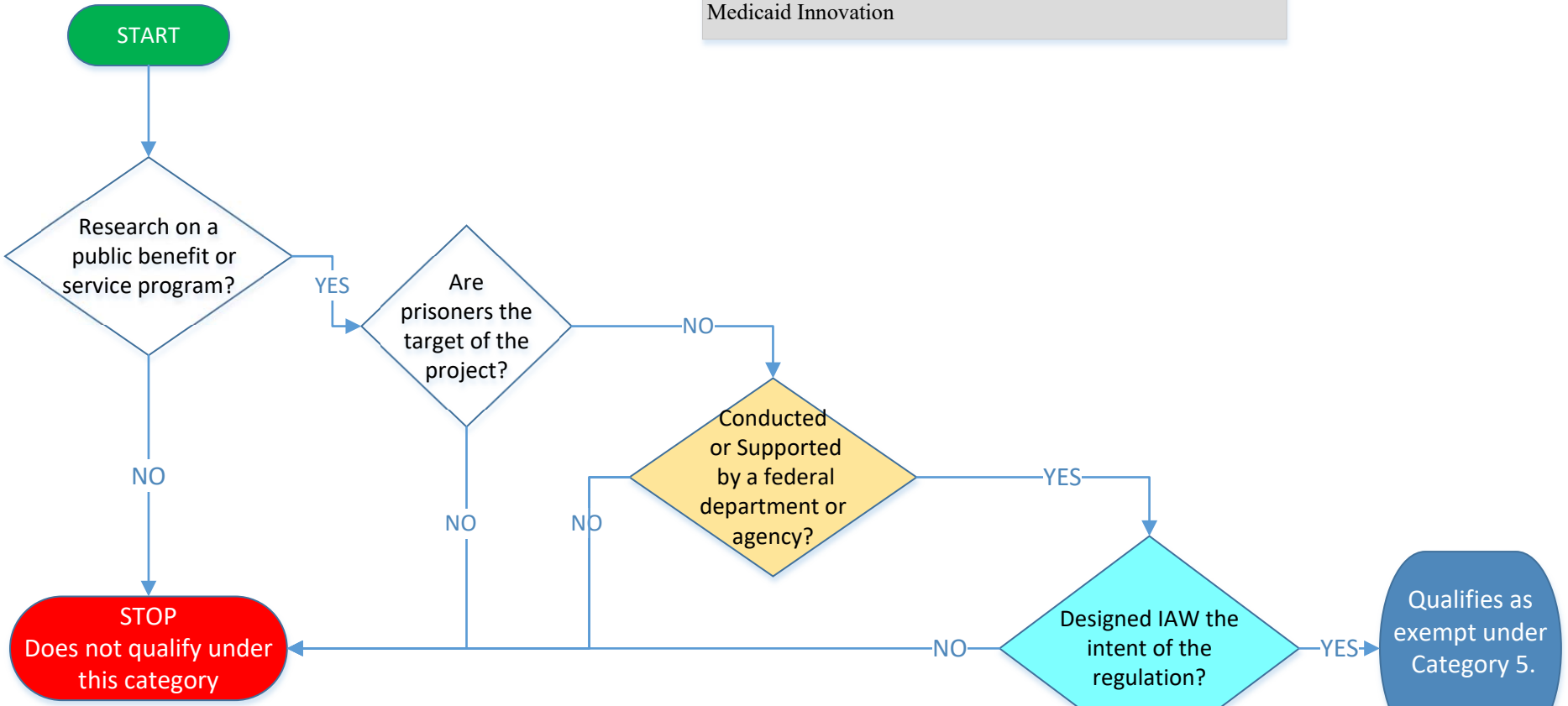
The subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research

2018 Exempt Category 5: Research and Demonstration Projects After 21 Jan 2019

Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve experimental, pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program.

Section 1115a establishes the Center for Medicare and Medicaid Innovation

V2 25 Jul 2018
mmk



HOWEVER

The research or demonstration project must be published on federally accessible website prior to commencing the research involving human subjects.

Designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

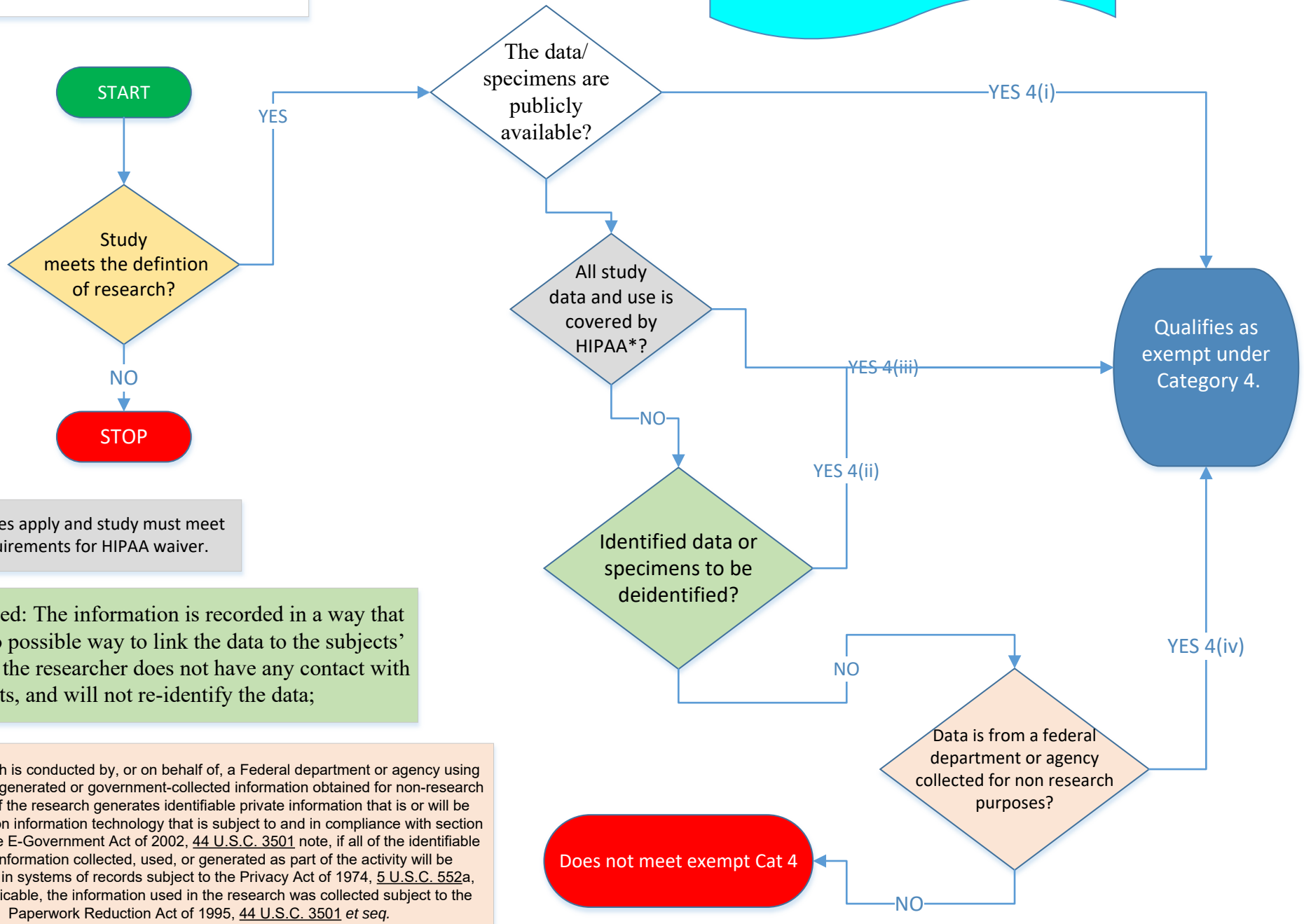
Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

Or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).

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



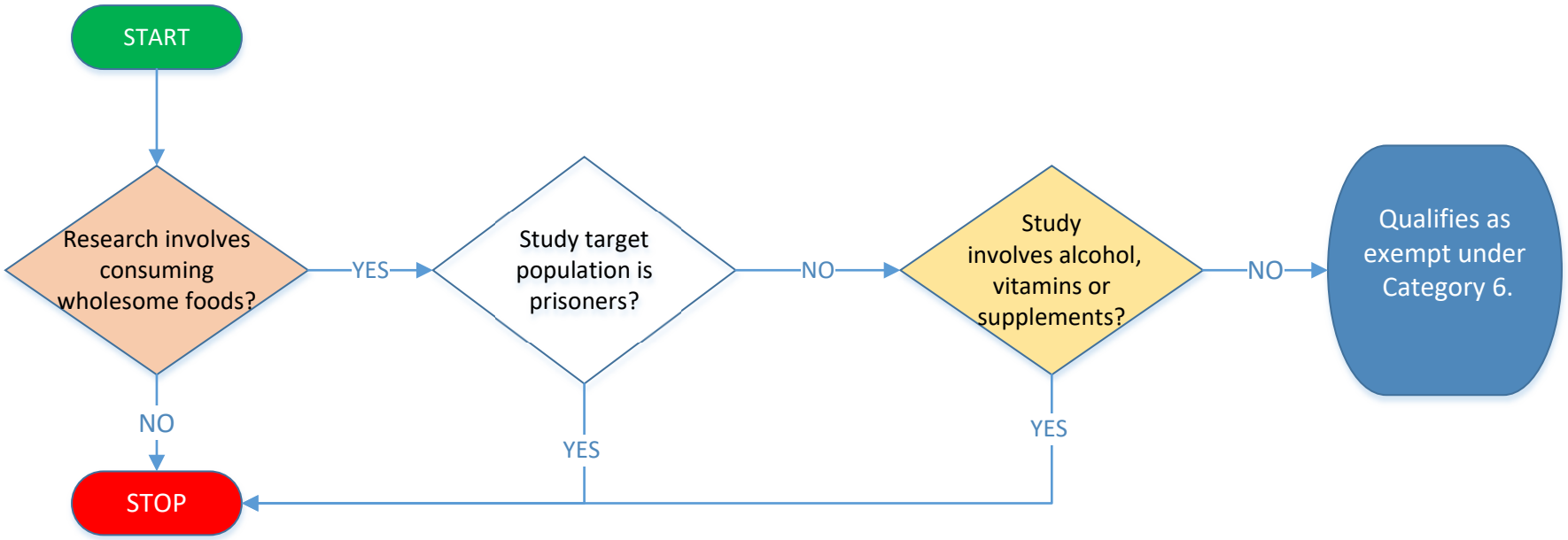
HIPAA Rules apply and study must meet the requirements for HIPAA waiver.

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.*

2018 Exempt Category 6:
Taste and Food Quality
After 21 Jan 2019

V1 25 Jul 2018
mmk

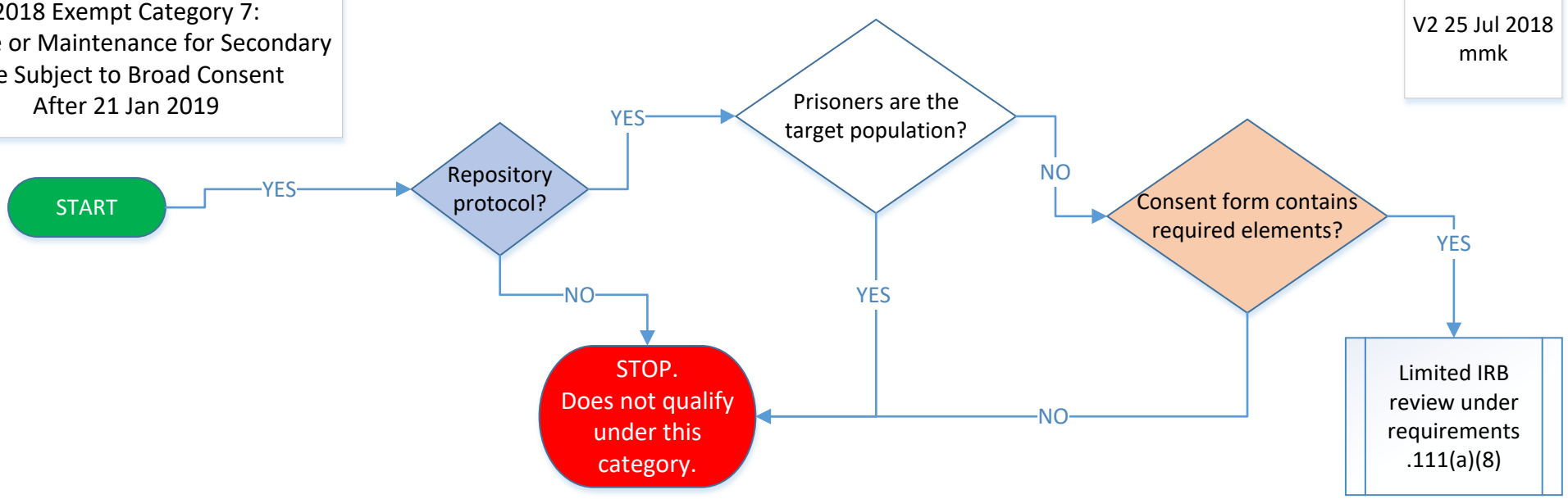


Wholesome foods: The food must be "wholesome" (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA.

Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for exempt status.

2018 Exempt Category 7:
Storage or Maintenance for Secondary Use Subject to Broad Consent After 21 Jan 2019

V2 25 Jul 2018 mmk



Repository activities involve three components: (i) the **collectors** of data/tissue samples; (ii) the **repository** storage and data management center; and (iii) the **recipient** investigators.

Consent required information: (1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section *(see below)*; (2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted; (3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens; (4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite); (5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies; (6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and (7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

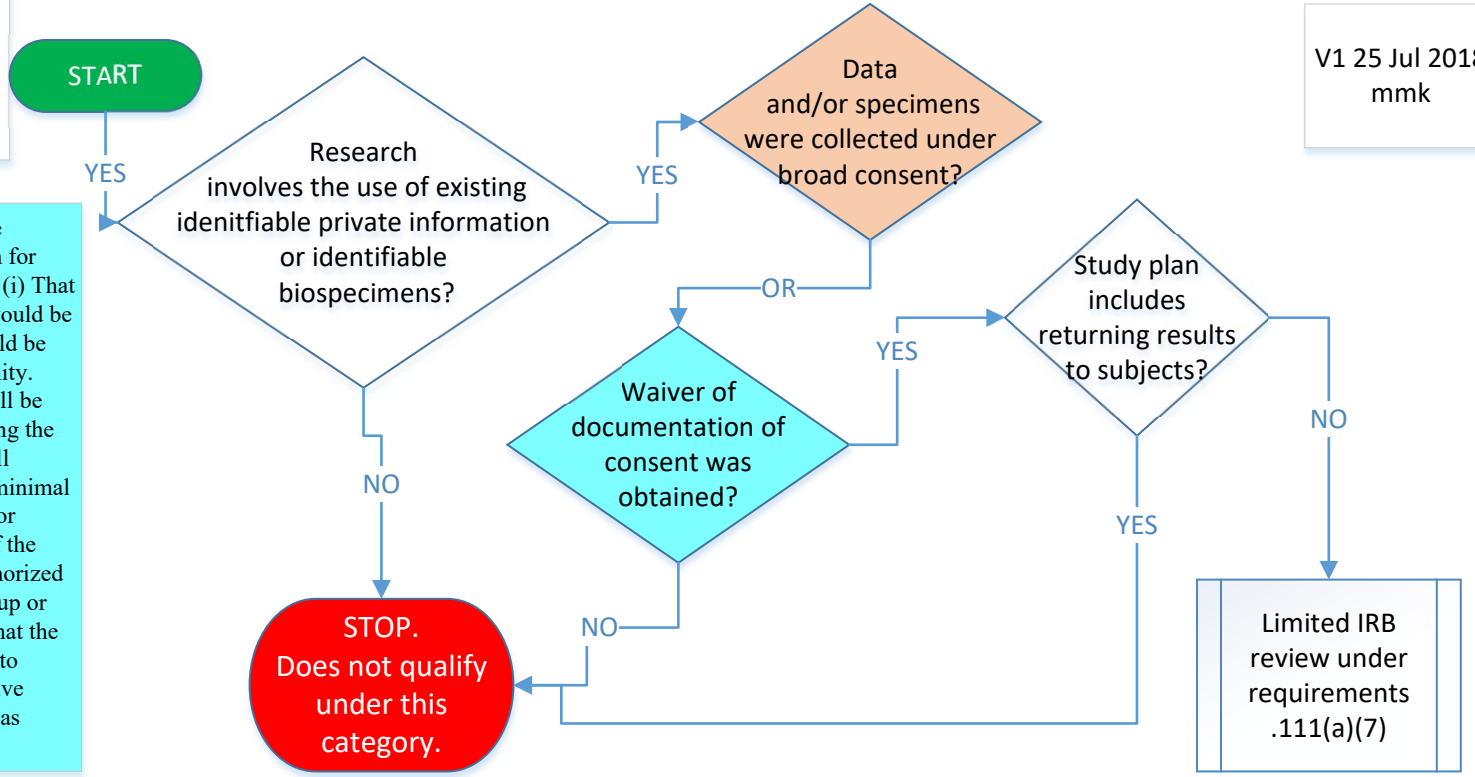
Further required elements of consent: b(2)A description of any reasonably foreseeable risks or discomforts to the subject; b(3) A description of any benefits to the subject or to others that may reasonably be expected from the research; b(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; b(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

As applicable: c(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

2018 Exempt Category 8: Secondary Research Under Broad Consent After 21 Jan 2019

V1 25 Jul 2018 mmk

.117(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds ANY of the following: (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or (iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.



Consent required information: (1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section *(see below)*; (2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted; (3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens; (4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite); (5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies; (6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and (7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Further required elements of consent: b(2)A description of any reasonably foreseeable risks or discomforts to the subject; b(3) A description of any benefits to the subject or to others that may reasonably be expected from the research; b(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; b(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; b(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

As applicable: c(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).