Chart 1

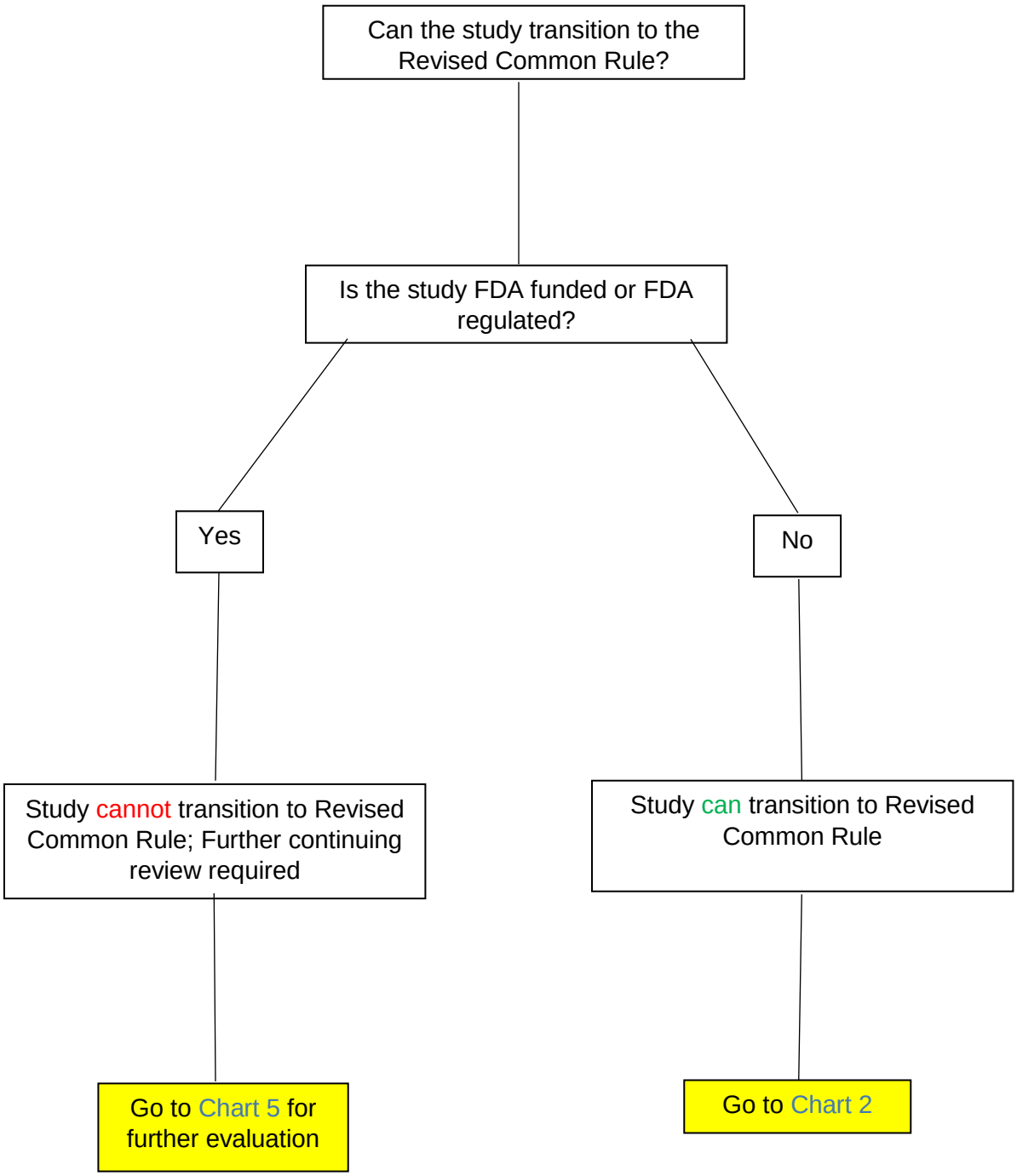

Can the study transition to the Revised Common Rule?
Is the study FDA funded or FDA regulated?
Yes
No
Study cannot transition to Revised Common Rule; Further continuing review required
Study can transition to Revised Common Rule
Go to Chart 5 for further evaluation
Go to Chart 2

Chart 2

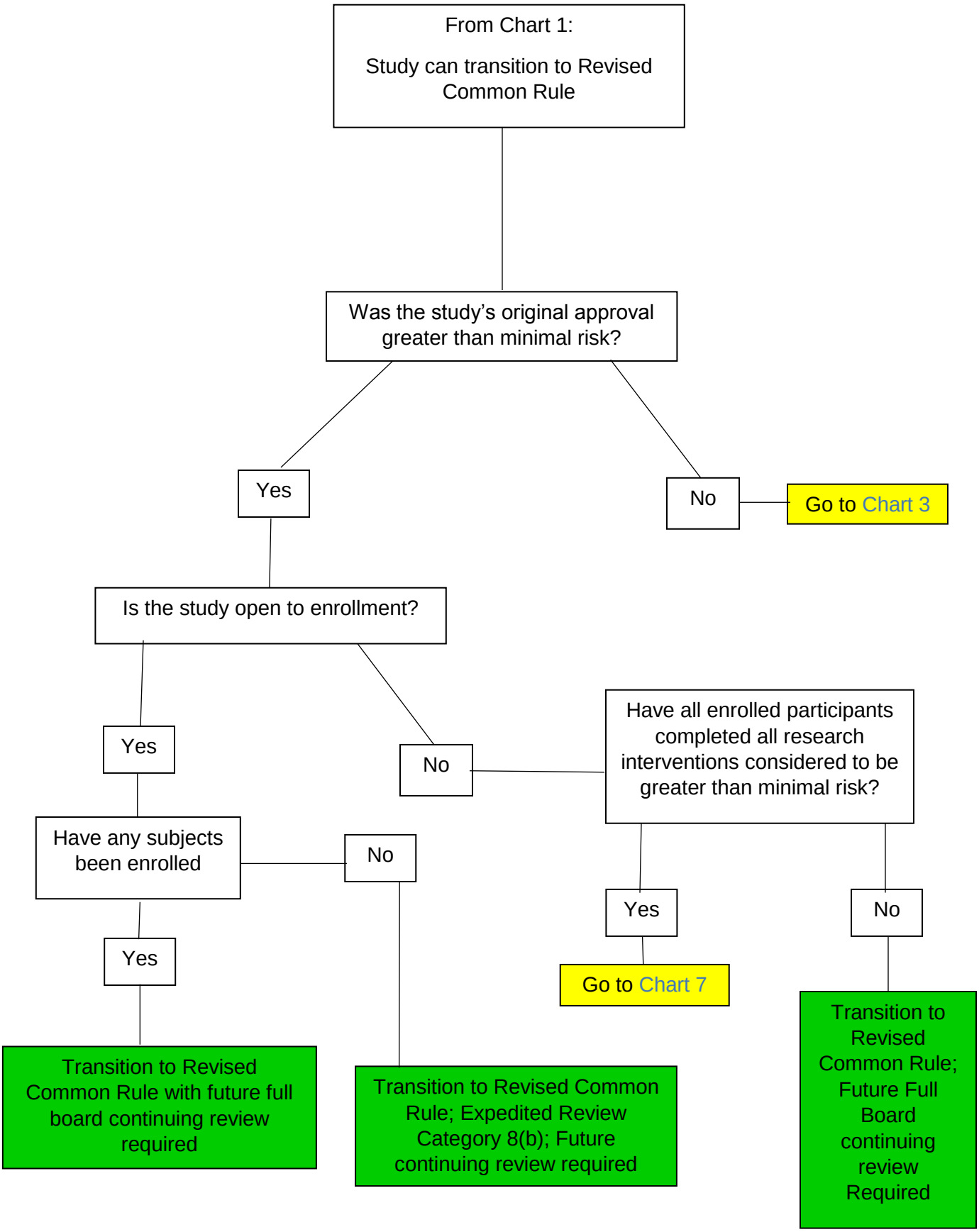

From Chart 1:
Study can transition to Revised Common Rule
Was the study's original approval greater than minimal risk?
Yes
No
Go to Chart 3
Is the study open to enrollment?
Yes
No
Have all enrolled participants completed all research interventions considered to be greater than minimal risk?
Have any subjects been enrolled
No
Yes
Yes
No
Go to Chart 7
Transition to Revised Common Rule with future full board continuing review required
Transition to Revised Common Rule; Expedited Review Category 8(b); Future continuing review required
Transition to Revised Common Rule; Future Full Board continuing review Required

Chart 3

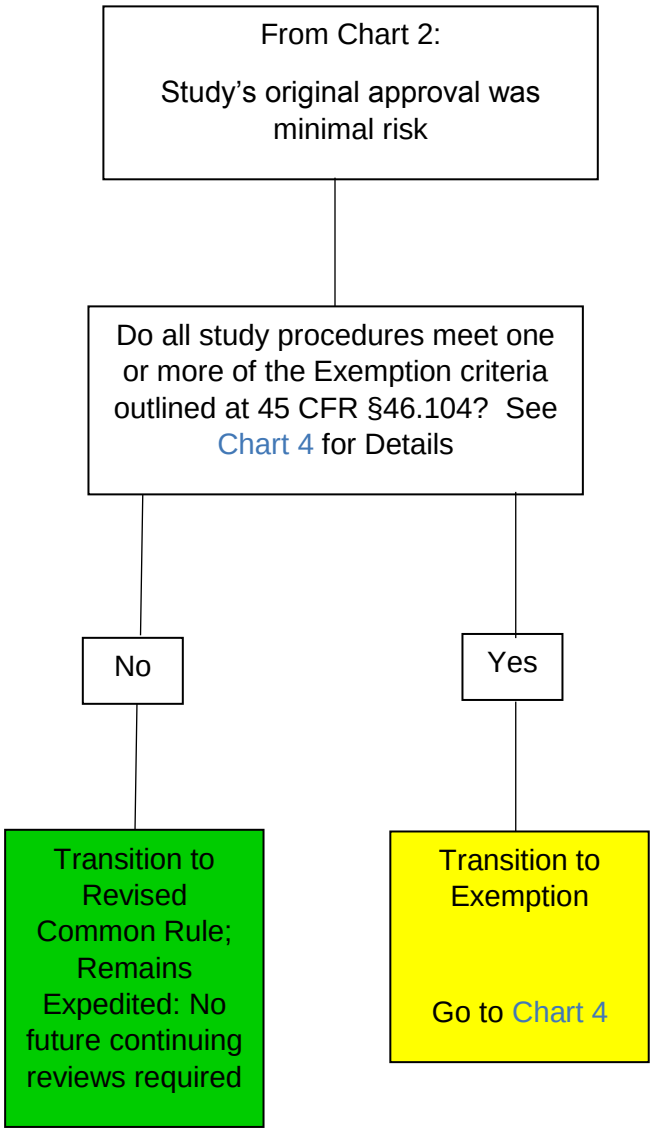

From Chart 2:
Study's original approval was minimal risk
Do all study procedures meet one or more of the Exemption criteria outlined at 45 CFR §46.104? See Chart 4 for Details
No
Yes
Transition to Revised Common Rule; Remains Expedited: No future continuing reviews required
Transition to Exemption
Go to Chart 4

Chart 4

From Chart 3:

Study transition to Exemption

Do all study procedures meet one or more of the following Exemption criteria?

Criteria 1: Educational Strategies, Curricula or Classroom Management in Education Settings

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

AND / OR

Criteria 2: Tests, Surveys, Interviews, Public Behavior Observation

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).

Please Note: Minors may only be included in the research if the research involves educational tests or observation of public behavior when the investigators do not participate in the activates being observed. **Survey research with minors cannot be exempt.**

AND / OR

Chart 4 Continued

Criteria 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses

3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) 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;

(B) 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

(C) 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).

(ii) For the purpose of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless 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.

Please Note: Exemption Criteria 3 only applies to adults

AND / OR

Chart 4 Continued

Criteria 4: Secondary research for which consent is not required

(4) 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;

(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) "HIPAA Exemption" 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 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.*

* Must obtain HIPAA Authorization of must meet criteria for a waiver of HIPAA Authorization

**Criteria iii does not apply if PHI is being disclosed to a non-HIPAA covered entity. Studies disclosing PHI to a non-HIPAA covered entity must be approved under expedited means

AND / OR

Criteria 5: Research and demonstration projects

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, 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), and that are 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. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Chart 4 Continued

AND / OR

Criteria 6: Taste and Food Evaluation and Acceptance Study

6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Yes

Transition to Revised Common Rule under appropriate Exemption Categories

No

Study cannot transition to Exempt under the Revised Common Rule.

Transition to Revised Common Rule; Remains Expedited: No future continuing reviews required

Chart 5

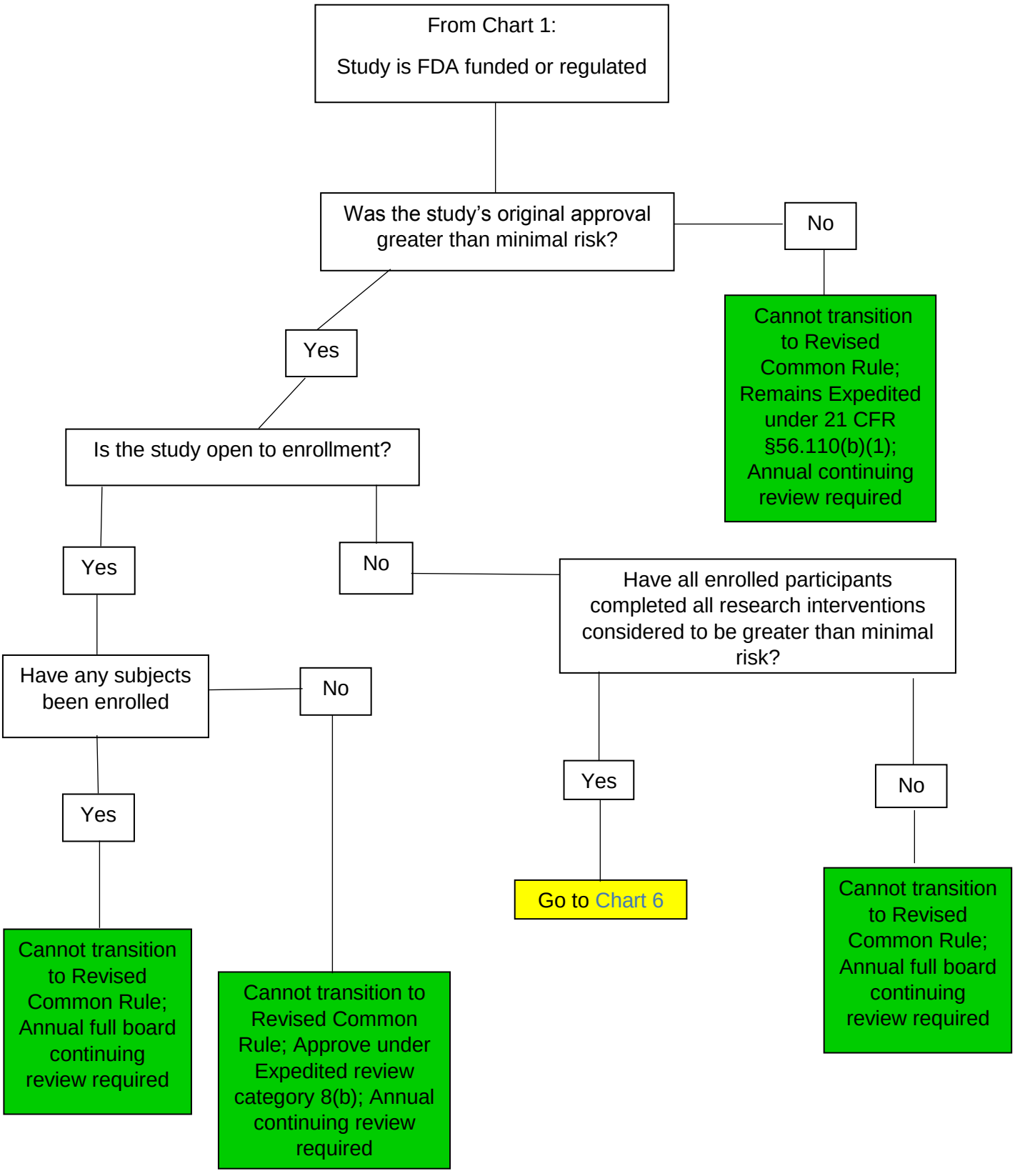
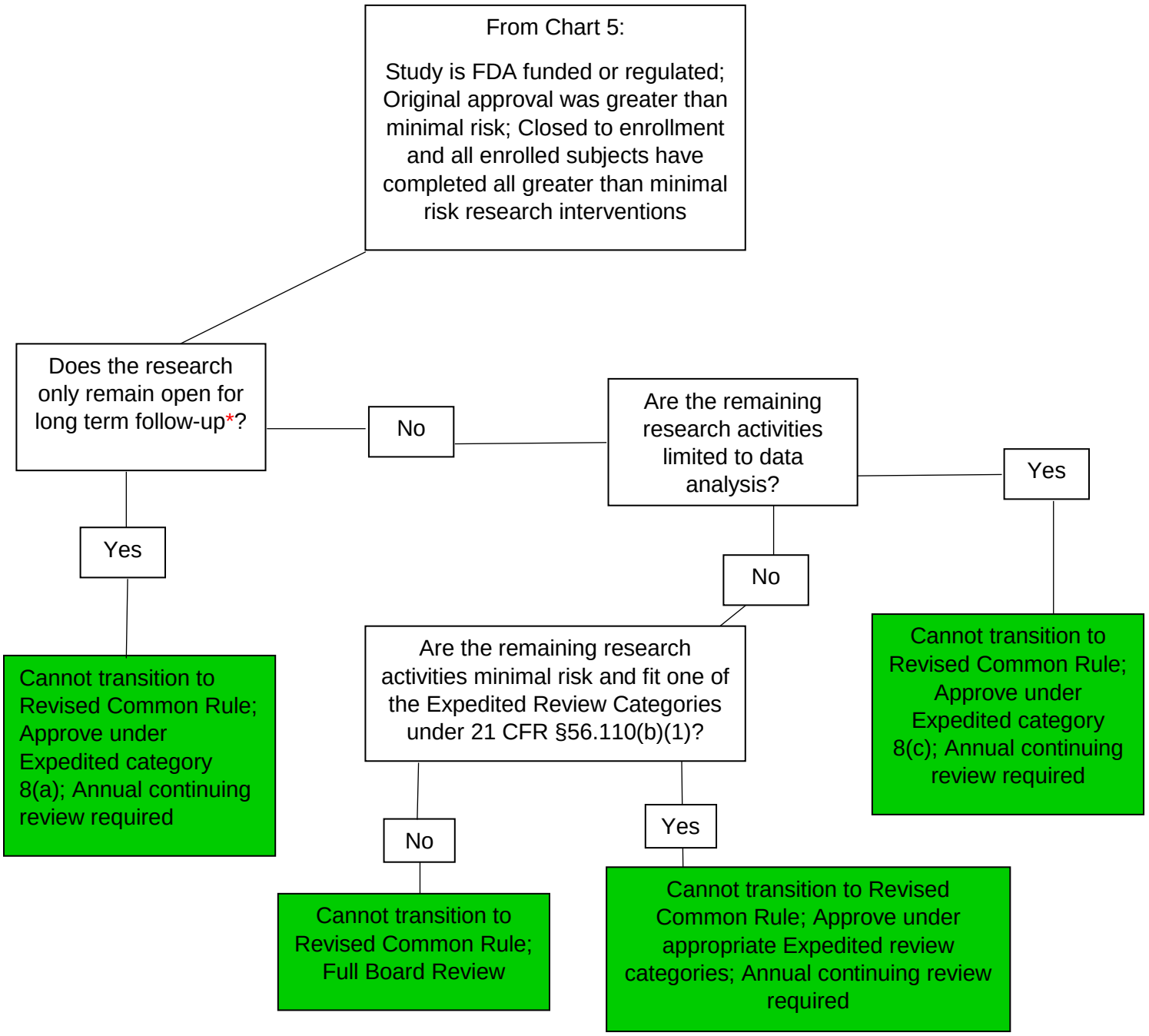
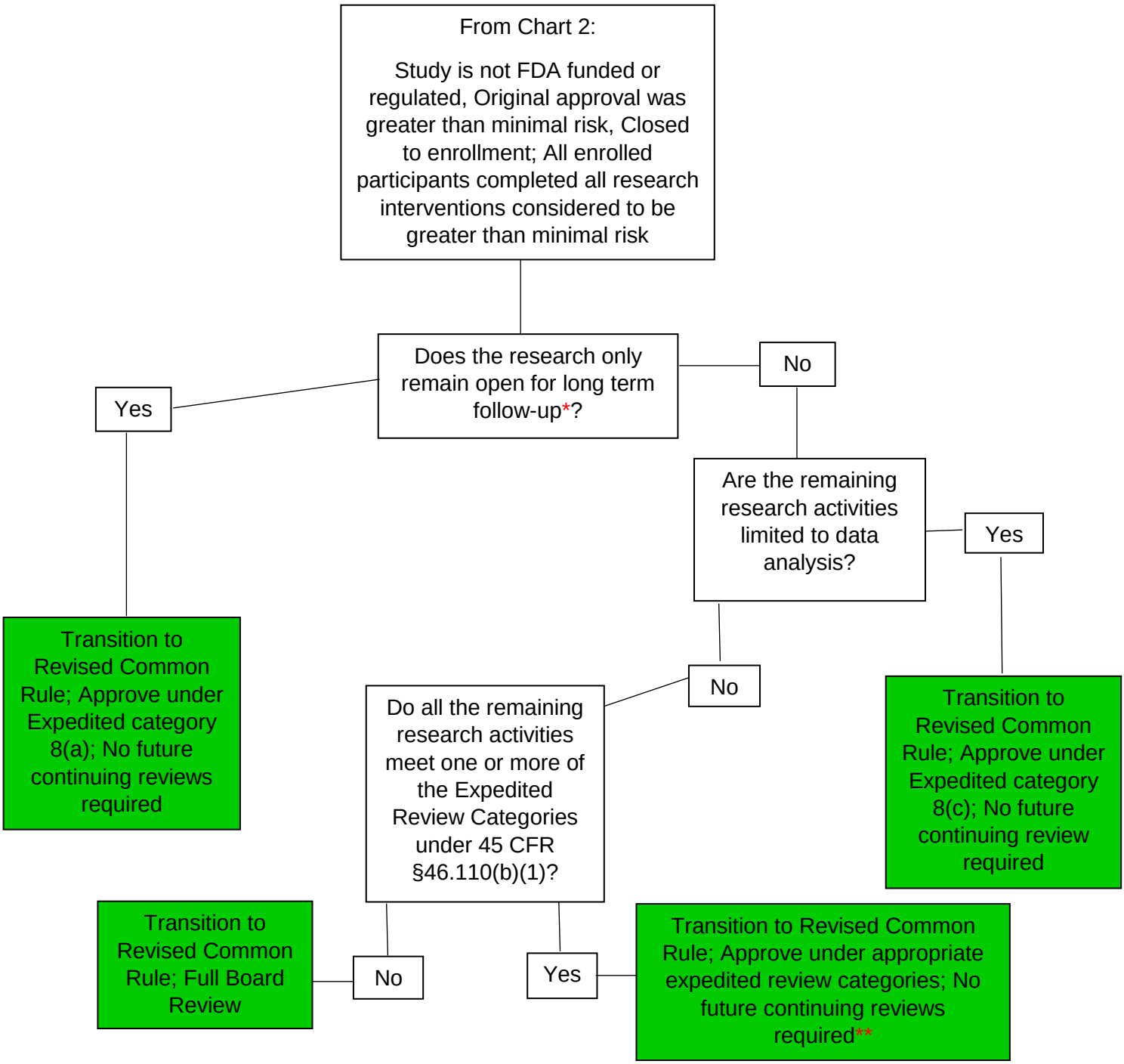

From Chart 1:
Study is FDA funded or regulated
Was the study's original approval greater than minimal risk?
No
Cannot transition to Revised Common Rule; Remains Expedited under 21 CFR §56.110(b)(1); Annual continuing review required
Yes
Is the study open to enrollment?
Yes
No
Have all enrolled participants completed all research interventions considered to be greater than minimal risk?
Have any subjects been enrolled
No
Yes
Yes
No
Go to Chart 6
Cannot transition to Revised Common Rule; Annual full board continuing review required
Cannot transition to Revised Common Rule; Approve under Expedited review category 8(b); Annual continuing review required
Cannot transition to Revised Common Rule; Annual full board continuing review required

Chart 6



*"long-term follow-up" includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys, phone calls, etc.), or collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or reassurance, regardless of whether the procedures or interventions are described in the research protocol. "Long term follow-up" excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involves no more than minimal risk.

Chart 7



*"long-term follow-up" includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys, phone calls, etc.), or collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or reassurance, regardless of whether the procedures or interventions are described in the research protocol. "Long term follow-up" excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involves no more than minimal risk.

**If the study was previously reviewed at a convened meeting and approved under expedited review category 9, annual expedited continuing review must be completed.

Additional Resources

Continuing Review – Criteria for Removing Continuing Review Requirements

Exemption Categories

Expedited Review Categories

Informed Consent & HIPAA Authorization – Required Elements

Reporting Screening and Enrollment Numbers to the IRB