



**Decision Charts
for**

**Notice of Proposed Rulemaking for the Federal Policy for the Protection of Human Subjects
80 Fed. Reg. 53933 (Sep. 8, 2015) (“NPRM”)**

These decision charts were prepared on September 29, 2015 by the Academic and Clinical Research Group (“ACRG”) of Verrill Dana LLP. For more information, please feel free to contact one of the following members of the ACRG:

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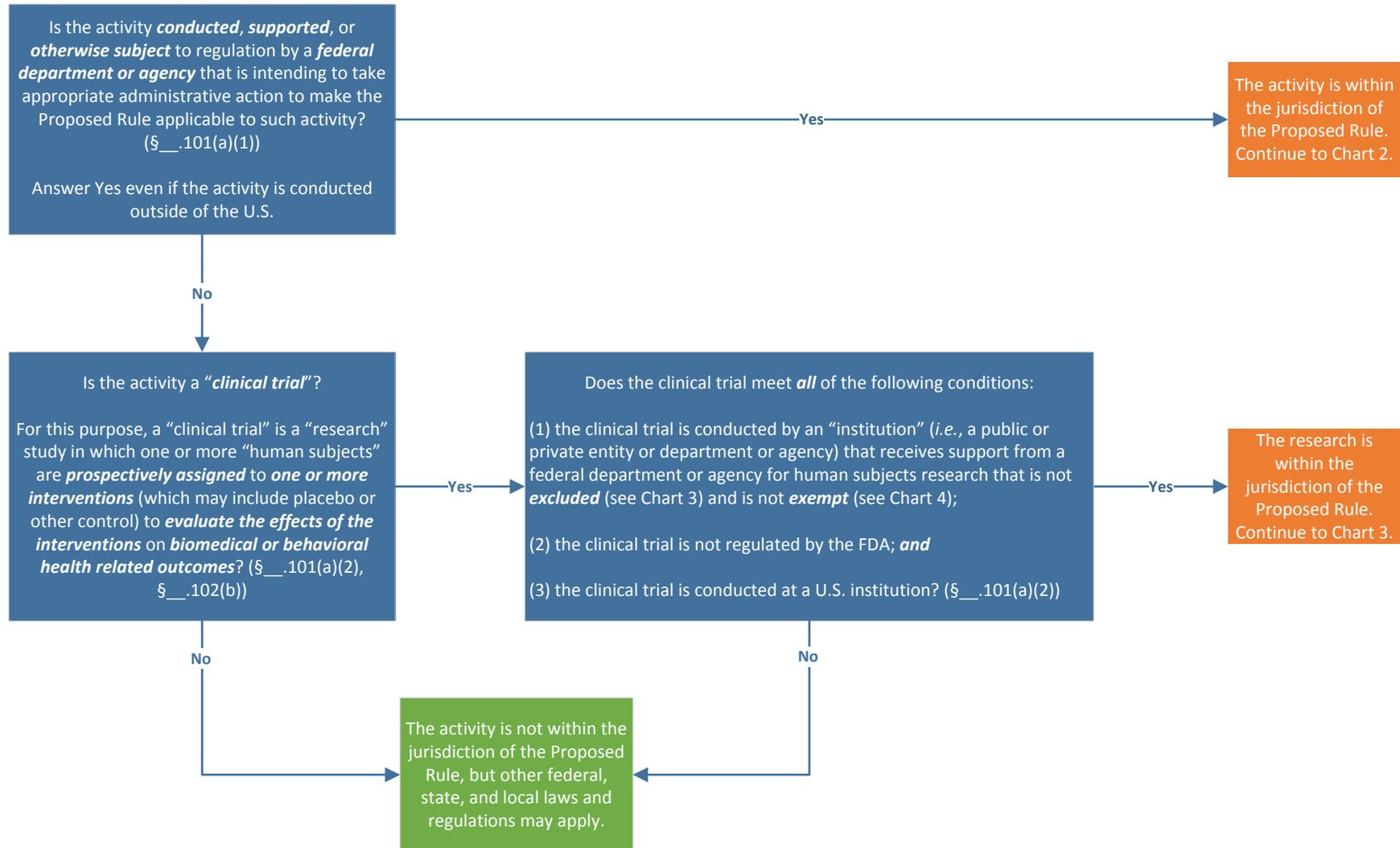
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Note: The purpose of these decision charts, which were inspired by the decision charts of the Office for Human Research Protections which address the current U.S. Department of Health and Human Services Common Rule (45 C.F.R. Part 46), is to provide a structure, in an accessible visual format, to help institutions, IRBs, and others analyze step-by-step whether a particular activity or project would be subject to the Common Rule were the NPRM to be adopted as proposed. By necessity, the decision charts condense and summarize the provisions of the NPRM relevant to these questions. The decision charts are not a substitute for reviewing the full text of the NPRM or for consulting with your own advisors regarding their application to a particular situation.

Chart 1: Is the activity within the jurisdiction of the Proposed Rule¹?



¹ As used in these charts, “Proposed Rule” means the proposed “Common Rule” regulations set forth in the Federal Register at 80 Fed. Reg. 53933 (Sep. 8, 2015).

Chart 2: Is the activity “research” involving “human subjects”?



Certain activities, as described on the first two pages of Chart 3, are **excluded** on the grounds that they are **not research**. At this point, you may elect to review whether these exclusions apply to the activity in question. If so, the analysis below is unnecessary. (§ __.101(b)(1))

Continue

Is the activity a **systematic** investigation **designed** to develop or to contribute to **generalizable** knowledge? (§ __.102(l))

No

Activity is not “research” and is not subject to the Proposed Rule.

Yes

Activity is “research.” Continue below to determine if the activity involves “human subjects.”

Continue

Does the research involve a **living individual** about whom an investigator conducting research (1) obtains data through “**intervention**” or “**interaction**” with the individual **and** (2) uses, studies, or analyzes the data? (§ __.102(e)(1)(i))

Yes

Research involves “human subjects.” Continue to Chart 3 to determine if the research is “excluded.”

No

Does the research involve a **living individual** about whom an investigator conducting research obtains, uses, studies, analyzes, or generates “**identifiable private information**”? (§ __.102(e)(1)(ii))

Yes

Research involves “human subjects.” Continue to Chart 3 to determine if the research is “excluded.”

No

Does the research involve a **living individual** about whom an investigator conducting research obtains, uses, studies, or analyzes **biospecimens**? (§ __.102(e)(1)(iii))

Yes

Research involves “human subjects.” Continue to Chart 3 to determine if the research is “excluded.”

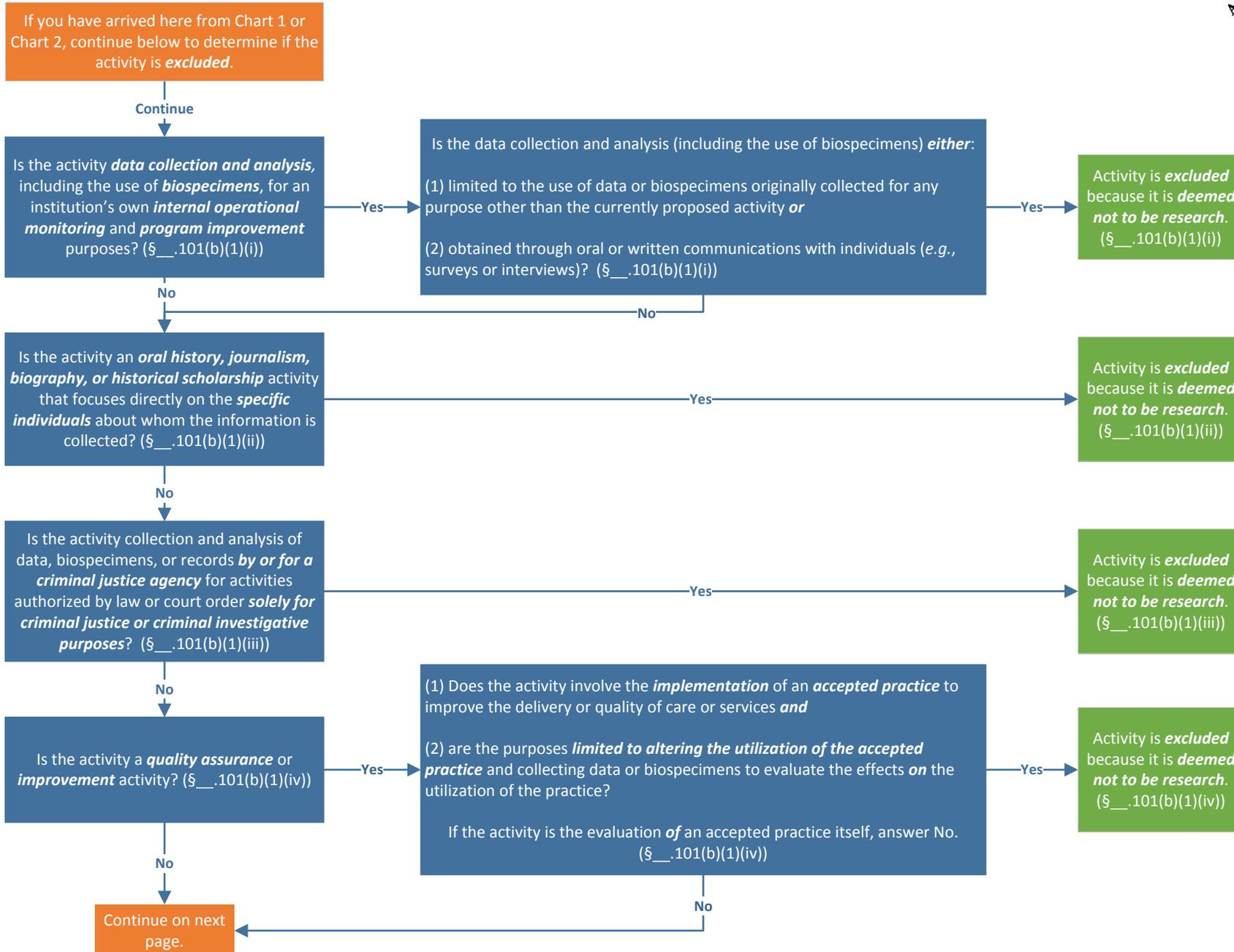
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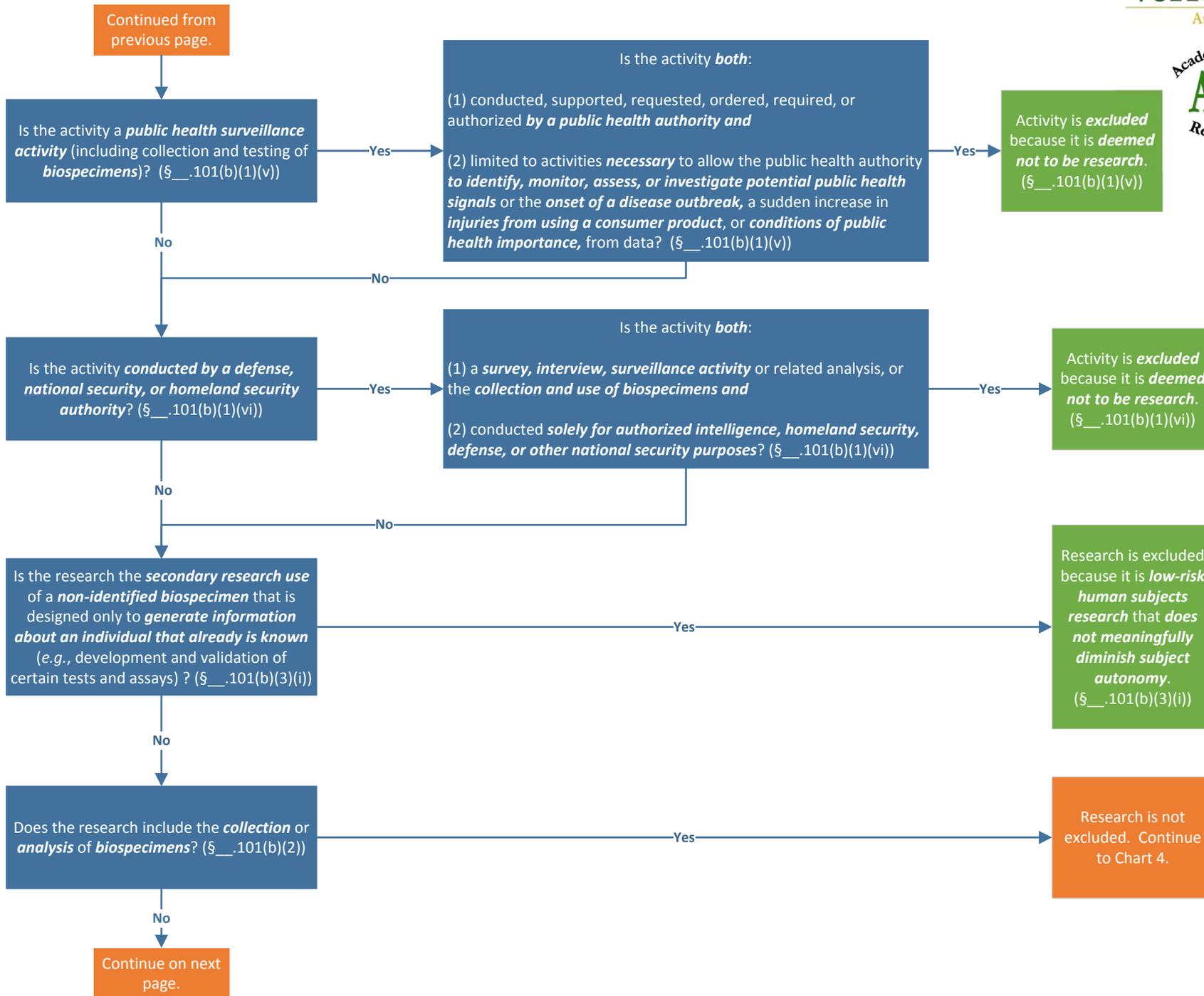
Research does not involve “human subjects” and is not subject to the Proposed Rule.

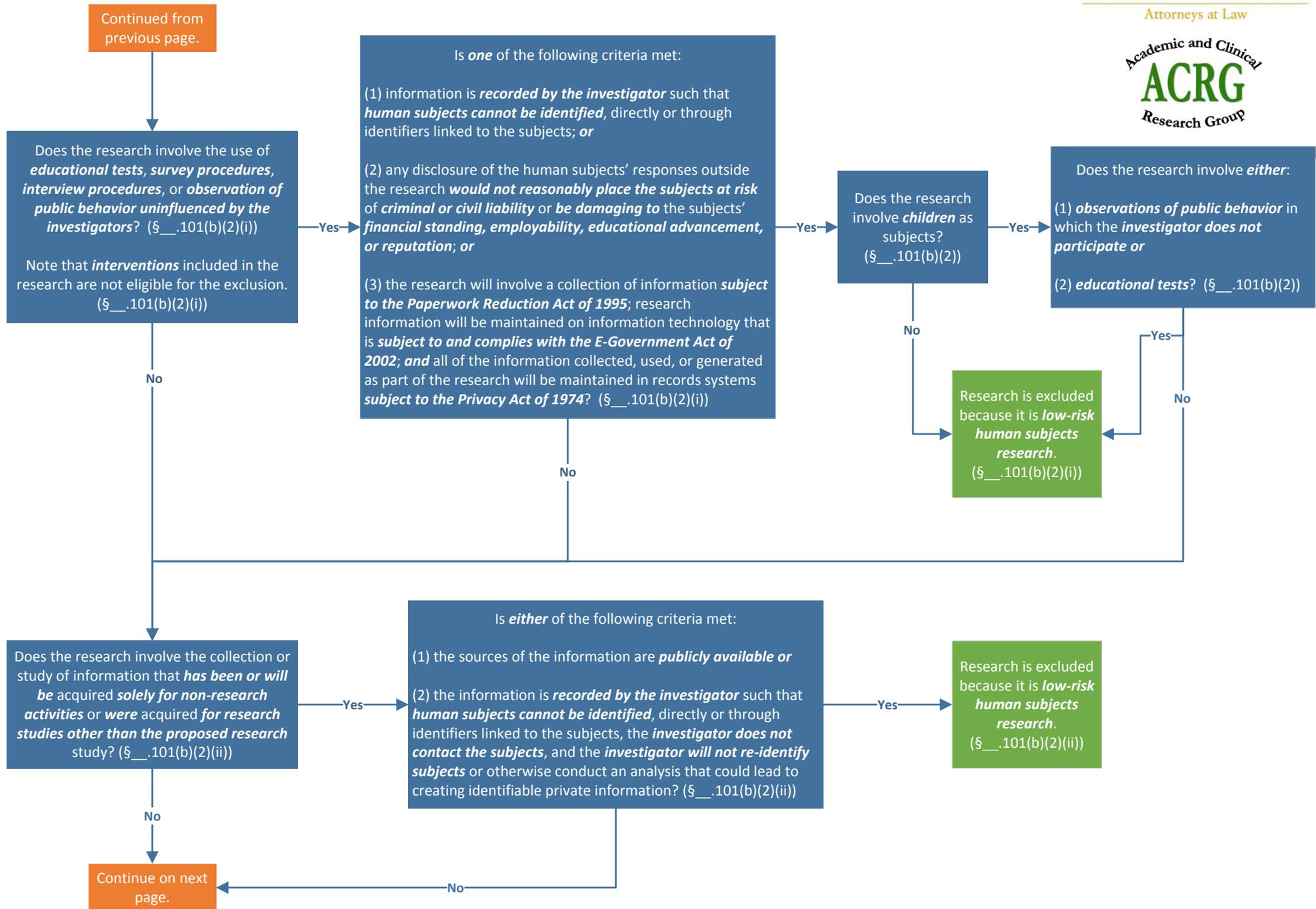
Definitions

- “**Intervention**” includes both physical procedures by which data are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. (§ __.102(e)(2))
- “**Interaction**” includes communication or interpersonal contact between investigator and subject. (§ __.102(e)(3))
- “**Private Information**” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be shared or made public (*e.g.*, a medical record or clinically obtained biospecimen). (§ __.102(e)(4))
- “**Identifiable private information**” is private information that is individually identifiable (*i.e.*, the identity of the subject is or may readily be ascertained by the investigator or associated with the information). (§ __.102(e)(5))

Chart 3: Is the activity *excluded* from the Proposed Rule?







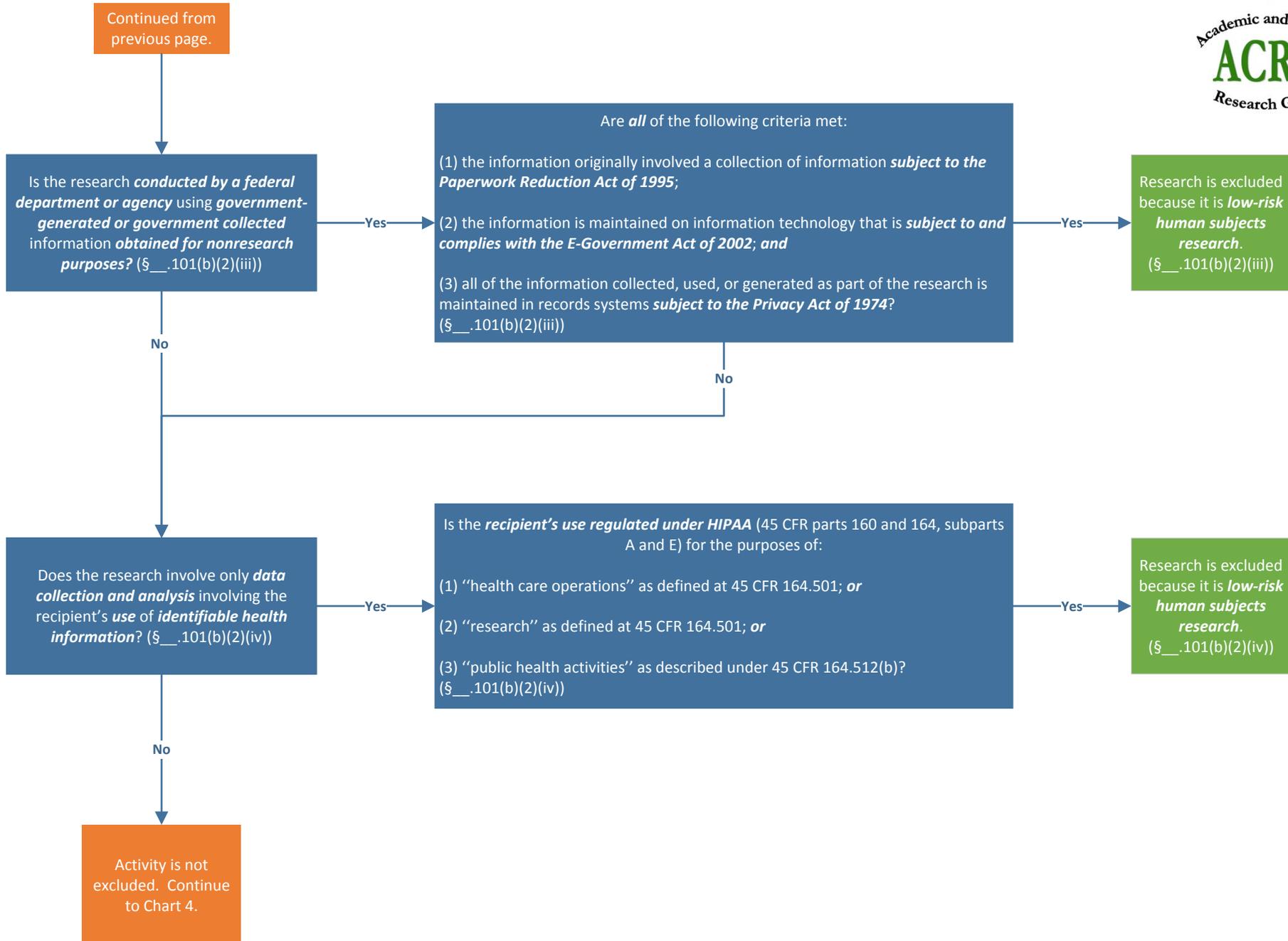
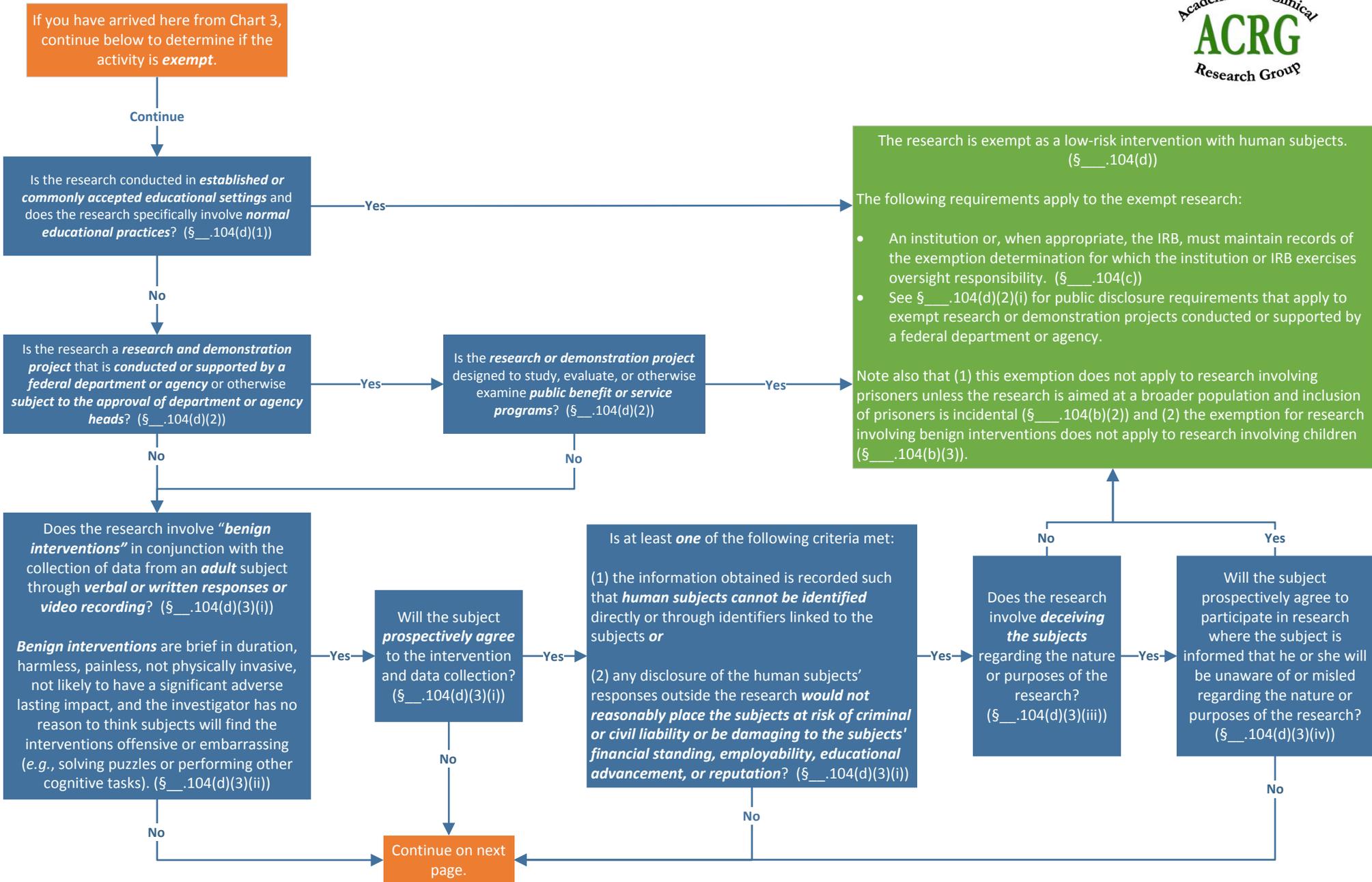
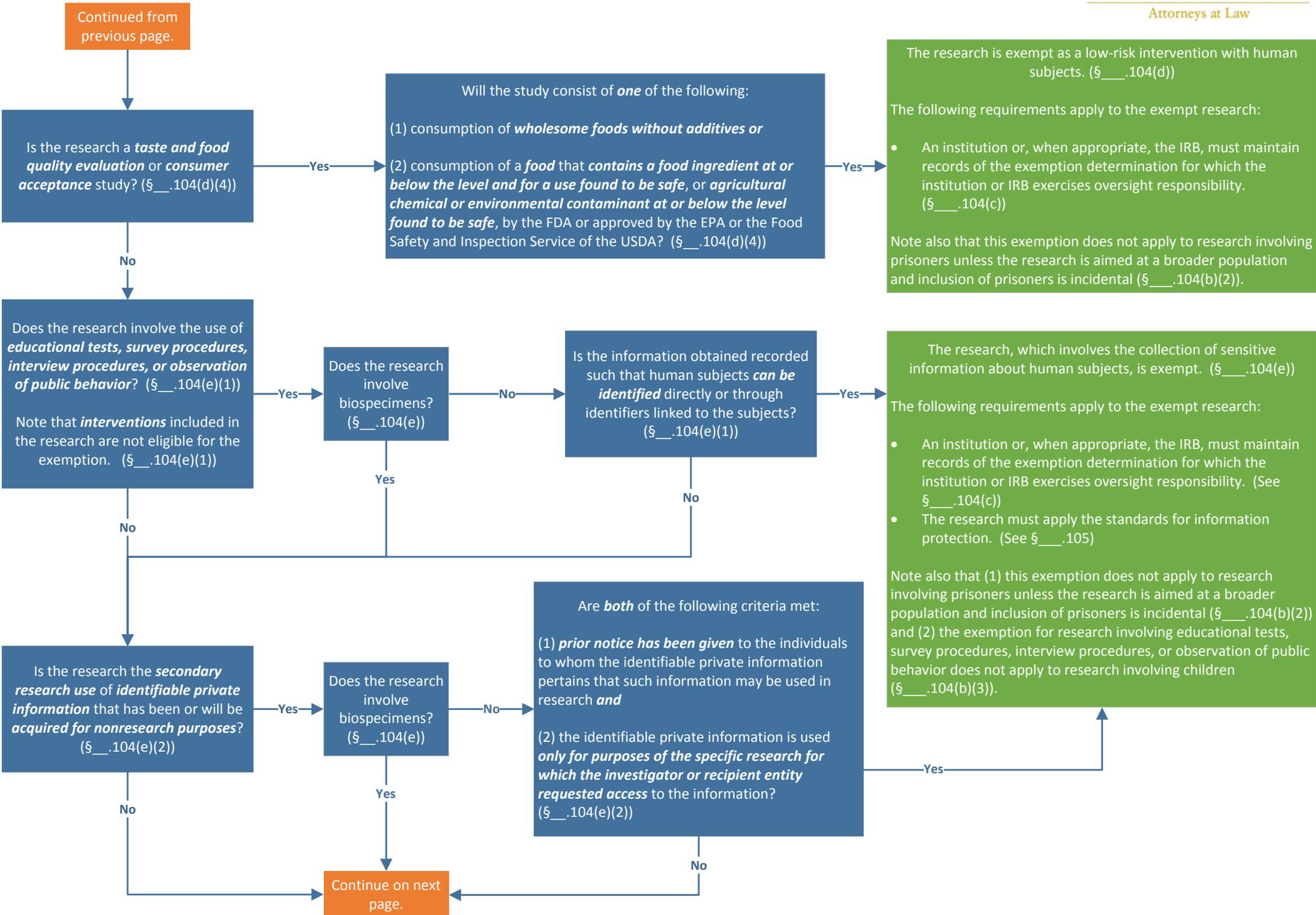


Chart 4: Is the research exempt from the Proposed Rule?







Continued from previous page.

Is the research the **storage or maintenance for secondary research use of biospecimens or identifiable private information** that have been or will be acquired for research studies other than for the proposed research study, or for nonresearch purposes? (§ __.104(f)(1)(i))

Yes

The research, which involves biospecimens or identifiable private information, is exempt. (§ __.104(f))

The following requirements apply to the exempt research:

- An institution or, when appropriate, the IRB, must maintain records of the exemption determination for which the institution or IRB exercises oversight responsibility. (See § __.104(c))
- The research must apply the standards for information and biospecimen protection. (See § __.105)
- The investigator must obtain informed consent (or, at the time of the secondary research use, confirm that informed consent was obtained) in accordance with specific criteria or as otherwise required by law. (§ __.104(f)) Regarding the specific criteria, the investigator must **either**:
 - Obtain **written consent** for the storage, maintenance, and secondary research use of the information or biospecimens, or confirm it was obtained, in accordance with § __.116(c) and (d)(2) (*i.e.*, “broad consent”) using the template published by the Secretary of HHS in accordance with § __.116(d)(1) **or**
 - **If** the proposed research is limited to the research use of identifiable private information initially acquired in accordance with **one of** the following activities, confirm that **oral consent** was obtained during the original data collection in accordance with § __.116(c) and (d)(3):
 - Activities **excluded** from this policy under § __.101(b)(2)(i) (*i.e.*, certain research involving **educational tests, survey procedures, interview procedures, or observation of public behavior**) **or**
 - Activities **exempt** from this policy in accordance with § __.104(d)(3) (*i.e.*, certain research involving **benign interventions**), § __.104(d)(4) (*i.e.*, certain research involving **taste and food quality evaluations**), or § __.104(e)(1) (*i.e.*, certain research involving **educational tests, survey procedures, interview procedures, or observation of public behavior**). (§ __.104(f)(1))
- The investigator must obtain limited IRB review with respect to the storage or maintenance as required by § __.111(a)(9) or as otherwise required by law. (§ __.104(f)(1)(i))

Note also that this exemption does not apply to research involving prisoners unless the research is aimed at a broader population and inclusion of prisoners is incidental. (§ __.104(b)(2))

No

Does the research involve the **use of biospecimens or identifiable private information** that have been **stored or maintained for secondary research use**? (§ __.104(f)(2)(i))

Yes

Does the investigator anticipate that **individual research results will be provided to a research subject**? (§ __.104(f)(2)(ii))

No

Yes

Research is not exempt.