Decision Charts
for
Notice of Proposed Rulemaking for the Federal Policy for the Protection of Human Subjects

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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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.

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Is the activity conducted, supported, or otherwise subject to regulation by a federal department or agency that is intending to take appropriate administrative action to make the Proposed Rule applicable to such activity? (§__.101(a)(1))

Answer Yes even if the activity is conducted outside of the U.S.

Is the activity a “clinical trial”? For this purpose, a “clinical trial” is a “research” study in which one or more “human subjects” are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes? (§__.101(a)(2), §__.102(b))

Does the clinical trial meet all of the following conditions:

1) the clinical trial is conducted by an “institution” (i.e., a public or private entity or department or agency) that receives support from a federal department or agency for human subjects research that is not excluded (see Chart 3) and is not exempt (see Chart 4);

2) the clinical trial is not regulated by the FDA; and

3) the clinical trial is conducted at a U.S. institution? (§__.101(a)(2))

The activity is within the jurisdiction of the Proposed Rule. Continue to Chart 2.

The activity is not within the jurisdiction of the Proposed Rule, but other federal, state, and local laws and regulations may apply.

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))

**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))

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1. Is the activity a systematic investigation designed to develop or to contribute to generalizable knowledge? (§___.102(l))
   - **Yes**: Activity is “research.” Continue below to determine if the activity involves “human subjects.”
   - **No**: Activity is not “research” and is not subject to the Proposed Rule.

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

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

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

If you have arrived here from Chart 1 or Chart 2, continue below to determine if the activity is excluded.

Is the activity data collection and analysis, including the use of biospecimens, for an institution’s own internal operational monitoring and program improvement purposes? (§__101(b)(1)(i))

If yes, activity is excluded because it is deemed not to be research. (§__101(b)(1)(i))

Is the data collection and analysis (including the use of biospecimens) either:
1. limited to the use of data or biospecimens originally collected for any purpose other than the currently proposed activity or
2. obtained through oral or written communications with individuals (e.g., surveys or interviews)? (§__101(b)(1)(i))

Yes → Activity is excluded because it is deemed not to be research. (§__101(b)(1)(i))
No → No

Is the activity an oral history, journalism, biography, or historical scholarship activity that focuses directly on the specific individuals about whom the information is collected? (§__101(b)(1)(ii))

Yes → Activity is excluded because it is deemed not to be research. (§__101(b)(1)(ii))
No → No

Is the activity collection and analysis of data, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes? (§__101(b)(1)(iii))

Yes → Activity is excluded because it is deemed not to be research. (§__101(b)(1)(iii))
No → No

Is the activity a quality assurance or improvement activity? (§__101(b)(1)(iv))

1. Does the activity involve the implementation of an accepted practice to improve the delivery or quality of care or services and
2. are the purposes limited to altering the utilization of the accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice?

If the activity is the evaluation of an accepted practice itself, answer No. (§__101(b)(1)(iv))

Yes → Activity is excluded because it is deemed not to be research. (§__101(b)(1)(iv))
No → No
Is one of the following criteria met:

1. Information is recorded by the investigator such that human subjects cannot be identified, directly or through identifiers linked to the subjects; or

2. 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

3. The research will involve a collection of information subject to the Paperwork Reduction Act of 1995; research information will be maintained on information technology that is subject to and complies with the E-Government Act of 2002; and all of the information collected, used, or generated as part of the research will be maintained in records systems subject to the Privacy Act of 1974?

Does the research involve children as subjects?

Does the research involve either:

1. Observations of public behavior in which the investigator does not participate?

2. Educational tests?

Research is excluded because it is low-risk human subjects research.

Is either of the following criteria met:

1. The sources of the information are publicly available or

2. The information is recorded by the investigator such that human subjects cannot be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects or otherwise conduct an analysis that could lead to creating identifiable private information?

Research is excluded because it is low-risk human subjects research.
Is the research conducted by a federal department or agency using government-generated or government collected information obtained for nonresearch purposes? (§__101(b)(2)(iii))

- Yes: Research is excluded because it is low-risk human subjects research. (§__101(b)(2)(iii))
- No: Activity is not excluded. Continue to Chart 4.

Are all of the following criteria met:
1. The information originally involved a collection of information subject to the Paperwork Reduction Act of 1995;
2. The information is maintained on information technology that is subject to and complies with the E-Government Act of 2002; and
3. All of the information collected, used, or generated as part of the research is maintained in records systems subject to the Privacy Act of 1974? (§__101(b)(2)(iii))

Does the research involve only data collection and analysis involving the recipient’s use of identifiable health information? (§__101(b)(2)(iv))

- Yes: Research is excluded because it is low-risk human subjects research. (§__101(b)(2)(iv))
- No: Activity is not excluded. Continue to Chart 4.

Is the recipient’s use regulated under HIPAA (45 CFR parts 160 and 164, subparts A and E) for the purposes of:
1. “Health care operations” as defined at 45 CFR 164.501; or
2. “Research” as defined at 45 CFR 164.501; or
3. “Public health activities” as described under 45 CFR 164.512(b)? (§__101(b)(2)(iv))
Chart 4: Is the research **exempt** from the Proposed Rule?

If you have arrived here from Chart 3, continue below to determine if the activity is **exempt**.

Is the research conducted in established or commonly accepted educational settings and does the research specifically involve normal educational practices? (§__.104(d)(1))

- **Yes**: The research is exempt as a low-risk intervention with human subjects.
- **No**: Continue below to determine if the activity is exempt.

Is the research a research and demonstration project that is conducted or supported by a federal department or agency or otherwise subject to the approval of department or agency heads? (§__.104(d)(2))

- **Yes**: Is the research or demonstration project designed to study, evaluate, or otherwise examine public benefit or service programs? (§__.104(d)(2))
  - **Yes**: Note also that (1) 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)) and (2) the exemption for research involving benign interventions does not apply to research involving children (§__.104(b)(3)).
  - **No**: Continue on next page.
- **No**: Does the research involve “benign interventions” in conjunction with the collection of data from an adult subject through verbal or written responses or video recording? (§__.104(d)(3)(i))
  - **Yes**: Will the subject prospectively agree to the intervention and data collection? (§__.104(d)(3)(ii))
    - **Yes**: Is at least one of the following criteria met:
      - (1) the information obtained is recorded such that human subjects cannot be identified directly or through identifiers linked to the subjects or
      - (2) 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? (§__.104(d)(3)(i))
    - **No**: Please refer to the chart on page 2 for further instructions.
  - **No**: Continue on next page.

Benign interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think subjects will find the interventions offensive or embarrassing (e.g., solving puzzles or performing other cognitive tasks). (§__.104(d)(3)(ii))

Is the research or demonstration project designed to study, evaluate, or otherwise examine public benefit or service programs? (§__.104(d)(2))

- **Yes**: Note also that (1) 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)) and (2) the exemption for research involving benign interventions does not apply to research involving children (§__.104(b)(3)).
- **No**: Continue on next page.

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. (§__.104(c))
- See §__.104(d)(2)(i) for public disclosure requirements that apply to exempt research or demonstration projects conducted or supported by a federal department or agency.

Does the research involve “benign interventions” in conjunction with the collection of data from an adult subject through verbal or written responses or video recording? (§__.104(d)(3)(i))

- **Yes**: Will the subject prospectively agree to the intervention and data collection? (§__.104(d)(3)(ii))
  - **Yes**: Is at least one of the following criteria met:
    - (1) the information obtained is recorded such that human subjects cannot be identified directly or through identifiers linked to the subjects or
    - (2) 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? (§__.104(d)(3)(i))
  - **No**: Please refer to the chart on page 2 for further instructions.
  - **No**: Continue on next page.
- **No**: Will the subject prospectively agree to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research? (§__.104(d)(3)(iv))
  - **Yes**: Does the research involve deceiving the subjects regarding the nature or purposes of the research? (§__.104(d)(3)(ii))
    - **Yes**: Is at least one of the following criteria met:
      - (1) the information obtained is recorded such that human subjects cannot be identified directly or through identifiers linked to the subjects or
      - (2) 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? (§__.104(d)(3)(i))
    - **No**: Please refer to the chart on page 2 for further instructions.
    - **No**: Continue on next page.
- **No**: No requirements apply to exempt research (§__.104(d)(2)(ii)).

Note also that (1) 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)) and (2) the exemption for research involving benign interventions does not apply to research involving children (§__.104(b)(3)).

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The research is exempt as a low-risk intervention with human subjects. (§__.104(d))

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. (§__.104(c))

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)).

The research, which involves the collection of sensitive information about human subjects, is exempt. (§__.104(e))

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 protection. (See §__.105)

Note also that (1) 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)) and (2) the exemption for research involving educational tests, survey procedures, interview procedures, or observation of public behavior does not apply to research involving children (§__.104(b)(3)).
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))