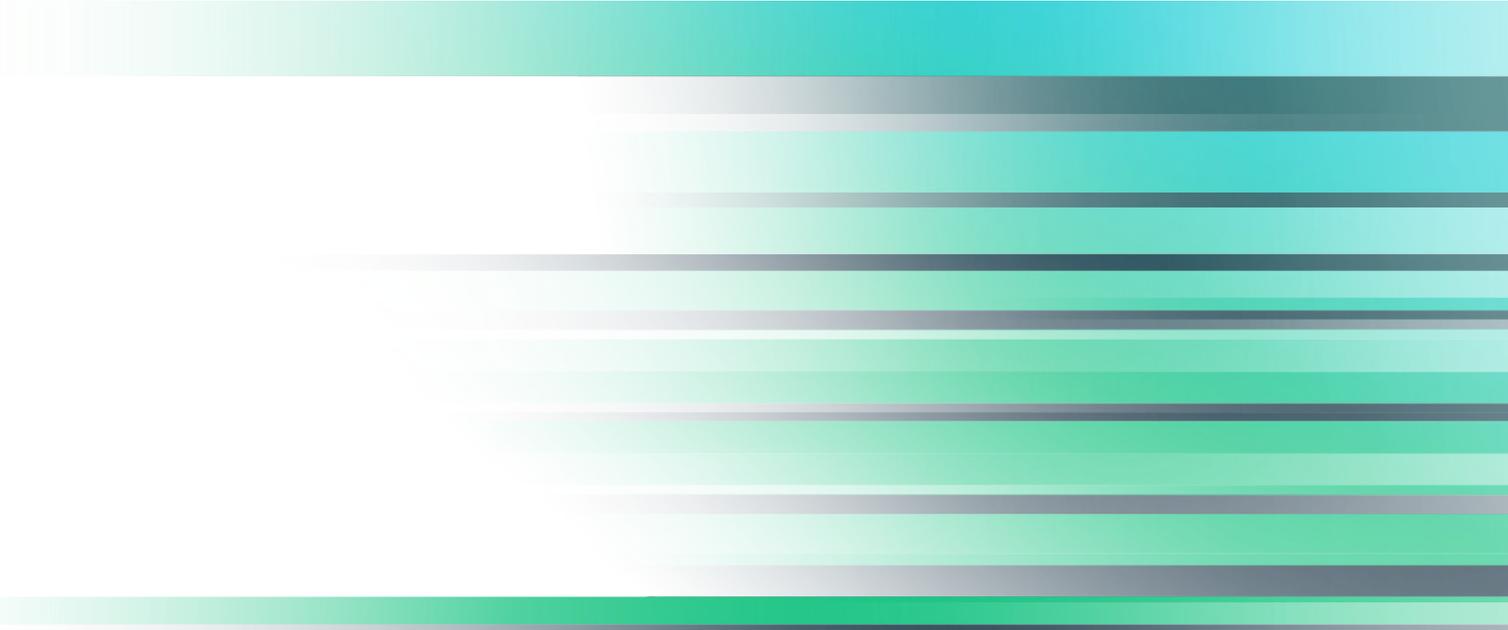

Common Rule Changes: The Proposal for Excluded Research

02/02/16

DESCRIPTION

A summary of the new excluded categories under the proposed rule, with explanations for how each Excluded Category impacts existing Exempt Categories where applicable.

TOPICS

- ACTIVITIES DEEMED NOT RESEARCH
 - ACTIVITIES THAT ARE LOW-RISK AND ALREADY SUBJECT TO INDEPENDENT CONTROLS
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Activities Deemed Not Research

This whitepaper summarizes the new excluded categories under the NPRM and provides explanations for how each Excluded Category impacts existing Exempt Categories where applicable.

These first three excluded categories of activities are intended to clarify applicability of the Common Rule where there has historically been ambiguity.

1. Program improvement activities¹

PROPOSAL

Exclude program improvement activities that include data collection and analysis, including the use of biospecimens, for an institution’s own internal operational monitoring and program improvement purposes, if limited to the use of data or biospecimens originally collected for any purpose other than the currently proposed activity or is obtained through oral or written communications with individuals (e.g., surveys or interviews).

EXPLANATION

This exclusion is intended to allow institutions to engage in the described activities in order to operate and improve operations without being subject to the restrictions of the common rule. The proposal sets this out as a separate “excluded” category, though poses the question as to whether this activity should simply be discussed in the text of the final rule’s preamble as an example of research that doesn’t meet the definition of human subjects research. If finalized as proposed, this would be a new “Excluded” Category and does not replace or modify an existing exempt category of research.

2. Oral history, journalism, biography, and historical scholarship activities²

PROPOSAL

Oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected would be excluded from the requirements of the common rule.

EXPLANATION

These categories of activities are thought to be impeded by the restrictions in the common rule. The drafters indicate the codes of ethics governing these fields as

well as the purpose of these types of activities (focusing on specified individuals) makes the application of the Common Rule inappropriate.

3. Criminal justice activities³

PROPOSAL

Exclude activities that involve data collection and analysis that enables the uniform delivery of criminal justice. Including 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. The activities must also be necessary for the operation and implementation of the criminal justice system.

EXPLANATION

The proposal indicates this provision would essentially codify current Federal interpretation that such activities are not deemed to be research under the Common Rule.

These next three excluded categories of activities are thought to serve the public welfare and are unnecessarily hindered by the application of the common rule.

4. Quality assurance & quality improvement⁴

PROPOSAL

Exclude quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services (including, but not limited to, education, training, and changing procedures related to care or services) if the purposes are limited to altering the utilization of the accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice.

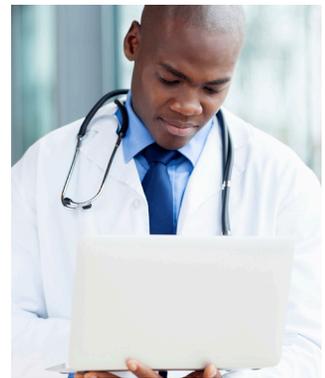
EXPLANATION

The proposal recognizes that the application of the common rule to QA and QI activities may have a chilling effect on innovation and the improvement of care. This exclusion applies only to the implementation of practices that are already accepted with a goal of improving delivery or quality of treatments or services. The exclusion does not, however, cover the evaluation of an accepted practice itself.

5. Public health surveillance⁵

PROPOSAL

Exclude public health surveillance activities, including the collection and testing of biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority and limited to those necessary to allow the public health authority to identify, monitor, assess, or investigate potential public health signals or the onset of a disease outbreak, including trends, or signals,



and patterns in diseases, or sudden increases in injuries from using a consumer product, or conditions of public health importance, from data, and including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health, including natural or man-made disasters.

EXPLANATION

This surveillance category applies to activities conducted by public health authorities. The activities excluded are required by law and help the public health authority to fulfill its mission to protect public health. These activities are conducted for non-research purposes, promoting public health. Furthermore, there are a number of protections in place for subjects of this surveillance and the public benefit of the activity is inappropriately burdened by the application of the common rule.

“The activities excluded are required by law and help the public health authority to fulfill its mission to protect public health.”

6. Intelligence surveillance⁶

PROPOSAL

Exclude surveys, interviews, surveillance activities and related analyses, or the collection and use of biospecimens where these activities are conducted by a defense, national security, or homeland security authority solely for authorized intelligence, homeland security, defense or other national security purposes.

EXPLANATION

The defense or national security-related activities is lawful conduct of the departments' and agencies' mandated missions for actively protecting security and are fundamentally not research. Though they collect identifiable information they are not designed to develop, or contributed to, generalizable knowledge; rather they are to fulfill the department or agency's legal mandate to ensure the safety and protection of the United States, its people, and its national security interests.

Activities that are Low-Risk and Already Subject to Independent Controls

These last four excluded categories are activities that are considered research; however they are either inherently low-risk or there are appropriate protections in place to mitigate risk. Imposing the common rule is burdensome and would offer little additional protection to subjects.

7. Educational tests, survey procedures, interview procedures, or observation of public behaviors⁷

PROPOSAL

Exclude research that involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recordings) uninfluenced by the investigators if at least one of the following is met:

- The information is recorded by the investigator in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; or
- 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
- The research will involve a collection of information subject to the Paperwork Reduction Act, will be maintained on IT that is subject to the E-Government Act, and all of the information collected, used, or generated as part of the research will be maintained in a system or systems of records subject to the Privacy Act of 1974

EXPLANATION

This exclusion would replace the exemption Category 2 and some additional government information collection research activities using the same methods. The methods described are the same and harms that must be considered are the same with the addition of the harm to educational advancement. The first element of Category 2 (relating to elected or appointed officials or candidates) has been omitted, as that it doesn't seem appropriate to single out this category of individuals for different treatment.



“Individuals have already provided the government with information for another purpose, so the requirement to obtain an “exempt” determination is considered burdensome.”

The third option under the proposed exclusion would allow the research activities even when the data have identifiers that may be sensitive or private (though not explicitly damaging to the individual) so long as the information is subject to specified statutes and regulations that require data security and privacy protections.

8. Research involving collection or study of information that has or will be collected⁸

PROPOSAL

Exclude the collection or study of information that has been or will be acquired solely for non-research activities or was acquired for research studies other than the proposed research study when the sources are publicly available, or the information is recorded by the investigator in such a manner 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 individually identifiable private information.

EXPLANATION

This Exclusion Category replaces exemption Category 4 but also modifies the Category. First, it does not include secondary research use of biospecimens. Second, it omits the requirement that the information be “existing” at the time the study was proposed for exemption. This is because this research involves no direct interaction or intervention with human subjects.

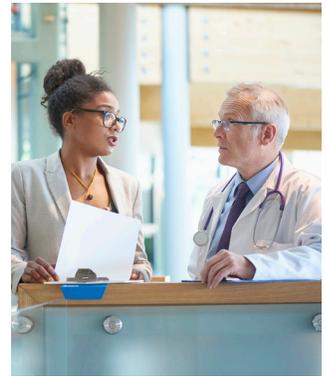
9. Research conducted by a government agency using government-generated or government-collected data⁹

PROPOSAL

Exclude research conducted by a federal department or agency using government-generated or government-collected information obtained for non-research purposes (including criminal history data), if the information originally involved a collection of information subject to the Paperwork Reduction Act, the information is maintained on IT that is in compliance with the E-Government Act and all of the information collected, used or generated as part of the research is maintained in a system or systems of records subject to the Privacy Act.

EXPLANATION

This exclusion is proposed for situations in which both the original data collection and the analysis are subject to notice requirements under federal law. Individuals have already provided the government with information for another purpose, so the requirement to obtain an “exempt” determination is considered burdensome.



10. Certain activities covered by HIPAA¹⁰

PROPOSAL

Exclude research that involves the use of protected health information by a HIPAA covered entity for "health care operations," "public health activities," or "research," as those three terms are defined under the HIPAA Rules.

EXPLANATION

The rationale for this proposed exclusion is that the risks are related only to privacy and confidentiality and are already subject to independent controls provided by HIPAA. This proposed exclusion would not apply if the investigator is not covered by the HIPAA Rules.

“The rationale for this proposed exclusion is that the risks are related only to privacy and confidentiality and are already subject to independent controls provided by HIPAA.”

REFERENCES

1. NPRM at § __.101(b)(1)(i), p. 53947 of NPRM.
2. NPRM at § __.101(b)(1)(ii), p. 53948.
3. NPRM at § __.101(b)(1)(iii), p. 53948.
4. NPRM at § __.101(b)(1)(iv), p. 53948.
5. NPRM at § __.101(b)(1)(v), p. 53949.
6. NPRM at § __.101(b)(1)(vi), p. 80 of NPRM.
7. NPRM at § __.101(b)(2)(i), p. 53951.
8. NPRM at § __.101(b)(2)(ii), p. 53952.
9. NPRM at § __.101(b)(2)(iii), p.53953.
10. NPRM at § __.101(b)(2)(iv), p. 53953.

About Kinetiq

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