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CLIENT ALERT

Six Key Changes to the Common Rule

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Executive Summary

On January 19, 2017, sixteen federal agencies, including the Departments of Health and Human Services and Labor, published the first revision to the federal regulations governing the protection of human subjects participating in research since 2005.[1] These regulations, often known as the "Common Rule," have been in place since 1991 and apply to all research that is conducted, supported, or regulated by the federal government. The amended regulations are scheduled to take effect on **January 19, 2018.** However, cooperative research projects have been given an additional two years to comply.

The amended regulations update only the basic human subject protections in Part A of the Common Rule; the special safeguards for pregnant women, fetuses, prisoners, and children were not changed. Moreover, the revisions to the Common Rule do not affect the human subject protection rules published by the Food and Drug Administration ("FDA"), which apply to all research that is regulated by the FDA or that is used to support an application to the agency.[2]

As discussed more fully below, major changes in the amended regulations include the following: (1) requirements for informed consent, (2) broad consent for research with biospecimens or individually identifiable data, (3) research exempt from the Common Rule, (4) authorization for a single institutional review board ("IRB") for cooperative research, (5) criteria for IRB approval of research, and (6) ongoing IRB review of research. In addition, the amended regulations contain several provisions intended to harmonize with the privacy regulations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and avoid overlaps.

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[1] 82 Fed. Reg. 7149 (Jan. 19, 2017), *available at:* https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects.

[2] 21 C.F.R. Parts 50 and 56.

Major Changes in the Amended Regulations

1. Requirements for Informed Consent

The amended regulations specify that "the information provided in an informed consent form must be presented in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts ...." Instead, the consent form must explain to the prospective subject or legally authorized representative the reasons why one might or might not want to participate. The amended regulations seek to balance the needs of regulated entities and individuals to pursue different and innovative approaches while ensuring that informed consents are clearly communicated to prospective subjects.

The amended regulations include the following requirements:

- Informed consents, including broad consents, must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

- The amended regulations anticipate that the beginning of the informed consent would include a concise explanation of the following: (a) the fact that consent is being sought for research and that participation is voluntary; (b) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research; (c) the reasonably foreseeable risks or discomforts to the prospective subject; (d) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (e) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

- A new provision requires the informed consent form used in a clinical trial to be posted on a "federal Web site" within 60 days from the close of enrollment into the study but allows redaction or exclusion of some information, including confidential commercial information, as agreed upon by the federal department or agency that is conducting or supporting the study.

2. Broad Consent for Research with Biospecimens or Individually Identifiable Data

The amended regulations permit researchers to seek broad consent, which covers both the subject of the investigator's current research and future unspecified research using the same data or biospecimens. The use of these specimens is a common practice and has not been regulated to date.[3] The exact number of specimens is not known but has been estimated in the billions.[4] Broad consent incorporates all of the current general

[3] *See, e.g.,* R. Skloot, The Immortal Life of Henrietta Lacks (2010).

[4] See HHS Secretary's Advisory Committee on Human Research Protections, Attachment D: FAQ's Terms and Recommendations on Informed Consent and Research Use of Biospecimens (July 20, 2011),

elements of informed consent and adds the following new elements intended to cover secondary research:

- If the biospecimens may be used for commercial profit, the consent must inform the subject of that potential use and must disclose whether the subject will or will not share in any commercial profit.

- If the possible research will (if known) or might include whole genome sequencing, that information must be disclosed.

- The consent must explain the types of research that may be conducted with identifiable private information or identifiable biospecimens.

- The consent must inform a subject if identifiable private information or identifiable biospecimens might be shared with other researchers or institutions and should include an explanation of the types of institutions or investigators that might conduct research with such information or biospecimens.

- If personally identifiable data or biospecimens will be stored, the consent must describe both the period of time allowed for storage and maintenance (even if indefinite) and the time period that such information or biospecimens may be used for research purposes (even if indefinite).

- Unless the subject or legally authorized representative will be provided details about specific research studies, the broad consent must include a statement that the subject or the legally authorized representative 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 the subject might have chosen not to consent to some of those specific research studies.

- Unless it is known that clinically relevant research results will be disclosed to the subject in all circumstances, the consent must include a statement that such results may not be disclosed to the subject.

- The consent must contain an explanation of whom to contact for answers to questions about the subject's rights 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.

3. Research Exempt from the Common Rule

The amended regulations revise and clarify the categories of research that is exempt from the Common Rule. There are eight categories of exemptions, which expand on the

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available at: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-d/.

current six categories. If the research involves pregnant women, fetuses, neonates, prisoners, or children, then the current additional safeguards may also apply.

The significant revisions include the following:

- Research involving educational methods remain exempt, but only if the research is not likely to adversely affect classroom instruction time or student performance.

- Educational testing remains exempt as long as (a) any recorded information is completely de-identified; (b) any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm; or (c) the recorded information cannot be de-identified and the procedures have been reviewed by an IRB.

- Research that involves benign behavioral interventions with adults is exempt from IRB review, but only if (a) any recorded information is completely de-identified, (b) any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm, or (c) the recorded information cannot be de-identified and the procedures have been reviewed by an IRB.

- The amended regulations create a new exemption for secondary research involving identifiable private information, which is regulated under HIPAA, or biospecimens collected by a researcher. This research may be exempt if (a) the identifiable information is already available to the public; (b) the information is not re-identified, and the researcher does not attempt to re-identify it; (c) the secondary research is already regulated under HIPAA; or (d) the secondary research is conducted by, or on behalf of, a federal entity and involves the use of federally generated nonresearch information as long as the information remains covered under existing federal privacy rules.

- The amended regulations create a new exemption for secondary research and for the storage and maintenance of identifiable private information or identifiable biospecimens, provided that the subject or donor has given a broad consent. Any secondary research may be exempt if the broad consent was properly obtained and documented, and if an IRB determines that the secondary research is within the scope of the broad consent.

It is also important to note that the definition of “human subject” does not include the use of non-identifiable biospecimens. Therefore, the use of non-identifiable biospecimens in research does not, on its own, mandate the application of the Common Rule to such research.

4. Authorization for a Single IRB for Cooperative Research

The Common Rule currently requires that each institution engaged in a cooperative research study obtain IRB approval of the study. Often, a local IRB for each institution

independently reviews the research protocol, informed consent forms, and other materials resulting in multiple reviews for one study. When any one of these IRBs requires changes to the research protocol that are adopted for the entire study, investigators have to re-submit the revised protocol to all of the reviewing IRBs, resulting in significant delays.

The amended regulations make the following changes:

- All institutions that are located in the United States and engaged in cooperative research must rely on a single IRB as their reviewing IRB for that study, except for (a) cooperative research for which more than single IRB review is required by law or (b) research for which any federal department or agency supporting or conducting the research determines that the use of a single IRB is not appropriate.

- The requirement for a single IRB for cooperative research rule has a delayed compliance date of January 20, 2020.

5. Criteria for IRB Approval of Research

Before an IRB can approve a study, the Common Rule requires the IRB to make determinations that relate to, among other things, minimizing risks to subjects, establishing that an appropriate relationship exists between risks and benefits, and ensuring the equitable selection of subjects. The amended regulations revise the following criteria:

- The category of vulnerable subjects of whom the IRB should be cognizant is amended to include children, prisoners, and individuals with impaired decision-making capacity or economically or educationally disadvantaged persons.

- As part of its review of these requirements for broad consent, the IRB should (a) review the appropriateness of the process proposed for obtaining broad consent, (b) ensure that the required elements of broad consent were appropriately included in the broad consent form (or process if broad consent is to be obtained orally), and (c) determine that consent is appropriately documented or that a waiver of documentation is appropriate. If a change is made for research purposes in the way that identifiable private information or identifiable biospecimens are stored or maintained, the IRB must determine that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data.

6. Ongoing IRB Review of Research

The amended regulations clarify the IRB's authority and eliminate continuing review for many minimal risk studies—primarily those that qualify for expedited review. Specifically, the amended regulations revise the Common Rule as follows:

- The Common Rule is amended to state that IRBs will review and have the authority to approve, require modifications in, or disapprove all covered research activities, including exempt research activities, for which limited IRB review is a condition of exemption.

- For studies initially reviewed by a convened IRB, once certain specified procedures are all that remain for the study, continuing review will not be required, unless specifically mandated by the IRB. These activities include (a) research eligible for expedited review or (b) research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (i) data analysis, including analysis of identifiable private information or identifiable biospecimens, or (ii) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

- Continuing review is not required for research reviewed in accordance with the limited IRB review procedure.

- Investigators are not required to provide annual confirmation to the IRB that such research is ongoing and that no changes have been made that would require the IRB to conduct continuing review. However, investigators would still have the current obligations to report various developments (such as unanticipated problems or proposed changes to the study) to the IRB.

Call to Action

Additional changes to Part A of the Common Rule are included in the amended regulations, which affect the process and substance of procedures by which researchers adhere to ethical and legal standards when conducting research involving human subjects and information or biospecimens obtained from human subjects, as well as changes to expedited review procedures. It is imperative that research hospitals, clinicians conducting research, and companies that sponsor and conduct research thoroughly review these changes and implement new policies and procedures before the amended regulations take effect next year.

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This Client Alert was authored by **Robert E. Wanerman, Mark S. Armstrong,** *and* **Bradley S. Davidsen.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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