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A Framework for Readying Your Institution for Complying With the Revised Common Rule

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Earlier this year, the long-awaited revision to the Federal Policy for the Protection of Human Subjects, known as the ''Common Rule,'' was published in the *Federal Register* (the ''Final Rule''). 82 Fed. Reg. 7149 (Jan. 19, 2017), available at https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf. The Final Rule, issued by 16 federal agencies and departments including the U.S. Department of Health and Human Services, seeks to modernize the regulations governing all research involving human subjects conducted, sponsored, or regulated by these federal government agencies and departments that have adopted the rule. The Final Rule fundamentally alters regulations that permeate institutions' standard operating procedures (''SOPs''), training, and expectations regarding human subjects research. Indeed, the revisions impact even basic issues, ranging from the types of research actually subject to the Final Rule to informed consent.

Given the broad sweep of the revisions, institutions engaged in covered research will need to make operational changes to ensure compliance. The current deadline for compliance with the majority of changes made is Jan. 19, 2018. Some entities have requested that the compliance date be delayed. *See, e.g.*, Association of American Medical Colleges Joint Letter Requesting an Extension of the Compliance Date for the Common Rule (June 23, 2017), available at https://www.aamc.org/advocacy/washhigh/highlights2017/480962/06231aamcjointletterrequestinganextensiontothecompliancedatefort.html. The White House Office of Management and Budget is reviewing a proposed rule that would delay the implementation date of the Common Rule revisions by one year, but it has not been published or finalized, so the Jan. 18, 2018, compliance date remains in effect. The OMB review notice is at https://www.reginfo.gov/public/do/eoDetails?rrid=127614.

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At this time, it is recommended that institutions not only become familiar with the changes to Final Rule, but also consider practical issues introduced by those changes. To assist that process, select changes made by the Final Rule and related questions for your institution to consider follow:

1. Broad Consent for Secondary Research Using Identifiable Private Information and Identifiable Biospecimens

Highlights. The revised rule allows (but does not require) researchers to request broad consent from subjects for secondary research involving identifiable private information and identifiable biospecimens. In other words, the research subject may consent to the use of the subject's identifiable private information and identifiable biospecimens for the researcher's specific study for which the specimen is collected *and* also to the use of the identifiable private information and identifiable biospecimens in later, unspecified (and perhaps not yet contemplated) research.

To obtain broad consent, the general requirements for informed consent must be met plus the subject must be informed of additional elements concerning the future, secondary research. Those additional elements include: (a) the potential use of the specimen for commercial profit; (b) if the subject will or will not share in the commercial profit; (c) if the potential research may include whole genome sequencing, a general description of the types of research that may be conducted; (d) a de-

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scription of the identifiable private information and identifiable biospecimens that might be used in the research; (e) if sharing of the identifiable private information and identifiable biospecimens might occur; (f) the types of institutions or researchers that might conduct the future research; (g) a description of the length of time that the identifiable private information and identifiable biospecimens might be stored and/or used for research; (h) a statement that the subject will not be informed of the details and purposes of specific research studies (unless the subject will be so informed); (i) a statement that the subject might have chosen not to consent to some future research studies if they had understood the details and purposes of the future research studies; and (j) a statement that clinically relevant research results, including the subject's research results, may not be disclosed to the subject (unless it is known that those will be disclosed in all circumstances).

Obtaining broad consent is one step towards use of the identifiable private information and identifiable biospecimens in secondary research. Additional steps must be taken to qualify as exempt, including, for example, limited Institutional Review Board (''IRB'') review. Also, if a subject refuses to provide broad consent, the Final Rule makes clear that an IRB cannot waive consent for the use of that specific subject's identifiable private information and identifiable biospecimens.

The use of de-identified data and biospecimens is not impacted by the Final Rule and, consequently, still falls outside the jurisdiction of the Final Rule.

Institutions will want to create new consent templates to allow for broad consent where appropriate. In addition, it is advisable to evaluate how these changes impact an institution's Health Insurance Portability and Accountability Act (''HIPAA'') authorization templates in the secondary research context and to create a procedure for tracking refusals to provide broad consent.

Questions to Consider:

■ What procedure will the Institution use to track refusals to provide broad consent?

■ What procedure will the Institution use to exclude from secondary research the identifiable private information and identifiable biospecimens of a subject who refused to provide broad consent?

■ What procedure will the Institution use to determine if future research falls within the scope of the broad consent?

■ For those subjects who refuse to provide broad consent, will the Institution destroy the identifiable private information and identifiable biospecimens or de-identify them for future research?

■ For those subjects who refuse to provide broad consent, will the Institution retain the identifiable private information and identifiable biospecimens for non-research purposes only?

■ Does the current IT system used by the Institution allow for detailed electronic tracking processes or will this need to be added to the budget?

■ What SOPs will be impacted?

■ Who will be charged with preparing the broad consent template?

■ Would it make sense to delay implementation of a broad consent procedure to a later date?

2. Informed Consent

Highlights. Along with allowing for broad consent for certain secondary research, the Final Rule contains requirements for informed consent documents and adds new elements of informed consent. Among other things, the Final Rule introduces new requirements that are designed to enhance the understanding of subjects and/or legally authorized representatives.

While these requirements are consistent with the goals of protecting human subjects, they may seem facially contradictory. For example, the Final Rule requires the informed consent to ''begin with a concise and focused presentation of key information'' to assist the subject in understanding the reasons why someone might or might not want to participate in the research. The Final Rule then stresses that it is not acceptable to ''merely provide lists of isolated facts'' during the informed consent process, but information must be presented in sufficient detail to again facilitate understanding the reasons why someone might or might not want to participate in the research.

The Final Rule also requires the publication of the informed consent form used in a covered clinical trial to be posted on a federal web site within sixty days of the close of enrollment into the study.

Questions to Consider:

■ Will the Institution provide guidance to investigators as to the type of information that qualifies as ''key information'' under the Final Rule?

■ Will the ''key information'' be incorporated into the informed consent form or provided separately during the informed consent process?

■ Have investigators become used to providing lists of facts in the informed consent forms to facilitate understanding? Will that approach need to be revised?

■ What changes will need to be made to training IRB members in connection with review and revisions to informed consent forms?

■ What procedure will the Institution use to ensure that informed consent forms are posted in a timely manner?

■ Will the Institution post all consent forms after the compliance deadline or only those consent forms related to research subject to the Final Rule?

3. Limited IRB Review

Highlights. The Final Rule introduces the concept of ''limited IRB review'' in connection with exempt research, expedited review, and the criteria for IRB approval of research. A driving concern underlying the new limited IRB review procedures is protecting the

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identity of subjects who may be identified directly or through identifiers.

To that end, use of limited IRB review procedures is a condition of exemption for (a) research that only includes interactions with adult subjects involving educational tests, survey procedures, interview procedures, or observation of public behavior if the information is recorded in such a way that the identity of the subjects can be readily ascertained; (b) research that involves benign behavioral interventions in connection with collecting information from adult subjects through agreed verbal, written, or audiovisual recording if the information is recorded in such a way that the identity of the subjects can be readily ascertained; (c) storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use; and (d) use of identifiable private information or identifiable biospecimens for secondary research use.

When conducting a limited IRB review, the IRB (or designated IRB member) is required to make and document the following determinations: (a) if broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained consistent with regulatory requirements; (b) if broad consent was appropriately documented or waiver of documentation was appropriate and consistent with regulatory requirements; and (c) when a change is made for research purposes in the way that the identifiable private information or identifiable biospecimens are stored or maintained, if adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data.

Questions to Consider:

■ What process will the IRB use for conducting limited IRB review?

■ Will the IRB designate a specific member to conduct limited IRB review?

■ What changes will need to be made to training IRB members and investigators?

■ What changes will need to be made to IRB application forms?

4. Federalwide Assurances (compliance date unclear)

Highlights. The preamble to the Revised Common Rule eliminates the option for Federalwide Assurance (''FWA'') holders to ''check the box,'' *i.e.*, voluntarily agree to comply with the Common Rule for its nonfederally funded research. Every institution engaged in research funded by a Common Rule agency or department must submit an FWA, which is a written assurance of compliance with the Common Rule for the covered research activities, to the Department of Health and Human Services' Office for Human Research Protections (''OHRP'').

In the past, institutions had the option to make a voluntary commitment to comply with the Common Rule for all human subjects research conducted at the institution, regardless of how the research was funded. The preamble eliminates this, stating that the ''voluntary extension will no longer be part of the assurance process and such research will not be subject to OHRP oversight.''

Because this change was made in the preamble to the rule rather than in the regulations, the compliance date for this change is unclear, and the issue should be evaluated as soon as possible.

Questions to Consider:

■ In the state where the Institution is operating, are there state laws governing research implicated by this change?

■ Should the Institution engage with state governmental authorities for guidance and interpretation of state human research laws?

■ Will the Institution implement the Final Rule for federally funded studies only or for all studies?

■ What risks may be introduced by using different SOPs for federally funded studies and other studies?

5. Ongoing Research

Highlights. The Final Rule specifically applies to research requiring initial IRB review on or after the relevant compliance date. The prior version of the Common Rule applies to research requiring initial IRB review before that date. However, there will be some research that ''straddles'' the compliance date, as well as other research commenced before the compliance date that will continue after the compliance date. Institutions may choose to proceed with separate sets of SOPs—one that applies to research commenced before the compliance date and another for research commenced on or after the compliance date. Alternately, institutions may choose to transition research commenced before the compliance date to the SOPs that accord with the Final Rule.

Among the SOPs that will need to be updated are: (1) the definition of research in the IRB's policies and procedures, which should be updated to reflect the new definition of research with its additional carve-outs; (2) the definition of ''human subject,'' which should now include ''identifiable biospecimen''; (3) exemptions; (4) the procedures and conditions for limited IRB review; (5) the IRB's continuing review policy to allow for the new exceptions; (6) the IRB's expedited review procedures; (7) the waiver process to address broad consent; and (8) screening and recruitment policies to remove the consent requirement.

Questions to Consider:

■ What procedure will the IRB use to track the rules that apply to research before and after the compliance date?

■ Will maintaining two sets of rules that apply to federally funded research introduce more risks than benefits?

■ Will the IRB transition research that meets the Final Rule conditions for research that is not subject to continuing review?

■ Will the IRB's decision to transition the research to one not subject to continuing review trigger other re-

quirements of the Final Rule, such as the new informed consent requirements?

■ Will the IRB begin to implement the provisions of the Final Rule prior to the compliance date?

6. Conclusion

Compliance with the Final Rule will require careful review and preparation. Even if the compliance date for most of the changes is delayed, institutions would be well-served to start evaluating what needs to be done and preparing plans for compliance as soon as possible.

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