

WILLIAMS & JENSEN, PLLC

MEMORANDUM

To: Research Society on Alcoholism

From: George G. Olsen

Date: October 8, 2015

Re: Proposed Modernization of the Common Rule

On September 8, several Federal departments and agencies [released](#) a Notice of Proposed Rulemaking (NPRM) to modernize the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. The NPRM seeks to simplify and enhance the current oversight system to strengthen protections for research subjects and facilitating research. The major changes to the Common Rule include improving informed consent by increasing transparency; requiring informed consent for the storage of biospecimens in secondary research; excluding certain categories from coverage; adding additional categories of exempt research; changing the conditions for waiver or alteration of consent; mandating reliance on a single institutional review board (IRB); and extending the scope of the policy to cover all clinical trials conducted at a U.S. institution that receives Federal funding for non-exempt human subjects research. Public comments on proposal must be submitted by December 7, 2015.

Changes to the Scope of the Regulations

The NPRM would change the definition of “human subject” to cover biospecimens regardless of identifiability. Informed consent would be required for research involving biospecimens in all but a limited number of circumstances and that consent could be obtained through broad consent for future unspecified research. This new definition would only apply prospectively and would be delayed until three years after publication of a final rule. Secondary research on stored biospecimens designed only to generate information about the person that is already known would be excluded. IRBs would also be able to waive the requirement for informed consent under very strict requirements in rare circumstances. The Common Rule standard for identifiability would not be modified.

The NPRM would create a new group of exclusions with eleven specific types of activities that would be outside the scope of the regulation. These activities will not have to satisfy any of the regulatory requirements nor undergo any type of review process to determine their status. The first six exclusion categories are activities that are deemed not to involve research and include activities that are inherently government functions. These six activities are (1) program improvement activities; (2) oral history, journalism, biography, and historical scholarship activities; (3) criminal justice activities; (4) quality assurance activities; (5) public health surveillance; and (6) intelligence surveillance activities.

Some of the exclusions identify research that is low-risk and non-intrusive making the protections provided by the regulations unnecessary. Although these activities are research, they would not be required to undergo IRB approval and consent under the Common Rule would not be required. Included in these exclusions are (1) educational tests, survey procedures, interview procedures, or observation of public behaviors; (2) research involving the collection or study of information that has been or will be collected for non-research activities; (3) research conducted by a government agency using government-generated or government-collected data; and (4) certain activities covered by the Health Insurance Portability and Accountability Act (HIPAA). The final exclusion, as discussed above, pertains to secondary research on stored biospecimens that is only designed to generate information about the person that is already known. This would include such things as the development of certain tests and assays as well as quality assurance and control activities.

In addition to exclusions, the Common Rule also includes exemptions designed to create procedural efficiencies for IRBs, administrators, and investigators while still ensuring that reasonable safeguards are in place for certain lower risk research activities. Federal departments and agencies would be required to develop one or more exempt determination tools or rely on a tool created by another government entity to ensure investigators make timely and accurate determinations. Institutions and investigators would be able to rely on the outcome as a “safe harbor” so long as the information provided was accurate. The NPRM anticipates that investigators will not be able to make determinations for themselves without the use of the decision tool to avoid a conflict of interest. The institution or IRB would be required to keep records of exempt determinations though IRB will not have the authority to review or approve, require modification, or disprove research that qualifies for an exemption.

Four of the proposed exemptions in the NPRM would not be subject to any additional requirements besides keeping a record of the exempt determination. These exemptions would be: (1) research conducted in established or commonly accepted educational settings; (2) research and demonstration projects conducted or supported by a Federal department or agency; (3) research involving benign interventions in conjunction with the collection of data from an adult subject; and (4) taste and food quality evaluation and consumer acceptance studies. Two exemption categories would be subject to the documentation requirement along with new privacy safeguards. The NPRM would eliminate the need for IRB review for studies involving the collection of identifiable private information so long as the proposed privacy safeguards, discussed below, are met. These categories are (1) research involving educational tests, surveys, interviews, or observation of public behavior if the information is recorded with identifiers and even if the information is sensitive and (2) secondary research use of identifiable information private information. The final two exemptions would be subject to the documentation requirement, privacy safeguards, limited IRB review, and broad consent. These two exemptions are (1) storage and maintenance for secondary research use of biospecimens or identifiable private information acquired for research studies other than for the proposed research study or for non-research purposes, and (2) secondary research use of biospecimens or identifiable private information where broad consent has been sought and obtained.

Changes to Informed Consent

The NPRM would address the presentation of information in the consent document; elements of consent; broad consent for secondary research; and changes in the waiver or alteration criteria for consent. The proposal would add new introductory language to emphasize the need to provide essential information that a reasonable person would want to know to make an informed decision. The expectation is that these new requirements would lead to substantially shorter consent forms and key information will not be buried in a long, overly complex document. Guidance will be published on how investigators can write consent forms to comply with the requirements. These new basic elements of consent would apply to all research collecting identifiable private information and informed consent must make it clear that either the non-identified data could be used in secondary research or that the data will not be used for any future research in any form. The NPRM would also add three additional elements of consent: (1) informing prospective subjects that their biospecimens could be used for commercial profit; (2) informing whether clinical research results or data will be shared with the subject; and (3) an option for subjects to consent or refuse to consent to investigators re-contacting the subject. Within 60 days after a trial closes for recruitment, the final version of the consent form would have to be posted on a publicly available Federal website for all clinical trials covered by the Common Rule.

The NPRM would allow broad consent for the storage or maintenance of biospecimens and identifiable private information for secondary research. The consent would be permissible for information and biospecimens originally collected for either research or non-research purposes. The broad consent would not be study-specific and would satisfy the consent requirements for two of the exempt categories described above. Consent would not be required for secondary research on non-identifiable information. The consent document should describe the biospecimens and information that would be covered. In the non-research context, broad consent would be limited to the biospecimens and information collected at the time the broad consent is sought or biospecimens and information collected for up to 10 years after broad consent is obtained. Subjects would also have to be informed that they may withdraw their consent, if feasible, at any time without penalty or loss of benefits. The Secretary of the Department of Health and Human Services (HHS) will publish templates for broad consent in the Federal Register.

The NPRM would create a new waiver criterion for research that could not be practically carried out without accessing or using identifiers. A waiver of consent would not be authorized where the subject refused to provide broad consent. IRBs would be allowed to approve a research proposal which would collect identifiable private information without informed consent for the purpose of screening or determining the eligibility of prospective subjects so long as the proposal includes an assurance proper information protection standards will be put in place.

Information Protection

The NPRM recognizes that IRBs were not designed to evaluate privacy risks and confidentiality so uniform standards could help ensure appropriate protections while reducing burdens. It proposes several sets of standards that may be used to ensure adequate safeguards are in place. The Secretary of HHS would publish a list of specific measures that could be readily implemented by investigators to meet the requirements. Investigators already required to comply or who choose to comply with HIPAA or other privacy statutes would satisfy the Common Rule

safeguard requirements. IRBs would generally not be required to review safeguards but would have to ensure proper protections for their records that contain identifiable private information. The NPRM would also limit the re-disclosure of biospecimens and identifiable private information obtained for research to four circumstances: (1) human subject research regulated under the Common Rule; (2) public health purposes; (3) any lawful purpose with consent of the subject; and (4) for other research purposes so long as there were adequate safeguards are in place.

Changes to IRBs

The NPRM would mandate that all institutions located in the U.S. engaged in cooperative research rely on a single IRB as the reviewing IRB for the study. This is intended to streamline the review process and reduce inefficiencies. There would be exceptions for research required by law to have more than one IRB or when the Federal department or agency supporting the research finds a single IRB inappropriate for a particular study. In addition, Common Rule departments and agencies would have the authority to directly enforce compliance against unaffiliated IRBs that are not operated by an assured institution. An external IRB and the institution relying on the IRB would need to establish and follow written procedures specifying the responsibilities of each entity to ensure compliance.

The NPRM also seeks to reduce the regulatory burden by eliminating continuing review for many minimal risk studies unless the reviewer documents why continuing review should take place. After the study reaches the stage where it is analyzing data or accessing follow-up clinical data, studies initially reviewed by a convened IRB would need to undergo continuing review unless mandated by the IRB. IRBs must receive annual confirmation that the research is ongoing and no changes requiring review have been made. Investigators would still submit change protocols to the IRB but institutions will have flexibility in implementing the requirement. Expedited review will be available for all studies identified by the Federal departments and agencies as having minimal risk unless the reviewer determines the study involves more than minimal risk. This list would be evaluated every eight years.

The NPRM would create a new form of IRB review for storing or maintaining data and biospecimens for secondary use by requiring the IRB to determine the procedures for obtaining broad consent were appropriate and determine whether the privacy safeguards meet information protection standards. NPRM also seeks to create consistency in the regulations for vulnerable populations by requiring IRBs to focus on coercion or undue influence. IRBs would also be required to determine whether a plan for returning research included in a protocol is appropriate but not whether the plan is needed.