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NEW GUIDANCE: FDA ALLOWS WAIVER OF INFORMED CONSENT FOR MINIMAL RISK RESEARCH

On July 25, 2017, the Food and Drug Administration ("FDA") issued guidance (the "Guidance") stating that it does not intend to object to an Institutional Review Board's ("IRB") wavier of the informed consent requirements for human subjects research involving no more than minimal risk. The Guidance, effective immediately, aligns the FDA's policy on the waiver of informed consent with Federal Policy for the Protection of Human Subjects (the "Common Rule").

BACKGROUND

In general, the FDA's regulations governing the protection of human subjects mirror the requirements of the Common Rule, which set forth the human subjects protections for research that is conducted or supported by the Department of Health and Human Services ("HHS") and 15 other federal departments and agencies. While the FDA regulations and the Common Rule share the same definition for "minimal risk"[1] studies, the Common Rule allows for a waiver of informed consent for minimal risk research when certain criteria are met. However, the current FDA human subjects regulations contain no corresponding waiver provision and only allow for an exception to the informed consent requirements in life-threatening situations or when the requirements for emergency research are satisfied.

As a result of the inability to waive informed consent for minimal risk research, many important minimal risk FDA-regulated studies have not proceeded because the FDA did not have statutory authority to permit a waiver of informed consent. However, on December 13, 2016, the 21st Century Cures Act was signed into law (the "Act"). The Act provided the FDA the authority to allow an exception to its existing informed consent requirements if the research poses no more than minimal risk to subjects and includes appropriate safeguards to protect the subjects' rights, safety and welfare.

The authority granted by the Act is in line with Secretary's Advisory Committee on Human Research Protections ("SACHRP") previous recommendations to the Secretary of HHS that the FDA adopt the Common Rule provisions for the waiver of informed consent for minimal risk research. The SACHRP noted that harmonization with the Common Rule would help eliminate confusion about when waiver of informed consent may be permitted and would also serve to facilitate FDA-regulated minimal risk studies.

GUIDANCE

The Guidance, issued in response to the Act, permits a waiver of the informed consent requirements for minimal risk research that is regulated by the FDA. In the Guidance, the FDA noted its intention to promulgate regulations and revise its current informed consent requirements to add waiver or alteration of informed consent for minimal risk research. However, until these regulations are promulgated, the FDA does not intend to object to an IRB approving a waiver or alteration of informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

These four requirements mirror the existing four requirements for waiver or alteration of informed consent for minimal risk studies under the Common Rule. However, it should be noted that the revised Common Rule regulations set to take effect on January 19, 2018 add an additional criterion to the existing waiver of informed consent framework. Under the new Common Rule regulations, the IRB must also determine that "if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format." While the Guidance does not include this fifth criterion, the FDA noted that it will consider including this requirement in any waiver provision that is added to the harmonizing regulations.

PRACTICAL TAKEAWAYS

The Guidance will remove what has historically been a barrier in conducting FDA-regulated minimal risk research and will allow researchers to obtain a waiver of informed consent for minimal risk research activities such as retrospective chart review. It will also allow researchers and sponsors to utilize the data obtained from such research in support of regulatory submissions to the FDA.

Institution IRBs should review and become familiar with the FDA requirements for an alteration or waiver of informed consent and may begin considering such requests by sponsors and investigators immediately.

The FDA noted its intent to withdraw the Guidance after it promulgates new regulations. While there is no time frame for when the new regulations will be issued, the FDA will consider comments received from stakeholders and will revise the Guidance as appropriate.

If you have any questions regarding the FDA's Guidance, or any other clinical research concerns, please contact:

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[1] "Minimal risk" is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."