The 21st Century Cures Act: Implications for Human Subject Protections

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The 21st Century Cures Act, initially introduced in May 2015, is an extensive set of regulations around the development of drugs, biologics and medical devices, with implications for all parties involved in the conduct of clinical research. The Act, which has gone through multiple revisions, has been developed with extensive input from multiple stakeholders. It has been controversial, with some believing that the changes it mandates will help to speed the drug development process, reduce waste, and bring promising new therapies to market faster; others feel that the changes will weaken the role of the FDA in assuring the safety and efficacy of new products prior to approval (e.g., by allowing "real-world" data to be considered in drug approvals; by requiring "flexible approaches" to facilitate the approval of medical devices that represent "breakthrough technologies").

The 21st Century Cures Act, recently approved by Congress and signed into law by President Obama on December 13, 2016, has many provisions which will help to improve the efficacy of human subject research while appropriately reducing the administrative burden. Several of these provisions are listed below.

- The Secretary of Health and Human Services (HHS) will be required to harmonize the HHS Office of Human Research Protection (OHRP) and Food and Drug Administration (FDA) human subject protection regulations to the extent possible. Harmonization of these guidelines will reduce the burden on investigators, sponsors and Institutional Review Boards (IRBs) who currently must comply with multiple sets of regulations each designed to protect research participants, but not entirely consistent with each other. (Section 3023)

- As one important feature, the Act will allow FDA to harmonize with the HHS regulations on allowing a waiver of consent for minimal risk research. Currently, the FDA regulations are much more restrictive than the HHS regulations regarding such waivers, stifling minimal risk research (such as retrospective record reviews and use of anonymized data) that could contribute to FDA decision-making without creating potential risk to research participants. (Section 3024)

"A drug is eligible for designation as a regenerative advanced therapy if—

'(A) the drug is a regenerative medicine therapy (as defined in paragraph (8)*);

'(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

'(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

** (8) DEFINITION.—For purposes of this section, the term 'regenerative medicine therapy' includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations."* [2]

- Similar to the recent policy of the National Institutes of Health (NIH), the Act encourages the use of central "lead" IRBs to reduce administrative burden in multi-center studies, with an emphasis on knowledge of local considerations and protection of vulnerable subjects. (Section 3023)

- The Act removes the existing FDA requirement for local IRB review of multi-center medical device studies (this restriction currently exists, although many are unaware of it as the FDA has not enforced this regulation). (Section 3056)

- The Act requires FDA to issue draft guidance within one year clarifying how the HHS Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies (see sidebar). (Section 3034)

- The Act helps to clarify when software should be regulated by the FDA as a medical device, reflecting many of the positions in the FDA guidance on mobile medical applications (Section 3060)

- The Act increases the protection of research participants' data by expanding the requirement for Certificates of Confidentiality to all research involving the collection of identifiable sensitive information. Previously, Certificates only applied to data collected for federally-funded studies. (Section 3060)

- The Act provides the Secretary of HHS with the authority "to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent "breakthrough technologies," (see sidebar). Critics argue that this weakens the authority of the FDA and could lead to the approval of devices that are not ready for use by the public. (Section 3051)

Breakthrough devices are defined as devices:

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2) (A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients." [3]

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References

[1] Final NIH Policy on Use of a Single Institutional Review Board for Multi-Site Research. 21 June 2016. Accessed at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

[2] 21st Century Cures Act, Section 2033

[3] 21st Century Cures Act, Section 3051