ClinicalTrials.gov

This letter provides notice of a recent Federal court decision that may affect your obligations to submit certain results information to the ClinicalTrials.gov.

A Federal court has held that Section 801 of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") requires submission of results information for any applicable clinical trial ("ACT"), as defined in section 402(j)(1)(A) of the Public Health Service ("PHS") Act, that was initiated after September 27, 2007, or that was ongoing as of December 26, 2007, if the ACT studied a product that is approved, licensed, or cleared by the U.S. Food and Drug Administration ("FDA") at any time, including after the primary completion date.

On September 21, 2016, the Department of Health and Human Services ("HHS") published the *Final Rule for Clinical Trials Registration and Results Information Submission*, 81 FR 64982 (Sept. 21, 2016) ("Final Rule"). The preamble to the Final Rule states that a responsible party is not required to submit to the ClinicalTrials.gov data bank results information under section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act for an ACT that was completed before January 18, 2017, the effective date of the Final Rule, if the ACT studied a product that was not approved, licensed, or cleared until after the ACT's primary completion date. 81 FR at 65067. On February 24, 2020, a Federal court rejected this interpretation, holding that FDAAA requires responsible parties to submit to the ClinicalTrials.gov data bank such results information for ACTs completed before January 18, 2017, if the ACT studies a product that is approved, licensed, or cleared by FDA *at any time*, including after the ACT's primary completion date. *Seife et al. v. HHS et al.*, No. 18-cv-11462-NRB, 2020 WL 883478 (S.D.N.Y., February 24, 2020). The Court set aside HHS's contrary interpretation in the preamble to the Final Rule, but did not change the regulations.

Please review your clinical trial(s) to determine whether it is affected by the Court's decision because it is an ACT that: (1) was initiated after September 27, 2007, or was ongoing as of December 26, 2007; (2) reached its primary completion date before January 18, 2017; and (3) studied a product that is approved, licensed, or cleared by FDA at any time, including after the ACT's primary completion date. If the product studied in the ACT *is not currently* approved, licensed, or cleared by FDA, but *is* at a future date, then the results information described above must be submitted within 30 days after the date that the product is approved, licensed, or cleared by FDA. If the product studied in the ACT *is currently* approved, licensed, or cleared by FDA, then you must submit the results information specified in section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act to the ClinicalTrials.gov data bank for such ACT as soon as possible.

FDA and the National Institutes of Health ("NIH") may take action against responsible parties if they do not submit required results information. Failure to submit required results information is a prohibited act under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(jj)(2), for which FDA could pursue civil monetary penalties under 21 U.S.C. 333(f)(3) against the ACT's responsible party. For an ACT for which a grantee is the responsible party, failure to submit required results information could result in NIH or FDA, as applicable, not releasing remaining funding for a grant or funding for a future grant in accordance with section 402(j)(5)(A) of the PHS Act.