Federal mandate has improved availability of consent forms for clinical trials, researchers say

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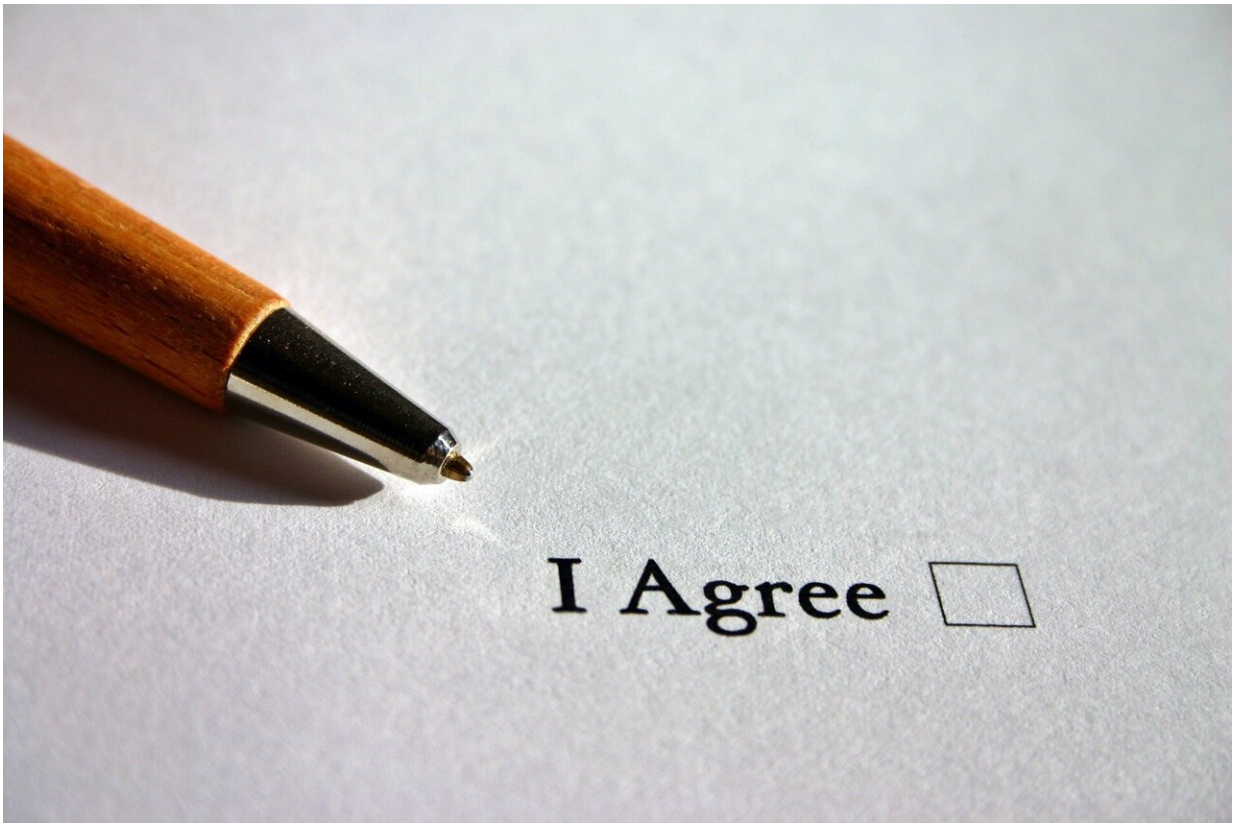

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A federal regulation called the Common Rule previously requested the public posting of participant consent forms to trials listed in the national

clinical study database clinicaltrials.gov, among other human research protections, since 1991. However, the forms were often not posted in a timely manner or at all.

To improve posting and posting timing, the rule was revised in 2018 to require the forms be posted within 60 days of the trial's completion date. Now, an analysis led by a Penn State researcher has found that the revised rule appears to be working.

Led by Sydney Axson, Penn State Ross and Carol Nese College of Nursing assistant professor, the team published their results in *JAMA Network Open*. They found that while the new requirement has gradually improved posting, the outcomes are still falling short of the 60-day timeline and recommend revising once more to require forms to be posted during the recruitment period.

Trial consent forms provide study information that can improve informed decision making for participants; however, it can often be difficult for prospective or current trial participants to find the forms as they can be buried in hundreds of pages of protocol documentation, if they're even posted at all.

"Consent forms play a unique role in decision making. If participants have this information, they can talk about it with other people, with their family, with their doctor, they can research more on what's important to them," Axson said. "How we present information about studies to people matters."

The revised Common Rule, implemented to help provide such information to potential study participants, requires that for each clinical trial conducted or supported by a federal department or agency, one institutional review board-approved consent form used to enroll subjects be posted on a publicly available federal website within 60 days. When

the rule was made a requirement in 2018, a two-year grace period was built in to give researchers time to adjust.

Axson and the team analyzed 10,311 National Institutes of Health trials from 2013 to 2023 and categorized them into three periods: pre-voluntary, voluntary and revised rule. The revised rule period refers to time after the mandated revised rule, the voluntary period for the two-year grace period leading up to the revised rule, and the pre-voluntary period for time before the revised rule and its grace period.

The researchers found that of these, only 1,716 trials posted participant consent forms. However, the percentage of researchers posting consent forms increased from 2.7% in the pre-voluntary period to 30.5% after the revised rule, and the posting time improved from 1,040 days in the pre-voluntary period to 103 days after the revised rule.

Axson's next steps will look to analyze the documents individually to better understand how to improve the informed consent process.

The research team said they believe sharing these forms with participants impacts trial recruitment and that making the forms publicly available and easily accessible even earlier in the trial process could be beneficial to prospective participants and their enrollment.

"Having these forms publicly available will facilitate the study of informed consent documents and, hopefully, enable researchers and providers to improve how important trial information is shared with research participants," Axson said.

More information: Sydney A. Axson et al, Consent Form Reporting on ClinicalTrials.Gov, 2013-2023, *JAMA Network Open* (2024). DOI: 10.1001/jamanetworkopen.2024.18895

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