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New SACHRP Recommendations on Interactions among Sponsors, Clinical Trial Sites, and Study Subjects

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The U.S. Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections ("SACHRP") recently issued recommendations on interactions between clinical trial sponsors (which could be either industry or academic entities) and clinical trial subjects.[1] Increased interactions between sponsors and patient populations have begun to blur the traditional division of roles between sponsors and investigators. SACHRP's recommendations contemplate such changes in the clinical trial enterprise, examine the key legal and ethical concerns in this area, and offer specific solutions for addressing these challenges.

SACHRP's recommendations highlight three prevalent scenarios that may give rise to legal and ethical challenges: (1) interactions between sponsors and potential study subjects for clinical trial recruitment; (2) programs through which sponsors engage current or former subjects to produce testimonials for the sponsor's own use; and (3) sponsor engagement of vendors to perform recruitment services on behalf of study sites. SACHRP's recommendations also include certain helpful case studies that illustrate these points.

Interactions between Sponsors and Potential Study Subjects

The U.S. Food and Drug Administration ("FDA")[2] and the Office for Human Research Protections ("OHRP")[3] both recognize recruitment of subjects as the beginning of the informed consent process. However, neither the FDA nor OHRP guidance on study subject recruitment covers in any detail the sponsor's role in the clinical trial recruitment process. According to the just-adopted SACHRP guidance, SACHRP recommends that trial-specific recruitment activities performed by sponsors be subjected to the same institutional review board ("IRB") oversight as recruitment activities conducted by investigators and study sites. Sponsors and any of their vendors engaged in recruitment should follow certain key principles:

- The recruitment section of a clinical trial protocol should incorporate the sponsor's recruitment activities and materials (e.g., scripts or template emails used for screening), so that these materials may undergo IRB review and oversight.
- Sponsors should refrain from discussing clinical trial eligibility with prospective subjects and limit the discussions to publicly available information (e.g., information posted on clinicaltrials.gov).
- Sponsors should bear in mind when undertaking subject recruitment activities that the study investigator remains responsible for determining a potential subject's eligibility for the trial.
- Sponsor staff engaged in clinical trial recruitment should be trained to adhere to subject recruitment principles articulated in FDA and OHRP guidance (e.g., inform subjects when a test article is investigational and has not been demonstrated to be safe or effective; refrain from promising free treatment when the only free treatment provided is the investigational product; avoid overemphasizing the payment to subjects for their participation in the trial).
- In order to protect subject privacy, sponsors that receive identifiable information in connection with recruitment activities should segregate any identifiers received during the recruitment process from coded data received on study case report forms.

- Institutions can complement IRB oversight by developing policies that determine whether specific recruitment activities are permissible at an institutional level.

Contact of Enrolled Study Subjects by Clinical Trial Sponsors

Clinical trial sponsors are increasingly interested in contacting subjects to obtain information regarding their experiences with the condition under investigation, as well as their experiences in the trial (e.g., for education, promotion, or fundraising efforts). SACHRP articulates certain key principles to manage such scenarios:

- The investigator should be responsible for making any initial proactive contact with the study subject, instead of the clinical trial sponsor, so as to preserve the traditional separation of roles between the sponsor and investigator.

- Sponsors should ensure that any of their contact with study subjects (e.g., asking subjects to participate in a video testimonial) is reviewed and approved by an IRB.

- IRBs should consider whether the study will likely suffer bias as a result of the sponsor's initiating and maintaining direct contact with subjects (e.g., a subject may believe that they were contacted by the sponsor because they experienced a good or bad outcome in the study, or that contact by the sponsor is an indication that the subject received the investigational product rather than placebo).

- Any publicly disseminated materials or subject testimonials should focus on the subjects' experiences with the disease or experience in the clinical trial, rather than on "success" of an experimental treatment, to avoid unintentional promotion of an investigational product; and materials should comply with FDA promotional concerns and adhere to U.S. Securities and Exchange Commission requirements.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Complexities and Handling Medical Information of the Potential Study Subjects

Clinical trial sponsors increasingly engage vendors to perform a wide variety of services on behalf of clinical trial sites (e.g., clinical trial recruitment or making travel arrangements for study subjects). Such activities may require clinical trial sites that are covered entities under HIPAA to disclose a subject's protected health information ("PHI") to the vendor. However, the vendor's activities often occur before a subject enrolls in the study and before the subject has signed a HIPAA authorization form. SACHRP emphasizes that all parties (i.e., sponsors, vendors, study sites, and researchers) should be mindful of each other's privacy-related obligations.

- Study sites and investigators are typically HIPAA-covered entities, and cannot share PHI unless the subject signs an authorization, or unless an exception to the authorization requirement applies.

- Study sites and investigators are bound by promises regarding disclosure and sharing of research-related information that were made during the informed consent process.

- Sponsors and their vendors, including those who are not HIPAA-covered entities, may have privacy obligations to subjects based on common law principles, state privacy laws, and/or prior promises that were made.

Key Takeaways

SACHRP's recommendations emphasize that clinical trial sponsors and third-party vendors involved in subject-recruitment activities should strive to maintain the traditional separation of roles between the sponsor and the clinical investigator to ensure that subjects do not perceive sponsor staff as their health care provider(s). Preserving such

separation of roles serves as a liability protection for sponsors and also preserves the integrity of the research process by ensuring that subjects understand that they should contact the investigator, and not the sponsor, with questions about the study or to seek advice regarding any adverse events experienced during the study.

SACHRP's recommendations also highlight that sponsors or vendors interacting with prospective subjects should review carefully whether their activities are subject to IRB oversight. Interactions should be designed to minimize the likelihood that subjects or their families will perceive that they have little meaningful choice but to cooperate in sponsor requests. Requests for subjects and their families to engage in media or public relations activities should ideally occur ***after*** the subject has completed the trial, unless there is a compelling reason for such activities to occur while a subject is still participating in the trial. Any subject interviews or "testimonials" should accurately portray clinical studies as research involving unproven, though promising, experimental agents or procedures.

Finally, SACHRP's recommendations underscore that all sponsor and vendor interactions with subjects or prospective subjects must be planned and executed to respect the various privacy obligations of all parties involved (e.g., the sponsor, vendor, study sites, clinical investigators, health care providers, and any research staff). This includes being mindful of which entities are subject to HIPAA and what permissions may be needed for the parties to exchange PHI with one another for purposes of the study.

If you have any questions, please contact Mark Barnes, David Peloquin or your usual Ropes & Gray advisor.

1. Secretary's Advisory Committee on Human Research Protections, New Challenges in Interactions among Sponsors, Clinical Trial Sites, and Study Subjects (2021), *available at*: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-new-challenges-sponsor-clinical-trial-site-subject.html.
2. *See* U.S. Food and Drug Administration, Recruiting Study Subjects (1998), *available at*: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects.
3. *See* U.S. Department of Health and Human Services, IRB Review of Clinical Trial Websites (2005), *available at*: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/clinical-trial-websites/index.html.