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Broad Considerations to Protect Non-Subjects From Research Risks

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The Secretary's Advisory Committee on Human Research Protections (SACHRP) recently submitted recommendations on the need for institutional review boards (IRBs) and organizations to formally address the threats they may not typically consider.[1] Specifically, the recommendations call on HHS to address the risks to which non-research participants may be exposed as a result of their relationship to those who are enrolled in studies.[2]

The following are among factors to be considered, according to SACHRP:

1. "During the process of IRB review and approval, IRBs should identify and seek to minimize risks to living individuals who are, or who are likely to be, exposed to research-related risk, even when they do not meet HHS or FDA [Food and Drug Administration] definitions of human subject.

2. "Although all research stakeholders are responsible for recognizing and addressing risks to non-subjects, and many IRBs regularly consider such risks, SACHRP takes the position that the IRBs should assume responsibility for protecting non-subjects who may be unknowingly exposed to risk and who cannot take self-protective measures or who may be exposed to experiential harms (e.g. the sexual partner of subject testing an investigational barrier contraceptive, stigma associated with the research results, etc.). This responsibility, however, should be limited in scope. In addition, where separate institutional oversight bodies provide expertise and authority in the assessment and management of risk to non-subjects, IRBs should be permitted to fulfill this obligation by relying on those reviews or seeking consultation when required or appropriate.

3. "Characterization of risk to non-subjects along the dimensions of probability, magnitude, foreseeability, and causal proximity during review may help establish thresholds for IRB decision-making.

4. "IRBs should not routinely consider research related harms that are no more likely or serious than those that represent the ordinary risks of daily life. SACHRP recommends that IRBs conduct review of non-subject risk only when those risks are greater than minimal risk.

5. "Regardless of the type of risk to the research team or other personnel, SACHRP recommends that IRBs be cognizant of risks to personnel and consider engaging the appropriate authorities within the institution to review and manage such risks.

6. "The IRB's assessment and management of risk to non-subjects requires a careful delineation of responsibilities in order to minimize a duplicative, unnecessary, or inexpert review better conducted by other institutional entities or in consultation with other entities.

7. "IRBs may consider mechanisms to inform non-subjects of potential harms related to research, may determine that low risk 'exposures' do not require disclosure, or may decide that disclosure may be impracticable or itself introduce harm to the subject.

8. "SACHRP recommends that IRBs consider the need to formalize in policy the review of risk to non-subjects and the referral to or coordination of review with other expert external or institutional bodies and functions.

9. "Whether the pregnant partners of participants in investigational treatment studies are research subjects has been the subject of controversy in part reflecting the disharmony in HHS and FDA definitions of research subject. SACHRP does not consider the collection of safety data from a person who becomes pregnant during the partner's research participation, in and of itself, to constitute human subject research, and therefore that pregnant individual does not fulfill the definition of human subject under HHS or FDA rules."