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U.S. Urged to be 'Silent' No More: Mandate Compensation for Research-Related Injuries

By Theresa Defino

Echoing numerous calls over the past decade or more, an international group of medical ethicists is renewing attention to the need for mandatory compensation for participants in clinical trials, stating that it is simply "unethical that the U.S. does not require all research subjects to receive comprehensive care for injuries they may experience as a result of their participation."[1]

Writing in a recent issue of the *Journal of Law, Medicine & Ethics*, Carolyn Riley Chapman, a faculty affiliate in the Division of Medical Ethics at New York University (NYU) School of Medicine, and four coauthors argue that the "U.S. lags behind other nations in its protection of human research subjects and that the establishment of a more comprehensive compensation system is both practical and feasible." The United States is an outlier here as "almost all other developed nations...have instituted policies to require researchers or sponsors to provide treatment or compensation," the authors say, quoting previous research.

Their proposal for coverage would require new federal legislation, but institutions could consider adopting such policies on their own, enlightened perhaps by the details of existing programs the paper described that are already in place in India, South Africa and Russia, as well as a few limited programs in three U.S. universities—among them the University of Washington (UW) and Wake Forest University.

"We agree with others that a decentralized no-fault compensation system is the best path forward as it minimizes administrative and logistical challenges," the authors write, and further "suggest mandating and strengthening existing mechanisms for compensating research participants for research-related injuries in the United States." Ultimately, Chapman and her coauthors propose an "insurance-based approach" in which "multiple stakeholders...share responsibility."

The authors note that, "Despite broad consensus that human research participants deserve medical care and/or other forms of compensation if they are injured as a result of research, U.S. regulations do not currently require research institutions or pharmaceutical sponsors to provide medical care or compensation for injured research subjects. The Code of Federal Regulations simply specifies that for research above minimal risk, informed consent forms must include an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained" as well as "whom to contact in the event of a research-related injury to the subject."

Some agencies, including the Department of Defense, Veterans Affairs and NIH via its clinical center "do provide medical treatment for participants in their studies who have research-related injuries. But in many cases, given the lack of a federal requirement to provide compensation, the tort system is the research subject's main recourse to get compensated by research institutions or sponsors in the event they experience harm as a result of participation in a study," according to the paper.