Financial Responsibility for Study-Related Injury

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A Key Research Ethics Issue

Recently, an Institutional Review Board (IRB) chairperson remarked that many research proposals are shifting financial responsibility for participant research-related injury from the study sponsor to the participant. That is, if a person agrees to participate in medical research, the cost of adverse events, such as infection and medication reactions, may fall on the participant.

Federal research grant funds do not cover compensation for injuries and recently many privately funded research protocols include a statement of no financial responsibility related to subject injuries.

This trend raises a serious question of organizational responsibility:

- Should IRBs approve protocols that disavow sponsor or researcher financial responsibility if the participant needs medical care as a result of participating in the study?

IRBs exist primarily to protect against the abuse of study subjects. The years following World War II through the 1960s brought to light many unethical research studies conducted abroad and in the United States. The Nazi atrocities, along with extreme cases in America, such as the Tuskegee Syphilis Study and the Willowbrook Hepatitis Study, left the world demanding some regulation and oversight of medical research.

By 1972, the demand for ethical oversight of human-subjects research led the United States Congress to pass The National Research Act, which established IRBs. A study involving human subjects must be approved by an IRB before it can proceed.

- While the IRB's role in human medical research entails examination of study design, conflicts of interest, and scientific due diligence, the primary role of IRBs is protection of vulnerable participant populations and ensuring respect for persons.

- When a facility IRB approves a study, it is essentially stating that the study is legitimate in its design and protocol – that it is just, fair, and ethically appropriate.

One major aspect of research that IRBs scrutinize is informed consent. This process, through which a study participant receives information about possible study risks, benefits, alternatives, and voluntary participation, also includes information about medical liability.

The informed consent documentation is one place IRBs look to understand how adverse events will be handled.

Participant Consent Is Not Enough

Some researchers assert that the informed consent documentation allows the participant the opportunity to refuse to take part if she considers the risk too great, and thus, researchers and sponsors have fulfilled their obligation to protect the subject.

This argument is flawed on at least three related points:

1. This assertion assumes that anything a study participant agrees to is, thereby, ethically justifiable. Some research and some research agreements do not meet ethics standards even if the informed consent process is clear and the sponsor, researcher, and participant find the arrangement acceptable.

    - One example is the Tuskegee Syphilis Study. Study participants were deceived and left untreated for known syphilis for many years. Even if the study participants had not been deceived, if they had been informed that their disease might not be treated, the study would still have failed by ethical standards because a safe, effective, inexpensive treatment for syphilis existed, and the study intentionally caused unnecessary harm.

    - No responsible IRB would approve of such a study simply because participants were informed and willingly agreed to be left untreated.

2. The second point follows from the first. Informed consent requires a reasonable sophisticated level of abstract understanding and analysis. A participant may not have adequate comprehension of risk and its future implications in terms of monetary cost, physical disability, and personal relationships.

    Further, even if a participant does understand risks quite fully, the voluntariness of participation may be influenced by the circumstances. There is an imbalance of power and influence between the doctor/researcher and the patient/study participant.

Even when the researcher does not wish or intend to engage in undue influence, prospective participants, who look to physicians and other researchers as subject matter experts and guardians of health, may decide to participate out of a sense of loyalty, duty, respect, or confusion.

Their informed consent may be adequate when the risk is low, but the fact that there is a signed consent form does not mean, by itself, that the participant understands fully and accepts willingly the fact that the sponsor is disavowing financial responsibility for injury-related costs.

3. The third point is the assertion that informed consent *is sufficient* assumes that the patient understands the difference between research and therapeutic interventions.

    Research protocols are designed *primarily* to achieve the sponsor's goals, but an individual may enter into a research protocol as an existing patient in a practice with no change in clinical site or addition of medical and research personnel.

In that circumstance, participants often see themselves as patients primarily, and only secondarily as study subjects. The roles of study subject and researcher need to be clearly defined. Patients who become study participants frequently do so in hope of an improved outcome.

If the primary intended benefit is to scientific knowledge and not to the patient/subject, this must be clear and explicit. This is not always the case.

Protection of Subjects

According to a 2012 *American Society of Law, Medicine and Ethics* publication, the U.S. lags behind other research-intensive countries by lacking mandatory systematic compensation for research-related injury: "[B]y not requiring systematic compensation, the Unites States has become a moral outlier and risks having important biomedical advances delayed."[1]

- While the U.S. has not yet passed legislation requiring systematic compensation, the topic has certainly received attention at very high levels.

  Since 1973, many national advisory committees have concluded that study subject compensation for injury should be mandated in the United States. In 2011, The Presidential Commission for the Study of Bioethical Issues reiterated this need and also stated that the United States tort system is inadequate to address the problem.[2]

One reason that the tort system is inadequate to address subjects' needs is that the injured person would need to provide proof that study participation was the cause of the injury.

Considering today's interdependent technologies and all of the possible ways injury can occur, the requirement of causality creates an unreasonable burden on the participant.

For this reason, most countries participate in no-fault systems, in which full coverage for study-related injury is included without proving causality.

What Should the IRB Do?

Getting back to the original question, should IRBs approve research that is otherwise ethically satisfactory but does not provide participant compensation for study-related medical harm?

- The above commentary points toward a NO answer. In principle, all study participants should be covered for injury. But the question of who provides that coverage might be open to negotiation.

  Sometimes an IRB position on subject protection can lead to the modification of a submitted protocol; sometimes other ways of assuring compensation for possible subject injuries can be found.

- Until the U.S. establishes a no-fault systematic compensation program for research subjects, many organizations will be left with difficult choices, and some research might just have to wait.

This ethics reflection was submitted by Leonard J. Weber, Ph.D. and Kelly Stuart, M.D., and represents the views of Dr. Weber and Dr. Stuart.

[1] *American Journal of Law and Medicine*, 38:1 (2012):40.
[2] *Ibid.*, 18.