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Research and legal liability

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ABSTRACT

Legal liability in the research realm is increasing, both in affluent and developing countries. This work outlines the liability risks of researchers, host institutions, research ethics committees, consulting bioethicists, and research sponsors through a review of sample cases involving these parties.

1. Introduction

Legal liability claims against health professionals were traditionally confined to those who engaged in clinical practice. However, in recent years an increasing number of civil claims have emerged in the health research realm. In this regard, three trends have emerged: (1) the types of legal claims have diversified; (2) the number and types of defendants named in such lawsuits have increased beyond researchers; and (3) Class action lawsuits are increasingly being lodged on behalf of groups of research subjects (Mello et al., 2003). While the overwhelming number of research-related lawsuits has arisen in affluent countries, the filing of multi-jurisdictional lawsuits against drug maker, Pfizer, in relation to its Trovan drug trial in Nigeria illustrates that developing countries are also becoming battlegrounds for lawsuits against those involved in research. This work outlines the liability risks of researchers, host institutions, research ethics committees, consulting bioethicists, and research sponsors through a review of sample cases involving these parties.

2. Researcher liability

Most early civil claims against researchers centered on the notion of informed consent. In the 1965 Canadian case of *Halushka v. University of Saskatchewan et al.* (1965) the defendants were physicians conducting research in the field of anesthesia. Halushka, a student, opted to participate in a study after being informed by the researchers that the experiment was a "safe test" and that there was nothing to be concerned about. However, he was not informed about the risks of using the experimental drug, the risks inherent in the procedure, nor the method by which the experiment would be carried out. Though he was expected to be able to return home shortly after the testing, Halushka suffered a heart attack as a result of the experiment, and remained unconscious for four days and in hospital for ten days. Halushka was unable to return to university as he suffered from fatigue and concentration lapses. He sued the doctors for trespass to person and negligence. The Saskatchewan Court of Appeal concluded that Halushka had not given informed consent to participate in the study. The court held that it is a physician's duty to give a fair and reasonable explanation of the proposed treatment, including probable effects, and special or unusual risks. The court held that disclosure must be consistent with what "competent medical men would have done in a similar situation." The court held that Halushka was entitled to a full and frank disclosure of all facts, probabilities, and opinions which a reasonable person might be expected to consider before consenting to the test. The court awarded Halushka $22,500 at trial and this judgment was upheld on appeal.

In the Canadian case of *Weiss vs Solomon* (1989), the heirs of a subject who died while a volunteer in a nontherapeutic study successfully sued the investigator and his university-affiliated hospital. The judge found the principal investigator and the hospital (through its research ethics committee) equivalently responsible for not disclosing a rare but fatal complication caused by fluorescein dye and not adequately screening the subject, who suffered from undisclosed hypertropic cardiomyopathy. The court endorsed the view that the duty owed by an experimenter to his subject is very high, and that, to be safe, an experimenter should err on the side of over-stressing the risks in a proposed experiment. The

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court held that with respect to purely experimental research, a doctor must disclose all of the risks, even those that are rare or remote, particularly if they are serious risks. Furthermore, the consent form approved by the hospital research committee ought not to have minimized the risks of the angiogram. Instead, these risks ought to have been explicitly explained to participants by the doctor in charge of the research. The court noted that the evidence showed that the procedure posed some risk of serious allergic reactions and cardiovascular incidents, on rare occasions causing death. However, the consent form said only that: "Some patients may develop a minor allergic reaction to this injection, but the majority of patients have no side effects". Significantly, the court found that the Research Committee that approved the consent form had minimized the risks of angiography, treating them like those prescribed in the therapeutic context. The court held that the choice of research participants should have been much more careful, in order to exclude any patients for whom fluorescein angiography would be contra-indicated. At the very least, the court found, the doctors responsible for the research program ought to have taken appropriate measures to prevent or respond effectively to adverse reactions including ventricular fibrillation. Accordingly, the court held that the researcher and his institution were jointly and severally liable.

Although the above cases focused largely on informed consent, other areas of potential litigation for researchers include breach of confidentiality, assault, infliction of emotional distress, fraud, breach of contract, product liability, and violation of privacy (Rozovsky and Adams, 2007). Lawsuits against researchers are also not limited to those involved in clinical research. Epidemiologists are also at risk of legal liability (Berger and Stallones, 1977), with confidentiality, informed consent, and privacy concerns forming the basis of potential claims against such researchers. The issue of property rights in relation to blood and tissue extracted from research participants is another area of potential litigation for researchers. This is best illustrated in the US case of *Moore v. Regents of the University of California* (1990).

In *Moore*, the plaintiff, John Moore, was diagnosed with hairy cell leukemia in 1976. Shortly thereafter, in early October 1976, Moore visited the UCLA Medical Centre where he consulted with, and was treated by, Dr David Golde. Golde confirmed the diagnosis after drawing bone marrow aspirate, blood, sperm, and other bodily fluids from Moore. After drawing the samples, Golde (and a fellow scientist, Quan, who was also named as a defendant in the matter) became aware that some of the samples were of potential commercial value. A few days after the samples were drawn Golde recommended that Moore's spleen be removed to retard the progression of his disease. Based upon this recommendation, Moore signed a written consent form authorizing the splenectomy. Following the surgery, and based on Golde's directives, Moore, who resided in Seattle, returned to the UCLA Medical Center several times between November 1976 and September 1983. During each visit Golde withdrew additional samples of bone marrow aspirate, skin, blood, blood serum, and sperm. Unbeknownst to Moore, Golde and the other defendants had been conducting research on Moore's cells. By August 1979, Golde and the other defendants had established a cell line from Moore's T-lymphocytes and had begun to commercialize it. When Moore discovered this, he brought an action against Golde and the other defendants, alleging Golde had failed to disclose preexisting research and economic interests in the cells before obtaining consent to the medical procedures by which they were extracted. The matter eventually reached the California Supreme Court.

In a landmark judgment the court ruled that Moore had neither property rights to his discarded cells, nor rights to any profits derived from them. However, the court held that Golde had a fiduciary duty to disclose his research activities and financial interest therein, to Moore. Moreover, that such disclosure ought to been made pursuant to the informed consent process. Accordingly, the court held that Moore had a valid cause of action against Golde for breach of fiduciary duty or lack of informed consent. This case is significant as it illustrates that although patients/research participants in California have no property rights in regard to their discarded body tissue, clinicians/researchers have a duty to disclose to patients that their discarded tissue is to be the subject of research. Researchers also have a duty to disclose their financial interests in relation to the research being undertaken. Such disclosures should be central to the informed consent process.

3. Institutional liability

As illustrated in the *Weis* case, institutional liability arises through the common law doctrine of vicarious liability, which holds superiors accountable for the wrongs of their subordinates.

In the 2002 US case of *Berman v. Fred Hutchinson Cancer Center* (2002) the husband of a research participant (Hamilton) who died in a chemotherapy trial brought an action against the Fred Hutchinson Cancer Center alleging that his wife's consent to participate in the study was not informed because the institution failed to disclose that: (1) the researchers had no idea whether the relevant drugs would have any protective effect against organ damage; (2) Hamilton would not receive the planned dosage of the drug if she were unable to ingest the oral version of the drug; (3) seven prior protocol participants had died, one of whom had suffered serious organ damage; and (4) there were alternative treatments that were less risky and were reporting a significantly higher cure rate. Put differently, Berman argued that his deceased wife did not give informed consent to participate in the trial as she was not informed that an experimental drug to prevent lethal side effects of chemotherapy was not available in intravenous form. After trying to swallow the pills, the participant vomited the pills and died. The trial court ruled that the Fred Hutchinson Cancer Research Center's failure to disclose the unavailability of the intravenous form of the drug invalidated Hamilton's consent to participate in trial.

In the US case of *Kus v Sherman Hospital* (1995), a patient who was implanted with experimental intraocular lenses brought an action against Sherman Hospital and a physician for failure to obtain his informed consent. The patient alleged that the consent form that he signed had been modified from the FDA-approved form and did not inform the patient that the lens was experimental and being evaluated for safety and effectiveness. The appellate court noted the general rule that physicians, not institutions such as hospitals, have the duty to obtain informed consent from their patients. The rationale underpinning this principle is that the physician has the knowledge and training necessary to advise a patient of the relevant risks, whereas an institution does not know the patient's medical history or the details of the particular surgery to be performed. However, the court held that intraocular implants were subject to US federal law (Drug and Food Administration regulations) in that informed consent was required of research participants. In accordance therewith, Sherman Hospital had established an institutional review board (IRB) to ensure that legally valid informed consent was solicited from research participants. Accordingly, the court held that while: ". . . generally a hospital is not in the best position to inform a patient of risks, here it is clear that Sherman Hospital undertook the responsibility to inform the plaintiff of the experimental nature of his surgery." Under those 'particular facts' (the creation of the IRB to vet informed consent forms) a hospital as well as a physician may be held liable for claims arising from the lack of informed consent. This Illinois Appellate Court decision is regarded as significant as it established that a hospital running a clinical trial assumed the obligation of ensuring that its researchers obtained valid consent from research participants. Other courts in