Compensation for Research Injuries: National Regulations and International Standards

Introduction
Patients taking part in clinical trials may suffer from permanent or temporary harm as a result of their participation in the research. Research regulations worldwide aim to prevent research injuries as well as to provide remedies for injuries suffered by research participants, regardless of what or who may have caused those injuries. The ICH-GCP guidelines mandate that sponsors make provisions for compensation for research-related injuries but largely leave compliance to applicable national or local regulatory requirements.

Though there is no dispute that remedial measures are required for research-related injuries, how patients are to be compensated is a hotly debated topic, and worldwide regulations differ considerably in this respect. At one end of the spectrum are countries like the United States, the United Kingdom, and Taiwan that prefer to address compensation issues within their existing laws on accidents and injuries requiring legal action. Developing nations have to seek expensive remedies through the courts or tribunal like the International Court of Justice to enforce a specific provision of the Declaration of Helsinki (DoH). The Malawian government must do it on their behalf and is therefore more likely to want the issue to be resolved domestically. Nevertheless, instruments of international law, i.e. treaties, declarations, guidelines, etc., can be used by the international community to pressure on nations to formulate domestic rules on compensation for injuries sustained by research participants. This section explores three such documents of international law.

First formulated in 1964, the World Medical Association’s DoH contains principles to protect the rights of research participants; however, until 2008, it contained no specific provision on compensation for injuries. The 2008 revision to the DoH contains a powerful acknowledgement of the principle that a provision for research injury compensation should be included in the study protocols, so that patients don’t have to seek expensive remedies through courts and tribunals.

Another influential international instrument is from the Council for International Organizations of Medical Sciences (CIOMS, 2002) which states that “investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap” (Guideline 19). However, a causal link must still be established to the experimental intervention, and compensation is not due when subjects suffer expected or foreseen adverse reactions which are similar to those seen in established interventions in standard medical practice.

The Good Clinical Practice (GCP) guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH, 1996) stipulate the following with respect to compensation for research injuries:

- Ethics committees (ECs) are required to consider whether compensation is available to subjects when granting approval for a clinical trial.
- The informed consent process must include explanations of the medical treatment and compensation options which may be available to participants in case of trial-related injuries.
- Sponsors are required to make provisions for compensation for research-related injuries in accordance with applicable national laws.

On the whole, the ICH-GCP guidelines adopt a deferential tone and largely exhort compliance with applicable national or local regulatory requirements. Therefore, they do not represent a standalone set of regulations that can govern the conduct of healthcare research, at least with respect to compensation for research-related injuries.
**National Law and Domestic Regulation**

The regulatory regimes that govern compensation for research-related injuries for some key nations are described below.

**People’s Republic of China (PRC)**

Article 93 of the Drug Administration Law of the PRC states in broad terms: “drug manufacturers, drug distributors or medical institutions that violate the provisions of this Law and thus cause harm and losses to users of drugs shall bear the liability of compensation in accordance with law.” However, it does not discuss the issue of injuries for participation in medical research. Chinese research participants may file a case for compensation in a civil court in case of injury. However Zhang (2008b) and Gourley et al. (2009) identified that in order to be eligible to receive any compensation, the fault between the medical treatment and the injury needs to be established and the compensation amount may not be adequate to cover the harm by the injury.

**India**

In 2011 the Indian Council for Medical Research (ICMR) provided specific guidance, introducing a ‘no-fault scheme’ including that the compensation is to be paid irrespective of (1) the cause of injury, (2) whether the injury was foreseeable, (3) whether consent was freely and appropriately obtained or (4) whether the injury was caused by a placebo or a treatment regimen in the control arm of the study (Pramesh & Badwe, 2012).

To make the ICMR guidelines more stringent, the Central Drugs Standards Control Organization (CDSCO) amended and published the Draft regulations (2011, 2012a, 2012b) in November 2011, July 2012 and August 2012 outlining the conditions in which compensation must be provided for research injuries. These regulations have now been finalised (30 January 2013) after a period of review during which strenuous objections were raised by the industry to some of the proposed provisions. The Ministry of Health and Family Welfare nevertheless decided to retain the most contentious of the provisions in the finalised regulations viz. compensation in case the investigational product or placebo fails to provide the intended therapeutic effect.

**Malaysia**

According to §5.8.1 of the Malaysian guidelines for GCP (National Committee for Clinical Research, 2011b), the sponsor is required to provide insurance and indemnity in the form of legal and financial coverage for investigators and research institutions against claims arising from the trial, except for malpractice and negligence, but only “if required by the applicable regulatory requirement(s).”

**New Zealand**

New Zealand’s no-fault, taxpayer-funded compensation scheme for accidents and injuries has been in place since 1974. Since 2005, medical injuries have been included in the scheme under the revised definition of ‘treatment injury’ as a “personal injury suffered by a person seeking treatment or receiving treatment and caused by treatment...” (Wallis & Dovey, 2011, p. 287).

**Taiwan (Republic of China)**

At present, Taiwan does not have any special guidelines for dealing with injuries arising from participation in healthcare research; general rules on civil liability apply.

**Uganda**

In the last two decades, the developing nations of Africa have become fertile sites for undertaking healthcare research, necessitating an examination of their laws on compensation for research injuries. In Uganda, the Uganda National Council for Science and Technology (2007) states that when a research injury is classified as “Definitely” or “Probably” related to participation in research, the subject is entitled to compensation that may consist of free medical treatment for the injury and financial and other assistance which compensates the subject equitably for the resultant impairment or disability (§75).

**United Kingdom**

The United Kingdom employs a classic courtroom approach to medical injuries, i.e. negligence or fault must be established in a court of law for compensation to be awarded to research participants. However, for many years, the Association of the British Pharmaceutical Industry (ABPI, 1994a) has recommended that research sponsors voluntarily pay compensation to patient-volunteers in Phase II and III clinical trials suffering bodily harm or death (in accordance with identified principles).

**United States**

As one of the most litigious societies, the United States makes available personal injury lawsuits filed in courts as the principal means of seeking compensation for research injuries. No-fault compensation systems have voluntarily been adopted by some research institutions, like the University of Washington, since the 1970s. However, at the federal level of regulation, the US research system has the following features per Beh (2005):
• Research institutions are not obliged to provide either compensation or reimbursement for medical expenses caused by research injuries.
• ECs are required only to ensure that where more than a minimum risk of injury exists, participants are informed during the consent process if provision for treatment or compensation in case of injury has been made.
• ICF cannot require participants to either waive their legal rights or release sponsors, investigators, and research institutions from liability for negligence.

Other Countries
Bioethics regulations in Brazil require that trial sponsors pay compensation to participants for trial-related injuries (PCSBI, 2011). No-fault compensation schemes for medical injuries were adopted in Sweden in 1975, Finland in 1987, Norway in 1988, and Denmark in 1992.

The German no-fault compensation scheme differs principally from that of New Zealand in that it is sponsor-funded and therefore does not present a taxpayer burden. Sponsors are required to create an insurance fund to cover research-related injuries. However, the insurance only covers economic loss, not pain or suffering. The research participant, within three years of the conclusion of the research, must establish both that there is a causal link of the injury to the research intervention and that no other person has any liability for the injury.

In the event of a research-related injury in France, sponsors are liable on a no-fault basis for non-therapeutic research. Interestingly, there is a presumption of fault and therefore liability on the sponsor in the case of therapeutic research. Therefore, the onus is on the sponsor to disprove fault and escape liability.

The relevant Spanish law presumes that injuries to the health of a subject during and within a year of the research are caused by the research. In cases where a research injury is not covered by liability insurance held by the sponsor, the sponsor, principal researchers, and medical director of the research institution are jointly liable for providing compensation to the research participant.
Conclusion
In order to prevent research participants against the harm to life and health involved in the research process, it is imperative for every country to adopt regulatory frameworks that are not only legally compliant but are also harmonious with the spirit of the instruments of international law like the DoH, the CIOMS guidelines, and the ICH-GCP guidelines.

References

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