Pharma & Healthcare Update

November 26, 2008

PAY TO PARTICIPANTS FOR RESEARCH RELATED INJURIES- SUGGESTS ICMR

India is fast becoming a hub for conducting clinical trials of medicines in pipeline. The market of clinical trials in India was approximately US $100 million in 2007 and is estimated to touch US $300 million in 2008. The most attractive advantages of investing in India are India's huge population and cheaper costs associated with conducting such trials in India.

The conduct of clinical trials in India is governed by following regulations:

(i) The Drugs and Cosmetics Rules, 1945
(ii) CDSCO's Good Clinical Practice Guidelines
(iii) Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000
(iv) Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
(v) Lastly, hospitals and institutions typically have their own internal codes and regulations

The statutes governing clinical trial activity in India currently do contain some provisions for granting of compensation in cases of research related injury; for instance;

- The Ethical Guidelines For Biomedical Research on Human Participants issued by the Indian Council of Medical Research[i] provides that "each research shall include an in-built mechanism for the compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human participant and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary."
- Schedule Y of the Drugs and Cosmetics Rules, 1945 provides that an essential element of a research participant's informed consent document is Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury.[ii]

However, till date there were no comprehensive guidelines for the enforcement of such provisions.

Acknowledging the fact that participation in clinical research carries inherent risks, which could lead to direct or indirect physical, psychological, social or economic harms, and acknowledging the inadequacy of the current statutes to provide adequate mechanisms for the enforcement of a research participant's rights, the Indian Council for Medical Research (ICMR), Forum for Ethics Review Committees In India (FERCI) and the Indian Society for Clinical Research (ISCR) have on 14th November, 2008 issued the Draft Guidelines For Compensation To Participants For Research Related Injury In India (**"Guidelines"**)[iii] for comments from stakeholders. After getting the comments from the stakeholders, the Guidelines will be finalized.

APPLICABILITY:

These Guidelines are to apply to all clinical research, whether such research is sponsored by the pharmaceutical or medical device industry, government or academia or by individual investigators. However, these Guidelines are not intended to be applicable to post marketing surveillance[iv] and ancillary care[v].

WHEN IS COMPENSATION PAYABLE:

Compensation is to be provided:

- When temporary or permanent injury occurs to a research participants due to participation in clinical research;
- To child injured in-utero through the participation of the parent in clinical research;
- When injury is caused by a procedure which has been undertaken to manage an adverse reaction occurring during the research

The Guidelines contemplate that compensation is to be payable irrespective of:

Research Papers

Littler International Guide (India) 2024
November 08, 2024

Unmasking Deepfakes
October 25, 2024

Are we ready for Designer Babies
October 24, 2024

Research Articles

The Bitcoin Effect
November 14, 2024

Acquirers Beware: Indian Merger Control Regime Revamped!
September 15, 2024

Navigating the Boom: Rise of M&A in Healthcare
August 23, 2024

Audio

Digital Lending - Part 1 - What's New with NBFC P2Ps
November 19, 2024

Renewable Roadmap: Budget 2024 and Beyond - Part I
August 26, 2024

Renewable Roadmap: Budget 2024 and Beyond - Part II
August 26, 2024

NDA Connect

Connect with us at events, conferences and seminars.

NDA Hotline

Click here to view Hotline archives.

Video

"Investment return is not enough" Nishith Desai with Nikunj Dalmia (ET Now) at FII8 event in Riyadh
October 31, 2024

Analysing SEBI's Consultation Paper on Simplification of registration for FPIs
September 26, 2024

- Whether the injury is foreseeable/predictable
- The fact that written free consent of the research participant was obtained
- The fact that injury was caused through a departure from the agreed protocol, scientific misconduct or negligence by the investigator

COMPENSATION:

- The Guidelines provide that compensation could be in the form of payment for immediate medical/surgical management of research related injuries. The investigator or the concerned institution is to ensure the availability of adequate finances/liquidity for such contingency.
- The Informed Consent document should clearly state that the research participant has a right to claim compensation in case of research related injuries and the contact person for enforcement of such rights. Schedule Y of the Drugs and Cosmetics Rules, 1945 currently prescribes a specified format for obtaining Informed Consent. The changes proposed to be introduced by these Guidelines would need to be included in the said form.
- Compensation need not be provided where the Independent Ethics Committee and the investigator determine that the injury has arisen through a wrongful act of a third party, contributory negligence by the research participant or through the use of affiliated medicines allowed as per protocol.

COMPENSATION MECHANISM:

- Claims for compensation may be made by the research participant, or in the case of death, by the participant's legal heir/ lawful guardian.
- Claims are to be made to the sponsor through the investigator. In case of medical management of research related injuries, the payment is to be made by the investigator/institution. The investigator should inform the IEC of all such claims.
- In case of a dispute or difference regarding the amount of compensation, an arbitration committee should be appointed by the institution consisting of one person nominated by each party in conflict, and a chairperson nominated by the selected arbitrators. In the case an independent ethics committee (not institutional) is overseeing the project the independent ethics committee should appoint the arbitration committee.
- In case of a dispute or difference between the involved parties whether the injury is due to departure from the agreed protocol or negligence by the investigator/research participant, a Grievance Redressal Committee should be appointed consisting of one person nominated by each party in conflict, and a chairperson nominated by the selected members. In the case an independent ethics committee (not institutional) is overseeing the project the independent ethics committee should appoint the Grievance Redressal Committee.
- Notwithstanding the dispute resolution procedures provided in the Guidelines, the research participant would have the right to seek legal redressal.

SPECIFIC OBLIGATIONS:

These Guidelines set out specific responsibilities for Sponsors, investigator/institutions, institutional/ independent ethics committee. The most pertinent among these are:

- Sponsor should facilitate availability of contingency amount with the investigator/ institution for payment for medical/ surgical management of research related injuries.
- It is recommended that the sponsor/ investigator/ institution should obtain insurance to cover compensation for clinical research related injury.

The Guidelines once finalized should clearly articulate the responsibility of the sponsor as against the institution / investigator. There would have to be clarity regarding the compensation and responsibility arising out of cases of medical management of research related injuries as against compensation arising out of cases of injury directly related to research. The Guidelines should also indicate the quantum of the compensation to be paid in certain cases as a guiding factor. In view of the procedures and mechanisms which the Guidelines seek to implement, appropriate amendments would have to be carried out in the relevant statutes which deal with clinical research and trials India.

- Rakhi Jindal, Dr. Milind Antani & Gowree Gokhale

[i] http://icmr.nic.in/ethical_guidelines.pdf last accessed on November 25, 2008.
[ii] http://cdsco.nic.in/html/Schedule-Y (Amended Version-2005) original.htm last accessed on November 25, 2008.
[iii] The full text of the Guidelines is available at http://icmr.nic.in/icmrnews/compensation_guide.pdf last accessed on November 25, 2008
[iv] The term "Post Marketing Surveillance" is used to describe those stages of clinical study which are primarily observational/ non experimental in nature.
[v] "Ancillary Care" refers to the treatment of complaints which are beyond the purview of the research.

Scope of judicial interference and inquiry in an application for appointment of arbitrator under the (Indian) Arbitration and Conciliation Act, 1996
September 22, 2024