Christian Medical College
Vellore
Tamil Nadu
India

Compensation Committee

Policies and Standard Operating Procedures

2014

COMPENSATION COMMITTEE GUIDELINES

As per the guidelines of the DCG(I) - Drug Controller general of India and what has been mentioned more recently this is a requirement. As per the guidelines, all cases where serious adverse events which may have involved death, in a clinical trial, it is necessary to have an opinion of the compensation committee.

This opinion will lay down the recommendation for compensation which is subsequently documented and forwarded to the CRA/sponsor of the trial and from there to the DCGI.

The committee meets on the day that the Silver IRB has its regular meeting.

The members of the compensation committee will include:

1. Senior Clinicians (2)
2. Experts in Clinical Trials- IRB members (2)
3. Finance Director or a suitable representative (1)
4. Vice Principal Research or a suitable representative (1)
5. A Clinical Pharmacologist (1)
6. Legal Officers (2)

All members of the committee are members of the Silver IRB and the Chairperson will be a Clinician adept in clinical trials.

Current members of the Compensation Committee

1	Dr. Thomas Kuriakose	MBBS, DO, DNB, FRCS(Edin)	Professor of Ophthalmology, Associate Director (Finance)	Internal, Clinician
2	Dr. B. Antonisamy	M.Sc, PhD, FSMS, FRSS	Professor, Biostatistics, Member Secretary, Research Committee, IRB, CMC, Vellore	Internal, Statistician
3	Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP (Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
4	Dr. L Jeyaseelan	M. Sc, PhD, FRSS	Professor, Biostatistics, CMC, Vellore	Internal, Statistician
5	Dr. Thambu David	MBBS, MD, DNB	Professor & Head, Medicine, CMC, Vellore	Internal, Clinician

6	Dr. Jayaprakash Muliyil	B. Sc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist &Epidemiologist
7	Dr. Binu Susan Mathew	MBBS, MD	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
8	Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
9	Mr. C. Sampath	B. Sc, BL	Legal Expert, Chairperson, Vellore	External, Legal Expert

The Principal Investigator on receipt of the queries in connection with SAE or death in connection from the DCGI will have to submit the following documents prior to the final deadline of the Silver IRB submission date:-

1. Format for Reporting Unanticipated or Serious Adverse events in Human Research Participants at CMC Vellore.
2. Outpatient chart of the patient
3. Inpatient Chart of the patient(If final admission was to CMC, Vellore)
4. bill of the patient(If the final admission was to CMC, Vellore)
5. Letter from DCGI through the sponsor
6. Prognosis of the disease in question
7. Adverse effect profile of the drug in usage for the trial
8. The nature of the relationship of the adverse event as a potential cause of death as documented as an SAE.
9. The functional nature of the patient in the community in relation to occupation.
10. The role of the patient in the family and nature of the dependence both financial and emotional in relation to the patient (e.g. children, grandchildren, parents etc.

The principle investigator needs to be present at the meeting.

The Compensation committee will use the guidelines provided by the DCG(I)- Drug Controller general of India and the Supreme Court that has been recommended in the following links http://www.cdsco.nic.in. for determining the compensation for the patients' dependents.

The Compensation committee will send a letter signed by the Committee chairman and the research Vice principal mentioning the degree of compensation that needs to be provided for the subjects dependents, and addressed to the principal investigator, recommending the amount that the sponsor should remit to the dependents of the patient.

DEFINITION OF CLINICAL TRIAL-RELATED INJURY & GUIDELINES BY DCG (I) DRUG CONTROLLER GENERAL OF INDIA

Injury or death occurring due to any of the following reasons is considered as a clinical trial- related injury or death and the nominees of the subject are entitled to financial compensation.

1. Adverse effect of investigational product

2. Violation of approved protocol, scientific misconduct or negligence by sponsor or investigator
3. Failure of investigational product to provide therapeutic effect
4. Use of placebo in placebo-controlled trial
5. Adverse effect due to concomitant medication, excluding standard care necessitated as a part of approved protocol
6. Injury to child in utero because of participation of parent in clinical trial
7. Clinical trial procedure involved in study

Additions to Clauses of Informed Consent

The investigator shall provide information to trial participants, through the process of informed consent, on their right to claim compensation in case of trial-related injury or death.
The investigator shall also inform the subjects or their nominees of their rights to contact the sponsors for the purpose of making claims in the case of in case of trial-related injury or death.

COMPENSATION IN CASE OF TRIAL-RELATED INJURY OR DEATH.

1. In case of injuries occurring in a trial subject, he/she shall be provided with free medical management as long as required to recover from the injury.
2. In case the injury occurring to trial subjects is due to the clinical trial, subjects shall be also entitled to financial compensation, which will be over and above any expenses incurred due to medical management of the subject.
3. In case of death occurring in the trial subjects, their nominees would be entitled to financial compensation, which will be over and above any expenses incurred due to medical management of the subject.
4. Expenses of medical management and financial compensation, in case of trial-related injury or death, shall be borne by the sponsor of the clinical trial.
5. The sponsor shall give an undertaking to the licensing authority, along with the application for clinical trial permission, to provide compensation in case of clinical trial-related injury or death.
6. In case the sponsor fails to provide free medical management for injury to the subject or financial compensation to the nominee of a subject who has died in a clinical trial, the licensing authority, after giving an opportunity to show cause will suspend or cancel the clinical trial and/or restrict the sponsor (including his representative) to conduct any further clinical trial in the country.

Procedure for Compensation

The Investigator shall report all serious and unexpected adverse events to the licensing authority, the sponsor and the ethics committee, within 24 hours of the occurrence of the events.

I. In Case of Trial Related Death

a) In case of occurrence of the serious adverse event of death, an independent expert committee constituted by the licensing authority will examine the cases and establish the cause of death and recommend to the licensing authority the quantum of compensation.

b) The ethics committee shall, after analysis, forward its report on the serious adverse event of death along with its opinion on financial compensation to the expert committee, with a copy of the report to the licensing authority, within 21 calendar days of occurrence of the serious adverse event(s).

c) The sponsor and the investigator shall forward the reports on the serious adverse Event of death, after analysis to the ethics committee , expert committee and the head of the institution (CMC) where the trial has been conducted, along with a copy of the report to the licensing authority (DCGI) and repetitive head of institution) within 10 calendar days after occurrence of the adverse event of death.

d) The expert committee shall examine the report of serious adverse event of death and give its recommendations to the licensing authority within 30 days of receiving the report from the ethics committee. While examining the event, the expert committee may take into consideration the reports of the investigator and sponsor.

e) The licensing authority shall decide the quantum of compensation for clinical trial-related injury and shall pass orders within 3 months of receiving the report of serious adverse events.

f) The licensing authority shall consider the recommendations of the expert committee and determine the cause of death and pass orders as deemed necessary.

g) The sponsor shall pay the compensation for clinical trial-related death as per the order of the licensing authority, within 30 days of the receipt of the order of the licensing authority.

h) The sponsor shall submit to the licensing authority details of compensation provided or paid for clinical trial-related death, within 30 days of the receipt of the order of the licensing authority.

II. In case of trial-related injury

a. The sponsor and the investigator shall, after analysis, forward the reports on serious adverse events to the ethics committee, licensing authority (DCGI) and the head of the institution (CMC) where the trial has been conducted, within 10 calendar days after occurrence of the adverse event of death, this is the section on injury, not death.

b. The Ethics committee (IRB and Compensation Committee) shall, after analysis, forward its report on serious adverse events to the licensing authority(DCGI), along with an opinion on financial compensation within 21 calendar days of occurrence of the serious adverse events.

c. The licensing authority (DCGI) shall determine the cause of injury and pass orders as deemed necessary. The licensing authority shall have the option to constitute an independent expert committee, wherever necessary, to arrive at the cause of the serious adverse events and quantum of compensation to be provided.

d. The licensing authority shall decide the quantum of compensation for clinical trial-related injury and shall pass orders within 3 months of receiving the report of serious adverse events.

e. The sponsor shall pay the compensation clinical trial-related injury as per the order of the licensing authority within 30 days of the receipt of the order of the licensing authority.

f. The sponsor shall submit details of compensation provided or paid for clinical trial-related death, this is the section on injury to the licensing authority within 30 days of the receipt of the order of the licensing authority.

Responsibility of investigator

I. In case of serious adverse event of death

1. The investigator shall report all serious and unexpected adverse events to the licensing authority, the sponsor and the ethics committee within 24 hours of their occurrence.

2. The investigator shall, after analysis, forward the reports on the serious adverse event of death to the ethics committee, expert committee and the head of the institution where the trial has been conducted, along with a copy of the report to the licensing authority (? repetitive and head of institution), within 10 calendar days after occurrence of the adverse event of death.

II. In case of serious adverse events other than death

1. The investigator shall report all serious and unexpected adverse events to the licensing authority, the sponsor and the ethics committee within 24 hours of their occurrence.
2. The investigator shall, after analysis, forward the reports on the serious adverse event of ?death (this is the section on events other than death) to the ethics committee, licensing authority and the head of the institution where the trial has been conducted, within 10 calendar days after occurrence of the adverse event of ?death (this is the section on events other than death).

Responsibility of the ethics committee

I. In case of the serious adverse event of death

The ethics committee shall, after analysis, forward its report on serious adverse event of death along with an opinion on financial compensation to the expert committee, with a copy of the report to the licensing authority within 21 calendar days of occurrence of the serious adverse event.

II. In case of serious adverse events other than death

The ethics committee shall, after analysis, forward its report on serious adverse event along with an opinion on financial compensation to the licensing authority within 21 calendar days of occurrence of the serious adverse events.

Procedure for reporting:

All interventional trials approved by the IRB of CMC Vellore will come under the purview of this policy (drugs, devices, and behavioral or educational interventions; single or multiple armed trials, randomized or non-randomized).

For all SAE reports: Within **24 hours** of learning about an unanticipated or serious adverse event, the principal investigator is responsible for notifying the **DCGI, the Study Sponsor (if external), the Ethics Committee (saeclinpharm@gmail.com) with a cc to the secretariat at the Office of Research CMC (research@cmcvellore.ac.in).** A hard copy of this document must also be sent to the IRB SAE co-ordinator, Clinical Pharmacology Unit, CMC Hospital, Vellore 632 004, Tamil Nadu.

Within **10 days** the principal investigator is to submit a follow up report to the same list of people as above. **IF IT IS A DEATH REPORT THEN THIS MUST ALSO BE SENT TO THE EXPERT COMMITTEE AND THE HEAD OF THE INSTITUTION (both should have a copy of the original report to the DCGI).**

Note: 1. Clinical trials with drug involved and intervention ongoing if comes across any SAE's has to be presented in the Compensation Committee.

Recent Updates from CDSCO - Compensation Formulas

Through a notice dated 15th Dec 2014, CDSCO office has released the final formulas to be considered for calculation of compensation in cases of death and injury other than death. Please visit the following link for full notification:

http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trial%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf

Please find below the formulas in nutshell:

1) Formula for death cases:
C = (B * F * R)/99.37,
where,
C = compensation
B = base amount = 8 lacs
F = Age factor
R = Risk factor

2) SAE causing permanent disability to the subject:

C1 = (C * D * 90) / (100*100)
where.
C1 = Compensation
C = Quantum of compensation which would have been due for payment to the subject's nominee in case of death of the subject
D = Percentage disability the subject has suffered.

3) SAE causing congenital anomaly or birth defect:

Compensation shall be a lumpsum amount such that if that amount is kept by way of fixed deposit or alike, it should bring a monthly interest amount which is approximately.

3) SAE causing congenital anomaly or birth defect:

Compensation shall be a lumpsum amount such that if that amount is kept by way of fixed deposit or alike, it should bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). Considering the base amount as 8 lacs, the quantum of compensation = 4 lacs (Half of base amount)

4) SAE causing Life - threatening disease &
5) Reversible SAE in case it is resolved

C = 2 * W * N
where,
C = Compensation

W = Minimum wage per day of the unskilled worker (In Delhi)
N = Number of days of hospitalization

Expert Committee address:

Chairman, Expert Committee,
The Drug Controller General of India,
FDA Bhavan, ITO, Kotla Road,
New Delhi -110002

Within 10 days the completed access database should be sent to the IRB SAE Co-ordinator at saeclinpharm@gmail.com.