STANDARD OPERATING PROCEDURE
[SOP]
REVISION VI [FEBRUARY 2018]

Amendment I [1st July 2019]

INSTITUTIONAL ETHICS COMMMITTEE
HM PATEL CENTRE
FOR
MEDICAL CARE AND EDUCATION
KARAMSAD, GUJARAT 388325

STANDARD OPERATING PROCEDURE [SOP]

Revision – VI, February 2018

Amendment 1

01/07/2019

In view of The New Drugs and Clinical Trial Rules, 2019 effective from 19th March 2019, certain amendments are mandated in the current IEC, HMPCMCE SOP. The contents of the amendments below were circulated to all the members with permission of the Chairperson and finalized following inputs, if any, from the members. Following The New Drugs and Clinical Trial 2019, composition of the IEC, HMPCMCE has been reconstituted with effect from 1st June 2019. The amendments were reviewed by all the members, including the new joinees from 1st June 2019 before finalization. These amendments would be effective from 1st July 2019.

SOP 1. AUTHORITY FOR FORMATION

No change

SOP 2. SOP for SOPs

No change

SOP 3. EC COMPOSITION

5. Terms of reference defining membership, appointment, reconstitution and resignation

- The Composition of the Committee shall be as follows:
  - Chairperson [mandatorily from outside the institution as per regulatory requirements as well as for maintenance of its independence]

- Deputy Chairperson [to officiate in absence of Chairperson/ when Chairperson himself/ herself is an investigator or has any other declared conflict of interest]
- Member Secretary [from within the institution]
- Deputy Member Secretary [optional]
- Legal expert
- Social scientist/ representative of non-governmental voluntary agency
- Lay person from the community
- 1 – 7 members from different departments/ specialties/ disciplines etc.
    - Basic medical scientists
    - Clinicians
    - Ethics Expert/ Ethicist/ Theologian [as invited member as and when need arises]
    - Subject Expert and representatives of different potential participant groups [as invited member as and when need arises]

To be added:

*The Ethics Committee shall consist of at least 50% of its members who are not affiliated with the institute or organization in which the committee is constituted.

*There shall be at least one-woman member in the committee.

Types of projects reviewed by IEC

- The IEC shall review scientific and ethical aspects of all types of research studies involving human participants that are sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations/universities [namely Regulated Clinical Trials], including Clinical Trial Registry.

To be replaced with:

The IEC shall review following types of research projects:

1. Regulated Clinical Trials [scientific and ethical aspects of all types of research studies involving human participants that are sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in

collaborations with international organizations/ universities, including Clinical Trial Registry

2. Multicentre epidemiological/ data based studies involving sponsorship by Pharmaceutical companies, Government of India/ NGOs or international organizations/ universities
3. Academic Clinical Trials, as per The New Drugs and Clinical Trial Rules, 2019

SOP 4. REVIEW OF CLINICAL TRIAL PROTOCOL

No change

SOP 5. PROCESS OF REVIEW

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4. Initial review of proposed clinical trial

After initial review of the project, all members shall enter their comments/ suggestions in the online software that automatically reach the Member Secretary. Upon receiving suggestions from all the members, MS then prepares a consolidated suggestion sheet for forwarding it to the Principal Investigator.

To be added:

Any member can take hard copy of submitted documents for review, if he/ she is not able to review online. Comments in these cases can be intimated to Member Secretary before or during the meeting offline too.

SOP 6. DECISION MAKING AND POST REVIEW ACTIVITIES

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9. Analysis and reporting of Serious Adverse Events

A Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (SADR) refers to an adverse event (AE) or adverse drug reaction (ADR) that is associated with death, inpatient hospitalization (in case the study was being conducted on out-patients), prolongation of

hospitalization (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

Any injury or death of the subject occurring in any approved research project [including clinical trial] due to following reasons will be considered as clinical trial related injury or death and the subject or his/ her nominee (s), as the case may be, are entitled for financial compensation for such injury or death *[7 criteria as mentioned under Rule 122 DAB and Appendix XII of Schedule Y to the Drugs and Cosmetics Rules]*:

a. adverse effect of the investigational product [s]
b. violation of the approved protocol, scientific misconduct or negligence by Sponsor or his representative or the investigator
c. failure of investigational product to provide intended therapeutic effect
d. use of placebo in a placebo-controlled trial
e. adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol
f. for injury to a child in-utero because of the participation of the parent in clinical trial
g. any clinical trial procedures involved in the study

To be replaced with:

Serious adverse event" means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalisation of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalisation where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event.

Any injury or death of the subject occurring in any approved research project [including clinical trial] due to following reasons will be considered as clinical trial related injury or death and the subject or his/ her nominee (s), as the case may be, are entitled for financial compensation for such injury or death *[7 criteria as mentioned under Rule 122 DAB and Appendix XII of Schedule Y to the Drugs and Cosmetics Rules]*:

A. adverse effect of the investigational product [s];
B. violation of the approved protocol, scientific misconduct or negligence by Sponsor or his representative or the investigator leading to serious adverse event;

C. failure of investigational product to provide intended therapeutic effect where, the required standard of care or rescue medication, though available, was not provided to the subject as per the clinical trial protocol;

D. not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo-controlled trial

E. adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol

F. adverse effect on a child in-utero because of the participation of the parent in the clinical trial;

G. any clinical trial procedures involved in the study leading to serious adverse event

SOP 7. MONITORING OF RESEARCH REPORTS

No change

SOP 8. ADMINISTRATIVE SUPPORT

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4. Financial dealings of Ethics Committee activities and functioning

Incomes and Expenditures towards functioning of the committee

- Standard fee will be charged for review of research proposals submitted by the investigators of the institution [HMPCMCE] for review in case of Industry Sponsored Clinical Trials.
    a. IEC fees for Clinical trials:
        - Rs. 50,000/- for initial review of each protocol
        - Rs. 5,000/- for review of each amendment
            - The revised fee structure will be applicable to new clinical trials submitted on or after 1st August 2017

2. Research projects initiated and submitted by investigators outside the institution [HMPCMCE] but to be conducted within the Centre will be accepted only after written permission granted by Institutional Research Group [on hard copy of the research proposal]
3. Research projects initiated and submitted by investigators outside the institution

[HMPCMCE] and also to be conducted outside the institution will not be accepted for review EXCEPT when the participant [s] to be recruited are from HMPCMCE institutions.

To be replaced with:

4. Financial dealings of Ethics Committee activities and functioning

Incomes and Expenditures towards functioning of the committee

- Standard fee will be charged for review of research proposals submitted by the investigators of the institution [HMPCMCE] for review in case of Industry Sponsored Clinical Trials:
    - Rs. 75,000/- for initial review of new clinical trial protocol
    - Rs. 15,000/- for review of each Serious Adverse Event [SAE] in an approved trial
    - Rs. 7,500/- for review of each amendment in full committee
- Standard fee will be charged for review of research proposals submitted by the investigators of the institution [HMPCMCE] for review in case of Academic Clinical Trial [as per The New Drugs and Clinical Trial Rules, 2019]:
    - Rs. 15,000/- for review of each Academic Clinical Trial, when Sponsored/ Funded by agency outside CAM [either fully or partial]
    - No fee shall be charged for review of non-sponsored Academic Clinical Trial [by any agency]
    - Rs. 1,000/- for review of each SAE in all Academic Clinical Trial to be paid by Principal Investigator/ funding agency [wherever applicable]
- The revised fee structure will be applicable to new clinical/ academic trials submitted on or after 1st July 2019

4. Research projects initiated and submitted by investigators outside the institution [HMPCMCE] but to be conducted within the Centre will be accepted only after written permission granted by Institutional Research Group [on hard copy of the research proposal]

SOP 9. RECORD KEEPING AND ARCHIEVAL

No change

SOP 10.TRAINING AND SELF ASSESSMENT

3. Conduct of training of IEC Member

Training of new IEC Members

- An individual selected as a new member of the IEC will be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC [no voting rights].

To be replaced with:

3. Conduct of training of IEC Member

- An individual selected as a new member of the IEC will be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC [with no voting rights].
- In an event where it is not possible for new member to attend one meeting as an 'Observer' before being inducted as a member of IEC, the same may be followed in the next scheduled meeting, if existing regulatory guidelines permit.