Technical Advisory Committee for Clinical Studies

I. Introduction

The Central Ethics Committee on Human Research (CECHR) guidelines suggests the formation of a Scientific Review Committee in addition to an Institute Ethics Committee (IEC) in major institutes to ensure the scientific soundness of a proposed research. The Technical Advisory Committee is a sub-committee under the IEC, formed in accordance with these guidelines. TAC is not an alternate to IEC but is a complementary body. It acts as the first level of filter to guard against unscientific studies. Scientific soundness and technical feasibility of the proposed work shall be the main concerns of TAC. TAC shall not approve any research project unless all of the following criteria for approval are satisfied:

- the study is scientifically sound
- the study is technically feasible, and
- the outcome of the study is clearly defined

The Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, has three independent Technical Advisory Committees for Clinical Studies, Public Health and Medical Devices.

- The Technical Advisory Committees will have a minimum of four members, including the Chair and the Member Secretary. The members shall be faculty members of the institute appointed by the Director.
- The Chair shall convene the meetings, ensure quorum and guide the review discussions.
- The Member Secretary shall be in charge of correspondence and documentation, including maintenance of the Minutes of meetings.
- At least three members should be present to complete quorum for any meeting.
- Any decision must be taken by broad consensus after the quorum requirements are fulfilled.
- A member must voluntarily withdraw from the Technical Advisory Committee (TAC) while making a decision on an application, which evokes a conflict of interest. This should be indicated in writing.
- If one of the members has his/ her own proposal for review, he/ she shall not participate in the discussion on the project.

II. Current Members of TAC for Clinical Studies

1. Dr. Harikrishnan S, Professor, Department of Cardiology	Chairman
2. Dr. Sylaja P N, Professor, Department of Neurology	Member
3. Dr. Manikandan S, Professor, Department of Anaesthesiology	"
4. Dr. Narayanan Namboodiri, Professor, Department of Cardiology	"
5. Dr. Unnikrishnan K P, Professor, Department of Anaesthesiology	"
6. Dr. Syam, Additional Professor, Department of Neurology	"
7. Dr. Sanjay G, Additional Professor, Department of Cardiology	"
8. Dr. Jayadevan ER, Additional Professor, Department of IS & IR	"
9. Dr. Ramshekhar, N Menon, Additional Professor, Dept. of Neurology	"
10. Dr. Deepti AN, Associate Professor, Department of Pathology	"
11. Dr. SabarinathMenon, Associate Professor, Department of CVTS	"
12. Dr. Jayanand Sudhir B, Assistant Professor, Department of Neurosurgery	"
13. Dr. Madhusoodanan UK, Assistant Professor, Department of Biochemistry	"
14. Dr. Srinivas G, Scientist, 'F', Department of Biochemistry	Member Secretary

III. Schedule of meetings

The Committee would meet on alternate months. The meeting is scheduled to precede the IEC meetings by about one month. The meeting schedule and the last date for submission of proposals may be obtained from the Institute website.

IV. Applications accepted by TAC

TAC accepts applications and is responsible for the following:
A. Initial review of any new proposal
B. Review of requests for extension
C. Major amendments in ongoing proposals

A. New Proposal

Investigators must submit a detailed research proposal in "TAC Application Form". The investigator should also submit properly filled IEC application form along with the TAC form, with all the required documents, including the Consent Forms in English and vernacular, and the study proposal.

It is important that the submission is complete in ALL respects in order to avoid delay in obtaining clearance.

1. **Please DO NOT submit without a) the CV and signature of any of the investigators b) Consent forms in English and Malayalam c) Proforma, and d) Any other information relevant to the proposal**

2. **It is important to ascertain that the TAC and IEC Forms do not contradict each other in any manner and please make sure that the title and the list of investigators remain the same in all the documents**

3. **Provide PI's contact number in the Informed Consent Form (ICF). ICF should carry the dated signature and contact details of the PI.**

4. **Include the telephone number of IEC Member Secretary in the consent form as a 'study-independent contact person' that the study participant can contact for any clarification.**

5. **Remove patient identifiers, including name and hospital number, in the proforma for retrospective case series using hospital data. In case identifiers are needed, obtain consent for the same.**

6. **Separate the patient information sheet from the consent form.**

7. **There should be no abbreviations in the title. In addition, expand the abbreviations at first mention in the proposal.**

8. **Explain all technical terms. The proposal is seen by people who are not experts in the field.**

9. **The patient information sheet and Informed Consent Form in Malayalam should be provided if the study is to be conducted in Kerala. If the study is to be conducted in another state, the translation in the relevant local language should be provided.**

10. **The English and Malayalam/ local language patient information sheet and consent form should match.**

11. **Spelling and grammatical mistakes in the consent form are to be corrected.**

12. **The informed consent should include information on the expenses that the patient may have to incur and the source of financial support to them, if it is given. The informed consent form should clearly mention what the researcher means by participation and the time that it will take to 'participate'.**

13. **The computation of sample size even for a hospital-based retrospective case series is relevant. Investigators should determine the appropriate sample size for such studies.**

14. **Only when the TAC Clearance recommends a study for exemption/expedited review can an investigator approach the IEC for waiver of consent/exemption from reviewer expedited review.**

15. **The PI may obtain signatures of DSMB members, where applicable.**

16. **Provide Declaration Form and Proforma.**

17. **Dean's and HOD's signature form**

18. **Please ensure that CV of all investigators conforms to IEC requirements.**

Those who want to submit project proposals to TAC-Clinical Studies may submit all relevant documents online. Online submission link "TAC-Clinical" is available under the Applications Menu of our Intranet website http://intranet.sctimst.ac.in. One may also directly use the link https://intranet.sctimst.ac.in/TAC-Clinical. Please use your SCT Net password for submission of the documents.

B. Extension of approved projects

For any project that is expected to extend beyond the period of approval by the IEC, an updated, fully integrated version of the protocol (with details of the work already completed and what is to be undertaken during the period of extension) should be submitted for review, along with the original approved protocol. Request for extension must be submitted at least eight weeks prior to the expiration of the previous approval.

C. Amendments

Principal Investigators planning a major change in an approved protocol should submit to the IEC a Request for Approval of Amendment. If the IEC feels that the proposal should be looked into by TAC, then it should be submitted to TAC. Such a request must include a signed

amendment, a description of the proposed change, an explanation as to why the change is needed, a description of the implications for the subjects and revised consent documents, if the change will affect the human subjects. Amendments should be discussed with each of the investigators and a declaration form should be obtained from the co-investigators. Updated version of the protocol (with revised text in bold) is to be submitted to TAC, along with the previously approved protocol.

V. Operations

The discussion by the TAC members shall place emphasis on the scientific soundness and technical feasibility of the study proposal. The decision will be based upon broad consensus. A negative decision shall always be supported by clearly defined reasons. The Member Secretary shall record the Minutes of the meeting and maintain all the records. The decisions arrived at the TAC meeting shall be communicated to the investigators within one week of the TAC meeting.

VI. Application for TAC approval

The investigator should ensure that sufficient information is provided in the TAC application to show that the study is scientifically sound, technically feasible, and that the expected outcome of the study is clearly defined. In addition, the documents submitted to TAC should also show clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge. Please ensure that the information provided in the TAC application is complete in all respects, and not lacking in any scientific information, or not in any way contradictory to the information provided in the IEC form and the project proposal. Once the TAC application is approved, the information provided in the IEC form and the project proposal should not be altered. Declaration page duly signed by the investigators (see Appendix 1) should be attached with the application.

VII. Review Process

The TAC shall review all the proposals to see whether they are scientifically sound and technically feasible, with well-defined expected outcome. The assessment process would also take note of the following:

1. Scientific quality of the proposal
2. Originality and innovation potential
3. Potential of the investigators to carry out the project
4. Adequacy of research design and methods
5. Scientific significance of the objectives and goals
6. Technical feasibility of the project with reference to the given time frame
7. Relevance of the project to the institute or to our patient population, and
8. Quality of partnership with other institutions (if applicable)

VIII. Action by the Committee (TAC)

The Committee may take the following actions with respect to a research proposal (new, request for extension and amendments) submitted for review:

- Approval
- Contingent approval pending review and acceptance of specific minor revisions to the protocol
- Proposal needing major revisions to be resubmitted with revisions

If the protocol is approved, a clearance certificate, signed and dated by the Member Secretary, is issued to the Principal Investigator. It is the responsibility of the Principal Investigator to make copies of the IEC form and resubmit the proposal along with the clearance certificate to the IEC. If the protocol is approved subject to revision, the Principal Investigator is called upon to revise the proposal in the light of TAC comments and provide a point-by-point response to TAC queries. After the revision, the Principal Investigator resubmits the revised documents at the earliest. If TAC is satisfied with the revision, a clearance certificate is issued.

Proposed dates of TAC (Clinical Studies) Meeting in 2020

March 7, 2020 (Saturday)
May 2, 2020 (Saturday)
July 4, 2020 (Saturday)
September 5, 2020 (Saturday)
November 7, 2020 (Saturday)
January 2, 2021(Saturday)

Application Form for TAC - Clinical Studies
STUDY DESIGN, SUBJECT/PARTICIPANT SELECTION AND DATA COLLECTION PROCEDURES

Note: Application for TAC approval is similar, but not identical, to Section II of the Institutional Ethics Committee Application Form. As far as possible, the total length of the TAC application, with the responses, should not exceed six pages or 2500 words. Use of simple language is preferred. Ensure that full forms or definitions of all *abbreviations and acronyms* are given. The investigator should ensure that sufficient information is provided to show that the study is scientifically sound and technically feasible, and that the expected outcome of the study is clearly defined. If the sub-sections A to H are not sufficient to provide these aspects of the research, additional details of the study should be provided in sub-section I.

(A)TITLE

(B) SUMMARY:

Briefly summarise the study design: 50 words.

(C) STUDY PURPOSE:

Give specific hypothesis, aim/goal and objectives:

(D) STUDY BACKGROUND:

Give summary of literature review and rationale for the proposed study:

(E) DESIGN (check all applicable)

[ ] **Phase – I**, [ ] **Phase – II**, [ ] **Phase – III**, [ ] **Phase – IV**; [ ] **Randomised** [ ] **Blinded**, [ ] **Multi-Centre**. **If Multi-Ce**ntre, is SCTIMST the coordinating centre? [ ] Yes, [ ] No [ ] **Epidemiological,** [ ] **Social Sciences,** [ ] **Survey,** [ ] **Focus Groups**, [ ] **In-depth interviews** [ ] **Case Studies**, [ ] **Observations**, [ ] **Any other (specify)** _____
Any general description of design, if needed

(F) SUBJECT/PARTICIPANT SELECTION

(a) TYPE: Explain who will be the subjects/participants and rationale for selecting them (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Prisoner, Normal/Healthy volunteer, Student, Staff of the institute).

(b) NUMBER: Explain subject/participant selection (please respond to each item)**: (i) total number, (ii) rational for having that number or sample size, (iii) sampling method, if any, (iv) what proportion of them will be women, (v) from where they will be recruited and (vi) whether screening of larger number will be required.**
(c) ELIGIBILITY: Explain Inclusion and Exclusion criteria, with specific explanation if the gender, class, caste, ethnicity, race, will be used as Inclusion and/or Exclusion criteria.
(d) RECRUITMENT: Explain who will do the recruitment of the subjects/participants and how.

(G) DATA COLLECTION PROCEDURES:

Explain, in sequence, the conduct of study and all data collection procedures. Please include information on (a) medical/surgical procedures, tests, (b) treatment, (c) interviews, discussions, observations, (d) follow up, (e) specific locations where they will be performed and (f) by whom. Specify if procedure involves banking of biological samples, HIV testing, genetic testing.

(H) DATA ANALYSIS:

Plan of data analysis – including by whom and how. Please mention whether data will be analysed to understand gender, caste, class, ethnicity, race differentials.

(I) BRIEF REVIEW OF STATUS OF RESEARCH AND DEVELOPMENT IN THE SUBJECT

(a) International status

(b) National status

(c) Importance of the proposed project in the context of current status

(d) Review of expertise available with proposed investigating group/institution in the subject of the project

(e) Patent details (domestic and international)

(J) ADDITIONAL INFORMATION (IF REQUIRED)

APPENDIX 1

Declaration

I / we hereby certify that I am / we are fully involved in the conception & design of this study and assume full responsibility for the ethical and scientific conduct of this study.

Designation	Name	Signature	Date
PI			
Co PI			
Co Investigators			