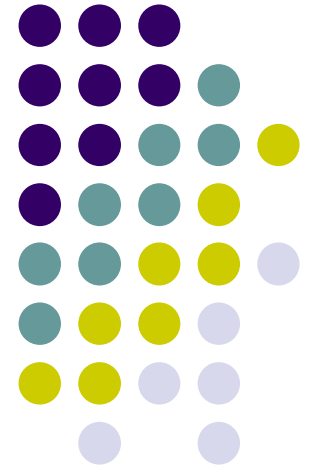




Discussion of the TAC functioning

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Introduction



- The Central Ethics Committee on Human Research (CECHR) guidelines (ICMR) recommendation
- The TAC is not an alternate to IEC, but is complimentary
- Acts as the first level of filter

Objectives



- Mainly directed towards scientific soundness and technical feasibility.
- The TAC shall not approve any research projects unless all of the following criteria for approval are satisfied:
 - *The study is scientifically sound*
 - *Study is technically feasible*
 - *Outcome of the study is clearly defined*

TAC Objectives



Critically analyze

- Scientific quality of the proposal
- Originality and innovation potential
- Potential to carry out the project
- Adequacy of research design and methods
- Scientific significance of the objectives and goals
- Technical feasibility of the project within the given time frame
- Relevance of the project to the institute /patient population
- Quality of partnership with other institutions (if applicable)

TAC Objectives



Parameters assessed on a rating scale of 1 – 5

- a) 1 – information missing
- b) 2 – inadequate
- c) 3 – adequate
- d) 4 – good
- e) 5 – excellent

Constitution (SCTIMST)



Three Technical advisory committees

- one for clinical studies
- one for public health and social sciences
- one for studies involving medical devices
- Each TAC will have four/five members
 - one Chair – a senior Professor
 - one member secretary
 - Two/three full time faculty members

Constitution (SCTIMST)



- The Chair
 - shall convene the meetings
 - ensure quorum
 - guide the review discussions
- The member Secretary
 - shall be in charge of correspondence
 - documentation
 - maintenance of minutes of meetings.
- At least three members to complete quorum

Operations



- All decisions based on broad consensus
- Member voluntarily withdraws from the TAC in case of conflict of interest
- Member voluntarily withdraws during review of his proposal



Operations

The TAC accepts applications and is responsible for the following.

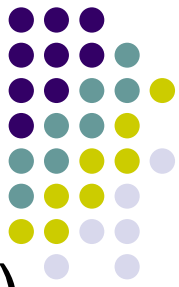
- Initial review of any new proposal
- Review of revised proposals
- Major amendments in ongoing proposals

Documents to be submitted



- Detailed Study proposal
- Clear Research objectives and rationale
for undertaking the investigation in human
subjects
- Subject Recruitment procedures
- Inclusion and exclusion criteria
- Precise description of methodology
- The plans for statistical analysis of the study

Documents to be submitted



- Recruitment materials (letters, advertisements)
- Investigational Drug Brochure (IDB),
- Device Manual, if applicable.
- Data collection instruments
- Informed consent
- Approval from DGCI for new drugs
- All significant previous decisions by other IECS
- Declaration page duly signed by the investigators.



Schedule of meetings

- Once in three months
- TAC meeting precedes the IEC meeting by at least two months

Action by the Committee



The Committee may take the following actions

- Approval;
- Contingent approval
(pending the review & minor revisions)
- Proposal needs major revisions
(Proposal needs to be resubmitted)

Expert opinion



If the TAC is undecided

*the proposal may be sent to an expert or a panel
within the institute or outside, for a decision.*

- The same will be communicated to the investigators
- All attempts shall be taken to maintain confidentiality

Time for approval by TAC



- Proposals with no revisions : 1 month
- Proposals with minor revisions : 1.5 months
- Proposals with major revisions : 3 – 4 months

Our experience



- Work load is different in different TACs
- Shaped by the nature of the research - hospital - more clinical
- Number of proposals screened
 - Hospital TAC: 6-8 /meeting- 25-30/yr
 - AMCHSS : 23/yr
 - Biomedical : 1-2 /meeting
- Time spent for each meeting- depends on the number of proposals screened
- On an average about 30 minutes per proposal

Advantages of TAC



- provides the IEC with more time to concentrate on ethical issues
- TAC provides the backup for scientific expertise in the analysis of proposals

Issues



- Does the TAC also examine issues of ethics?
- If it does identify a problem what is its mandate for intervention?
- How can we suggest modifications for multicentric studies?

Issues



- Need for a second review of a proposal already cleared by a higher review board like DST,ICMR
- Timing of meetings – inadequate time for PI to submit revised proposals before the next IEC
- TAC members are full time faculty members – time & resource constraints