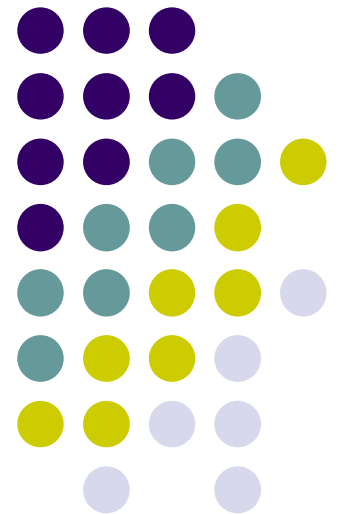
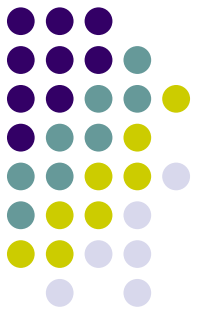


Discussion of the IEC functioning and costs

Anoopkumar Thekkuveetil
Member Secretary, IEC
SCTIMST



IEC at SCTIMST



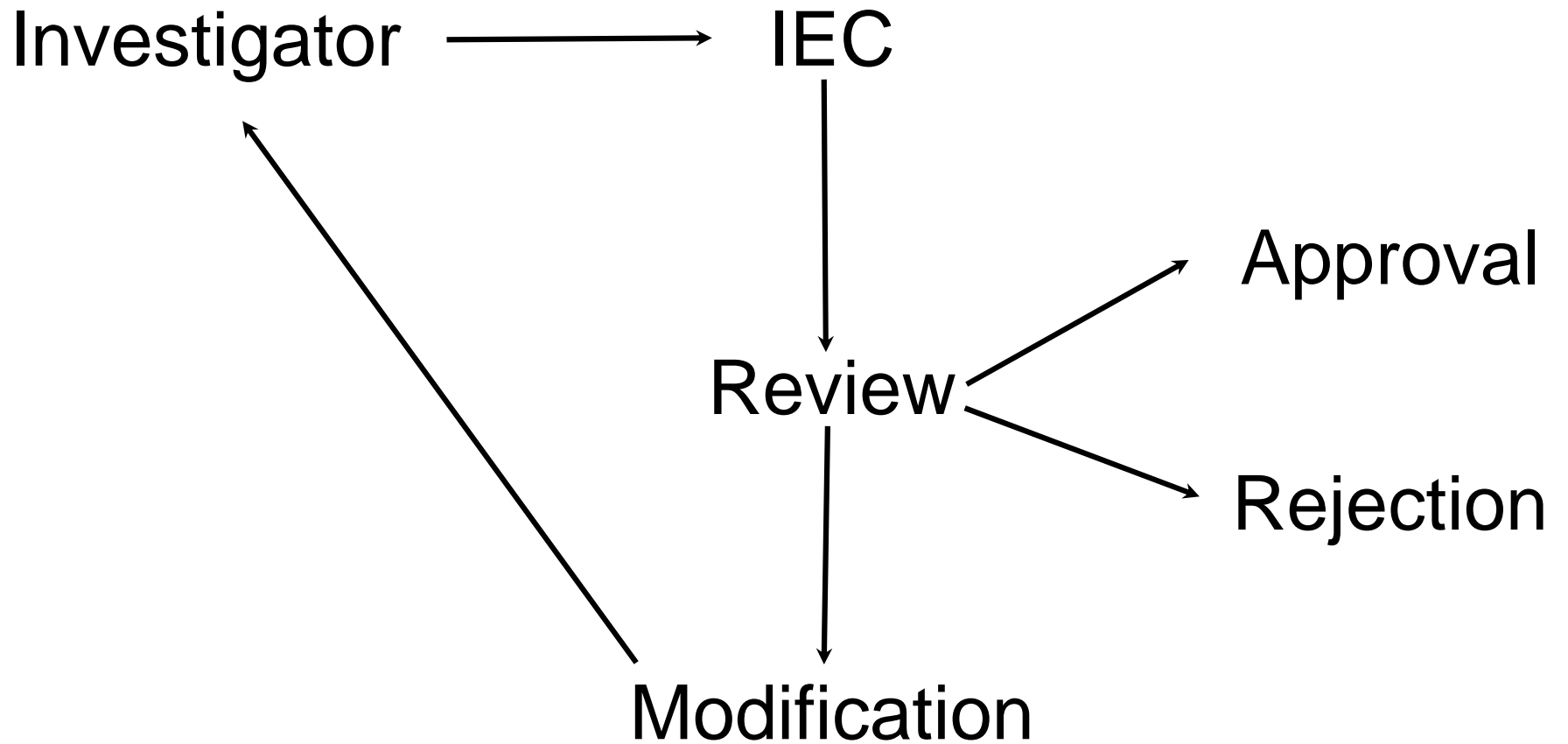
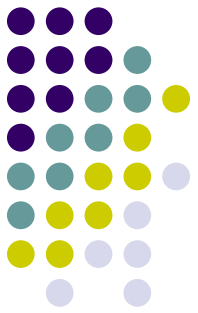
IEC constitution

- As per ICMR guideline
- Internal members: 4
- External members: 8

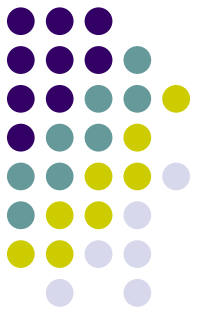
Members:

- Clinicians: 3
- Ethicist: 3
- Layperson: 1
- Basic scientists: 4
- Psychiatrist: 1
- Pharmacologist: 1
- Biomedical tech. experts: 2
- Biotechnology expert: 1
- Public health expert: 1
- Legal expert: 1
- Women members: 4

IEC



IEC - cost



IEC secretariat expenses

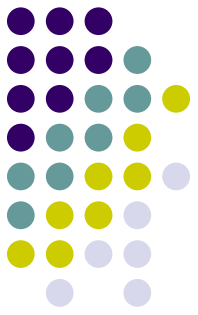
- Verification and Classification of study proposals
- Assigning reviewers
- Posting the proposals to to IEC members

IEC meeting expenses

- Travel of IEC members
- Meeting expenses

Investigator's expenses

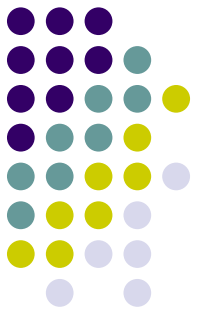
- Submission of proposals in multiple copies
- Time for reviewing the proposals
- Resubmission expenses, if needed



IEC - reducing cost

Solutions

- Classify proposals based on study type
- Have full committee only for those studies which has high risk
- Reduce the time of the meeting
- Have efficient review process
- Educating Investigators about the requirements of IEC

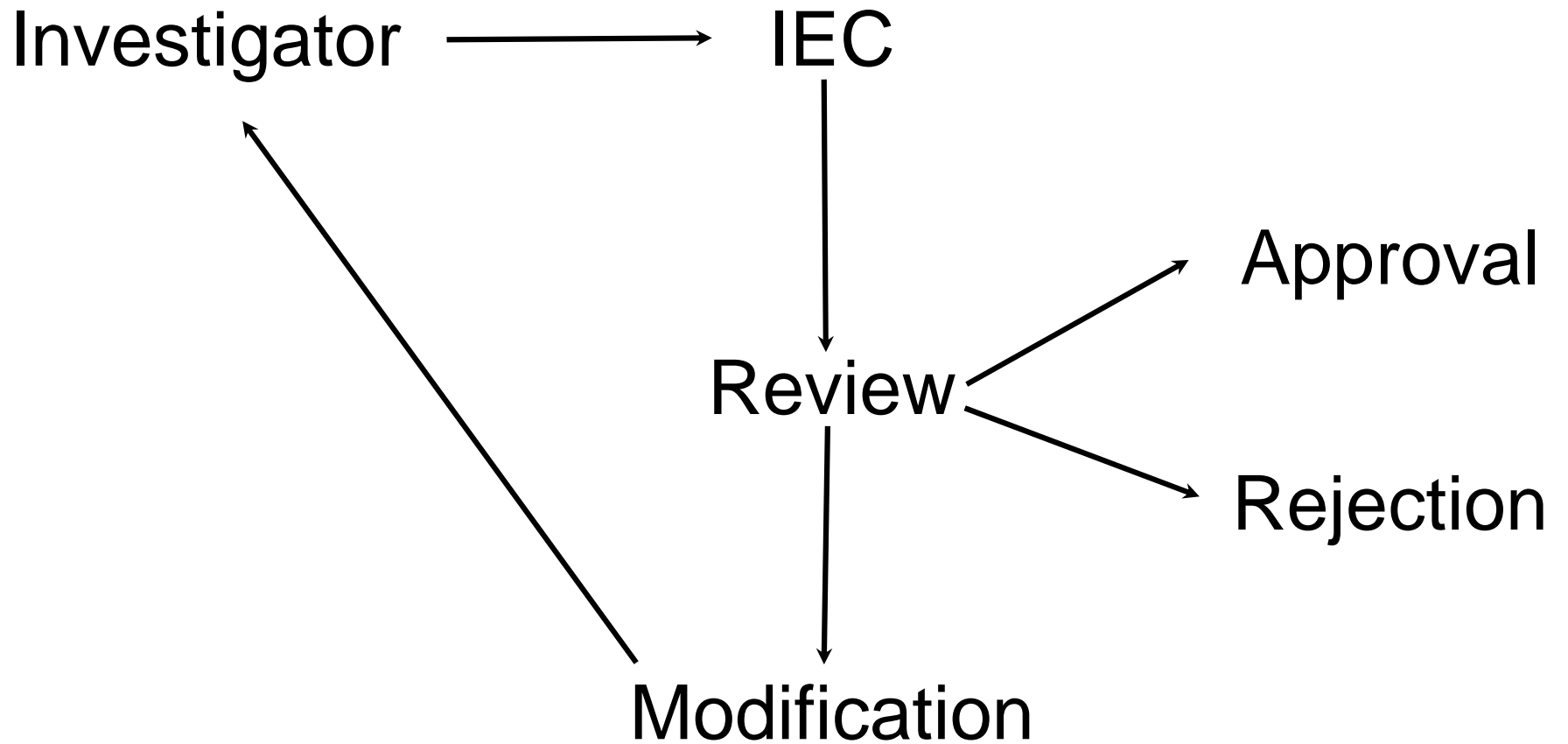
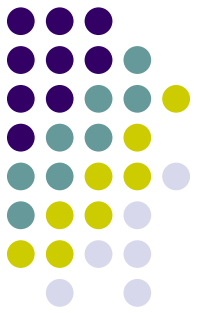


IEC- reducing cost

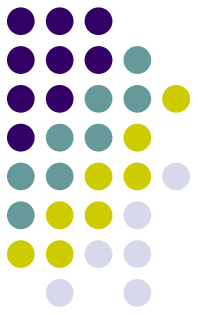
For investigator

- Proposals can be presented in soft copies
- Dates of IEC meetings are announced well in advance
- Full IEC meetings in every 3 months
- Expedited reviews and sub committees as and when required

IEC



IEC- efficient review process



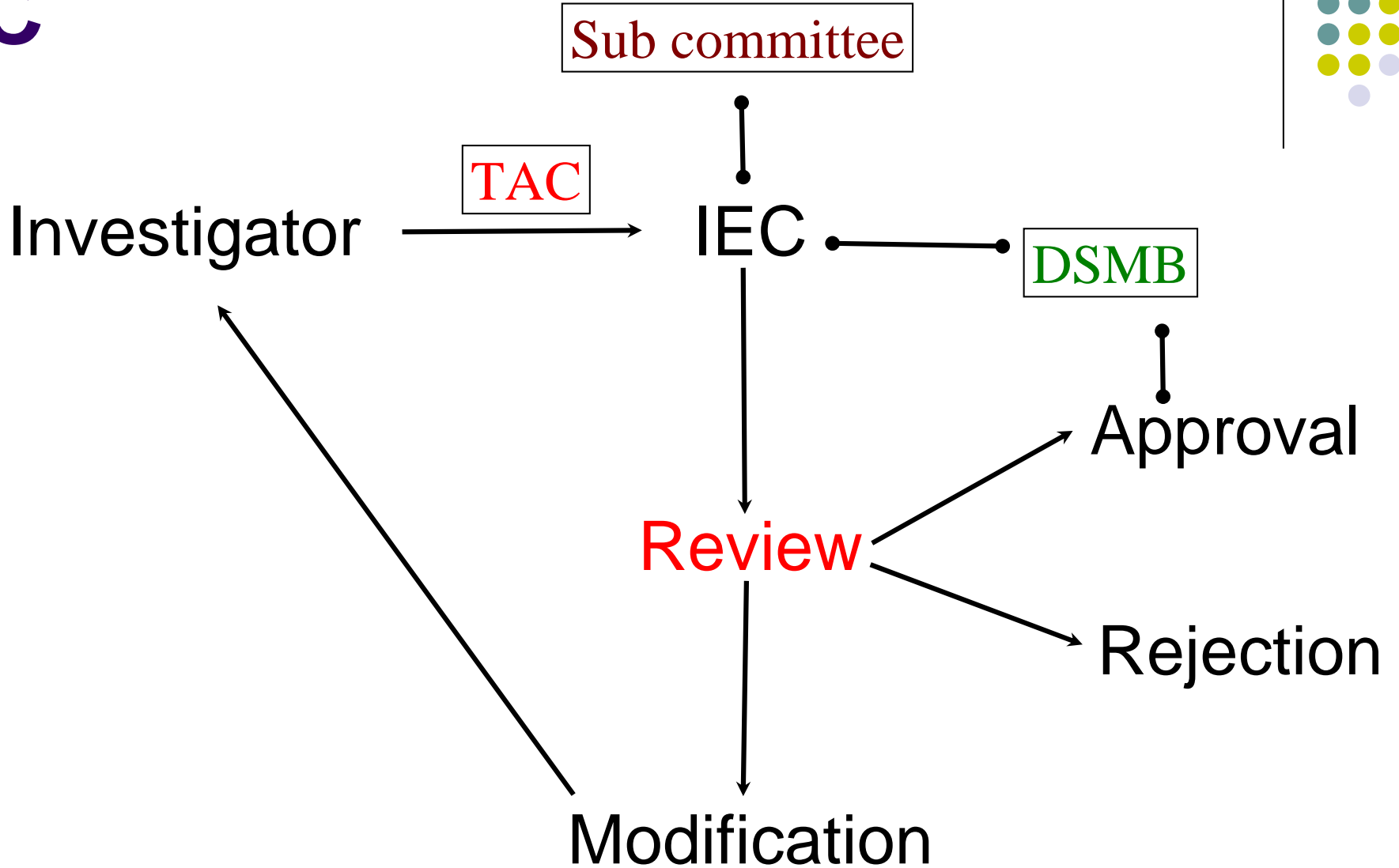
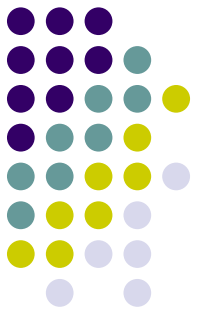
Form additional groups to help IEC in decision making

- Technical advisory committee
- Sub committee to review
- Data safety monitoring board

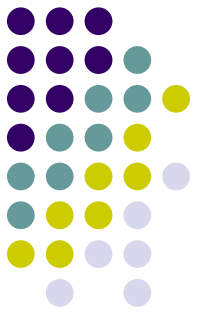
Make informed decision making

- Avoid presentation of Investigator
- IEC members are assigned as primary and secondary reviewers. This not only reduce the time spent on a proposal but also thorough reviewing of proposals

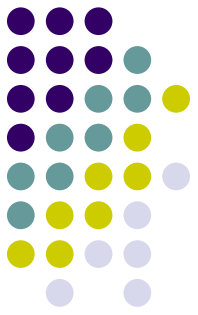
IEC



IEC- specify requirements to investigators

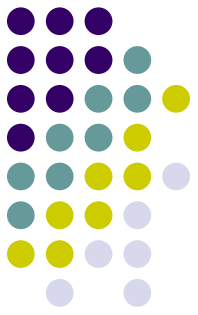


- Application forms for IEC submissions
- Adverse event reporting form and procedures
- SOP
- Helping in classifying proposals
- Helping in writing informed consent forms



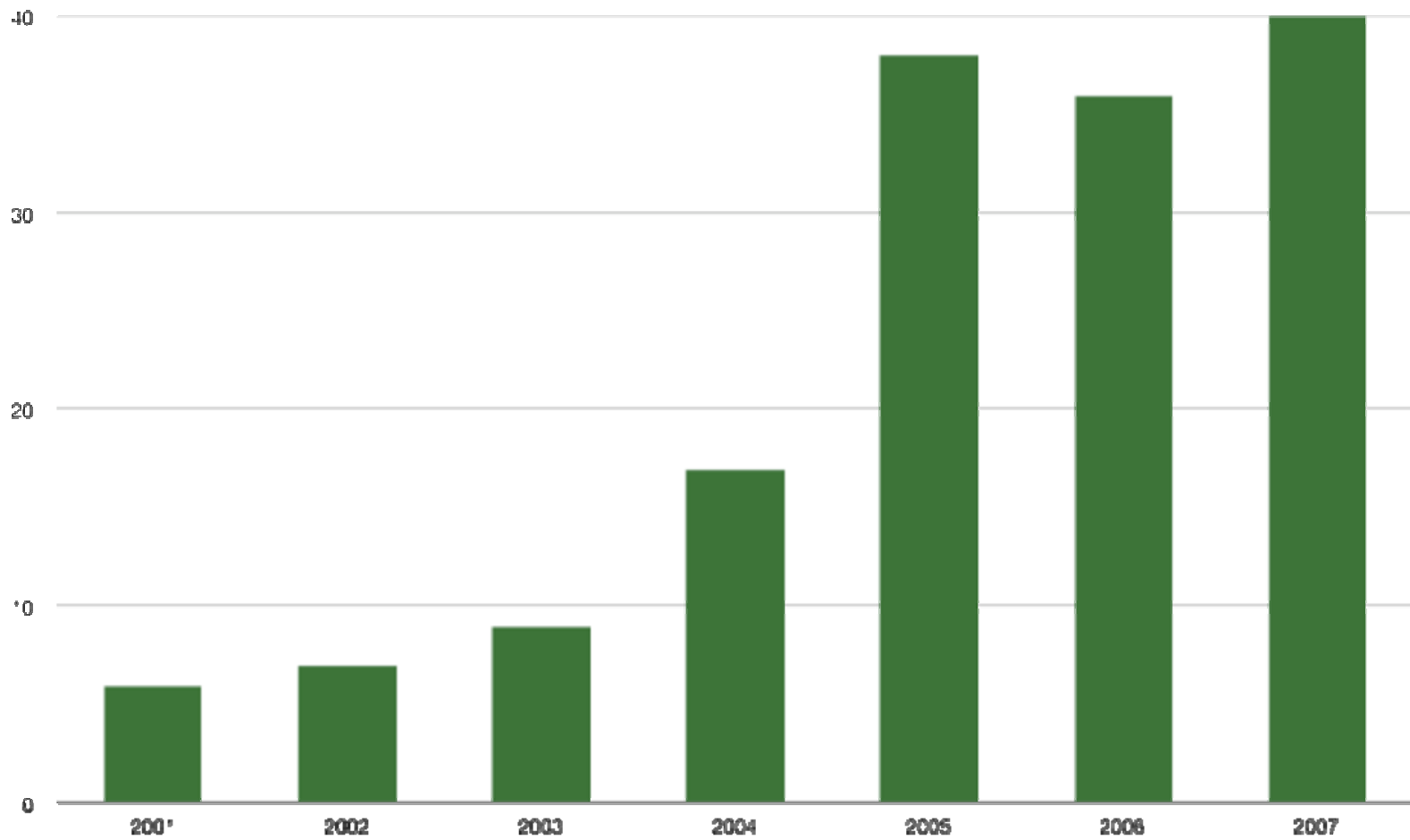
Faster communication of IEC decision to the PI

- Minutes of the meeting is prepared on the same day of meeting by the member secretary in consultation with the chairperson
- Minutes circulated by email to all members for comments
- Minutes approved within 1-2 days after the meeting.
- Letters mailed to the PI's within a weeks time after the meeting

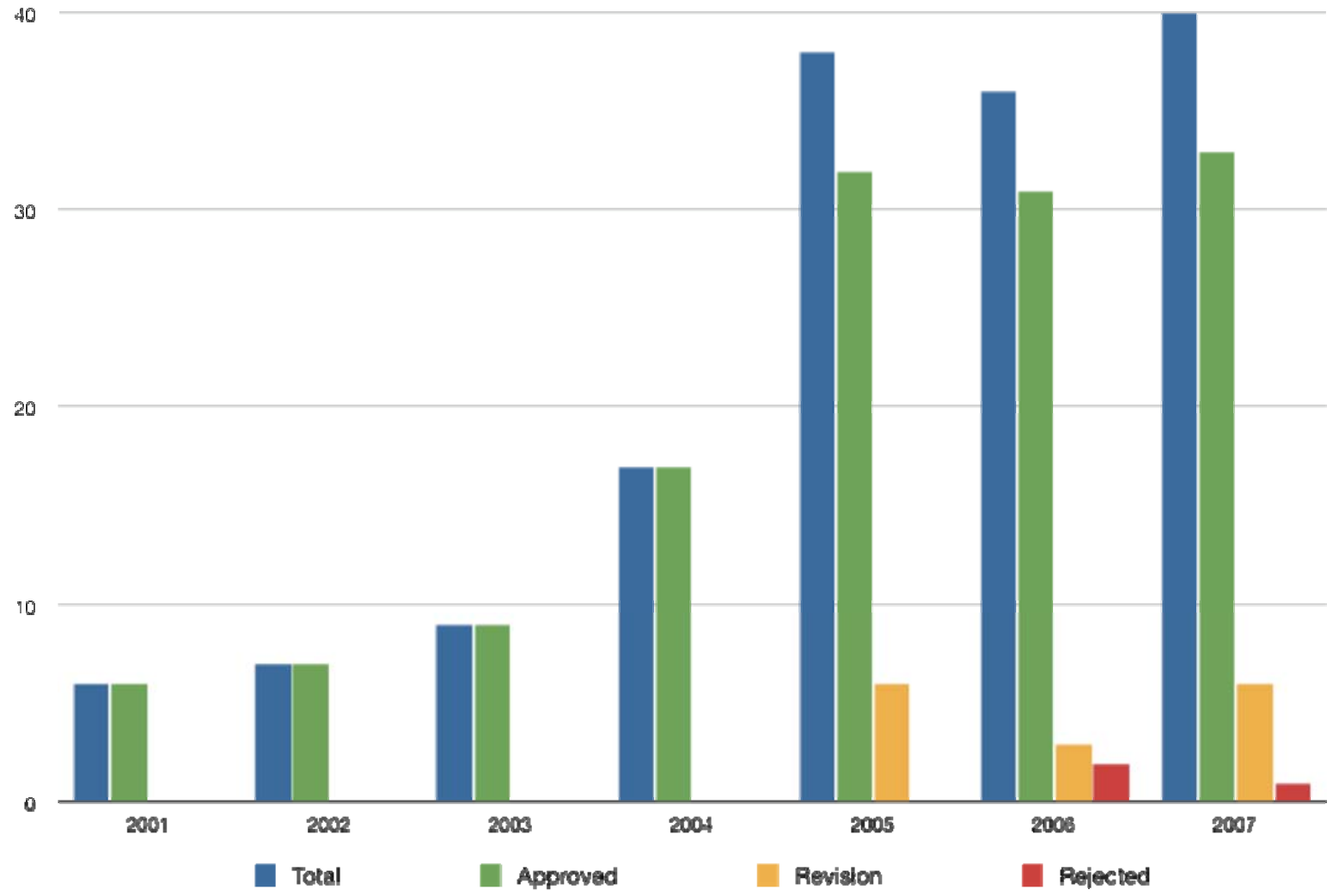


IEC- implementation of review charges

- All industry sponsored proposals are charged Rs 10,000 when a proposal is submitted for the initial review
- No additional charges for subsequent reviews
- No charges for student projects or government sponsored projects.



Number of proposals reviewed/year



Review outcome of proposals