

ANNUAL REPORT

January 2006 – December 2006

A total of **214** projects were submitted to the Ethics Committee from **JAN 2006 – DEC 2006**.

The details of these projects given in tables 1, 2 and 3.

Table 1 - Pharmaceuticals Projects: No of projects - 56

Table 2 - Government Projects: No of projects - 08

Table 3 - Academic Projects: No of projects - 150

Table 1: Details of Pharmaceutical – Sponsored Projects.

Department of the Principal Investigator	Number of Projects (n = 56)					
	Submitted for review	Approved	Received provisional approval	Reply to EC comments awaited	Not approved	Study Terminated
Anaesthesia	1	1	-	-	-	-
Cardiology	8	-	-	7	1	-
Chest Medicine	1	1	-	-	-	-
Dermatology	9	1	-	8	-	-
Endocrinology	5	4	-	1	-	-
ENT	2	-	-	2	-	-
Gastroenterology	5	3	-	2	-	-
Haematology	1	-	-	1	-	-
Medicine	5	3	-	2	-	-
Nephrology	3	1	-	2	-	-
Neurology	2	-	-	2	-	-
Neonatology	1	-	-	1	-	-
Obst & Gynaec	1	-	-	-	-	1
Orthopaedics	1	-	-	1	-	-
Paediatrics	3	2	-	1	-	-
Pharmac & Therap.	1	-	-	1	-	-
Psychiatry	6	2	-	4	-	-

Surgical Gastro.	1	1	-	-	-	-
Total	56	19	-	35	1	1

None of the Pharmaceutical projects were approved at first submission as there were scientific and ethical lacunae in the submitted protocols. ECRHS comments, pertaining to modifications in the protocol were sent to investigators. The answers to ECRHS comments of these projects were then reviewed.

Till date **36** projects of the **56** projects submitted to the ECRHS have been approved. **2** studies were not approved, **2** studies were terminated and **4** studies were withdrawn by the sponsor. Reply to ECRHS comments is awaited for **12** projects.

Table 2: Details of Government – Sponsored projects.

Department of the Principal Investigator	Number of Projects (n = 8)			
	Submitted for review	Approved	Reply to EC comments awaited	Withdrawn
Anatomy	1	1	-	-
Gastroenterology	1	1	-	-
Medicine	1	-	-	1
Microbiology	2	2	-	-
Obstetrics & Gynaecology	3	3	-	-
Total	8	7	-	1

Out of the government projects, 3 projects were approved at first submission.

Till date **6** projects of the **8** submitted to the ECRHS have been approved. **1** study was withdrawn by the investigator.

Table 3: Details of Non-Sponsored Projects are as follows

Department	Number of Projects (n = 150)			
	Submitted for review	Dissertation	Other Academic	ICMR studentship
Anaesthesia	16	13	3	-
Anatomy	3	2	1	-

Biochemistry	6	6	-	-
Cardiology	1	-	-	1
Chest Medicine	1	-	-	1
Clinical Pharmacology	10	4	3	3
CVTS	3	2	1	-
Dermatology	1	-	1	-
Diet	1	-	1	-
Endocrinology	11	5	5	1
Gastroenterology	4	3	1	-
Medicine	24	12	6	6
Microbiology	4	2	2	-
Nephrology	1	1	-	-
Neonatology	1	1	-	-
Neurology	3	1	1	1
Neurosurgery	1	-	-	1
Obstetrics & Gynaecology	7	2	1	4
Occupational Therapy	2	1	1	-
Orthopaedics	2	-	1	1
Paediatrics	19	10	4	5
Pharmacology & Therapeutics	4	1	3	-
Physiology	8	6	2	-
Physiotherapy	7	6	1	-
PSM	1	-	1	-
Psychiatry	4	-	2	2
Radiology	1	1	-	-
Surgery	1	-	1	-
Surgical Gastroenterology.	2	-	-	2
Urology	1	1	-	-
Total	150	80	42	28

Out of the non-sponsored projects, **24** projects were approved at first submission. The other **126** projects were not approved at first submission as there were scientific and ethical lacunae in the submitted protocols. For these projects, ECRHS comments, concerning modifications in the protocol were sent to investigators.

Till date out of the **150** non-sponsored projects **104** projects have been approved by ECRHS. Reply to ECRHS comments is awaited for **46** projects.

The status (ongoing/completed/withdrawn/terminated) of all the above projects submitted from **January 2005 – December 2005** will be asked for by the ECRHS in December 2006.

In 1st January 2007, the investigators were requested to provide the status of ongoing projects. This is as given below.

	Ongoing	Completed	Study stopped / closed	Rejected	Pending	Study Withdrawn/ Terminated	Not Initiated	Status not submitted.	Total
PHARMA	20	13	2	1	4	2	1	-	43
GOVT	7	1	-	-	1	-	-	-	9
ACA	28	75	-	-	19	1	6	52	181
TOTAL	55	141	2	1	24	3	7	52	233

Status of the ongoing projects as on 31st December 2006

- 1 out of the 136 projects submitted in 1999 is ongoing.
- 2 out of the 142 projects submitted in 2000 are ongoing.
- 10 out of the 141 projects submitted in the Year 2001 are ongoing.
- 1 out of 190 projects submitted in the Year 2002 are ongoing
- 4 out of 185 projects submitted in the Year 2003 are ongoing
- 19 out of 193 projects submitted in the Year 2004 are ongoing
- 55 out of 233 projects submitted in the Year 2005 are ongoing