

## ANNUAL REPORT

January 2005 – December 2005

A total of **234** projects were submitted to the Ethics Committee from **JAN 2005 – DEC 2005**.

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

Table 1 - Pharmaceuticals Projects: No of projects - 43

Table 2 - Government Projects: No of projects - 09

Table 3 - Academic Projects: No of projects - 182

**Table 1: Details of Pharmaceutical – Sponsored projects.**

Department of the Principal Investigator	Number of Projects (n = 43)					
	Submitted for review	Approved	Received provisional approval	Reply to EC comments awaited	Not approved	Study withdrawn
Anaesthesia	1	1	-	-	-	-
Cardiology	3	3	-	-	-	-
Chest Medicine	5	2	-	3	-	-
Clinical Pharmac	1	1	-	-	-	-
Dermatology	5	4	-	1	-	-
Endocrinology	2	1	-	1	-	-
Gastroenterology	1	-	-	1	-	-
Haematology	1	-	-	1	-	-
Medicine	3	3	-	-	-	-
Microbiology	1	-	-	1	-	-
Nephrology	3	1	-	2	-	-
Neurology	6	5	-	1	-	-
Obst & Gynaec	2	1	-	1	-	-
Orthopaedics	1	-	-	1	-	-
Paediatrics	1	-	-	1	-	-
Pharmac & Therap.	1	1	-	-	-	-
Psychiatry	3	1	-	1	-	1
Radiology	1	-	-	-	1	-
Surgical Gastro.	1	1	-	-	-	-
Urology	1	1	-	-	-	-
<b>Total</b>	<b>43</b>	<b>26</b>	<b>-</b>	<b>15</b>	<b>1</b>	<b>1</b>

**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 **26** projects of the 43 submissions have been approved. Reply to ECRHS comments is awaited for **15** projects. **1** study was not approved and **1** study was withdrawn by the investigator.

**Table 2: Details of Government – Sponsored projects.**

Department of the Principal Investigator	Number of Projects (n = 9)		
	Submitted for review	Approved	Reply to EC comments awaited
Clinical Pharmacology	2	1	1
CVTS	1	-	1
Endocrinology	1	1	-
Haematology (Co- Investigator)	1	1	-
Medicine	1	1	-
Obstetrics & Gynaecology	2	1	1
Pharmacology & Therapeutics	1	1	-
<b>Total</b>	<b>9</b>	<b>6</b>	<b>3</b>

**None** of the government projects were approved at first submission and clarifications were sought from investigators. The answers to ECRHS comments of these projects were reviewed.

Till date **6** projects of the 9 submissions have been approved. Reply to ECRHS comments is awaited for 3 projects.

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

Department	Number of Projects (n = 181)			
	Submitted for review	Dissertation	Other Academic	ICMR studentship
Anaesthesia	9	9	-	-
Biochemistry	5	4	1	-
Cardiology	4	-	3	1
Chest Medicine	1	-	-	1
Clinical Pharmacology	11	2	6	3
CVTS	2	-	2	-
Dermatology	3	2	-	1
Endocrinology	7	3	4	-
Gastroenterology	1	1	-	-

General Surgery	3	-	1	2
Medicine	15	6	2	7
Microbiology	9	6	1	2
Nephrology	4	3	-	1
Neonatology	1	-	1	-
Neurosurgery	2	1	1	-
Obstetrics & Gynaecology	10	3	3	4
Ophthalmology	2	1	-	1
Orthopaedics	1	-	-	1
Paediatrics	17	6	3	8
Pathology	1	-	1	-
Pharmacology & Therapeutics	4	1	3	-
Physiology	1	1	-	-
PSM	3	-	-	3
Psychiatry	9	2	1	6
Radiology	1	-	-	1
Surgical Gastroenterology.	1	-	-	1
Surgical Pathology	1	-	1	-
Occupational Therapy	35	34	1	-
Physiotherapy	18	18	-	-
<b>Total</b>	<b>181</b>	<b>-</b>	<b>-</b>	<b>-</b>

Out of the non-sponsored projects, **27** projects were approved at first submission. **1** project was not reviewed as it was not forwarded by the Principal Investigator and the Head of the Department. The other **154** 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 181 non-sponsored projects **141** projects have been approved by ECRHS. Reply to ECRHS comments is awaited for **40** 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 December 2005, the investigators were requested to provide the status of projects submitted during January 2004 - December 2004. This is given below:

**Total Projects reviewed by ECRHS in 2004 = 193**

Projects completed, report submitted	<b>50</b>
Projects completed, report not submitted	<b>40</b>

Projects not approved as answers to ECRHS suggestions not received:	<b>37</b>
Projects that were approved but not initiated:	<b>8</b>
Projects not approved	<b>2</b>
Ongoing projects:	<b>50</b>
Studies that did not come under ECRHS purview	<b>3</b>
Projects approved but withdrawn by investigator/sponsor	<b>2</b>
Status of projects not submitted by Investigator:	<b><u>1</u></b>
<b>Total</b>	<b>193</b>

**1** out of the 136 projects submitted in **1999** is ongoing.

**2** out of the 142 projects submitted in **2000** are ongoing.

**13** out of the 141 projects submitted in the Year **2001** are ongoing.

**8** out of 190 projects submitted in the Year **2002** are ongoing

**11** out of 185 projects submitted in the Year **2003** are ongoing