

ANNUAL REPORT OF THE ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS FOR
JANUARY 2007 – DECEMBER 2007

A total of **424** projects were received by the Ethics Committee during **January 2007 to December 2007**.

The detailed break up of these projects is given in tables 1, 2 and 3.

Table 1 – Projects sponsored by Pharmaceutical companies (total no. - 50)

Table 2 - Projects sponsored by Government agencies (total no. - 19)

Table 3 - Academic Projects (total no. - 355)

Table 1: Projects sponsored by Pharmaceutical companies.

| Department of the Principal Investigator | Number of Projects (n = 50) | | | | | |
|--|-----------------------------|----------|-------------------------------|------------------------------|--------------|------------------|
| | Submitted for review | Approved | Received provisional approval | Reply to EC comments awaited | Not approved | Study Terminated |
| Anaesthesia | 1 | 1 | - | - | - | - |
| Cardiology | 4 | 1 | - | 3 | - | - |
| Chest Medicine | 1 | - | - | 1 | - | - |
| CVTS | 1 | - | - | 1 | - | - |
| Clinical Pharmacology | 2 | - | - | 2 | - | - |
| Dermatology | 3 | 2 | - | 1 | - | - |
| Endocrinology | 7 | 2 | 1 | 3 | - | 1 |
| ENT | - | - | - | - | - | - |
| Gastroenterology | 3 | - | 2 | 1 | - | - |
| Haematology | 1 | - | - | - | - | 1 |
| Medicine | 6 | 2 | - | 3 | - | 1 |
| Microbiology | 1 | - | - | 1 | - | - |
| Nephrology | 2 | 1 | - | 1 | - | - |
| Neurology | 3 | - | 1 | - | - | 2 |
| Neonatology | - | - | - | - | - | - |

| | | | | | | |
|-------------------|-----------|-----------|----------|-----------|---|----------|
| Obst & Gynaec | - | - | - | - | - | - |
| Orthopaedics | 3 | 2 | - | 1 | - | - |
| Paediatrics | 3 | - | 1 | 1 | - | 1 |
| Pharmac & Therap. | 2 | 1 | - | 1 | - | - |
| Psychiatry | 1 | - | - | 1 | - | - |
| Surgery | 5 | 3 | 1 | 1 | - | - |
| Surgical Gastro. | 1 | - | - | 1 | - | - |
| Total | 50 | 15 | 6 | 23 | | 6 |

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

Till date **15** projects of the **50** projects submitted to the ECRHS have been approved. **6** studies were terminated by the investigators. For **23** projects, the ECRHS has not received any communication from the investigators on comments offered on their projects.

Table 2: Projects sponsored by Government agencies

| Department of the Principal Investigator | Number of Projects (n = 19) | | | |
|--|-----------------------------|-----------|------------------------------|-----------|
| | Submitted for review | Approved | Reply to EC comments awaited | Withdrawn |
| Clinical Pharmacology | 4 | 4 | - | - |
| Endocrinology | 1 | | 1 | - |
| Microbiology | 4 | 3 | 1 | - |
| Obstetrics & Gynaecology | 4 | 3 | 1 | - |
| Pathology | 1 | 1 | - | - |
| Paediatrics | 1 | 1 | - | - |
| Pharmacology 7 Therapeutics | 4 | 4 | - | - |
| Total | 19 | 16 | 3 | - |

Out of the government projects, 2 projects were approved at first submission. Till date 16 projects of the 19 submitted to the ECRHS have been approved. For 3 projects For 23 projects, the ECRHS has not received any communication from the investigators on comments offered on their projects .

Table 3: Academic Research Studies

| Department | Non-Sponsored Projects (n = 355) | | | | | |
|-----------------------------|----------------------------------|--------|------------------|------------------|------|----------------|
| | Submitted for review | Thesis | ICMR studentship | MUHS Studentship | KVPY | Other Academic |
| Anaesthesia | 41 | 39 | - | - | - | 2 |
| Anatomy | 3 | 3 | - | - | - | - |
| Biochemistry | 3 | 2 | - | - | - | 1 |
| Cardiology | 2 | - | - | - | - | 2 |
| Chest Medicine | 8 | 6 | 1 | - | - | 1 |
| Clinical Pharmacology | 4 | 1 | - | - | - | 3 |
| CVTS | 10 | 9 | - | - | - | 1 |
| Dermatology | 3 | 2 | - | - | - | 1 |
| Endocrinology | 2 | 1 | 1 | - | - | - |
| ENT | 7 | 7 | - | - | - | - |
| Gastroenterology | 6 | 3 | 1 | - | - | 2 |
| Haematology | 2 | 2 | - | - | - | - |
| Medicine | 40 | 29 | 1 | - | 2 | 8 |
| Microbiology | 24 | 16 | 2 | - | - | 6 |
| Nephrology | 5 | 3 | 1 | - | - | 1 |
| Neonatology | 2 | 1 | - | - | 1 | - |
| Neurology | 6 | 5 | - | - | - | 1 |
| Neurosurgery | 1 | - | - | - | - | 1 |
| Obstetrics & Gynaecology | 16 | 14 | - | - | - | 2 |
| Occupational Therapy | 16 | 15 | - | - | - | 1 |
| Ophthalmology | 6 | 5 | - | - | - | 1 |
| Orthopaedics | 3 | 3 | - | - | - | - |
| Paediatrics | 22 | 14 | 2 | - | 1 | 5 |
| Pathology | 12 | 12 | - | - | - | - |
| Pharmacology & Therapeutics | 9 | 4 | 2 | - | - | 3 |

| | | | | | | |
|----------------------------|------------|------------|-----------|----------|----------|-----------|
| Physiology | 14 | 13 | - | - | - | 1 |
| Physiotherapy | 33 | 33 | - | - | - | - |
| Plastic Surgery | 2 | - | 1 | - | - | 1 |
| PSM | 19 | 13 | 4 | - | - | 2 |
| Psychiatry | 12 | 4 | 4 | 1 | - | 3 |
| Radiology | 10 | 7 | - | - | - | 3 |
| Surgery | 8 | 8 | - | - | - | - |
| Surgical Gastroenterology. | 3 | 1 | - | - | - | 2 |
| Urology | 1 | - | - | - | - | 1 |
| Total | 355 | 275 | 20 | 1 | 4 | 55 |

Out of the non-sponsored projects, **81** projects were approved at first submission. The other **274** 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 communicated to the investigators.

Till date out of the **355** non-sponsored projects **323** projects have been approved by ECRHS. For **31** projects, the ECRHS has not received any communication from the investigators on comments offered on their projects. **One** study was terminated.

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

Status of the ongoing projects as on 11th June 2008

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

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

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

1 out of **190** projects submitted in the Year **2002** is ongoing

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

14 out of **193** projects submitted in the Year **2004** are ongoing

87 out of **233** projects submitted in the Year **2005** are ongoing

25 out of **64** sponsored projects submitted in the Year **2006** are ongoing.

For 63 out of **150** academic projects submitted in the Year **2006**, updated status has been requested from the investigators.