

Annual Report 2016

Current SOPs Version 4, 1st September 2013

Received SIDCER re-recognition award

for compliance to national & international standards

in November 2016 for the period of four years (from 23st Nov 2016 to 23rd Nov 2020)

Both committees presently functions according to the requirements laid down in Schedule Y and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research.

1] Activities of the IEC-I in the year 2016

A total of **12 full board meetings** were held in the year 2016. A total of **13 pharmaceutical** sponsored projects, **4 government** sponsored projects, **106 other academic projects** and **123 thesis / dissertations** were submitted to the IEC-I for initial review during the year.

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 IEC-I members, pertaining to modifications in the protocol were sent to investigators. The answers to IEC-I comments were then reviewed and the project was granted approval. Following is the status of the projects submitted to the IEC-I in the year 2016

| Year 2016 | Projects reviewed | Under Process | Approved |
|-----------------------------------|--------------------------|----------------------|-----------------|
| Pharmaceutical sponsored projects | 13 | 10 | 3 |
| GOVT sponsored projects | 4 | 2 | 2 |
| Thesis | 123 | 51 | 72 |
| Other Academic | 106 | 61 | 45 |
| Total | 246 | 124 | 122 |

In regards to sponsored studies:

| Year 2016 | | PHARMA | GOVT |
|------------|--|-----------------|----------|
| I | Total no. of projects reviewed by IEC-I | 13 | 4 |
| III | Type of study | Phase I | - |
| | | Phase II | - |
| | | Phase III | 7 |
| | | Phase IV | 5 |
| | | Epidemiological | 1 |
| | | NA | - |

Total active (ongoing) projects of IEC-I as on 31st January 2017

| Year | PHARMA | GOVT | Other Academic | Thesis | Total Active |
|---------------------|-----------|-----------|----------------|------------|--------------|
| 2001 | 1 | - | - | - | 1 |
| 2004 | - | 1 | - | - | 1 |
| 2005 | 1 | - | - | - | 1 |
| 2007 | - | 1 | - | - | 1 |
| 2009 | - | 1 | - | - | 2 |
| 2010 | - | 1 | - | - | 1 |
| 2011 | 1 | 2 | - | - | 3 |
| 2012 | 5 | 1 | - | - | 8 |
| 2013 | 2 | 6 | 6 | 18 | 35 |
| 2014 | 5 | 3 | 20 | 60 | 91 |
| 2015 | 5 | 3 | 54 | 126 | 189 |
| 2016 | 2 | 2 | 45 | 72 | 129 |
| Total Active | 22 | 21 | 125 | 276 | 462 |

2] Activities of the IEC-II in the year 2016

A total of **11 meetings** were held in the year 2016. A total of **11 pharmaceutical** sponsored projects, **4 governments** sponsored projects, **110 other academic** projects and **121 thesis / dissertations** were submitted to the IEC-II for initial review during the year.

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 IEC-II members, pertaining to modifications in the protocol were sent to investigators. The answers to IEC-II comments were then reviewed and the project was granted approval. Following is the status of the projects submitted to the IEC-II in the year 2016

| Year 2016 | Total reviewed projects | Under Process | Approved |
|----------------|-------------------------|---------------|------------|
| PHARMA | 11 | 8 | 3 |
| GOVT | 4 | 4 | - |
| Thesis | 121 | 56 | 65 |
| Other Academic | 110 | 57 | 53 |
| Total | 246 | 125 | 121 |

| | Year 2016 | PHARMA | GOVT |
|-----------|---------------------------------------|-----------|----------|
| I | Total no. of projects reviewed | 11 | 4 |
| II | Type of study | Phase I | - |
| | | Phase II | - |
| | | Phase III | - |
| | | Phase IV | - |
| | | NA | 4 |

Total active (ongoing) projects of IEC-II as on 31st January 2017

| Total Active Year | PHARMA | GOVT | OA | Thesis | Total Active |
|---------------------|----------|----------|------------|------------|--------------|
| 2009 | - | - | 2 | - | 2 |
| 2010 | | | 5 | | 5 |
| 2011 | | | 2 | | 2 |
| 2012 | | 1 | 5 | | 6 |
| 2013 | 2 | 1 | 9 | 54 | 66 |
| 2014 | 1 | 4 | 19 | 59 | 83 |
| 2015 | 2 | 1 | 54 | 109 | 166 |
| 2016 | 3 | - | 53 | 65 | 121 |
| Total Active | 8 | 7 | 149 | 287 | 451 |

**3] Activities of the Serious Adverse Events(SAE) Subcommittee
In the year 2016**

A total of **29 SAE Subcommittee meetings** were held in the year 2016.

| | Particulars | PHARMA | GOVT | OA | Thesis | |
|---|---|--------------------|------|----|--------|---|
| 1 | Total no. of SAE at our site: | Initial report | 2 | 2 | 3 | - |
| | | Follow up report | 3 | 1 | 3 | - |
| | | causality | - | - | - | - |
| 2 | Total no. of death | - | 2 | 3 | - | |
| 3 | Our site late reporting (after 24 hours) | - | - | - | - | |
| 4 | Responses (query) from EC regarding our site SAEs | Query letters sent | 4 | 2 | 5 | - |
| | | Noted letters sent | 2 | 1 | 3 | - |
| 7 | Total no. of Adverse Events (AE) reported | - | - | - | - | |
| 8 | Total no. of SUSAR/CIOMS reported: | 3174 | - | - | - | |

Total projects reviewed by the IEC-I & II in the year 2016

| | Departments | PHARMA | GOVT | Thesis | Other Academic | Total |
|-----|-----------------------|---------------|-------------|---------------|-----------------------|--------------|
| 1. | Anaesthesia | 0 | 0 | 18 | 20 | 38 |
| 2. | Anatomy | 0 | 0 | 2 | 1 | 3 |
| 3. | Biochemistry | 0 | 0 | 0 | 2 | 2 |
| 4. | Cardiology | 1 | 0 | 0 | 2 | 3 |
| 5. | Clinical Pharmacology | 2 | 0 | 0 | 8 | 10 |
| 6. | Chest Medicine | 0 | 0 | 4 | 2 | 6 |
| 7. | CVTS | 0 | 2 | 0 | 2 | 4 |
| 8. | Dermatology | 0 | 0 | 1 | 4 | 5 |
| 9. | Dentistry | 0 | 0 | 0 | 2 | 2 |
| 10. | Endocrinology | 1 | 1 | 0 | 8 | 10 |
| 11. | ENT | 0 | 0 | 7 | 0 | 7 |
| 12. | Forensic Medicine | 0 | 0 | 1 | 0 | 1 |
| 13. | Gastroenterology | 5 | 0 | 0 | 20 | 25 |
| 14. | General Surgery | 2 | 0 | 15 | 3 | 20 |
| 15. | Hematology | 0 | 0 | 0 | 1 | 1 |
| 16. | Medicine | 4 | 0 | 16 | 10 | 30 |
| 17. | Microbiology | 2 | 2 | 6 | 7 | 17 |
| 18. | Neurology | 2 | 1 | 0 | 4 | 7 |
| 19. | Neuro surgery | 0 | 1 | 0 | 0 | 1 |
| 20. | Neonatology | 0 | 0 | 0 | 8 | 8 |
| 21. | Nephrology | 0 | 0 | 0 | 2 | 2 |
| 22. | Nuclear medicine | 0 | 0 | 2 | 0 | 2 |
| 23. | OBGY | 0 | 1 | 40 | 17 | 58 |
| 24. | Orthopaedics | 0 | 0 | 20 | 14 | 34 |
| 25. | Ophthalmology | 3 | 0 | 3 | 1 | 7 |
| 26. | OT | 0 | 0 | 10 | 0 | 10 |

| | | | | | | |
|-----|-----------------------------|-----------|----------|------------|------------|------------|
| 27. | Pathology | 0 | 0 | 16 | 2 | 18 |
| 28. | Paediatrics | 1 | 0 | 14 | 8 | 23 |
| 29. | Paediatrics surgery | 0 | 0 | 0 | 4 | 4 |
| 30. | Plastic Surgery | 0 | 0 | 0 | 1 | 1 |
| 31. | Psychiatry | 0 | 0 | 5 | 7 | 12 |
| 32. | PSM | 1 | 0 | 17 | 27 | 45 |
| 33. | Pharmacology & Therapeutics | 0 | 0 | 6 | 7 | 13 |
| 34. | Physiology | 0 | 0 | 3 | 2 | 5 |
| 35. | PT | 0 | 0 | 31 | 2 | 33 |
| 36. | Radiology | 0 | 0 | 5 | 1 | 6 |
| 37. | Social Service | 0 | 0 | 0 | 1 | 1 |
| 38. | Surgical Gastroenterology | 0 | 0 | 0 | 0 | 0 |
| 39. | Transfusion Medicine | 0 | 0 | 2 | 3 | 5 |
| 40. | Urology | 0 | 0 | 0 | 13 | 13 |
| | TOTAL Reviewed | 24 | 8 | 244 | 216 | 492 |

Constitution of IEC-I

| Sr. No. | Name | Position on IEC-I | Designation & Affiliation | Qualification | Gender |
|---------|-------------------------|--------------------------------|--|--|--------|
| 1 | Dr. Padmavathy Menon | Chairperson (External) | Consultant Endocrinologist, Jupiter Hospital, Thane & LH Hiranandani Hospital, Powai, Mumbai. | M.D. | F |
| 2 | Dr. Sharmila Jalgaonkar | Member Secretary | Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai. | M.D. | F |
| 3. | Dr. Smrati Bajpai | Member | Assistant Professor (Medicine) Seth GS Medical College and KEM Hospital Mumbai. | M.D., DNB. | F |
| 4 | Dr. Yashashri Shetty | Member | Assistant Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai. | M.D., DBM. | F |
| 5 | Dr. Uma Jadhav | Member (Social scientist) | Community Development Officer (Social Services) Seth GS Medical College and KEM Hospital Mumbai. | M.S.W., L.L.B, Ph.D (Health Systems Studies) | F |
| 6 | Ms. Veena Johari | Member (External Legal Expert) | Independent Lawyer | L.L.B. | F |

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|----|-------------------------|-------------------------------------|---|---------------------------------------|---|
| 7 | Mrs. Gitaali Pawaar | Member (External Lay person) | Trustee / Chairperson, Little MORE Charitable Trust, Mumbai. | B.A., D.C.A., PGDEM, M.E.M. | F |
| 8 | Dr. Kaizad Damania | Member (External Scientific Expert) | Professor (Obstetrics & Gynaecology) N. Wadia Maternity Hospital, Mumbai. | M. D., DNB., F.C.P.S., D.G.O., D.F.P. | M |
| 9 | Dr. Rujuta Mehta | Member (External Scientific Expert) | HOD Paediatric Orthopaedic, Bai Jerbai Wadia Hospital for children, Mumbai. | M.S., DNB. | F |
| 10 | Dr. Sona Dave | Member (External Scientific Expert) | Professor, (Anaesthesiology) TNMC & BYL Nair Charitable Hospital, Mumbai. | M.D., DA., DNB | F |
| 11 | Dr. Sharad Patel | Member | Associate Professor (Adhoc) (Physiology) Seth GS Medical College and KEM Hospital Mumbai. | M.D. | M |
| 12 | Ms. Jaimala Shetye | Member | Associate Professor (Physiotherapy) Seth GS Medical College and KEM Hospital Mumbai. | MPT | F |
| 13 | Dr. Alka A. Subramanyam | Member (External Scientific Expert) | Assistant Professor (Psychiatry) TNMC & BYL Nair Charitable Hospital, Mumbai. | M.D., D.N.B., DHA. | F |
| 14 | Dr. Urmila Thatte | Member | Professor & Head (Clinical Pharmacology) Seth GS Medical College and KEM Hospital Mumbai. | M.D., DNB., Ph.D. | F |

Constitution of IEC-II

| | Name | Position on IEC-II | Designation & Affiliation | Qualification | Gender |
|----|------------------------|------------------------------------|---|--|---------------|
| 1. | Dr. Sangeeta Desai | Chairperson (External) | Professor and Office in Charge, Molecular Pathology, Tata Memorial Centre, Mumbai. | M.D., DTM. | F |
| 2. | Dr. Snehalata Gajbhiye | Member Secretary | Assistant Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai. | M.D., FICS. | F |
| 3. | Dr. Yuvaraj B. Chavan | Member | Professor (Additional) (PSM) Seth GS Medical College and KEM Hospital Mumbai. | M.D. | M |
| 4. | Dr. Shobha Itollikar | Member (External) | - | M.D., D.N.B. | F |
| 5. | Dr. Padmaja Marathe | Member | Professor (Additional) (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai. | M.D. | F |
| 6. | Dr. Nilesh Thakre | Member (External Social Scientist) | Associate Professor, Psychology, SNTD Women's University, Mumbai. | Ph.D. Psychology, M.A (Industrial & Business Psychology), M.I.R.P.M., M.A. (Clinic | M |

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|-----|-------------------------|--------------------------------------|--|--|---|
| | | | | al Psychology), N.E.T in Psychology, PGDICP., Dip TD. | |
| 7. | Dr. Subodh Sirur | Member (External Legal Expert) | Consultant, Dermatology & Venerology, Mahatma Gandhi Memorial Hospital, Mumbai | MBBS, DVD, LLM | M |
| 8. | Ms. Leena Pednekar | Member (External Lay person) | Chief Dietician, Mahatma Gandhi Memorial Hospital, Mumbai. | P.G. in the area of Dietetics and Applied Nutrition. | F |
| 9. | Dr. PadmajaSamant | Member | Professor, (Obstetrics & Gynaecology) Seth GS Medical College and KEM Hospital Mumbai. | Professor, (Obstetrics & Gynaecology) GSMC & KEMH | F |
| 10. | Dr. Santosh Kondekar | Member (External) | Associate Professor, (Pediatrics) Topiwala National Medical College and B. Y. L. Nair Charitable Hospital, Mumbai. | M.D., D.N.B., D.C.H., F.C.P.S., F.M.E. | M |
| 11. | Dr. Sujata Aiyer | Member | Associate Professor, (Orthopaedics) Seth GS Medical College and KEM Hospital Mumbai. | M.S., F.R.C.S.(UK), General Medical Council (UK)., ECFMG. | F |
| 12. | Dr. Sweta Salgaonkar | Member | Professor (Anesthesiology) Seth GS Medical College and KEM Hospital Mumbai. | M.D. | F |
| 13. | Dr. Sunil Kuyare | Member (External) | Assistant Professor, (Microbiology) Dr.R.N.Cooper Municipal General Hospital Bhaktivedanta Swami Marg,JVPD,Juhu,Mumbai. | M.D., PGDHA,FME. | M |
| 14. | Dr. Shilpa Adarkar | Member | Assistant Professor,(Psychiatry) Seth GS Medical College and KEM Hospital Mumbai. | M.D. | F |
| 15. | Mrs. Chhaya Verma | Member | Professor (Physiotherapy) Seth GS Medical College and KEM Hospital Mumbai. | MPTth | F |

Alternate Members of IEC-I & II

| | Name | Position on IEC-II | Designation & Affiliation | Qualification | Gender |
|---|---------------------------|--|--|--|--------|
| 1 | Dr. Pradnya Talawdekar | Alternate Member (External legal Expert) | Project Manager, Ojus Medical Institute, The Tulip Star, Juhu Tara Road Juhu, Mumbai. | B.A.M.S., L.L.M. | F |
| 2 | Mrs. Sushma Singh | Alternate Member (External legal Expert) | - | B. Pharm. LL.B. LL.M Certificate in Alternative Disputes Resolution (ADR) | F |
| 3 | Ms. Nivedita Chalill | Alternate Member (External Social Scientist) | - | M.A., Ph.D., M.Phil in social work, B.Sc(Occupational Therapy), PG Dip in Guidance & Counseling. | F |
| 4 | Dr. (Mrs.) Helen | Alternate Member | - | M.S.W., M. Phil., Ph.D. | F |

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|---|------------------------|---------------------------------------|--------------------------|---|---|
| | Joseph | (External Social Scientist) | | | |
| 5 | Mrs. Sharmila Kher | Alternate Member (External Layperson) | - | M. SC. Part 1 (Biotechnical science), Dip. In Journalism, PGDHA | F |
| 6 | Mrs. Manisha NaikDalal | Alternate Member (External Layperson) | - | M.Com | F |
| 7 | Mrs. Manju Manda | Alternate Member (External Layperson) | Section officer Railways | B.Sc. Pharmacy | F |
| 8 | Dr. Sai Kulkarni | Alternate Member (External Layperson) | - | PhD, M.A, | F |

IEC-I & II Office bearers

| | Name | Designation | Committee | Contact Details |
|----|-------------------------|------------------------|----------------------------------|--|
| 1. | Mrs. Janhavi Katkar | Administrative Manager | IEC-I, IEC-II & SAE Subcommittee | Direct no.: 24122188 Inter com no. 7515 iec-1@kem.edu iec-2@kem.edu |
| 2. | Ms. Manali Vengurlekar, | Executive Assistant | IEC-I | |
| 3. | Ms. Manasi Lad | Executive Assistant | IEC-I & SAE Subcommittee | |
| 4. | Ms. Shweta Surve | Executive Assistant | IEC-II | |
| 5. | Ms. Prajakta Auti | Executive Assistant | IEC-II & SAE Subcommittee | |
| 6. | Mr. Mangesh Khochade | Office Attendant | IEC-I, IEC-II & SAE Subcommittee | |
| 7. | Mr. Vijay Chavan | Office Attendant | IEC-I, IEC-II & SAE Subcommittee | |

Activities of the IEC

1. Training programs attended by IEC members and IEC staff:

- Dr. Yashashri Shetty attended the “Capacity Building Workshop on Ethics and Regulation of Clinical Trials in India” on 8th -9th Jan 2016 at Topaz Auditorium, YWCA
- Dr. Yashashri Shetty participated in ISCR- Ethics Council Monthly telecon_08-Jun-2016 -2:00 pm - 3:00 pm.
- Dr. Yashashri Shetty Faculty for “Introduction to GCP and Role of sponsor” as a part of our Good Clinical Practice workshop conducted on 8th August 2016 from 11.45 pm to 3.30 pm in the Department of Anaesthesiology library at KEMH
- Dr. Yashashri Shetty Faculty for Research methodology workshop by Dept of Dental sciences at Terna Dental College, Nerul, Navi Mumbai on “Biomedical Research: Scope and Avenues
- Dr. Yashashri Shetty Selection of Research Topic and Framing a Research Question with Group Exercises on 11th August 2016 at SEMINAR HALL ,Ground floor from 08.30am - 12.30 pm
- Dr. Uma Jadhav attended the “Capacity Building Workshop on Ethics and Regulation of Clinical Trials in India” on 8th -9th Jan 2016 at Topaz Auditorium, YWCA.

- Dr. Snehalata Gajabhiye & Dr. Uma Jadhav participated as delegate in SIDCER Training course program to do site monitoring as a trainee surveyor at Tata Hospital Ethics Committee from 22nd August to 24th August 2016.
- Dr. Uma Jadhav faculty for Research methodology workshop by Homi Bhabha Centre for Science Education, Tata Institute of Fundamental Research (TIFR) on 7th February 2016 for Post-Graduate (M.Ed) Students on "Ethics & Research".
- Sharmila Jalgaonkar, Mrs. Janhavi Katkar, Prajakta Auti, Shweta Surve, Manali Vengurlekar, Snehalata Gajabhiye, Padmaja Marathe, Chhaya Verma, Manisha NaikDalal Participated as delegates in a Current Regulatory Requirements for Members of Institutional Ethics Committees (An Awareness Program) on February 17-18, 2016 at Tata Memorial Hospital, Mumbai.
- Dr. Sharmila Jalgaonkar, Dr. Snehalata Gajabhiye, Dr. Yashashri Shetty, Dr. Sweta Salgaonkar and Ms. Prajakta Auti participated as delegate in a Indian Society for clinical research pre-conference workshop on Causality Assessment of SAEs on 7th Jan 2016 at Trident Hotel, Mumbai.

2. Presented papers / poster related to research ethics at conference:

- 1) Katkar Janhavi made a poster presentation about "Profile of Institutional Ethics Committee" during the 16th International Conference, "Toward Research Ethics Harmonization in Asia and the Western Pacific", organized by FERCAP on 20th to 23rd Nov 2016 at Bangkok, Thailand.

3. Publication related to research ethics in scientific journals

| | Topic | Authors | Journal |
|---|---|--|---|
| 1 | An Audit of Protocol Deviations Submitted to an Institutional Ethics Committee of a Tertiary Care Hospital | Jalgaonkar SV , Bhide SS, Tripathi RK, Shetty YC , Marathe PA , Katkar JV , Thatte UM | PLOS ONE DOI:10.1371/journal.pone.0146334 January 6, 2016 :1-9 |
| 2 | Is Coercion Involved in the Decision-Making of Medical Students Participating in Research? -A Cross-Sectional Study. | Vaidya P, Kamat S, Shetty YC , Singh KM. | Asian Bioethics Review March 2016 Volume 8, Issue 1; Pg 20-36. |
| 3 | Impact of recent regulatory notifications on the functioning of the Institutional Ethics Committee of a tertiary care teaching hospital in Mumbai | Bhide SS, Jalgaonkar SV , Katkar JV , Shetty YC , Tripathi RK, Marathe PA , Thatte UM | Indian Journal of Medical Ethics October-December 2016; Vol I, No 4 :210-14. |
| 4 | Serious Adverse Events Reports: Analysis and Outcome of Review by an Institutional Ethics Committee of a Tertiary Care Hospital in Mumbai, India. | Raakhi Tripathi, Padmaja Marathe , SandipKapse, Yashashri Shetty , Sandhya Kamat, Urmila Thatte | Journal of Empirical Research on Human Research Ethics 1556264616654809, first published on July 2016 11: 267-273 doi:10.1177/1556264616654809. |
| 5 | Abortion Rights: At Last, A Judgment of Shining Hope! | Johari V , Jadhav U . | Indian Journal of Medical Ethics. (Accepted for Publication) |
| 6 | An audit of the approval letters | Bhide SS, Katkar JV , Mourya | Published in PICR Vol 7 |

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| | issued by Drugs Controller General of India to Ethics Committees in India | M, Gogtay NJ, Thatte UM. | /Issue 4/ Oct-Dec 2016 www.picronline.org |
| 7 | Ethics Committees in India- Past, Present and Future | Thatte UM, Marathe PA. | Invited review article for a special edition of ' <i>Perspectives in Clinical Research</i> ' to be published in January 2017. Accepted for publication in November 2016. |
| 8 | Human rights and Vulnerability | Marathe Padmaja, IngoleNayana | a review article in INARCH which is an annual bulletin of the GSMC MUHS UNESCO Bioethics Unit of Seth GSMC and KEMH. Published on the occasion of the World Bioethics Day- 19 th October 2016 |

6. Winning Prizes for papers /posters related to research ethics at conferences:

- a) **Marathe PA.**- Won a prize in the international case study writing completion on Research Ethics organized by '*TRUST- Equitable research partnerships*', organization for creating and enhancing trustworthy, responsible and equitable partnerships in international research. The case study on '*Clinical trials on Bhopal gas Tragedy Victims*' has been ranked in the **first five winners** with a cash prize.
- b) **Mrs. Janhavi Katkar** secured **first place** for poster presentation about "Profile of Institutional Ethics Committee" during the 16th Annual International Conference of the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) on 20th to 23rd Nov 2016 at Bangkok, Thailand.
- c) Vaidya PH, Kamat SK, **Shetty YC**, Singh KNM. Is coercion involved in medical student's Participation in research studies? Kritarth presented the paper at 195th Staff society e-poster presentation on 24th Feb 2016 at Seth GSMC & KEM H and secured **first place**.
- d) Study on "An Audit Of Approval Letters Issued By The Drugs Controller General Of India (DCGI) To Ethics Committees" by Bhide SS, **Katkar JV**, Maurya MR, Gogtay NJ, **Thatte UM** won **first prize** in poster session at ISCR Conference- 2016. Presented by Dr. SS Bhide, Assoc. Prof., Dept. of Pharmacology & Therapeutics.

Training Given:

Dr. Padmaja Marathe

1. Conducted a session on " Ethical considerations in Good Clinical Practice" in Good Clinical Practice (An Awareness Program held in Tata Memorial Hospital, Mumbai organised by Clinical Development Services Agency, under the aegis of Department of Biotechnology, Ministry of Science and Technology, Government of India on 16th February 2016
2. Conducted a session on the topic, "Compensation for study related injury with exercises" in the preconference workshop on "Regulatory Environment for conducting Clinical Research in India – Empowering Sites & Ethics Committees" at Nehru Center, Mumbai. South Asian Chapter of American College of Clinical Pharmacology Conference on "Clinical Pharmacology of Women and Child Health on 28th April 2016.

3. Conducted a session on ' Ethics Review Procedures' in a workshop on research ethics for investigators and EC members organized by National Institute of Research in Reproductive Health held on 24th August 2016.
4. Faculty for Research methodology workshop for the topic, 'Ethics in Clinical Research' organized by Department of medical education of Rajiv Gandhi Medical College, Thane on 9th June 2016.
5. Conducted a session on ' Preparing Standard Operating Procedures for Ethics Committees' in a workshop for Ethics committee members held on 6th May 2016 organised by Forum for Ethical review Committees in India and CREATE.
6. Conducted sessions on bioethics related topics in 3 workshops (29th February, 2nd March and 3rd August 2016) for MBBS, Nursing, Occupational Therapy and Physiotherapy students.
7. Conducted sessions on "Ethics in Clinical Research" on 22nd June 2016 at the MUHS approved "Basic workshop in Research Methodology" organized by Department of Medicine , Seth GS Medical College.

Dr. Snehalata Gajabhiye

1. Faculty for Workshop on Thesis Research and Protocol Writing For students of DNB Organized and conducted by the Department of Clinical Pharmacology, KEM Hospital on 29th April 2016.
2. Faculty for Biostats module for the course postgraduate diploma in clinical research organized and conducted by DY Patil University Nerul on 16th April and 18th June 2016.
3. Conducted and coordinated 'Basics of GCP in Clinical Research' workshop at Ulhasnagar Medical College Jalgaon, on 25th February 2016.
4. Resource person for MUHS approved Research Methodology Workshop organized by Department of Anesthesia from 28-30th June 2016.
5. Resource person for Research Methodology Workshop at Terna Dental College from 27 -29 Sept 2016 organized by Department of Pharmacology and Therapeutics, Seth GSMC.
6. Resource person for Research Methodology Workshop at MGM Dental College on 23rd August 2016 organized by Department of Pharmacology and Therapeutics, Seth GSMC.
7. Resource person for Research Methodology Workshop at Yerala Dental College Kharghar on 13th July organized by Department of Dentistry.
8. Resource person for Research Methodology Workshop at TNMC & BYL Nair Ch Hospital on 22nd September organized by Department of Pharmacology.
9. Resource person for Research Methodology Workshop at TNMC & BYL Nair Ch Hospital on 5th April 2016 organized by PG academic committee.
10. Resource person for Good Clinical Practice workshop at Seth GSMC and KEM Hospital on 8th August 2016 organized by Department of Anesthesiology.

11. Resource person for Good Clinical Practice workshop at Seth GSMC and KEM Hospital on 13th June 2016 organized by Department of Medicine.
12. Resource person for MUHS approved Research Methodology Workshop organized by Department of Obstetrics and Gynecology on 4th July 2016.

Other Achievements-

- Dr. Sharmila Jalgaonkar and Dr. SnehalataGajbhiye underwent and received recognition from Strategic Initiative in Developing Capacity building in Ethical Review (SIDCER) for Institutional Ethics Committee Seth GSMC & KEM Hospital in the capacity of Member Secretary.

Dr. Sharmila Jalgaonkar
Member Secretary
IEC-I

Dr. SnehalataGajbhiye
Member Secretary
IEC-II