



टाटा स्मारक केंद्र  
TATA MEMORIAL CENTRE

कैंसर उपचार, अनुसंधान एवं शिक्षा का प्रगत केंद्र  
ADVANCED CENTRE FOR TREATMENT, RESEARCH  
& EDUCATION IN CANCER

ACTREC-IRB  
OUTWARD NO: 196/2015

397

TMC - ACTREC IEC  
Room No. 128, First Floor,  
Paymaster Shodhika,  
Kharghar,  
Navi Mumbai - 410 210.  
Phone/Fax No.: +91-22-2740 5154

## Institutional Ethics Committee

w.e.f 15<sup>th</sup> Oct, 2013

Date: 27.04.2015

To  
Dr. Sanjay Gupta  
Principal Investigator  
ACTREC

**Ref: Final Approval of project # 164**

Dear Dr. Gupta,

Institutional Ethics Committee reviewed and discussed your application dated **16.02.2015** to conduct the research study entitled "**Profiling of Histone alterations in human cancers for potential clinical applications - A retrospective study**" during the **42nd TMC-ACTREC IEC-III meeting held on 17.04.2015 at 10 a.m. in the Board room, 3<sup>rd</sup> Floor, Paymaster Shodhika at ACTREC.**

**The following members of the TMC-ACTREC IEC-III were present:**

Sl. No.	Name & Position	Affiliation	Gender	Expertise
1.	Dr. Rita Mulherkar Chairperson	Kharghar, Navi Mumbai.	Female	Basic Scientist
2.	Dr. Nobhojit Roy Co- Chairperson	Dept of Surgery, BARC Hospital, Mumbai	Male	Surgeon
3.	Dr. Vedang Murthy Member Secretary	Associate Professor, Dept. of Radiation Oncology, ACTREC	Male	Radiation Oncologist
4.	Dr. B.B. Singh Member	Advocate, Mumbai High Court	Male	Legal Expert
5.	Dr. Bharat Rekhi Member	Professor, Dept of Pathology, Tata Memorial Hospital, Mumbai.	Male	Pathologist (Basic Scientist)
6.	Mrs. Lakshmi. R. Member	Co-ordinator, Sanjeevani life beyond cancer, Mumbai.	Female	Social Scientist
7.	Mrs. Deepa Ramani Member	Ex-play group teacher, store and purchase in-charge, Kharghar.	Female	Layperson
8.	Dr. Tejpal Gupta Member	Associate Professor, Dept. of Radiation Oncology, ACTREC	Male	Radiation Oncologist
9.	Dr. Navin Khattry Member	Professor, Dept of Medical Oncology, ACTREC	Male	Medical Oncologist
10.	Dr. Kumar Prabhash Member	Professor Dept of Medical Oncology, Tata Memorial Hospital	Male	Medical Oncologist
11.	Dr. Prasanna V Member	Scientific Officer 'F', ACTREC	Female	Basic Scientist

12.	Dr. Manoj Mahimkar Member	Scientific Officer 'F', ACTREC	Male	Basic Scientist
13.	Mrs. Sadhana Kannan Member	Scientific Officer 'E' Data Manager, ACTREC	Female	Bio-statistician

**The following documents were reviewed:**

1. Project submission form
2. Study Protocol
3. Case Record Form
4. Waiver of consent request form
5. CVs & GCP of Investigators
6. Reply to IEC dated 01.04.2015

**Decision: The study is approved in the present form. IEC approved the continuation of the study till 27.04.2016. It is mandatory to submit study status report annually. You are requested to submit annual status report on or before 27.04.2016.**

**Your request for Intra Mural funding support will be forwarded to TRAC for further action.**

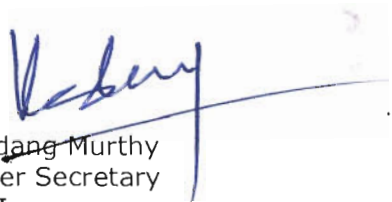
Following points must be noted:

1. **IEC has approved recruitment 130 tissue samples and their respective blocks on this study.**
2. **IEC should be informed of the yearly progress of the study by the PI. Failure to submit the continuing review application/annual status report may result in withdrawal of IEC approval.**
3. **IEC has approved the conduct of the study at Tata Memorial Centre Mumbai.**
4. Principal Investigator and study team should be GCP trained
5. PI and other investigators should notify initiation of the study.
6. PI and other investigators should co-operate fully with data and safety monitoring Sub-committee (DSMSC), who will monitor the study from time to time.
7. The decision was arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC. Member(s) of the committee who is/are listed as investigator(s) on a research proposal opted out from all deliberations on the proposal and did not participate in decision making. Neither PI nor any of proposed study team members participated during the decision making of the IEC. IEC members with any conflict of interest opted out from all deliberations on the proposal and did not participate in decision making.
8. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD and/or convener of the PI's DMG and IEC. Status report, including accounts details should be submitted to HOD and extramural sponsors.

9. The IEC functions in accordance with its SOP and is compliant with the Schedule Y (Drugs & Cosmetic Act 1940), ICMR guidelines and ICHGCP
10. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:
  - a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
  - b) Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
  - c) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Institutional Ethics Committee for approval.
  - d) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
  - e) If there are any amendments in the study design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the SRC and IEC, only then can they be implemented.
  - f) Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the IEC.
  - g) Any deviation/violation/waiver in the protocol must be informed to the IEC.

Thanking you,

Yours sincerely,



Dr Vedang Murthy  
Member Secretary  
IEC III

## TMC- Research Administrative Council (TRAC)

IEC/0715/001

July 20, 2015

To,  
Dr. Sanjay Gupta,  
Principal Investigator,  
ACTREC.

Ref: IEC Project No. 164

Dear Dr. Gupta,

Your project entitled "**Profiling of histone alterations in human cancers for potential clinical applications – A retrospective study**" submitted for consideration of competitive "Intramural funding" was scrutinized and reviewed by Chairperson, TRAC.

It is our pleasure to inform you that your above referenced project has been approved for financial support as indicated below.

Financial year – 2015-2016

Funding Source – ACTREC (IM)

Sanctioned amount- Rs.1,106,000/- (Amount in Words : Eleven Lac six Thousand Only.).

The details of the fund sanctioned are as follows:

Sr. No.	Head	(2015-2016)
1.	Manpower	336,000.00
2.	Drugs/consumables	720,000.00
3.	Miscellaneous	50,000.00
	Total	1,106,000.00

**\* The budget should be utilized only for the purpose for which it is sanctioned.**

You are advised to open the study account with the 'Accounts Department' TMH / ACTREC for your study. Please inform the accounts department regarding amount to be used for various heads such as human resources, equipment, contingency etc. Kindly note that, no additional office space will be provided for personnel, equipment for this project.

As Principal Investigator you should note that the Intramural Research Grants are sanctioned essentially to facilitate the implementation of new projects and to generate preliminary data, which can underpin the project prior to the financial support from other agencies like DBT, ICMR, DST etc. If further financial support is required, PIs are encouraged to apply for financial support from external sources as soon as possible.

You are requested to submit the continuing review applications timely as per DSMSC guidelines. It is mandatory for Principal Investigators to submit the project progress report (not more than 3 pages) to TRAC (Ms. RohiniHawaldar) on or before **30<sup>th</sup> June, 2016**. The report should cover the points mentioned below:

## TMC- Research Administrative Council (TRAC)

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- a. Start date of project
- b. Work completed till **May 2016**
- c. Work remaining
- d. Funds utilized and Balance
- e. Details of attempts made for funding from other agencies like DBT, ICMR etc.
- f. In case the Principal Investigator has been unable to generate funds he/she should make a written request for further financial support from TMC with continuing review report.
- g. Kindly submit the revised budget sheet with justification incase of any revision from original budget submitted.
- h. Any publication/presentation of the study (duly acknowledging the funding agency)

Thanking you,

Yours sincerely,

  
**Ms. Rohini Hawaldar,**  
**TRAC Administrator**

cc:

Director, TMC  
Director, TMH  
Director, ACTREC  
Deputy Director CRC, ACTREC  
Director Academics  
MS, TMH  
HOD of PI  
Secretary, IEC  
CAO, TMC  
JCA, TMC





TATA MEMORIAL CENTRE

टाटा स्मारक केन्द्र

TATA MEMORIAL HOSPITAL

टाटा स्मारक अस्पताल

Institutional Ethics Committee

w.e.f. 15<sup>th</sup> October, 2013

INSTITUTIONAL REVIEW BOARD

IEC/0314/466/002

March 3, 2014

Dr. S V Shrikhande,  
Principal Investigator,  
TMH

Ref.: Project No.466 "Identification of post translational modifications / variants of histones for exploitation as biomarker in patients with gastric cancer"

Dear Dr. Shrikhande,

The letter dated 06.01.2014 regarding extension of the project with request for paraffin imbedded tissue block (100 nos.) depending on the salient findings of the project was discussed during the Institutional Ethics Committee- (IEC- II) meeting held on 14.02.2014 at 8.30 am in Institutional Review Board Meeting Room, Main Bldg, 3<sup>rd</sup> Floor, Tata Memorial Hospital.

The following members of the Institutional Ethics Committee-II were present:

Sr. No.	Names	Affiliation	Gender	Expertise
1.	Dr.(Mrs) Urmila Thatte, Chairperson	Professor & Head, Dept. of Clinical Pharmacology, KEM Hospital	Female	Clinical pharmacologist
2.	Dr. Siddhartha Laskar, Member Secretary	Professor, Dept. of Radiation Oncology, Tata Memorial Hospital	Male	Radiation Oncologist
3.	Dr. Vikram GS, Member	Clinical Pharmacologist, Advanced Centre for Treatment, Research and Education in Cancer (ACTREC)	Male	Clinical Pharmacologist
4.	Dr. Subodh Sirur, Member	Dermatologist, Mahatma Gandhi Memorial Hospital & Consultant at Medlawindia	Male	Medico-legal expert
5.	Dr. Mrunal Marathe, Member	Counselor, on Children's Palliative Care (CPC)	Female	Social Scientist
6.	Mrs. Manisha Naikdalal, Member	Member of Ethics Committees at KEM Hospital(ECRHS)& Hinduja Hospital(CREC)	Female	Lay Person
7.	Dr. T. Teni, Member	Scientific Officer, Advanced Centre for Treatment, Research and Education in Cancer (ACTREC)	Female	Basic Scientist
8.	Dr. Vani Parmar, Member	Associate Professor, Dept. of Surgical Oncology, Tata Memorial Hospital	Female	Surgeon
9.	Dr. Prachi Patil, Member	Associate Professor, Dept. of Digestive Diseases and Clinical Nutrition, Tata Memorial Hospital & Jt. Secretary, Data Safety and Monitoring Subcommittee, TMH	Female	Gastroenterologist
10.	Dr. M H Thakur, Member	Professor & Head, Dept. of Radio-diagnosis, Tata Memorial Hospital	Female	Radiologist
11.	Dr. P.N. Jain, Member	Professor, Dept. of Anaesthesia, Tata Memorial Hospital	Male	Anesthesiologist & Pain physician

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E-mail : tmhethics@gmail.com  
Website : <http://tmh.gov.in>

Cancer is curable, if detected early

विशेष अर्थ की ऑफिस  
डॉ. ई. बोरजेस मार्ग, परेल  
मुंबई - ४०० ०१२, भारत  
दूरभाष : ०२२-२४१७ ७२६२  
फैक्स : ०२२-२४१५ ४००५

जल्द इलाज होने पर कैंसर ठीक हो सकता है।

## Institutional Ethics Committee

w.e.f. 15<sup>th</sup> October, 2013

12.	Dr. Kedar Deodhar, Member	Associate Professor, Dept. of Pathology, Tata Memorial Hospital	Male	Pathologist
13.	Ms. Rohini Hawaldar, Member	Scientific Officer, Tata Memorial Hospital	Female	Statistician

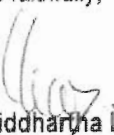
**Status: Approved.**

This decision was taken by consensus.

Neither Principal Investigator nor any of study team members was present during the decision making of the IEC.

Thanking you,

Yours faithfully,

  
Dr. Siddhartha Laskar,  
Member-Secretary,  
Institutional Ethics Committee-II

**COPY**10<sup>th</sup> September 2014

Dr. Sanjay Gupta  
 Cancer Research Institute  
 Advanced Centre for Treatment Research  
 and Education in Cancer  
 Tata Memorial Centre  
 Kharghar  
 Navi Mumbai 410210.

Dear Dr. Gupta,

This has reference to your online application for the year 2014-15 for financial assistance for your institutional research project titled **"HISTONE DEACETYLASE INHIBITOR AS A POTENTIAL SENSITIZER FOR CHEMOTHERAPEUTIC DRUGS FOR INCREASING THEIR THERAPEUTIC GAIN IN GASTRIC CANCER: A PRECLINICAL STUDY"** to be carried out at the Advanced Centre for Treatment Research and Education in Cancer, Navi Mumbai.

Your research project was scrutinized by Members of our Indian Scientific Advisory Committee (ISAC), and you were, thereafter, invited to make a presentation before the ISAC at our July 19, 2014 interview meeting.

We are glad to inform you that on the recommendation of the Members of our Indian Scientific Advisory Committee, the Trustees have sanctioned a partial financial support of Rs.5,00,000/- per year, for your above 2-year research project. The grant will be disbursed in two equal instalments in the following manner :

YEAR	AMOUNT (Rs.)
2014-2015	5,00,000/-
2015-2016	5,00,000/-
<b>Total :</b>	<b>10,00,000</b>

Our cheque for Rs.5,00,000/- drawn in favour of the **DIRECTOR-ACTREC, TMC**, is enclosed, being the grant for the first year, with a request to kindly acknowledge receipt in due course.

*[Signature]*  
 19/9/14