

File No. ECR/1/AFMS/Inst/DL/2013
Directorate General of Health Services
Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India

Dated: 12/02/2014

To,

The Chairman,
Ethics Committee,
All India Institute of Medical Sciences,
Room No. 102, 1st Floor, Old O.T. Block,
Ansari Nagar, New Delhi-110029,
India.

SUB: - Ethics Committee Registration No. ECR/538/Inst/DL/2014 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

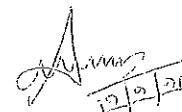
Sir/Madam,

Please refer to your application no. nil dated 30.01.2014 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers **ETHICS COMMITTEE, ALL INDIA INSTITUTE OF MEDICAL SCIENCES** situated at **ROOM NO. 102, 1st FLOOR, OLD O.T. BLOCK, ANSARI NAGAR, NEW DELHI-110029, INDIA** with Registration number **ECR/538/Inst/DL/2014** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. This Registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
2. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.
6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).
7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.
9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public
10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.
11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
12. Members should be conversant with the provisions of clinical trials under Schedule Y, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:
 - I. Basic medical scientist (preferably one pharmacologist)
 - II. Clinician
 - III. Legal expert
 - IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
 - V. Lay person from community
14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.
15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.
17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and registration is sought for Institutional Ethics Committee.


12/12/2014

(A. Visala)

Deputy Drugs Controller (I) & Licensing Authority

A. Visala
Deputy Drugs Controller
Dir. General of Health Services
Central Drugs Standard Control Organisation
POA Bhawan, Kailash Road, New Delhi-110002

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To,
The Chairman,
Ethics Committee,
All India Institute of Medical Sciences,
Room No. 102, 1st Floor, Old O.T. Block,
Ansari Nagar, New Delhi-110029,
India.

Subject: Ethics Committee Registration No. ECR/538/Inst/DL/2014 issued under Rule 122DD of the Drugs & Cosmetics Rules 1955

Sir/Madam,

Please refer to your application no. Nil dated 30.1.2014 submitted to this office for registration of Ethics Committee.

Your newly constituted ethics committee is hereby registered vide Registration No. ECR/538/Inst/DL/2014 with the following composition.

However it is to inform you that your earlier ethics committee registration vide registration certificate no. ECR/1/Inst/DL/2013 dated 01.04.2013 stands cancelled. Accordingly you are requested to surrender the earlier registration certificate (ECR/1/Inst/DL/2013 dated 01.04.2013) to this Directorate at the earliest.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Prof. Shashi Wadhwa	MBBS, MS	Chairman
2.	Dr. Pramod Kumar Garg	MBBS, MD (Internal Medicine)	Member Secretary/Clinician
3.	Dr. Peush Sahni	MBBS, MS (General Surgery), M.Ch	Clinician
4.	Dr. Sameer Bakshi	MBBS, MD (Pediatrics)	Clinician
5.	Dr. S.K. Kabra	MBBS, MD (Pediatrics)	Clinician
6.	Prof. Nikhil Tandon	MD (Internal Medicine), Ph. D. (Cantab), FNAsc	Clinician
7.	Dr. Virender Kumar Bansal	MBBS, MS, FACS (Surgery)	Clinician
8.	Dr. (Prof.) S.C. Tiwari	MD (Medicine), DM (Nephrology)	Clinician
9.	Dr. Sameer Bakhshi	MBBS, MD (Pediatrics)	Clinician
10.	Dr. Arun Agarwal	MBBS, MS (ENT)	Clinician
11.	Dr. Chandar Shekhar	MD (Epidemiology)	Basic Medical scientist
12.	Dr. Subir Kumar Maliik	MD (Pharmacology)	Basic Medical scientist
13.	Dr. D.R. Saini,	MA, Ph. D., M.Ed., LLB	Lay Person
14.	Sh. Mahmood Pracha	LLB	Legal Expert
15.	Prof. Rama V. Baru	Ph. D.	Social Worker

(A. Visala)

Deputy Drugs Controller (I) & Licensing Authority

The Institute Ethics Committee for Postgraduates for Basic Science will act as a Sub-Committee for the Institute Ethics Committee for Postgraduates Research. The-Sub Committee will comprise of the following members:

1. Prof. Shashi Wadhwa, -Chairperson
Ex- Dean AIIMS &
Ex- Professor of Anatomy, AIIMS
B-114, Sector- 30, Noida, U.P.
2. Prof. S.K. Kabra, -Co-Chairman
Deptt. of Paediatrics
3. Prof. Jaya S. Tyagi, -Member
Deptt. of Biotechnology
4. Prof. Anand Kumar -Member
Head, Deptt. of Reproductive Biology
5. Prof. Rama Choudhry -Member
Deptt. of Microbiology
6. Prof. A. Sharieff, -Member
Deptt. of Anatomy
7. Prof. M.C.Sharma, -Member
Deptt. of Neuro-Pathology
8. Dr. T. Velpandian, -Member
Addl. Professor of Ocular Pharmacology
9. Dr. D.N.Sharma, -Member
Addl. Professor of Radio Therapy (Dr. BRAIRCH)
10. Dr. Tulika Seth, -Member
Addl. Professor of Haematology
11. Dr. Sanjeev Sinha -Member Secretary
Addl. Professor, Deptt. of Medicine

The Institutional ethical clearance for academic Post Graduates research projects will meet regularly. The applications for ethical clearance will be considered within 1 month of submission in the format for ethical clearance prepared by the Committee. The Institutional Ethics Committee will function as per specified operating procedure (SOP) defined in the ICMR and DCGI guidelines. The SOP will be updated periodically depending on changing requirements.



(K.K.VAID)
SR. ADMN. OFFICER (DO)

Distribution:

1. All concerned
2. All Chair of Centers
3. Head of the Deptt./ Sr. Officer/Unit
4. PS to Director/DD(A)/Dean(Acad/Research/Exam)/MS/Sr.FA/CAO

24 FEB 2014

MEMORANDUM

Sub: Constitution of INSTITUTE ETHICS COMMITTEE FOR POST GRADUATE RESEARCH at the AIIMS, New Delhi.

In supersession to all previous orders on the subject cited above, the Director, AIIMS has been pleased to reconstitute the Institute Ethics Committee for Post Graduate Research at the AIIMS, New Delhi as under:

1. Prof. Shashi Wadhwa, -Chairman
Ex- Dean AIIMS &
Ex- Professor of Anatomy, AIIMS
B-114, Sector-30, Noida, U.P.
Mobile No. 9910769909
Email Id: shashiwadhwa@hotmail.com
2. Prof. S.K.Kabra, -Co-Chairman
Deptt. of Paediatrics, AIIMS, New Delhi
Telephone No. 26594610
Email Id: skkabra@hotmail.com
3. Prof. Rita Sood, -Member
Deptt. of Medicine, AIIMS, New Delhi
Telephone No. 01126594998
Email Id: ritasood@gmail.com
4. Prof. Suman Kumar, -Member
Principal, Blue Bell School,
Kailash Colony, New Delhi.
Mobile No. 9810517781
Email Id: contactus@bluebellinternational.com
5. Sh. Mahmood Pracha, -Member
SLC, AIIMS
C-253, 2nd Floor, Defence Colony,
New Delhi-49
Office Tel. No. 41404040
Mobile No. 9811023019
Email Id: mp@legalaxis.net
6. Prof. Rama V. Baru, -Member
Social Scientist,
Deptt. of Centre for Social Medicine and Community Health
J.N.U., New Delhi.
7. Prof. Neerja Bhatia, -Member
Deptt. of Obst. & Gynaecology
Tel.No. Off. 01126594991
Email Id: neerjabhatia07@gmail.com

P.T.O.

- 2
8. Prof. S.N. Dwivedi, ~~Dr. JAGRITI BHATIA~~ -Member
 Deptt. of Biostatistics, New Delhi ADDL. PROF.
 Tel No. Resi. 91-11-26588441 DEPTT. OF PHARMACOLOGY,
 Off. 91-11-26593387
 Mobile No. 91-9810571956
 Emails: dwivedi7@gmail.com
dwivedi@aiims.ac.in
9. Prof. Pramod Kumar Garg, -Member
 Sub-Dean (Research),
 Professor of Gastroenterology, AIIMS,
 New Delhi
 Tel. No. 01126594425
 Mobile No. 9810038116
 Email Id: pgard10@gmail.com
10. Prof. Vimi Rewari, -Member
 Deptt. of Anaesthesiology, AIIMS, New Delhi
 Telephone No. 01126593212
 Email Id: vimirewari@hotmail.com
11. Dr. Rohit Bhatia, -Member
 Addl. Professor of Neurology, AIIMS, New Delhi
 Tel. No. 01126596625
 Email Id: rohitbhatia71@yahoo.com
12. Dr Ambuj Kumar -Member
 Additional Professor of Cardiology,
 AIIMS, New Delhi
 Tel No. 01126594420
 Email Id: drambujroy@gmail.com
13. Dr. Maneesh Singhal, -Member
 Addl. Profesor Surgery (JPNATC),
 AIIMS, New Delhi
 Tel. No. 01126594809
 Mobile No. 9868397713
 Email Id: drmaneesh@gmail.com
14. Dr. V.K.Bansal, -Member
 Sub-Dean (Academic) &
 Addl. Professor, Deptt. of Surgery,
 AIIMS, New Delhi
 Tel. No. 26594622
 Fax No. 01126589766
 Mobile No. 9868397725, 9810348479
 Email Id: drvkbansal@gmail.com
15. Dr. Sanjeev Sinha -Member Secretary
 Addl. Professor, Deptt. of Medicine,
 AIIMS, New Delhi
 Tel. No. 2659440
 Mobile No. 9868397242, 9810164416
 Email Id: sanjusinha@hotmail.com

All research projects related to Post Graduates e.g. MD/MS/DM/MCH/Ph.D and other courses will be submitted to (IEC PG).

P.T.O.

- 2
8. Prof. S.N. Dwivedi, **Dr. JAGRITI BHATIA** -Member
 Deptt. of Biostatistics, New Delhi **ADDL. PROF.**
 Tel No, Resi. 91-11-26588441 **DEPTT. OF PHARMACOLOGY,**
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 Mobile No. 91-9810571956
 Emails: dwivedi7@gmail.com
dwivedi@aiims.ac.in
9. Prof. Pramod Kumar Garg, -Member
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 Email Id: pgard10@gmail.com
10. Prof. Vimi Rewari, -Member
 Deptt. of Anaesthesiology, AIIMS, New Delhi
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 Email Id: vimirewari@hotmail.com
11. Dr. Rohit Bhatia, -Member
 Addl. Professor of Neurology, AIIMS, New Delhi
 Tel. No. 01126596625
 Email Id: rohitbhatia71@yahoo.com
12. Dr Ambuj Kumar -Member
 Additional Professor of Cardiology,
 AIIMS, New Delhi
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 Email Id: drambujroy@gmail.com
13. Dr. Maneesh Singhal, -Member
 Addl. Profesor Surgery (JPNATC),
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 Email Id: drmaneesh@gmail.com
14. Dr. V.K.Bansal, -Member
 Sub-Dean (Academic) &
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 Email Id: drvkbansal@gmail.com
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 Addl. Professor, Deptt. of Medicine,
 AIIMS, New Delhi
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 Mobile No. 9868397242, 9810164416
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