


CONSTITUTION OF THE ETHICS COMMITTEE (HUMAN) FOR Ph.D. RESEARCH PROJECTS

The **Ethics Committee (Human)** for **Ph.D. Research Projects** of the University has been reconstituted comprising of the following members for a period of **two** years w.e.f. **1st January 2019**:

Sl. No.	Name	Designation
1	Dr. B.C.Kotintot, Professor and Head, Department of Pharmacology, Belgaum Institute of Medical Sciences (BIMS), Dr. B.R. Ambedkar Road, Belagavi	Chairman
2	Dr. Anil P.Hogade, Vice-Principal & Professor & HoD of Pharmacology, J.N.Medical College, Belagavi	Member
3	Dr.N.M.Patil Professor & HoD of Psychiatry, J.N.Medical College, Belagavi	Member
4	Dr. M.S.Ganachari, Professor & HoD of Pharmacy Practice, KLE CoP, Belagavi and Deputy Registrar, KAHER, Belagavi	Member
5	Dr. Anil Ankola Professor & Head, Department of Community & Public Health Dentistry, KLE V. K. Institute of Dental Sciences, Belagavi	Member
6	Dr. P. G. Jadar Professor & Vice-Principal, KLE Shri BMK Ayurveda Mahavidyalaya, Belagavi.	Member
7	Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi	Member
8	Shri Vijay V.Durdunde, Assistant Professor, B.V.Bellad Law College, Belagavi	Member
9	Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KAHER and Professor of ObG, JNMC, Belagavi	Member-Secy.

Note:

1. The Committee shall meet as and when needed as per the directions of the Chairman.
2. The Committee shall evaluate all the Ph.D. Research Projects / works of all the constituent units except those involving Animal experimentation which shall be continued to be submitted to the Ethics Committee (Animal) for ethical clearance.
3. The Member Secretary shall circulate the Meeting Notice and maintain necessary documents relating to conduct of the meetings viz. Meeting Notice, Agenda, Minutes, Action Taken Reports, etc.


ATTESTED

Dr V.A.Kothiwale
 Registrar

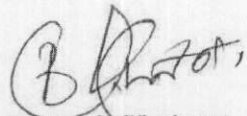
Ref. No. KLEU/EC-Ph. D/19-20/D-

10th February 2020

CIRCULAR

A meeting of KAHER Ethical Committee (Human) for Ph. D. Research is convened on **Thursday, the 20th February, 2020** from **3.00 p.m.** onwards in the Academic Affairs of KAHER. The copies of Ph. D. research proposals to be reviewed for Ethical Clearance in the meeting are enclosed herewith.


Dr. (Mrs.) Anita Dalal,
Member Secretary
Ethics Committee (Human) for Ph.D. Research Projects
Deputy Director, Academic Affairs,
KAHER, Belagavi


Dr. B. C. Kotintot,
Chairperson
Ethics Committee (Human) for Ph.D. Research Projects
Prof. and Head, Dept. of Pharmacology
Belgaum Institute of Medical Sciences
(BIMS), **Belagavi**

To,
All the Members,

1. **Dr. B. C. Kotintot**, Prof. and Head, Dept. of Pharmacology, BIMS, **Belagavi**
2. **Dr. Anil P. Hogade**, Vice-Principal & Prof. & HoD of Pharmacology, JNMC, **Belagavi**
3. **Dr. N. M. Patil**, Prof. & HoD of Psychiatry, JNMC, **Belagavi**
4. **Dr. M. S. Ganachari**, Prof. & HoD of Pharmacy Practice, CoP, Belagavi and Deputy Registrar, KAHER, **Belagavi**
5. **Dr. Anil Ankola**, Prof. & Head of Community & Public Health Dentistry, VKIDS, **Belagavi**
6. **Dr. Jyoti Hiremath**, Assistant Professor, B.V. Bellad Law College, **Belagavi**
7. **Shri Vijay V. Muradande**, Assistant Prof. Assistant Professor, B.V. Bellad Law College, **Belagavi**
8. **Dr. Anita Dalal**, Deputy Director, Academic Affairs, KAHER Prof. of ObG, JNMC, **Belagavi**

To,
The Ph. D. Research Scholars, **2019-20 batch**
Ms. Anushri Patil, Ph.D. Scholar, 2018-19 batch

Cc to:

1. Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
2. The Registrar, KAHER, Belagavi
3. Director Academic Affairs, KAHER, Belagavi

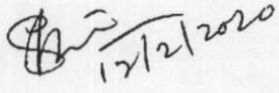
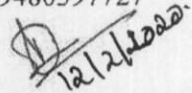
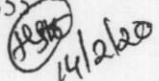

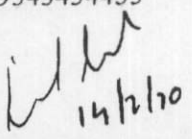
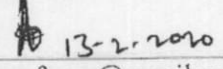
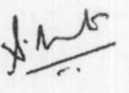
ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

} for information

Ethics Committee (Human) for Ph.D. Research Projects three years
w.e.f. 1st January 2019

Sl. No.	Name and Address	Designation	Email_ID / Contact numbers
1.	Dr. B. C. Kotintot, Professor and Head, Department of Pharmacology, Belgaum Institute of Medical Sciences (BIMS), Dr. B.R. Ambedkar Road, Belagavi	Chairman	drbckotinatot@gmail.com 9449287809  12/21/2020
2.	Dr. Anil P. Hogade, Vice-Principal & Professor & HoD of Pharmacology, J.N.Medical College, Belagavi	Member	anneel_anneell@yahoo.co.in 9480397727  12/21/2020
3.	Dr. N. M. Patil Professor & HoD of Psychiatry, J.N.Medical College, Belagavi	Member	nmpatil22@gmail.com 9886373355  14/2/20
4.	Dr. M. S. Ganachari, Professor & HoD of Pharmacy Practice, KLE CoP, Belagavi and Deputy Registrar, KLE Academy of Higher Education and Research, Belagavi	Member	msganachari@gmail.com 9448634457  12/02/2020
5.	Dr. Anil Ankola Professor & Head, Department of Community & Public Health Dentistry, KLE V. K. Institute of Dental Sciences, Belagavi	Member	drankola@yahoo.com 9343434455  14/2/20
7.	Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi	Member	swadarshan13@gmail.com 9241083528  13-2-2020
8.	Shri Vijay V. Muradande, Assistant Professor Assistant Professor, B.V. Bellad Law College, Belagavi	Member	profvvm@gmail.com 9632190500
9.	Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KLE Academy of Higher Education and Research & Professor of ObG, JNMC, Belagavi	Member- Secretary	anitamgan@gmail.com 9448140343 

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2

5

Ref. No. KAHER/Ph.D./EC/19-20/D-

29th April 2019

CIRCULAR

There will be a meeting of KAHER's Ethics Committee (Human) for Ph.D. Research on Tuesday, 14th May 2019 between 3.00 p.m. to 5.00 p.m. in the Board of Studies Hall, KAHER. The copies of Ph. D. Research proposals to be reviewed for Ethical Clearance in the meeting are enclosed herewith.


(Dr. Anita Dalal)

Member-Secretary

Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.


(Dr. B.C. Kotinatot)

Chairman

Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

To,

All the Members,

1. Dr. B. C. Kotinatot, Professor and Head, Department of Pharmacology, BIMS, Belagavi
2. Dr. Anil P. Hogade, Vice-Principal & Professor & HoD of Pharmacology, JNMC, Belagavi
3. Dr. N. M. Patil, Professor & HoD of Psychiatry, J.N. Medical College, Belagavi
4. Dr. M. S. Ganachari, Prof. & HoD of Pharmacy Practice, CoP, Deputy Registrar, KAHER, Belagavi
5. Dr. Anil Ankola, Prof. & Head, Dept. of Community & Public Health Dentistry, VK IDS, Belagavi
6. Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi
7. Shri Vijay V. Muradande, Assistant Prof., B.V. Bellad Law College, Belagavi
8. Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KAHER Prof. ObG, JNMC, Belagavi


To,

Ph. D. Research Scholars, Batch 2018-19.
Ph.D. Research Scholar 2017-18

Cc to:

1. Special Officer to Hon. Vice Chancellor, KLE University, Belgaum
 2. The Registrar, KLE University, Belgaum
 3. Director Academic Affairs, KLE University, Belgaum
- } for information

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

3


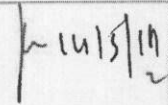
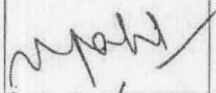

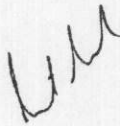
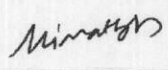
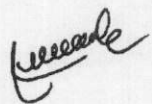
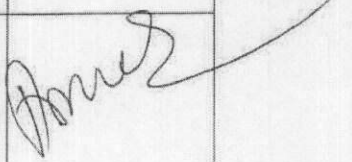
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (Formerly known as KLE University)

(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
FAX: 0831-2493777 Web: <http://www.kledeemeduniversity.edu.in> E-mail: info@kledeemeduniversity.edu.in

14th May 2019

*Members present in the Ethics Committee (Human) for Ph.D. Research on Tuesday,
14th May 2019 between 3.00 p.m. to 5.00 p.m. in the Board of Studies Hall, KAHER.*

Sl. No.	Name	Designation	Signature
1.	Dr. B. C. Kotintot, Professor and Head, Department of Pharmacology, Belgaum Institute of Medical Sciences (BIMS), Dr. B.R. Ambedkar Road, Belagavi	Chairman	
2.	Dr. Anil P. Hogade, Vice-Principal & Professor & HoD of Pharmacology, J.N.Medical College, Belagavi	Member	
3.	Dr. N. M. Patil Professor & HoD of Psychiatry, J.N.Medical College, Belagavi	Member	
4.	Dr. M. S. Ganachari, Professor & HoD of Pharmacy Practice, KLE CoP, Belagavi and Deputy Registrar, KLE Academy of Higher Education and Research, Belagavi	Member	
5.	Dr. Anil Ankola Professor & Head, Department of Community & Public Health Dentistry, KLE V. K. Institute of Dental Sciences, Belagavi	Member	
6.	Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi	Member	
7.	Shri Vijay V. Muradande, Assistant Professor Assistant Professor, B.V. Bellad Law College, Belagavi	Member	
8.	Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KLE Academy of Higher Education and Research & Professor of ObG, JNMC, Belagavi	Member- Secretary	

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE
ACADEMY OF HIGHER
EDUCATION AND RESEARCH
Deemed-to-University u/s 3 of the UGC Act, 1956

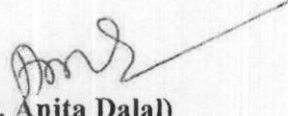
(Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: <http://www.kledeemeduniversity.edu.in>
E-mail: info@kledeemeduniversity.edu.in

Ref. No. KAHER/EC-Ph.D/17-18/D- 410

26th March, 2018

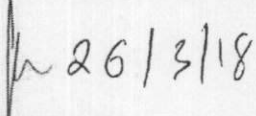
MEETING NOTICE

A meeting is convened of the KAHER's Ethical Committee (Human) for Ph. D. Research scholars on **Thursday, 19th April 2018 at 3.00 p.m.** in the BoS Hall of KAHER.


(Dr. Anita Dalal)

Member-Secretary

Ethical Committee for Ph. D. Research
KAHER, Belagavi.


(Dr. Anil Hogade)

Chairman

Ethical Committee for Ph. D. Research
KAHER, Belagavi.

(Anil P. Hogade)

To,
All the Members,

1. Dr. N. M. Patil, Prof. & Head of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. M. S. Ganachari, Prof. & Head of Pharmacy Practice, College of Pharmacy, Belagavi.
3. Mrs. Jyoti Hiremath, Assistant Prof., B V Bellad Law College, Belagavi.
4. Dr. Deepa Metgud, Prof. of Pediatric Physiotherapy, Institute of Physiotherapy, Belagavi.
5. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.

To,
Ph. D. Research Scholars, Batch 2017-18

Cc to:

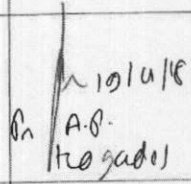
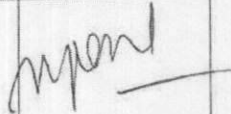


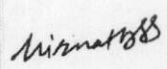
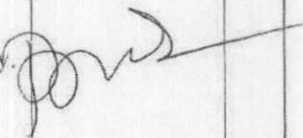
1. The Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
 2. The Registrar, KAHER, Belagavi
 3. Director Academic Affairs, KAHER, Belagavi
- } for information

ATTESTED


Dr. V.A. Kothiwale⁵
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Members present in the Ethical Committee Meeting (Human) held on Thursday, the 19th April 2018 at 3.00 PM in the Board of Studies Hall, Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra & Bhaishajya Kalpana, KLE Shri BMK AMV, Belagavi	Member	
4.	Dr. Deepa Metgud, Professor of Paediatric Physiotherapy, Institute of Physiotherapy, Belagavi	Member	—
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Assistant Professor, B V Bellad Law College, College Road, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG, J. N. Medical College, Belagavi. Deputy Director, Academic Affairs, KAHER, Belagavi.	Member-Secy.	

ATTESTED


 Dr. V.A. Kothiwate
 Registrar

KLE Academy of Higher Education and Research
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

Placed in Category 'A' by MHRD (GoI)

Director, Academic Affairs

JNMC Campus, Nehru Nagar, Bealavi-590 010, Karnataka State, India

☎: 0831-2444444/2493779 FAX: 0831-2493777 Web: <http://www.kleuniversity.edu.in> E-mail: info@kleuniversity.edu.in

Ref. No. KLEU/EC-Ph. D/16-17/D-

9th March, 2017

MEETING NOTICE

A meeting is convened of the KLE University's Ethical Committee (Human) for Ph. D. Research scholars on **Wednesday, 22nd March 2017 at 3.00 p.m.** in the BoS Hall of KLE University.

Anita Dalal

(Dr. Anita Dalal)
Member-Secretary

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

Anil Hogade

(Dr. Anil Hogade)
Chairman

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

(Dr. Anil Hogade)

To,
All the Members,

1. Dr. N. M. Patil, Professor of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.
3. Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi.
4. Dr. M. S. Ganachari, Prof of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
5. Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.

To,
Ph. D. Research Scholars, Batch 2016-17

Cc to:

1. The Special Officer to Hon. Vice Chancellor, KLE University, Belagavi
2. The Registrar, KLE University, Belagavi
3. Director Academic Affairs, KLE University, Belagavi
4. PRO, K.L.E. University, Belagavi.

} for information

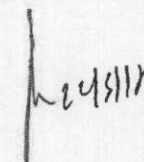
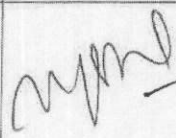
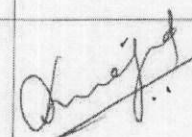

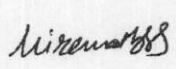
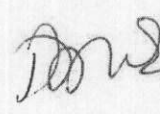
ATTESTED

V.A. Kothiwate
Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

O/C

Members present in the Ethical Committee Meeting (Human) held on Wednesday, the 22nd March 2017 at 3.00 PM in the Board of Studies Hall, Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi	Member	
4.	Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi	Member	
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG J. N. Medical College, Belagavi.	Member-Secy.	

ATTESTED


Dr. V.A. Kothiwate 8
Registrar



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)

[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

Placed in Category 'A' by MHRD (GoI)

Director, Academic Affairs

JNMC Campus, Nehru Nagar, Bealavi-590 010, Karnataka State, India

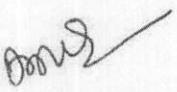
☎: 0831-2444444/2493779 FAX: 0831-2493777 Web: <http://www.kleuniversity.edu.in> E-mail: info@kleuniversity.edu.in

Ref. No. KLEU/EC-Ph. D/16-17/D-103

17th June 2016

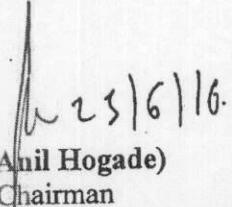
MEETING NOTICE

A meeting is convened of the KLE University's Ethical Committee (Human) for Ph. D. Research scholars on **Wednesday, 29th June 2016** between 3.30 p.m. in the Academic Affairs Hall of KLE University.


(Dr. Anita Dalal)
Member-Secretary

Ethical Committee for Ph. D. Research
KLE University, Belagavi.




(Dr. Anil Hogade)
Chairman

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

(Dr. A. S. Hogade)

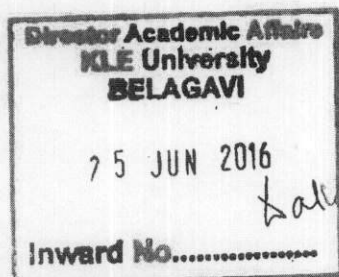
To,
All the Members,

1. Dr. N. M. Patil, Professor of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.
3. Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi.
4. Dr. M. S. Ganachari, Prof of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
5. Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.

To,
Ph. D. Research Scholars, Batch 2015-16

Cc to:

1. The Special Officer to Hon. Vice Chancellor, KLE University, Belagavi
 2. The Registrar, KLE University, Belagavi
 3. Director Academic Affairs, KLE University, Belagavi
 4. PRO, K.L.E. University, Belagavi.
- } for information

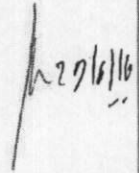
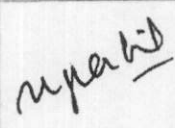
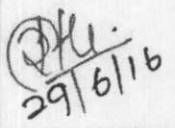

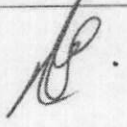
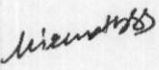


ATTESTED



Dr. V.A. Kothiwate
Registrar

9
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Members present in the Ethical Committee Meeting (Human) held on Wednesday, the 29th June 2016 at 3.30 PM in the Director Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi	Member	
4.	Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi	Member	
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG J. N. Medical College, Belagavi.	Member-Secy.	

ATTESTED


Dr. V.A. Kothiwate 10
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

Placed in Category 'A' by MHRD (GoI)

Director, Academic Affairs

JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India

☎: 0831-2444444/2493779 FAX: 0831-2493777 Web: <http://www.kleuniversity.edu.in> E-mail: info@kleuniversity.edu.in

Ref. No. KLEU/EC-Ph. D/14-15/D-652

Date: 9th March 2015

MEETING NOTICE

A meeting is convened of the KLE University's Ethical Committee (Human) for Ph. D. Research scholars on **Monday, 23rd March 2015** between **3.00 p.m. to 5.00 p.m.** in the Academic Council Hall of KLE University. The copies of Ph. D. Research proposals to be reviewed for Ethical Clearance in the meeting are enclosed herewith.

Ambal
(Dr. Anita Dalal)
Member-Secretary



hmm
(Dr. Anil Hogade)
Chairman

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

To,
All the Members,

1. Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.
3. Dr. Deepa Metgud, Associate Professor, KLE Institute of Physiotherapy, Belagavi.
4. Dr. M. S. Ganachari, Prof of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
5. Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.

To,
Ph. D. Research Scholars, Batch 2014-15.

1. Mr. Aruna C, Dept of Microbiology, J.N.M.C., Belagavi.
2. Dr. Sameer Haveri, Dept of Orthopaedic, J.N.M.C., Belagavi.
3. Dr. Rajendra Metgudmath, Dept of ENT, J.N.M.C., Belagavi.
4. Dr. Sudhigouda Patil, Dept of MPH, K.L.E. University, Belagavi.
5. Dr. Shruti Murthy, Dept of MPH, K.L.E. University, Belagavi.
6. Ms. Vineeta Dhyani, College of Pharmacy, Belagavi.
7. Mrs. Sujata Patil, KLEs M S Sheshagiri Coll. of Engineering & Technology, Belagavi
8. Miss Narmada A S, Dr. PK Basic Science Research Centre, Belagavi
9. Mrs. Geetanjali Salimath, KLEs College of Pharmacy, Belagavi
10. Mr. Ashish Sign Parihar, Collage of Pharmacy, Belagavi.
11. Bindiya Chauwan, 2012-13 batch, Collage of Pharmacy, Belagavi.
12. Nitin Ambore, 2013-14 batch, Collage of Pharmacy, Belagavi.

Cc to:

1. Special Officer to Hon. Vice Chancellor, KLE University, Belagavi
2. The Registrar, KLE University, Belagavi
3. Director Academic Affairs, KLE University, Belagavi
4. PRO, K.L.E. University, Belagavi.


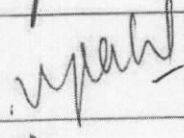
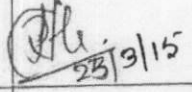
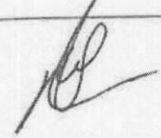
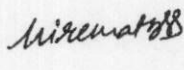
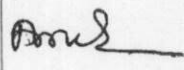
11/3/15
Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Members present in the Ethical Committee Meeting (Human)

held on Monday, the 23rd March 2015 at 3.00 PM in the

Director Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi	Member	 23/3/15
4.	Dr. Deepa Metgud, Associate Professor, KLE Institute of Physiotherapy, Belagavi	Member	
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG J. N. Medical College, Belagavi.	Member-Secy.	

ATTESTED


Dr. V.A. Kothiwate

Registrar

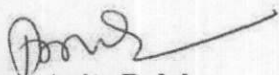
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

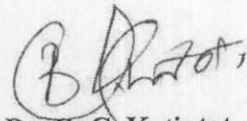
Ref. No. KLEU/EC-Ph. D/19-20/D-

10th February 2020

CIRCULAR

A meeting of KAHER Ethical Committee (Human) for Ph. D. Research is convened on **Thursday, the 20th February, 2020** from **3.00 p.m.** onwards in the Academic Affairs of KAHER. The copies of Ph. D. research proposals to be reviewed for Ethical Clearance in the meeting are enclosed herewith.


Dr. (Mrs.) Anita Dalal,
Member Secretary
Ethics Committee (Human) for Ph.D. Research Projects
Deputy Director, Academic Affairs,
KAHER, Belagavi


Dr. B. C. Kotintot,
Chairperson
Ethics Committee (Human) for Ph.D. Research Projects
Prof. and Head, Dept. of Pharmacology
Belgaum Institute of Medical Sciences
(BIMS), **Belagavi**

To,
All the Members,


1. **Dr. B. C. Kotintot**, Prof. and Head, Dept. of Pharmacology, BIMS, **Belagavi**
2. **Dr. Anil P. Hogade**, Vice-Principal & Prof. & HoD of Pharmacology, JNMC, **Belagavi**
3. **Dr. N. M. Patil**, Prof. & HoD of Psychiatry, JNMC, **Belagavi**
4. **Dr. M. S. Ganachari**, Prof. & HoD of Pharmacy Practice, CoP, Belagavi and Deputy Registrar, KAHER, **Belagavi**
5. **Dr. Anil Ankola**, Prof. & Head of Community & Public Health Dentistry, VKIDS, **Belagavi**
6. **Dr. Jyoti Hiremath**, Assistant Professor, B.V. Bellad Law College, **Belagavi**
7. **Shri Vijay V. Muradande**, Assistant Prof. Assistant Professor, B.V. Bellad Law College, **Belagavi**
8. **Dr. Anita Dalal**, Deputy Director, Academic Affairs, KAHER Prof. of ObG, JNMC, **Belagavi**

To,
The Ph. D. Research Scholars, **2019-20 batch**
Ms. Anushri Patil, Ph.D. Scholar, 2018-19 batch

Cc to:

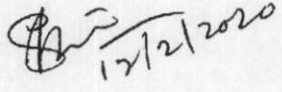
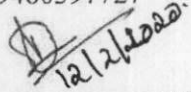
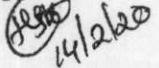
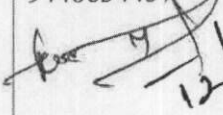
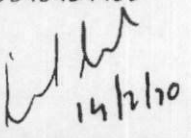
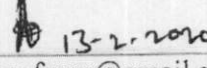
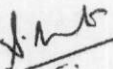
1. Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
2. The Registrar, KAHER, Belagavi
3. Director Academic Affairs, KAHER, Belagavi

ATTESTED


Dr. V.A. Kothiwate
Registrar

1
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Ethics Committee (Human) for Ph.D. Research Projects three years
w.e.f. 1st January 2019

Sl. No.	Name and Address	Designation	Email_ID / Contact numbers
1.	Dr. B. C. Kotintot, Professor and Head, Department of Pharmacology, Belgaum Institute of Medical Sciences (BIMS), Dr. B.R. Ambedkar Road, Belagavi	Chairman	drbckotinatot@gmail.com 9449287809  12/21/2020
2.	Dr. Anil P. Hogade, Vice-Principal & Professor & HoD of Pharmacology, J.N.Medical College, Belagavi	Member	anneel_anneell@yahoo.co.in 9480397727  12/21/2020
3.	Dr. N. M. Patil Professor & HoD of Psychiatry, J.N.Medical College, Belagavi	Member	nmpatil22@gmail.com 9886373355  14/2/20
4.	Dr. M. S. Ganachari, Professor & HoD of Pharmacy Practice, KLE CoP, Belagavi and Deputy Registrar, KLE Academy of Higher Education and Research, Belagavi	Member	msganachari@gmail.com 9448634455  12/02/2020
5.	Dr. Anil Ankola Professor & Head, Department of Community & Public Health Dentistry, KLE V. K. Institute of Dental Sciences, Belagavi	Member	drankola@yahoo.com 9343434455  14/2/20
7.	Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi	Member	swadarshan13@gmail.com 9241083528  13-2-2020
8.	Shri Vijay V. Muradande, Assistant Professor Assistant Professor, B.V.Bellad Law College, Belagavi	Member	profvvm@gmail.com 9632190500
9.	Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KLE Academy of Higher Education and Research & Professor of ObG, JNMC, Belagavi	Member- Secretary	anitamgan@gmail.com 9448140343 

ATTESTED


Dr. V.A. Kothiwate
Registrar

2

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Ref. No. KAHER/Ph.D./EC/19-20/D-

29th April 2019

CIRCULAR

There will be a meeting of KAHER's Ethics Committee (Human) for Ph.D. Research on Tuesday, 14th May 2019 between 3.00 p.m. to 5.00 p.m. in the Board of Studies Hall, KAHER. The copies of Ph. D. Research proposals to be reviewed for Ethical Clearance in the meeting are enclosed herewith.


(Dr. Anita Dalal)

Member-Secretary

Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.


(Dr. B.C. Kotinatot)

Chairman

Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

To,

All the Members,

1. Dr. B. C. Kotinatot, Professor and Head, Department of Pharmacology, BIMS, Belagavi
2. Dr. Anil P. Hogade, Vice-Principal & Professor & HoD of Pharmacology, JNMC, Belagavi
3. Dr. N. M. Patil, Professor & HoD of Psychiatry, J.N. Medical College, Belagavi
4. Dr. M. S. Ganachari, Prof. & HoD of Pharmacy Practice, CoP, Deputy Registrar, KAHER, Belagavi
5. Dr. Anil Ankola, Prof. & Head, Dept. of Community & Public Health Dentistry, VK IDS, Belagavi
6. Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi
7. Shri Vijay V. Muradande, Assistant Prof., B.V. Bellad Law College, Belagavi
8. Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KAHER Prof. ObG, JNMC, Belagavi


To,

Ph. D. Research Scholars, Batch 2018-19.
Ph.D. Research Scholar 2017-18

Cc to:

1. Special Officer to Hon. Vice Chancellor, KLE University, Belgaum
 2. The Registrar, KLE University, Belgaum
 3. Director Academic Affairs, KLE University, Belgaum
- } for information

ATTESTED


Dr. V.A. Kothiwate

Registrar

3

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)

(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)

Accredited 'A' Grade by NAAC (2nd Cycle)

Placed in Category 'A' by MHRD (GoI)

JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India


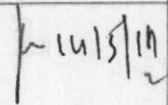
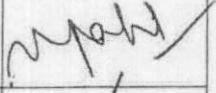

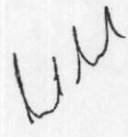
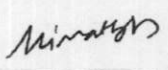
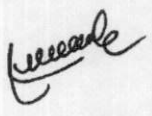
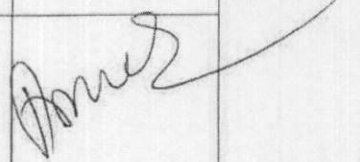
FAX: 0831-2493777

Web: <http://www.kledeemeduniversity.edu.in>

E-mail: info@kledeemeduniversity.edu.in

14th May 2019

Members present in the Ethics Committee (Human) for Ph.D. Research on Tuesday,
14th May 2019 between 3.00 p.m. to 5.00 p.m. in the Board of Studies Hall, KAHER.

Sl. No.	Name	Designation	Signature
1.	Dr. B. C. Kotintot, Professor and Head, Department of Pharmacology, Belgaum Institute of Medical Sciences (BIMS), Dr. B.R. Ambedkar Road, Belagavi	Chairman	
2.	Dr. Anil P. Hogade, Vice-Principal & Professor & HoD of Pharmacology, J.N.Medical College, Belagavi	Member	
3.	Dr. N. M. Patil Professor & HoD of Psychiatry, J.N.Medical College, Belagavi	Member	
4.	Dr. M. S. Ganachari, Professor & HoD of Pharmacy Practice, KLE CoP, Belagavi and Deputy Registrar, KLE Academy of Higher Education and Research, Belagavi	Member	
5.	Dr. Anil Ankola Professor & Head, Department of Community & Public Health Dentistry, KLE V. K. Institute of Dental Sciences, Belagavi	Member	
6.	Smt. Jyoti Hiremath, Assistant Professor, B.V. Bellad Law College, Belagavi	Member	
7.	Shri Vijay V. Muradande, Assistant Professor Assistant Professor, B.V. Bellad Law College, Belagavi	Member	
8.	Dr. (Mrs.) Anita Dalal, Deputy Director, Academic Affairs, KLE Academy of Higher Education and Research & Professor of ObG, JNMC, Belagavi	Member- Secretary	 ATTESTED

Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE
ACADEMY OF HIGHER
EDUCATION AND RESEARCH
Deemed-to-University u/s 3 of the UGC Act, 1956

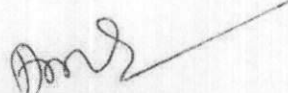
(Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: <http://www.kledeemeduniversity.edu.in>
E-mail: info@kledeemeduniversity.edu.in

Ref. No. KAHER/EC-Ph.D/17-18/D-410

26th March, 2018

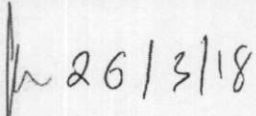
MEETING NOTICE

A meeting is convened of the KAHER's Ethical Committee (Human) for Ph. D. Research scholars on **Thursday, 19th April 2018 at 3.00 p.m.** in the BoS Hall of KAHER.


(Dr. Anita Dalal)

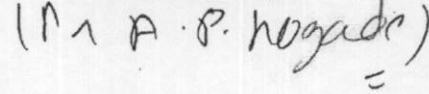
Member-Secretary

Ethical Committee for Ph. D. Research
KAHER, Belagavi.


(Dr. Anil Hogade)

Chairman

Ethical Committee for Ph. D. Research
KAHER, Belagavi.



To,
All the Members,

1. Dr. N. M. Patil, Prof. & Head of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. M. S. Ganachari, Prof. & Head of Pharmacy Practice, College of Pharmacy, Belagavi.
3. Mrs. Jyoti Hiremath, Assistant Prof., B V Bellad Law College, Belagavi.
4. Dr. Deepa Metgud, Prof. of Pediatric Physiotherapy, Institute of Physiotherapy, Belagavi.
5. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.

To,
Ph. D. Research Scholars, Batch 2017-18

Cc to:

1. The Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
 2. The Registrar, KAHER, Belagavi
 3. Director Academic Affairs, KAHER, Belagavi
- } for information

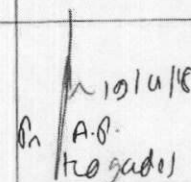
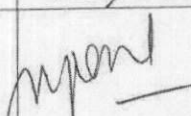

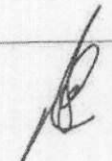
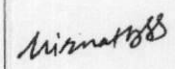
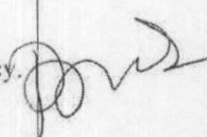
ATTESTED


Dr. V.A. Kothiwale
Registrar

5

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Members present in the Ethical Committee Meeting (Human) held on Thursday, the 19th April 2018 at 3.00 PM in the Board of Studies Hall, Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra & Bhaishajya Kalpana, KLE Shri BMK AMV, Belagavi	Member	
4.	Dr. Deepa Metgud, Professor of Paediatric Physiotherapy, Institute of Physiotherapy, Belagavi	Member	—
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Assistant Professor, B V Bellad Law College, College Road, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG, J. N. Medical College, Belagavi. Deputy Director, Academic Affairs, KAHER, Belagavi.	Member-Secy.	

ATTESTED


 Dr. V.A. Kothiwate
 Registrar

6
 KLE Academy of Higher Education and Research
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

Placed in Category 'A' by MHRD (GoI)

Director, Academic Affairs

JNMC Campus, Nehru Nagar, Bealavi-590 010, Karnataka State, India

☎: 0831-2444444/2493779 FAX: 0831-2493777 Web: http://www.kleuniversity.edu.in E-mail: info@kleuniversity.edu.in

Ref. No. KLEU/EC-Ph. D/16-17/D-

9th March, 2017

MEETING NOTICE

A meeting is convened of the KLE University's Ethical Committee (Human) for Ph. D. Research scholars on **Wednesday, 22nd March 2017 at 3.00 p.m.** in the BoS Hall of KLE University.

Anita Dalal

(Dr. Anita Dalal)
Member-Secretary

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

Anil Hogade
(Dr. Anil Hogade)
Chairman

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

(Dr. Anil Hogade)

To,
All the Members,

1. Dr. N. M. Patil, Professor of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.
3. Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi.
4. Dr. M. S. Ganachari, Prof of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
5. Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.

To,
Ph. D. Research Scholars, Batch 2016-17

Cc to:

1. The Special Officer to Hon. Vice Chancellor, KLE University, Belagavi
2. The Registrar, KLE University, Belagavi
3. Director Academic Affairs, KLE University, Belagavi
4. PRO, K.L.E. University, Belagavi.

} for information

ATTESTED

V.A. Kothiwate
Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

Members present in the Ethical Committee Meeting (Human) held on Wednesday, the 22nd March 2017 at 3.00 PM in the Board of Studies Hall, Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi	Member	
4.	Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi	Member	
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG J. N. Medical College, Belagavi.	Member-Secy.	

ATTESTED

Dr. V.A. Kothiwate
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)

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Accredited 'A' Grade by NAAC

Placed in Category 'A' by MHRD (GoI)

Director, Academic Affairs

JNMC Campus, Nehru Nagar, Bealavi-590 010, Karnataka State, India

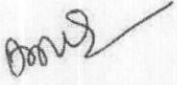
☎: 0831-2444444/2493779 FAX: 0831-2493777 Web: http://www.kleuniversity.edu.in E-mail: info@kleuniversity.edu.in

Ref. No. KLEU/EC-Ph. D/16-17/D-103


17th June 2016

MEETING NOTICE

A meeting is convened of the KLE University's Ethical Committee (Human) for Ph. D. Research scholars on **Wednesday, 29th June 2016** between 3.30 p.m. in the Academic Affairs Hall of KLE University.


(Dr. Anita Dalal)
Member-Secretary




(Dr. Anil Hogade)
Chairman
Ethical Committee for Ph. D. Research
KLE University, Belagavi.

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

(Dr. A. S. Hogade)

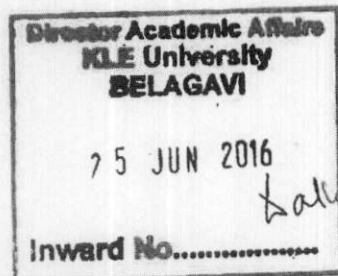
To,
All the Members,

1. Dr. N. M. Patil, Professor of Psychiatry, J. N. Medical College, Belagavi.
2. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi.
3. Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi.
4. Dr. M. S. Ganachari, Prof of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
5. Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.


To,
Ph. D. Research Scholars, Batch 2015-16

Cc to:

1. The Special Officer to Hon. Vice Chancellor, KLE University, Belagavi
 2. The Registrar, KLE University, Belagavi
 3. Director Academic Affairs, KLE University, Belagavi
 4. PRO, K.L.E. University, Belagavi.
- } for information

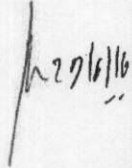
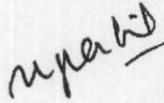
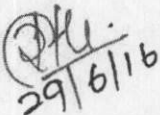

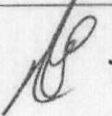
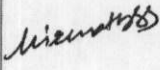


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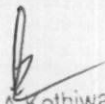

Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Members present in the Ethical Committee Meeting (Human) held on Wednesday, the 29th June 2016 at 3.30 PM in the Director Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi	Member	
4.	Dr. Deepa Metgud, Professor, KLE Institute of Physiotherapy, Belagavi	Member	
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG J. N. Medical College, Belagavi.	Member-Secy.	

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Ref. No. KLEU/EC-Ph. D/14-15/D-652

Date: 9th March 2015

MEETING NOTICE

A meeting is convened of the KLE University's Ethical Committee (Human) for Ph. D. Research scholars on **Monday, 23rd March 2015** between 3.00 p.m. to 5.00 p.m. in the Academic Council Hall of KLE University. The copies of Ph. D. Research proposals to be reviewed for Ethical Clearance in the meeting are enclosed herewith.

Anita Dalal
(Dr. Anita Dalal)
Member-Secretary



Anil Hogade
(Dr. Anil Hogade)
Chairman

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

Ethical Committee for Ph. D. Research
KLE University, Belagavi.

To,
All the Members,

1. Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi. *NPW*
2. Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi. *CV*
3. Dr. Deepa Metgud, Associate Professor, KLE Institute of Physiotherapy, Belagavi. *DLK*
4. Dr. M. S. Ganachari, Prof of Pharmacy Practice, KLE College of Pharmacy, Belagavi. *DLK*
5. Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.

To,
Ph. D. Research Scholars, Batch 2014-15.

1. Mr. Aruna C, Dept of Microbiology, J.N.M.C., Belagavi.
2. Dr. Sameer Haveri, Dept of Orthopaedic, J.N.M.C., Belagavi.
3. Dr. Rajendra Metgudmath, Dept of ENT, J.N.M.C., Belagavi.
4. Dr. Sudhigouda Patil, Dept of MPH, K.L.E. University, Belagavi.
5. Dr. Shruti Murthy, Dept of MPH, K.L.E. University, Belagavi.
6. Ms. Vineeta Dhyani, College of Pharmacy, Belagavi.
7. Mrs. Sujata Patil, KLEs M S Sheshagiri Coll. of Engineering & Technology, Belagavi
8. Miss Narmada A S, Dr. PK Basic Science Research Centre, Belagavi
9. Mrs. Geetanjali Salimath, KLEs College of Pharmacy, Belagavi
10. Mr. Ashish Sign Parihar, Collage of Pharmacy, Belagavi.
11. Bindiya Chauwan, 2012-13 batch, Collage of Pharmacy, Belagavi.
12. Nitin Ambore, 2013-14 batch, Collage of Pharmacy, Belagavi.

Cc to:

1. Special Officer to Hon. Vice Chancellor, KLE University, Belagavi. *11/3/15*
2. The Registrar, KLE University, Belagavi. *REJ*
3. Director Academic Affairs, KLE University, Belagavi. *REJ*
4. PRO, K.L.E. University, Belagavi.

Dr. V.A. Kothiwate
Registrar



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belgaum)
[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

Members present in the Ethical Committee Meeting (Human)

held on Monday, the 23rd March 2015 at 3.00 PM in the

Director Academic Affairs Office of the University.

Sl. No.	Name	Designation	Signature
1.	Dr. Anil Hogade Vice-Principal, Prof. & Head of Pharmacology J.N. Medical College, Belagavi	Chairman	
2.	Dr. N. M. Patil, Professor & HoD of Psychiatry, J. N. Medical College, Belagavi.	Member	
3.	Dr. Rudramma Hiremath, Reader, Dept of Rasashastra, KLE Shri BMK AMV, Belagavi	Member	 23/3/15
4.	Dr. Deepa Metgud, Associate Professor, KLE Institute of Physiotherapy, Belagavi	Member	
5.	Dr. M. S. Ganachari Prof & HoD, Dept of Pharmacy Practice KLE College of Pharmacy, Belagavi.	Member	
6.	Mrs. Jyoti Hiremath, Lecturer, B V Bellad Law College, Belagavi.	Member	
7.	Dr. Anita Dalal Professor, Dept of ObG J. N. Medical College, Belagavi.	Member-Secy.	

ATTESTED

Dr. V.A. Kothiwate 12
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956),
Belagavi-590 010, Karnataka

National Accreditation Board for Hospitals & Healthcare Providers

(Constituent Board of Quality Council of India)

Certificate of Accreditation

Ethics Committee, KLE University
Nehru Nagar, J.N. Medical College Campus
Belagavi - 590010, Karnataka

*has been assessed and found to comply with NABH
Accreditation Standards for Ethics Committee (E.C)
under clinical trial program.*

*This certificate is valid subject to continued compliance
with NABH Accreditation Requirements.*


Valid from : January 21, 2018

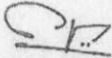
Valid thru : January 20, 2021

Certificate No.

EC-CT-2018-0015




Dr. Harish Nadkarni
Chief Executive Officer


Dr. Nandakumar Jairam
Chairman

ATTESTED

National Accreditation Board for Hospitals & Healthcare Providers, 5th Floor, ITPI Building, 4A, Ring Road, IP Estate, New Delhi 110 002, India
Phone: +91-11-42600600, Fax: +91-11-2332 3415 • Email: helpdesk@nabh.co • Website: www.nabh.co


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

non-medical, scientific and non-scientific areas with at least,

- (i) one lay person;
- (ii) one woman member;
- (iii) one legal expert;
- (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, 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.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. 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.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7; provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8: Provided that the approving Ethics Committee shall

such case be responsible for the study at the centre: Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.


29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940 and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

The Strategic Initiative for Developing
Capacity in Ethical Review



in collaboration with the



Forum for Ethical Review Committees in
Asia and the Western Pacific Region

hereby awards recognition to the

**Institute Ethics Committee
KLE University, Belgaum
(Nehru Nagar, Belagavi, India)**

for its compliance with the
Declaration of Helsinki, International Conference on
Harmonization (ICH) Guidelines, Good Clinical Practice (GCP)
Standards, Council for International Organizations of Medical
Sciences (CIOMS) Guidelines, World Health Organization
(WHO) Standards and Operational Guidance for Ethics Review
of Health-Related Research and Surveying and Evaluating
Ethical Review Practices, EC/IRB Standard Operating
Procedures (SOPs), and Local Regulations and Standards in
Ethical Review

Awarded during the 17th FERCAP General Assembly
in New Delhi, India on November 22, 2017

JINTARA KARBWANG
SIDCER Coordinator

KENJI HIRAYAMA
FERCAP Chair

ATTESTED

Dr. V.A. Kothiwate
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALENCE STUDY

Registration No. ECR/211/Inst/KA/2013/RR-19

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee, KLE University, KLE University KLE Dr.PK Hospital and MRC Nehru Nagar Belagavi Belagavi Belagavi (Belgaum) Karnataka - 590010 Contact No.: 08312470400 Fax No.: 08312493099 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.


Place : New Delhi
Date : 16-SEP-2019

V G
SOMANI
Central Licencing Authority
Stamp

Digitally signed by V G SOMANI
DN: cn=V G SOMANI, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION,
2.5.4.20+11119906081941485096d4ce
4a9114a2222e4e48131124b8d1240f
E=v.g.somani@cdsc.gov.in, ou=V G
SOMANI
Date: 2019.09.16 17:13:53 +0530'



ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Submission#: 427654
IORG#: IORG0001102
Institution: KLE Academy of Higher Education and Research

OMB No. 0990-0279
Approved for use through February 28, 2022

**U.S. Department of Health and Human Services (HHS)
Registration of an Institutional Review Board (IRB)**

This form is used by institutions or organizations operating IRBs that review:

- a) **Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research; and/or**
- b) **Clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services**

This form is to be used for the following purposes:

- a. To register an IRB if your institution or organization has not previously registered an IRB
- b. To update or renew the registration of an IRB previously registered by your institution or organization
- c. To add another IRB to those previously registered by your institution or organization

Fields with an * are required for OHRP IRBs and FDA IRBs

Fields with an are required for OHRP IRBs but are optional for FDA IRBs

Fields with an ‡ are required for FDA IRBs but are optional for OHRP IRBs

Fields with no symbol are optional for both OHRP IRBs and FDA IRBs

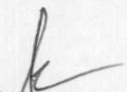
1. *Has your institution or organization previously registered an IRB with the Office for Human Research Protections (OHRP)?

Yes, proceed to section 2 No, proceed to section 3

2. *What is your institution or organization (IORG) number? IORG0001102

This number was provided by OHRP the first time your institution or organization registered an IRB. If you do not know your IORG number, search for your institution or organization on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daq-staff.html> or by telephone at 1-866-447-4777.

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(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka

3. Name of Institution or Organization Operating the IRB(s)

*Name of Institution or Organization: **KLE Academy of Higher Education and Research**

*Mailing Address: **Nehru Nagar
JNMC Campus, Nehru Nagar
Belagavi
590010**

*Street Address (if different from the Mailing Address above):

*City: **Belgaum**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

4. Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities Performed by the IRB(s)

*First Name: **Niranjana** Middle Initial: **S** *Last Name: **Mahantshetti**

Earned Degree(s): **MD** Title or Position: **Principal**

*Mailing Address (if different from the Mailing Address in section 3):

**KLES Dr Prabahakar Kore Hospital and MRC Site Management Office G02 Nehru
Nehru Nagar
590010
590010**

*City: **Belgaum**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

*Phone: **91 831 2471701** *FAX: **91 831 2470759** *E-Mail: **niranjanasn@yahoo.com**

5. Contact Person Providing this Registration Information

*First Name: **Madiwalayya** Middle Initial: **S** *Last Name: **Ganachari**

Earned Degree(s): **M.Pharm ,Ph. D.** Title or Position: **Deputy Registrar**

Name of Institution or Organization (if different from the Name in section 3):

KLE Academy of Higher Education and Research

*Mailing Address (if different from the Mailing Address in section 3):


**Nehru Nagar
Karnataka
590010
590010**

*City: **Belgaum**

*State/Province:

*Zip/Postal Code:

ATTESTED


Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

*Country (if outside the U.S.): **INDIA**

*Phone: **+91 9448634457** *FAX: **+91 831 249 3777** *E-Mail: **msganachari@gmail.com**

6. IRB Registration Information (to be completed separately for each IRB being renewed/updated or newly registered)

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Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

[X] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00001499**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

[] No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

JNMC - Inst Ethics Committee on Human Subjects Rsc IRB #1

C. Location of the IRB

*Mailing Address (if different from the Mailing Address in section 3):

**IEC of KLE Academy of Higher Education and Research
Nehru Nagar
Karnataka
590010**

*Street Address of the IRB (if different from the Mailing Address of the IRB):

*City: **Belgaum**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

*Phone: **+918312474200**

*FAX: **+91 831 247 2891**

*E-Mail: **kleclinicalresearch@gmail.com**

D. Approximate number of full time equivalent positions devoted to the IRB's administrative activities:

2


E. Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

25

F. Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review

4

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Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

procedure during the preceding 12 months):

- G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products:

5

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

<input checked="" type="checkbox"/>	human drugs	food additives
	medical devices	color additives
	biological	other
		Specify:

H. IRB Chairperson

*First Name: **Subarna** Middle Initial: *Last Name: **Roy**

Earned Degree(s): **M.Sc, Ph.D.** Title or Position: **Scientist 'F'**

Mailing Address (if different from the Mailing Address in section 3):

Nehru Nagar

Belagavi

590010

City: **Belgaum**


State/Province:

Zip/Postal Code:

Country (if outside the U.S.): **INDIA**

*Phone: **91 831 247 5478** FAX: **91 831 247 5479** *E-Mail: **drsubarnaroy@gmail.com**

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Belagavi-590 010, Karnataka

I. IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Roy, Subarna	M	Ph. D	S	Reproductive Biology	N	
Goudar, Shivaprasad	M	MD, MHPE	S	Physiology, Medical Education	Y	Basic Medical Scientist
Patil, Paragouda	M	MD	S	Pharmacology	N	Basic Medical Scientist
Hegde, Harsha	M	M.Sc,Ph.D	S	Scientific Member	N	Scientific Member
Hiremath, Praveen	M	LLB	N	Legal Expert	N	Legal Expert
Ganachari, M.S.	M	M.Pharm ,Ph. D	S	Pharmacist	Y	Member -Secretary
Bellad, Roopa	F	MD	S	Pediatrics	Y	Clinician
Hashilkar, Nayana	F	MD	S	Pharmacology	Y	Basic Medical Scientist
Salimath, Geetanjali	F	M Pharm	S	Scientific Member	Y	Scientific Member
Pujar, Yeshita	F	M.D.	S	Obstetrics and Gynecology	Y	Clinician
Kivadasannavar, Vaishnavi	F	MSW	N	Social Work	N	Social Worker
Kore, Tammanna	M	Primary Schooling	N	Community Social Work	N	Lay Person from the Community

Alternative Members

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.


Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

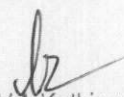
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When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.

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Public burden for this collection of information is estimated to average one hour for an initial IRB registration, and thirty minutes for updating or renewing the registration of a previously registered IRB. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503, 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*

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


KLE ACADEMY OF HIGHER EDUCATION & RESEARCH, BELAGAVI

CPCSEA for Research and Education purpose on small animals

Sl.No	Name of the Institute	Registration Number (Old)	Registration Number (Renewal)
1	Jawaharlal Nehru Medical College, Belagavi	627/02/a/CPCSEA	627/PO/Re/S/02/CPCSEA
2	K L E Shri B M Kankanwadi Ayurveda Mahavidyalaya, Belagavi	1017/c/06/CPCSEA	1017/PO/Re/S/06/CPCSEA
3	K L E College of Pharmacy, Belagavi	221/CPCSEA	221/PO/Re/S/2000/CPCSEA
4	K L E College of Pharmacy, Hubali	126/1999/CPCSEA	126/PO/ReBi/S/99/CPCSEA
5	K L E College of Pharmacy, Bangalore	626/02/a/CPCSEA	626/PO/Re/S/02/CPCSEA

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Dr. V. A. Kothiwate

Registrar

KLE Academy of Higher Education and Research
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Belagavi-590 010, Karnataka

Print

Noted
 23/1/18

F. No. 25/373/2010-AWD
 Government of India
 Ministry of Environment, Forest & Climate Change
 Animal Welfare Division
 O/o Committee for the Purpose of Control and Supervision of
 Experiments on Animals (CPCSEA)

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
 Jor Bagh Road, New Delhi - 110003

28/12/2017

To

Dr. Parwati Patil, Chairperson, IAEC
K.L.E.Society's Jawaharlal Nehru Medical College
Nehru Nagar, Belgaum - 590 010 KarnatakaTel:
0831-2471701/02
Email:docparwati@yhoo.co.in
Mobile:9449019436

Subject: Renewal of Registration and Reconstitution of
 Institutional Animals Ethics Committee (IAEC)-regarding
 Madam,

The registration of Animal House Facility of your
 establishment with CPCSEA has been renewed **for a period of
 five years from the date of issue of this letter.**

- The new registration number of Animal House Facility of your establishment is **627/PO/Re/S/02/CPCSEA for Research for Education Purpose on small animals.** Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr Parwati Patil	Biological Scientist, Chairperson
2	Dr Rekha M.R. Nayaka	Scientist from different discipline, Member Secretary
3	Dr. Sumati A Hogade	Scientist Incharge of Animal House Facility
4	Dr. Shilpa M. Bhimalli	Scientist from different discipline
5	Dr. Sudha Devareddy	Veterinarian

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Dr. V.A. Kothiwate
 Registrar

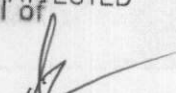
KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

- CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

S.No.	Name	Nominated as
1	Dr. P.A. Patil 'Vishilp' 23-A, II Main, II Cross, Bauxite Road, Belagavi - 590010, Karnataka Contact No :9448989519 Email :drpapatil@yahoo.co.in	Main Nominee
2	Dr. Viswanatha Swamy A.H.M. Associate Professor, Deptt. Of Pharmacology & Toxicology, Karnataka Lingayat Education Society's College of Pharmacy, Vidyanagar, Hubli - 580 031, Karnataka Contact No :9448667355 Email :Vmhiremath2004@yahoo.com	Link Nominee
3	Dr. Banappa S Unger Scientist -D (Pharmacology), Regional Medical Research Centre, Indian Council of Medical Research, Nehru Nagar, Belgaum-590010, Karnataka Contact No :9916379018 Email :banappas@gmail.com	Scientist from outside the Institute
4	Shri. Sunil R Patil. At/po: Nidasoshi, Tq: Hukkeri, Dist: Belgaum, Karnataka - 591236 Contact No :9901243037 Email :goshale@rediffmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.

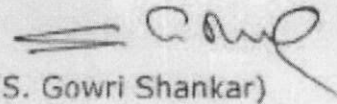
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3
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

same on the website of the CPCSEA.

- **It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings .Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.**
- It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours faithfully,



(S. Gowri Shankar)

Deputy Secretary (AW) & Member Secretary (CPCSEA)
Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

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Dr. V.A. Kothiwate 4
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

No.25/1/99 – AWD (Pt.)
Government of India

Ministry of Statistics & Programme Implementation
(Committee for the Purpose of Control and Supervision of Experiments on
Animals)

Shastri Bhavan, New Delhi-110001.
Dated the 19th June 2002.

2: JUN 2002

To

The Principal/Director/Dean
K.L.E. Society's Jawaharlal Nehru Medical College
Nehru Nagar
Belgaum - 590 010
Karnataka

Subject: Registration of Establishments/ Breeders under Rule 5(a) of
the "Breeding of and Experiments on Animals (Control and
Supervision) Rules 1998".

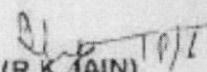
Sir/Madam,

With reference to your application on the above-mentioned subject, this is
to inform that your Establishment is hereby registered for "Research". Your
Registration Number is **627/02/a/CPCSEA**. The nominee of CPCSEA on the
Institutional Animal Ethics Committee (IAEC) of your Establishment will be
intimated in due course.

1. You are requested to quote the above Registration Number in all your
future correspondence with the Committee.
2. You are also requested to convene IAEC meeting at the earliest.
3. For further correspondence you are requested to contact Office of
CPCSEA at Chennai, at the address given below:

Office of the CPCSEA,
Ministry of Statistics & Programme Implementation
3rd Seaward Road, Valmiki Nagar,
Thiruvanmiyur, Chennai-600 041 (Tamil Nadu)

Yours faithfully,


(R.K. JAIN)

MEMBER SECRETARY (CPCSEA) / DIRECTOR (AW)
Tel. No.3381498

Copy to: - Ms. Prema Veeraraghavan, Expert Consultant (CPCSEA), 3rd
Seaward Road, Valmiki Nagar, Thiruvanmiyur, Chennai

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Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka

Print

F. No. 25/369/2010-AWD
 Government of India
 Ministry of Environment, Forests & Climate Change
 Animal Welfare Division
 O/o Committee for the Purpose of Control and Supervision of
 Experiments on Animals (CPCSEA)

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
 Jor Bagh Road, New Delhi - 110003
 24/11/2016

To

Dr. B. S. Prasad
 Chairperson IAEC
 K.L.E. Society's Shri. B.M. Kankanawadi Ayurved
 Mahavidyalaya, Shahapur, Belgaum-590
 003Karnataka
 E-mail: dr_bsprasad@rediffmail.com
 Mobile: 9448569289

Subject: Renewal of Registration and Reconstitution of
 Institutional Animals Ethics Committee (IAEC)-regarding
 Sir,

The registration of your establishment with CPCSEA has
 been renewed **for a period of five years from the date of
 issue of this letter**

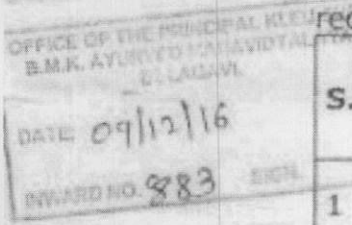
- The new registration number of your establishment is:
**1017/PO/Re/S/06/CPCSEA for Research for
 Education purpose, on small animals**. Henceforth,
 the new registration number may kindly be quoted in all
 your future correspondence with this office.
- The CPCSEA has accepted the following members
 recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr Giridhar Vedantam	Scientist from different discipline
2	Dr Santosh F Patil	Scientist from different discipline
3	Dr.B.S. Prasad	Biological Scientist, Chairperson
4	Dr Rudramma R Hiremath	Scientist Incharge of Animal House Facility, Member Secretary
5	Dr VinayKumar Sangrole	Veterinarian

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Dr. V.A.Kothiwate
 Registrar

6



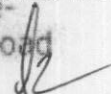
- CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

S.No.	Name	Nominated as
1	Mr. Mallikarjun S. Kolhar, Lecturer, H.S.K.College of Pharmacy, Bagalkot-587101, Karnataka Contact No :9964608890 Email :m.kolharpharma@gmail.com	Main Nominee
2	Dr. H.S. Somashekar, Professor and HOD, HOD of Pharmacology, S.S. Institute of Medical Sciences & Research Centre, "Jnanashankara", N.H.-4, Bypass Road, P.B.No.1, Davangere-577 005 Karnataka Contact No :09343863263 Email :info@ssimsrc.com	Link Nominee
3	Mr. Praksh Geriyol , Senior Research Scientist, S/ O Gopalappa G., Srigokula, # 320, K.E.B. First Cross, High School Extension, Honnali, Davavngere- 577217, Karnataka Contact No :9594972066 Email :prakash_zoology@rediffmail.com	Scientist from outside the Institute
4	Shri. Sunil R Patil, Goshala Secretary, At/po: Nidasoshi, Tq: Hukkeri, Dist: Belgaum, Karnataka - 591236 Contact No :9901243037 Email :goshale@rediffmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.
- You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload

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Belagavi-590 010, Karnataka

the same on the website of the CPCSEA.

- It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

Yours faithfully,


(S. Gowri Shankar)


Deputy Secretary (AW) & Member Secretary (CPCSEA)
Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

By RRH
Ch
7/12/14

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8


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

No.25/10/2003 - AWD

Government of India

Ministry of Environment & Forests

(Committee for the Purpose of Control and Supervision of Experiments on Animals)

8th Floor, Jeevan Prakash Building,

25, Kasturba Gandhi Marg, New Delhi - 110 001

Dated the 19th December, 2006

To

The Principal/Director/Dean

K.L.E. Society's

Shri B.M. Kankannawadi Ayurved

Mahavidyalaya, Shahapur

Bdgaum-590 003, Karnataka

Subject:

Registration of Establishments/ Breeders under Rule 5(a) of the
"Breeding of and Experiments on Animals (Control and Supervision)
Rules 1998".

Sr/Madam,

With reference to your application on the above-mentioned subject, this is to inform
that your Establishment has been registered for "Experiment". Your Registration Number is
1017/e/06/CPCSEA. The above Registration Number may be quoted in all your future
correspondence with the Committee.

2. Dr S.J. Nagajothimath, 25, Shanta, Bauxite Road, Nehru Nagar, Balgaum - 590 010,
Karnataka will be IAFEC nominees of CPCSEA for your Institute. IAFEC meetings may be
convened at the earliest.

3. For further correspondence you are requested to contact Office of CPCSEA at
Chennai, at the address given below:

Office of the CPCSEA,
Ministry of Environment & Forests
13/1, 3rd Seaward Road, Valmiki Nagar,
Thiruvanniyur, Chennai-600 041 (Tamil Nadu)

Yours faithfully,

(Sanyal, Dave)

Director (AW) & Member-Secretary, CPCSEA

Tel/Fax 23318553

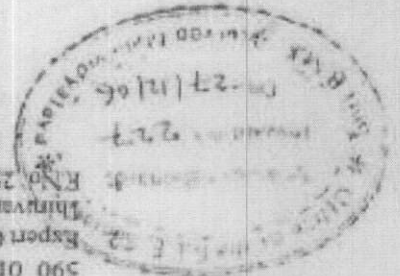
Copy to: - 1. Dr. S.J. Nagajothimath, 25, Shanta, Bauxite Road, Nehru Nagar, Balgaum -

590 010, Karnataka.

Expert Consultant (CPCSEA), 13/1, 3rd Seaward Road, Valmiki Nagar,

Thiruvanniyur, Chennai - 600 041

R.No. 25/39/2004-AWD



ATTESTED

Dr. V.A. Kothiwale

Registrar

9

KLE Academy of Higher Education and Research,
(Deemed-to-be-University w/s 3 of the UGC Act, 1956)
Belgaum-590 010, Karnataka

No. 25/447/2009-AWD

Government of India
Ministry of Environment, Forests & Climate Change
Animal Welfare Division
O/o Committee for the Purpose of Control and Supervision of Experiments on
Animals (CPCSEA)

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
Jor Bagh Road, New Delhi - 110003
23/01/2017

To

Dr. B.M.Patil ,
Chairman IAEC,
K.L.E.Society's College of Pharmacy
KLE University, JNMC Campus, Nehru Nagar, Belgaum - 590 010, Karnataka
Email: bmpatil59@hotmail.com
Mobile: 09448634245

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics
Committee (IAEC)-regarding

Sir,

The registration of your establishment with CPCSEA has been renewed for a
period of five years from the date of issue of this letter.

- The new registration number of your establishment is 221/PO/Re/S/2000/CPCSEA for Research for Education purpose, on small animals. Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr. B.M. Patil	Biological Scientist, Chairperson
2	Dr. P.A.Patil	Scientist from different discipline
3	Dr. N.A.Khatib	Scientist Incharge of Animal House Facility, Member Secretary
4	Dr. Sudha Devareddy	Veterinarian
5	Dr. V.P. Rasal	Scientist from different discipline

ATTESTED

Dr. V.A.Kothiwate
Registrar 10

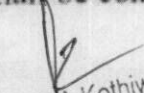
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

S.No.	Name	Nominated as
1	Dr. Vinod Kumar C.S. Professor, Dept. Of Microbiology, S.S. Institute of medical Sciences And Research Centre, Davangere – 577 005, Karnataka Contact No :9964402525 Email :vinodmicro@yahoo.com	Main Nominee
2	Dr. Prakash V. Diwan, Research Director, Flat No.703, Zenith, Lotus county, Mandoli Road, Tilakawadi, Belgaum-590 006 Karnataka Contact No :9880034503 Email :diwanpv@gmail.com	Link Nominee
3	Dr. Banappa S Unger Scientist –D (Pharmacology), Regional Medical Research Centre, Indian Council of Medical Research, Nehru Nagar, Belgaum-590010, Karnataka Contact No :9916379018 Email :banappas@gmail.com	Scientist from outside the Institute
4	Shri. Sunil R Patil., Goshala Secretary At/po: Nidasoshi, Tq: Hukkeri, Dist: Belgaum, Karnataka - 591236 Contact No :9901243037 Email :goshale@rediffmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.
- You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.
- It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings .Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC.Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year.Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

ATTESTED

 Dr. V.A. Kothiwale
 Registrar
 KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

Yours faithfully,

(S. Gowri Shankar)

Deputy Secretary (AW) & Member Secretary (CPCSEA) Copy for necessary action to:
Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA.

ATTESTED


Dr. V.A. Kothiwate
Registrar

12

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Kamataka

Inward No. 200

No. 25/1/99-AWD
Government of India
Ministry of Social Justice and Empowerment
(Committee for the Purpose of Control and Supervision of Experiments on Animals)

Shastri Bhavan, New Delhi-110001.
Dated the 16th June, 2000

To

Dr. F.V. Manvi,
KLE Society's College of Pharmacy,
J.N.M.C. Campus, Nehru Nagar,
Belgaum-590010(Karnataka).

Subject: Registration of Establishments/ Breeders under Rule 5(a) of the "Breeding of and Experiments on Animals (Control and Supervision) Rules 1998".

Sir,

With reference to your application on the above-mentioned subject, this is to inform that your Establishment is hereby registered for "Teaching and Research on Animals". Your Registration Number is 221/CPCSEA. Dr. Kusuma Neelakantan will be the nominee of the Institutional Animal Ethics Committee of the Establishment.

2. You are requested to quote the above Registration Number in all your future correspondence with the Committee.
3. For further correspondence you are requested to contact Office of CPCSEA at Chennai, at the address given below:

Office of the CPCSEA,
Ministry of Social Justice and Empowerment,
C/o Secretary, Animal Welfare Board of India,
No.11, Venkataraman Street, Srinivasa Avenue,
R.A Puram, Chennai-600028.

Yours faithfully,



(DILIP SINGH)

MEMBER SECRETARY(CPCSEA)

Tel. No.338759

Fax No.3384918

- Copy to:-1. Dr. Kusuma Neelakantan, Chairman, Centre for Advanced Studies in Marine Biology, Kodibagh Karwar (Kar). Kindly acknowledge the receipt of the letter at the Chennai address given above.
2. Ms. Prema Veeraraghavan, Expert Consultant(CPCSEA), No.11, Venkataraman Street, Srinivasa Avenue, R.A. Puram, Chennai-600028.

ATTESTED


Dr. V.A. Kothiwate
Registrar

13

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Telegrams : "WELFARE"
Fax : 3384918



P.G.

"वसुधैव कुटुम्बकम्"

OFFICE OF THE PRINCIPAL
K.L.E.S. COLLEGE OF PHARMACY
VI ... HUBLI - 31
Date: 2-7-99
Inward No. 211

भारत सरकार
सामाजिक न्याय और
अधिकारिता मंत्रालय
GOVERNMENT OF INDIA
MINISTRY OF SOCIAL
JUSTICE AND EMPOWERMENT

Regd. Post

श्री श्री भवन/Shastri Bhawan,
नई दिल्ली-New Delhi-110001

Committee for the Purpose of Control and Supervision of Experiments on Animals

Date: 29/6/99

संख्या/No. 126/1999/CPCSEA

To

The Principal,
K.L.E. Society's College of Pharmacy,
Vidya Nagar,
HUBLI - 580 031

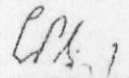
Subject: Registration of Establishments/ Breeders under Rule 5(a) of the "Breeding of and Experiments on Animals (Control and Supervision) Rules 1998"

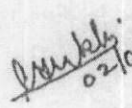
Sir,

With reference to your application for registration on the above mentioned subject, you are hereby registered for breeding of and experiments on animals. Your registration No is 126/1999/CPCSEA.

You are requested to quote the above registration no. in all your future correspondence with CPCSEA.

Yours faithfully,


(A.P. Singh)
Member-Secretary (CPCSEA)
29/6/99


02/07/1999
Adv SMA/ACC/ISK.

ATTESTED


Dr. V.A. Kothiwate
Registrar

14

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Kamataka

F. No. 25/365/2009-AWD

Government of India
Ministry of Environment, Forests & Climate Change
Animal Welfare Division
O/o Committee for the Purpose of Control and Supervision of Experiments
on Animals (CPCSEA)

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
Jor Bagh Road, New Delhi - 110003

14/02/2017

To

Dr. V.G. Jamakandi ,
Chairman IAEC,
K.L.E. Society's College of Pharmacy,
Vidyanagar, Hubli - 580 031 Karnataka.
Email: vilasj@rediffmail.com
Mobile: 9448337221

Subject: Renewal of Registration and Reconstitution of Institutional Animals
Ethics Committee (IAEC)-regarding

Sir,

The registration of your establishment with CPCSEA has been
renewed **for a period of five years from the date of issue of this letter.**

- The new registration number of your establishment is 126/PO/ReBi/S/99/CPCSEA for Research for Education purpose and Breeding for in-house use, on small animals. Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr B C Koti	Scientist from different discipline
2	Dr V G Jamakandi	Scientist from different discipline, Chairperson
3	Dr P C Gadad	Scientist Incharge of Animal House Facility, Member Secretary
4	DR M M Nadaf	Veterinarian
5	Dr AHM Viswanatha Swamy	Biological Scientist

- CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

ATTESTED


Dr. V.A. Kothiwate
Registrar

15

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

S.No.	Name	Nominated as
1	Dr. Vinod Kumar C.S. Professor, Dept. Of Microbiology, S.S. Institute of medical Sciences And Research Centre, Davangere – 577 005, Karnataka Contact No :9964402525 Email :vinodmicro@yahoo.com	Main Nominee
2	Dr. Lakshmishree KT Dept of Anatomy, Veterinary College, Karnataka Veterinary, Animal and Fisheries Sciences University (KVAFSU), Shivamogga-577 204 Contact No :09480580972 Email :drlshree@gmail.com	Link Nominee
3	Dr. Banappa S Unger Scientist –D (Pharmacology), Regional Medical Research Centre, Indian Council of Medical Research, Nehru Nagar, Belgaum-590010, Karnataka Contact No :9916379018 Email :banappas@gmail.com	Scientist from outside the Institute
4	Mr. Mallikarjun S. Kolhar H.S.K.College of Pharmacy, Bagalkot-587101, Karnataka Contact No :9964608890 Email :m.kolharpharma@gmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.
- You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.
- It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.
- It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

ATTESTED

Yours faithfully,


Dr. V.A. Kothiwate
Registrar

16
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

(S. Gowri Shankar)


Deputy Secretary (AW) & Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA.

ATTESTED


Dr. V.A. Kothiwate
Registrar

17

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Print

F. No. 25/453/2009-AWD

Government of India
 Ministry of Environment, Forest & Climate Change
 Animal Welfare Division
 O/o Committee for the Purpose of Control and Supervision of Experiments on Animals
 (CPCSEA)

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
 Jor Bagh Road, New Delhi - 110003
 03/11/2017

To

Prof. Purnima Ashok, Chairperson, IAEC
 K.L.E.Society's College of Pharmacy
 P.B.No.1062, II Block, RajajinagarBangalore - 560 010, Karnataka
 Email:purnimaa1@yahoo.com
 Mobile:9341920793

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics
 Committee (IAEC)-regarding

Madam,

The registration of Animal House Facility of your establishment with CPCSEA
 has been renewed **for a period of five years from the date of issue of this
 letter.**

- The new registration number of Animal House Facility of your establishment is **626/PO/Re/S/02/CPCSEA for Research for Education purpose on small animals**. Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr. UmaShankar BC	Veterinarian
2	Prof Purnima Ashok	Biological Scientist, Chairperson
3	Prof. ShivaKumar HN	Scientist from different discipline
4	Prof Karki SS	Scientist from different discipline
5	Prasanna GS	Scientist Incharge of Animal House Facility, Member Secretary

ATTESTED
 Dr. V.A.Kothiwate
 Registrar

18

- CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

S.No.	Name	Nominated as
1	Dr. Girdhar P. Joint Director (R & D), IAH & VB, Hebbal, Bangalore - 24, Karnataka Contact No :9448186432 Email :girdhara_p@yahoo.com	Main Nominee
2	Dr. Krushnarvind Babalbhal Patel 542, Perody Nest, 5th Main, Vijaya Bank Layout, Bangalore-560076, Karnataka Contact No :9663310372 Email :patelkb_2000@yahoo.com	Link Nominee
3	Dr. Shiva Kumar Head Technical & Labs Provimi Animal Nutrition India Pvt Ltd.(formerly known as Vetcare group of companies or Tetragon Chemie Pvt Ltd), IS-40, KHB Industrial Area Yelahanka New Town, Bangalore - 560064, Karnataka Contact No :099 0019 7269 Email :shivakumar@provimi.in	Scientist from outside the Institute
4	Ms. Rosa J. Samuel Central Animal Facility, Indian Institute of Science, Bangalore 560 012, Karnataka Contact No :9980190810 Email :rosaj66@hotmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)


- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.
- You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.
- It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman.

Dr. V.A. Kothiwale
Registrar

IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

- It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours faithfully,


(S. Gowri Shankar)

Deputy Secretary (AW) & Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA.

ATTESTED


Dr. V.A. Kothiwale
Registrar

No. 25/1/99 - AWD (P)

Government of India

Ministry of Statistics & Programme Implementation

(Committee for the Purpose of Control and Supervision of Experiments on

Animals)

Shakti Bhawan, New Delhi-110001

Dated the 19th June 2002

To

The Principal/Director/Dean

K.L.E. Society's College of Pharmacy

P.B. No. 1062, B Block

Rajajinagar

Bangalore - 560 010

Subject: Registration of Establishments/ Breeders under Rule 5(a) of

the "Breeding of and Experiments on Animals (Control and

Supervision) Rules 1988".

Sir/Madam

With reference to your application on the above-mentioned subject, the

to inform that your Establishment is hereby registered for "Research" Your

Registration Number is 628/02/CPCEA. The names of CPCEA on the

Institutional Animal Ethics Committee (IAEC) of your Establishment will be

intimated in due course

1. You are requested to quote the above Registration Number in all your

future correspondence with the Committee

2. You are also requested to convene IAEC meeting at the earliest

3. For further correspondence you are requested to contact Office of

CPCEA at Chennai, at the address given below

Office of the CPCEA

Ministry of Statistics & Programme Implementation

3rd Seaward Road, Valmiki Nagar

Thiruvananthapuram, Chennai-600 041 (Tamil Nadu)

Yours faithfully,

(R.K. JAIN)

MEMBER SECRETARY (CPCEA) / DIRECTOR (AW)

Tel. No. 2381458

ATTESTED

Dr. V.A. Kothiwala

Registrar

Scanned by CamScanner
KLE Academy of Higher Education and Research,
(Deemed-to-be-University) us 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

F. No. 25/453/2009-AWD

Government of India

Ministry of Environment, Forest & Climate Change

Animal Welfare Division

D/o Committee for the Purpose of Control and Supervision of Experiments on Animals
(CPCSEA)

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
Jor Bagh Road, New Delhi - 110003

03/11/2017

To

Prof. Purnima Ashok, Chairperson, IAEC
K.L.E.Society's College of Pharmacy
P.B.No.1062, II Block, Rajajinagar Bangalore - 560 010, Karnataka
Email:purnimaa1@yahoo.com
Mobile:9341920793

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics
Committee (IAEC)-regarding

Madam,

The registration of Animal House Facility of your establishment with CPCSEA
has been renewed for a period of five years from the date of issue of this
letter.

- The new registration number of Animal House Facility of your establishment is **626/PO/Re/S/02/CPCSEA for Research for Education purpose on small animals**. Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr. UmaShankar BC	Veterinarian
2	Prof Purnima Ashok	Biological Scientist, Chairperson
3	Prof. ShivaKumar HN	Scientist from different discipline
4	Prof Karki SS	Scientist from different discipline
5	Prasanna GS	Scientist Incharge of Animal House Member Secretary

ATTESTED

Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

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KLE College of Pharmacy
A Constituent Unit of
KLE Academy of Higher Education and Research
(Deemed to be University)

JNMC Campus, Nehru Nagar, Belagavi - 590 010, Karnataka, India



Phone: 0831-2471399

Fax: 0831-2472387

Web: <http://www.klepharm.edu>

E-mail: principal@klepharm.edu

KLE College of Pharmacy, Belagavi

INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]

Registered NO: 221/Re/S/CPCSEA/2000

GUIDLINES FOR IAEC

AS PER

COMPODIUM OF CPCSEA

2018

ATTESTED

A handwritten signature in black ink, appearing to be 'V.A. Kothiwale'.

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research

Belagavi-590 010, Karnataka

Standard Operating Procedures (SOP) for IAEC

1. Objective:

The motto of Prevention of Cruelty to Animals (PCA) Act 1960 as amended in 1982, is to prevent infliction of unnecessary pain or suffering on animals. The Central Government as enumerated under PCA Act 1960 has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them. For this purpose, the Government has made "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998" as amended during 2001 and 2006, to regulate the experimentation on animals.

The objective of this SOP is to contribute to the effective functioning of the Institutional Animals Ethics Committee (IAEC) so that a quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding of and Experimentation (Control and Supervision) Rules 1998, as amended in 2001 and 2006.

2. IAEC has been designed to secure the following objectives:

- (a) Every experiment shall be performed by or under the supervision of a person duly qualified in that behalf, that is, Degree holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;
- (b) That experiments are performed with due care and humanity and as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals from feeling pain;
- (c) That animals who, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily medically allowed to death while still under influence of anaesthetic;
- (d) That experiments on animals are avoided wherever it is possible to do so.
- (e) That experiments on larger animals are avoided when it is possible to achieve the same results by experiments on small laboratory animals like guinea-pigs, rabbits, mice, rats etc;
- (f) That, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
- (g) That animals intended for the performance of experiments are properly looked after before, during and after experiments;
- (h) That suitable records are maintained with respect to experiments performed on animals

ATTESTED


Dr. V.A. Kothiwate

Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka

3. Functions of IAEC

As defined in "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998"

"Institutional Animals Ethics Committee (IAEC)" means a body comprising of a group of persons recognized and registered by the Committee for the purpose of control and supervision of experiments on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee;

The primary duty of IAEC is to work for achievement of the objectives as mentioned above. IAEC should focus mainly on ensuring ethical and methodical handling of animals during and after experiments, so that they have less suffering.

IAEC will review and approve all types of protocols for research involving small animal experimentation before the start of the study. For approval of experimentation on large animals, the case is required to be forwarded to CPCSEA in prescribed manner with recommendation of IAEC.

IAEC is required to monitor the research throughout the study and after completion of study, IAEC shall obtain the periodic reports on research development and shall ensure visit to animal house facility and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

4. Composition of IAEC

Institutional Animals Ethics committee shall include eight members as follows:

A. IAEC members from the establishment (05 members):

- i. One biological scientist
- ii. Two scientists from different biological disciplines
- iii. One veterinarian involved in the care of animal
- iv. One scientist in charge of animal facility of the establishment concerned


The Chairperson of the Committee and Member Secretary would be nominated by the establishment from amongst the above five members. However, if the establishment wants to propose its administrative head, who is from non-scientific background, as Chairperson, then six members of IAEC may be proposed.

Having a Veterinarian in IAEC is mandatory for judging level of care and handling of Laboratory animals in a given protocol.

B. Nominees from the CPCSEA:

- i. Main Nominee (01)
- ii. Link Nominee *
- iii. Scientist from outside the Institute (01)
- iv. Socially Aware Nominee (01)

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****Link Nominee shall substitute the main nominee in case main nominee conveys his unavailability in writing to the chairperson of the IAEC in advance as per described procedure.***

The CPCSEA shall endeavour that nominees appointed by CPCSEA in any private establishment should not be from the establishments which is having the same objectives as to the establishment where the nominees are being nominated, so as to avoid the conflict of interest between the establishments.

In addition to the above IAEC members, a specialist may be co-opted of the relevant field while reviewing special project using hazardous agents such as radio- active substance and deadly microorganisms.

5. The minimum qualification for the IAEC Members is as below:

- a. B.V.Sc. or
- b. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- c. M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research. or
- d. M. Pharm. with experience in animal handling and animal research, or
- e. MD/ MS with research experience in laboratory animal handling.

6. The qualification for Nominee(s) of CPCSEA is as under:

I. The minimum qualification for Nominee should be:

- i. B.V.Sc. or
- ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii. M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research. or
- iv. M. Pharm. with experience in animal handling and animal research, or
- v. MD/ MS with research experience in laboratory animal handling.

II. The minimum qualification for Socially Aware nominee should be at least Graduate from any subject. Preference will be given to those with a background in Biological Sciences.

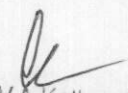
7. Upper age limit for the Nominees of CPCSEA:

The upper age limit for the Nominees of CPCSEA is 65 years. However, the nominees who are already working in the IAECs and are above 65 years of age will be allowed to be continued till the end of their tenure in the present IAECs.

****Link Nominee shall substitute the main nominee in case main nominee conveys his unavailability in writing to the chairperson of the IAEC in advance as per described procedure.***

The CPCSEA shall endeavour that nominees appointed by CPCSEA in any private establishment

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should not be from the establishments which is having the same objectives as to the establishment where the nominees are being nominated, so as to avoid the conflict of interest between the establishments.

In addition to the above IAEC members, a specialist may be co-opted of the relevant field while reviewing special project using hazardous agents such as radio- active substance and deadly microorganisms.

8. The minimum qualification for the IAEC Members is as below:

- i. B.V.Sc. or
- ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii. M.Sc. (Life Sciences/Biological Sciences/ Biochemistry/ Biotechnology) with experience in animal handling and animal research or
- iv. M. Pharm. with experience in animal handling and animal research or
- v. M.D. (Microbiology and Pharmacology) with experience in animal handling and animal research.

9. The qualification for Nominee(s) of CPCSEA is as under:

I. The minimum qualification for Nominee should be:

- i) B.V.Sc. or
- ii) M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii) M.Sc. (Life Sciences Biological Sciences/ Biochemistry/ Biotechnology) with experience in animal handling and animal research. or
- iv) M. Pharm. with experience in animal handling and animal research or
- v) M.D. (Microbiology and Pharmacology) with experience in animal handling and animal research.

II. The minimum qualification for Socially Aware nominee should be at least Graduate from any subject. Preference will be given to those with a background in Biological Sciences.

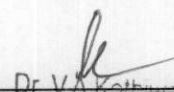
10. Upper age limit for the Nominees of CPCSEA:

The upper age limit for the Nominees of CPCSEA is 65 years. However, the nominees who are already working in the IAECs and are above 65 years of age will be allowed to be continued till the end of their tenure in the present IAECs.

11. Authority under which IAEC is constituted and duration:

The IAEC of an establishment is constituted by CPCSEA at the time of registration for a period of 5 years. During these 5 years, revision in IAECs may be made in deserving cases with the approval of CPCSEA. The IAEC would be reconstituted at the time of renewal, duly approved by CPCSEA,

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for another 5 years. The establishments are required to send names of 5 members at the time of constitution and at every reconstitution. It is mandatory that at least half of the members of IAEC are new at the time of reconstitution.

12. IAEC requirements:

- a. The duration of appointment is for a period of 5 years (coterminous with registration).
- b. The committee is required to be reconstituted at the time of renewal of registration, and at least half of the internal IAEC members is required be replaced at the time of renewal.
- c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- f. Conflict of interest should be declared by members of the IAEC.
- g. IAEC is required to formulate a SOP for its working requirements and follow it in all the meetings.
- h. Foreign Nationals shall not be allowed as member of the IAECs of any establishments.


13. Quorum requirements:

The minimum of six members shall be required to form quorum of the IAEC meetings. All decisions shall be required to be undertaken in the meetings of IAEC and not by the method of circulation of project proposals. Presence of main nominee of CPCSEA nominee is a must. It shall be a must for the establishment to invite all nominees of IAEC for attending the meeting and the meeting notice shall invariably be issued by Registered Post at least 15 days before the date of the meeting. Link nominee can attend in case main nominee conveys his unavailability in writing to the Chairperson of IAEC. Socially aware member's presence is *compulsory* in all cases referred to CPCSEA and their presence is mandatory at least in one meeting of IAEC of the establishment in a calendar year. It shall be the duty of establishment to inform to CPCSEA about the continuous absence of nominees of CPCSEA in a calendar year.

14. Conduct of business:

The Chairperson of the IAEC shall be responsible for conducting at least two meeting of IAEC in a calendar year with the help of the Member Secretary of IAEC. If for reasons beyond control, the Chairperson is not available, or has conflict of interest an *ad-hoc* Chairperson will be elected from amongst the present members, who will conduct the business of the meeting. The Member Secretary of IAEC is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairperson after NOC from all members before communicating to the researchers with the approval of the appropriate authority. A copy of minutes is required to be sent to Member Secretary CPCSEA within 15 days of the meeting, otherwise, the meeting will not be considered valid.

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15. Participation by Investigators / experts in IAEC.

IAEC may call upon subject experts who may provide special inputs of selected research protocols, if need be. They are required to give their specialized views but not to take part in the decisions making process which will be made by the members of the IAEC only. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.

16. Application Procedures:

- a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation.
- b. All relevant documents as per checklist should be enclosed with application form
- c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be submitted to IAEC.

17. Review procedures:

- a. The meeting of the IAEC should be held on scheduled intervals as prescribed in the concerned SOP of the IAEC and additional meetings may be held if there are reasons to do so.
- b. The proposals will be sent to members at least 15 days in advance.
- c. Decisions will be taken by consensus after discussions. Negative view points should be recorded in the minutes. CPCSEA shall consider only those decisions which are arrived with consensus. In case consensus is not arrived and the case merits special attention of CPCSEA, such cases may be forwarded to CPCSEA with approval of the chairman of the IAEC of the establishment along with the detailed reason for forwarding the matter to CPCSEA and points of consideration for CPCSEA.
- d. Researchers will be invited to offer clarifications, if needed.
- e. Independent consultants/Experts will be invited to offer their opinion on specific Research proposals, if needed.
- f. The decisions of the IAEC will be minute and Chairperson's approval shall be taken in writing with signature of all the IAEC members present.

18. Decision-making of IAEC of the Establishment:

- a. Members will discuss all the related issues concerning the welfare of animals before arriving at a consensus decision.
- b. A member should withdraw from the meeting during the decision procedure concerning an application where a *conflict of interest arises* and this should be informed to the chairperson prior to the review of the application and the same should be recorded in the minutes.
- c. Decisions of IAEC shall be valid where the quorum of IAEC is complete.
- d. Only members of IAEC can vote for the decision. The experts / investigators / invitees may only offer their opinions.

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- e. In case of research protocols on small animals, the IAEC of the establishment shall be empowered to grant approval for experiment on animals considering the welfare of the animals. For carrying out the experiment on **large animals**, approval of CPCSEA is a must and IAEC may only recommend the research protocol for consideration of CPCSEA. Specific suggestions for modifications in the research protocol and reasons for rejection should be clearly indicated.
- f. In cases of conditional decisions on research protocol, suggestions for subsequent review and the procedure for having the application reviewed may be specified clearly.
- g. Modified proposals may be reviewed by an expedited review through identified members.
- h. Procedures for appeal by the researchers should be clearly defined by the respective IAEC.

19. Communicating the decision

- a. Decisions of the IAEC will be communicated by the Member Secretary in writing to CPCSEA within 15 days of conduct of the meeting.
- b. Suggestions for modifications in research protocols, if any, should be dealt by IAEC but minuted and sent to CPCSEA.
- c. Reasons of rejection of the research protocol should be informed to the researchers in writing.
- d. The schedule / plan of ongoing review by the IAEC should be communicated to the PI.

20. Follow up procedures

- a. Reports of Research Protocols/ Project completion report should be submitted for consideration of IAEC of the establishment at prescribed intervals for review and it should not exceed the timeline of the research as mentioned in the Form B.
- b. Final report should be submitted to the IAEC of the establishment at the end of study.
- c. All Serious Adverse Events (SAE's) and the interventions undertaken should be intimated to IAEC.
- d. Protocol deviation, if any, should be informed with adequate justifications to IAEC and in case of large animals, it should be intimated to CPCSEA immediately for consideration of CPCSEA. The procedural deviations in research protocol shall be treated as a fresh research protocol by CPCSEA.
- e. Any new information related to the study should be communicated to IAEC immediately.
- f. Premature termination of study should be notified to the IAEC with reasons along with summary of the data obtained so far.
- g. Change of investigators / sites should be informed and approval of IAEC should be undertaken first.

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a Record keeping and Archiving:

- b. IAEC shall maintain the Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics attended.
- c. Copy of all study protocols with enclosed documents, progress reports shall be maintained by IAEC.
- d. Minutes of all meetings duly signed by the Chairperson and the members shall be maintained by IAEC.
- e. Copy of all existing relevant national and international guidelines on animal ethics and laws along with amendments shall be maintained by IAEC.
- f. Copy of all correspondence with members, researchers and other regulatory bodies shall be maintained by IAEC.
- g. Project completion report of the approved projects shall be maintained by IAEC.
- h. Record of Breeding of animals, supply etc, if breeding of animals is undertaken shall be maintained by IAEC.
- i. Record of import of animals with species, source, quantity, usage etc shall be maintained by IAEC.
- j. Record of all Contract research, if conducted at the institute shall be maintained by IAEC.
- k. Record of rehabilitation of large animals, if done, shall be maintained by IAEC.
- l. All documents should be archived for period as prescribed in the SOP formulated by the IAEC of concerned establishment.

21. Updating IAEC members:

- a. All relevant new guidelines and amendments to the Rules and Act pertaining to CPCSEA should be brought to the attention of the members.
- b. Members should be encouraged to attend national and international training programs / workshops / conferences in research ethics for maintaining quality in ethical review and be aware of the latest developments in the area.

22. Reporting to CPCSEA:

- a. IAEC is required to send a copy of minutes of IAEC meeting to CPCSEA within 15 days.
- b. Inspection report of animal house with photographs by IAEC members is required to be sent once in a calendar year. If action is required, the facility must provide ATR within 30 days.

23. Reimbursement to CPCSEA representative

CPCSEA representative(s) on the IAEC or authorized person(s) sent for inspection of the establishment(s) or otherwise by CPCSEA for any other purpose are required to be paid Rs. 2000/- each as sitting fees/visiting fee per day (or as revised from time to time) along with the reimbursement of actual expenditure incurred in this regard (if not provided by the establishments

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/ organizations).

24. Payable to CPCSEA:

S.No.	Purpose	Code	Fee to be charged	
			Small	Large
1	Registration for the purpose of <i>Research for education</i>	Re	Rs. 10,000.00	Rs. 10,000.00
2	Registration for the purpose of <i>Research for commercial</i>	Rc	Rs. 10,000.00	Rs. 10,000.00
3	Registration for the purpose of <i>Research</i>	R	Rs. 10,000.00	Rs. 10,000.00
4	Registration for the purpose of <i>Non-Research Commercial</i> (i.e. Production of Hyperimmune Plasma and Serum)	NRc	-	Rs. 10,000.00
5	Registration for <i>Breeding for in-house use</i>	Bi	Rs. 15,000.00	Rs. 25,000.00
6	Registration for <i>Breeding for the purpose of Trade</i>	Bt	Rs. 25,000.00	Rs. 25,000.00
7	Renewal for the purpose of <i>Research for education</i>	Re	Rs. 2,500.00*	Rs. 2,500.00*
8	Renewal for the purpose of <i>Research for commercial</i>	Rc	Rs. 2,500.00*	Rs. 2,500.00*
9	Renewal for the purpose of <i>Research</i>	R	Rs. 2,500.00*	Rs. 2,500.00*
10	Renewal for the purpose of <i>Non-Research Commercial</i> (i.e. Production of Hyperimmune Plasma and Serum)	NRc	-	Rs. 2,500.00*
11	Renewal for <i>Breeding for in-house use</i>	Bi	Rs. 2,500.00*	Rs. 2,500.00*
12	Renewal for <i>Breeding for the purpose of Trade</i>	Bt	Rs. 2,500.00*	Rs. 2,500.00*
13	Revision of IAEC	-	Rs. 1,000.00	
14	Protocol on Large Animals (educational) where the Joint Director (Research) or Dean (Research) or competent authority equivalent to Joint Director (Research) or Dean (Research) would certify that the particular protocol under this category is a thesis project (per protocol)	-	Rs. 1,000.00	
15	Protocol on Large Animals (educational other than thesis project) (per protocol)	-	Rs. 5,000.00	

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16	Protocol on Large Animals (non-educational) (per protocol)	-	Rs. 5,000.00
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The establishments which are not doing efforts to renew their Animal House Facilities before the date of expiry of the registration, they shall be charged registration fee for the respective purpose as per fee structure (enclosed) in place of renewal fee.


Note:

- i. The establishments which are **applying for registration** with CPCSEA, for different purposes are required to submit the fee(s) as per their purpose(s). *If the purpose is more than one, the fee is to be added accordingly.*
- ii. The establishments already registered with CPCSEA and **applying for renewal of registration** are required to submit the renewal fee(s) as per their purpose(s) (as mentioned in the table above). *If the purpose is more than one, the fee is to be added accordingly.*

25. All communications must be addressed to:

Member Secretary (CPCSEA)
Office of the CPCSEA,
Animal Welfare Division,
5th Floor, Vayu Block,
Indira Paryavaran Bhawan,
Jor Bagh Road, New Delhi – 110003.
Phone: 011-24695232, 24695424,
E-mail: cpcsea-mef@gov.in,
Website: <http://cpcsea.nic.in>

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CPCSEA GUIDELINES FOR LABORATORY ANIMAL FACILITY - 2015

Good Laboratory Practices (GLP) for animal facilities is intended to assure quality maintenance and welfare of animals used in laboratory studies while conducting biomedical and behavioural research and testing of products.

1. GOAL

The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioural research and testing with the basic objective of providing specifications that will enhance animal well being, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

2. VETERINARY CARE

a. Adequate veterinary care must be provided and is the responsibility of a veterinarian or a person who has training or experience in laboratory animal sciences and medicine.

b. Daily observation of animals can be accomplished by someone other than a veterinarian; however, a mechanism of direct and frequent communication should be adopted so that timely and accurate information on problems in animal health, behaviour, and well being is conveyed to the attending veterinarian.

c. The veterinarian can also help the establishment in designing appropriate policies and procedures for ancillary aspects of veterinary care, such as use of appropriate methods to prevent and control diseases (e.g. vaccination and other prophylaxis, disease monitoring and surveillance, quarantine and isolation), operative and post-operative care, diagnosis and treatment of diseases as well as injuries, reviewing protocols and proposals, animal husbandry and animal welfare; monitoring occupational health hazards containment, and zoonosis control programs; and supervising animal nutrition and sanitation. Institutional requirements will determine the need for full-time or part-time or consultative veterinary services.

3. ANIMAL PROCUREMENT

a. All animals (like cattle, buffalo, sheep, goat, pigs, equine etc.) must be acquired lawfully as per the CPCSEA guidelines. Small animals and dogs can be procured from registered breeders. Large animals can be procured from farm, farmers or as per guidance of wild life department, as is done in case of macaques. Cats can be bred for their use. Rodents can be imported from abroad after necessary licence from Director General of Foreign trade (DGFT) is obtained for import.

b. A health surveillance program for screening incoming animals should be carried out before purchase to assess animal quality. Methods of transportation should also be taken into account (Annexure - 4).

c. Each consignment of animals should be inspected for compliance with procurement specifications, and the animals should be quarantined and stabilized according to procedures appropriate for the species and circumstances.

4. QUARANTINE, STABILIZATION AND SEPARATION

a. Quarantine is the separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined. An

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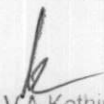
effective quarantine minimizes the chance for introduction of pathogens into an established colony. The duration at quarantine in small lab animals is from one week to one month and large animals allowed up to 6 weeks (cat, dog, monkey, etc). However, duration of quarantine can be increased depending on type of infection / suspected infection noticed in the animals.

- b. Effective quarantine procedures should be used for non-human primates to help limit exposure of humans to zoonotic infections. The period varies from 2 to 3 months depending on the reaction of TB testing. Any macaque found positive for TB for at least two times and shows signs of weight loss or ill health should be euthanized as is practiced internationally to prevent spreading of TB to workers and other macaques.
- c. Regardless of the duration of quarantine, newly received animals should be given a period for physiologic, psychologic and nutritional stabilization before their use. The length of time stabilization will depend on the type and duration of animal transportation, the species involved and the intended use of the animals.
- d. Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate anxiety and possible physiological and behavioural changes due to interspecies conflict.
- e. Such separation is usually accomplished by housing different species in separate rooms; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators can be used as suitable alternatives.
- f. In some instances, it shall be acceptable to house different species in the same room, for example, if two species have a similar pathogenic status and are behaviourally compatible. Separate set of personnel should be identified for taking care of these infected (sick) animals and other workers should be restricted from entering in to the facilities unless otherwise required and after handling these animals they should not be handling any other animals in the facilities

5. SURVEILLANCE, DIAGNOSIS, TREATMENT AND CONTROL OF DISEASE

- a. All animals should be observed for signs of illness, injury, or abnormal behaviour by animal house staff. As a rule, this should occur daily, but more-frequent observations might be warranted, such as during postoperative recovery or when animals are ill or have a physical deficit. It is imperative that appropriate methods be in place for disease surveillance and diagnosis (Annexure 1 & 2).
- b. Post-mortem examination and signs of illness, distress, or other deviations from normal health condition in animals should be reported promptly to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease should be isolated from healthy animals in the colony. If an entire room of animals is known or believed to be exposed to an infectious agent (e.g. Mycobacterium tuberculosis in non-human primates), the group should be kept intact and isolated during the process of diagnosis, treatment, and control. Animals suffering from contagious diseases like Tuberculosis etc. must be euthanized as is practiced internationally to prevent its spread to other animals and often animal handlers.
- c. The isolation, quarantine and stabilization programs for newly arrived animals are necessary to provide time to assess their health status, allow them to recover from the stress of shipment and an opportunity to adapt to their new environment. The extent of these programs depends on several factors, including species and source of the animals as well as their intended use. For some animals,

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such as rodents obtained from reliable sources for which health status is known, visual inspection on arrival may suffice. For species such as nonhuman primates, farm animals, wild animals, dogs, cats and non-specific pathogen free rabbits and rodents, appropriate quarantine and isolation procedures must be employed.

- d. Preventive medicine programs such as vaccinations, ecto- and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular species and source. Only animals of defined health status should be used in research and testing unless a specific, naturally occurring or induced disease state is being studied. Systems should be established to protect animals within the institution from exposure to diseases.
- e. Transgenic and mutant animals may be particularly susceptible to diseases and may require special protection to ensure their health. Systems to prevent spread of disease may include facility design features, containment/isolation equipment, and use of standard operating procedures. Training of animal care and research staff is essential to prevent spread of animal diseases.
- f. Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic and microbiological agents that may cause overt or unapparent disease. Additionally, cells, tissues, fluids, and transplantable tumors that are to be used in animals should be monitored for infectious or parasitic agents that may cause disease in animals. The type and intensity of monitoring necessary will depend upon professional veterinary judgment and the species, source, use and number of animals housed and used in the facility.
- g. Diagnostic laboratory services must be available and used as appropriate. Laboratory services should include necropsy, histopathology, microbiology, clinical pathology, serology, and parasitology as well as other routine or specialized laboratory procedures, as needed. It is not necessary that all of these services be available within the animal facility (Facilities from other laboratories with appropriate capabilities may be used).
- h. Animals with infectious / contagious disease must be isolated from others by placing them in isolation units or separate rooms appropriate for the containment of the agents of concern. In certain circumstances, when an entire group of animals is known or suspected to be exposed or infected, it may be appropriate to keep the group intact during the time necessary for diagnosis and treatment, for taking other control measures, or for completion of a project.
- i. The veterinarian must have authority to use appropriate treatment or control measures, including euthanasia in consultation with at least one more additional veterinarian if required, following diagnosis of an animal disease or injury. If possible, the veterinarian should discuss the situation with the principal investigator to determine a course of action consistent with experimental goals. However, if the principal investigator is not available, or if agreement cannot be reached, the veterinarian must have authority to act to protect the health and well- being of the institutional animal colony and workers.

6. ANIMAL CARE AND TECHNICAL PERSONNEL

- a. Animal care programs require technical and husbandry support. Institutions should employ people trained in laboratory animal science or provide for both formal and on-the-job training to ensure

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effective implementation of the program (Annexure-7).

7. PERSONAL HYGIENE

- a. It is essential that the animal care staff maintain a high standard of personal cleanliness. Facilities and supplies for meeting this obligation should be provided with appropriate Personnel Protective Equipment (PPE) e.g. showers, change of uniforms, footwear etc.
- b. Clothing suitable for use in the animal facility should be supplied and laundered by the institution. A commercial laundering service is acceptable in many situations; however, institutional facilities should be used to decontaminate clothing exposed to potentially hazardous microbial agents or toxic substances. It is acceptable to use disposable gloves, masks, head covers, coats, coveralls and shoe covers. Personnel should change clothing as often as is necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility.
- c. Washing and showering facilities appropriate to the program should be available. Personnel should not be permitted to eat, drink, smoke or apply cosmetics and perfumes in animal rooms. They should finish the work with animals as early as possible and sit somewhere else, outside and not in the animal rooms / areas. A separate area or room should be made available for these purposes.

8. ANIMAL EXPERIMENTATION INVOLVING HAZARDOUS AGENTS

- a. Institutions should have policies governing experimentation with hazardous agents. Institutional Bio-safety Committee whose members are knowledgeable about hazardous agents are in place in most of the higher-level education, research institutes and in many pharmaceutical industries for taking care of safety issues. This committee shall also examine the proposal on animal experiments involving hazardous agents in addition to its existing functions (Annexure - 8).
- b. Since the use of animals in such studies requires special considerations, the procedures and the facilities to be used must be reviewed by both the Institutional Bio-safety committee and Institutional Animal Ethics Committee (IAEC). Disposing of tissues and fluids from such used animals must also be appropriately governed as per the laid in practices of the institution / bio-safety regulation.

9. MULTIPLE SURGICAL PROCEDURES ON SINGLE ANIMAL

- a. Multiple surgical procedures on a single animal for any testing or experiment are not to be practiced unless specified in a protocol only approved by the IAEC.
- b. Individual animals should not be used in more than one experiment, either in the same or different projects, without the express approval of the IAEC. However, it is noted that appropriate re-use of animals may reduce the total number of animals used in a project, result in better design of experiments, and reduce stress or avoid pain to additional animals. Animals that are used in more than one experiment should be permitted to recover fully from the first experiment before the subsequent experiment is performed. Certification of attending veterinarian is however, required before subjecting animal to the second experiment.

10. DURATIONS OF EXPERIMENTS

No animal should be used for experimentation for more than 3 years unless adequate justification is provided.

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11. PHYSICAL RESTRAINT

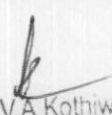
- a. Brief physical restraint of animals for examination, collection of samples, and a variety of other clinical and experimental manipulations can be accomplished manually or with devices be suitable in size and design for the animal being held and operated properly to minimize stress and avoid injury to the animal.
- b. Prolonged restraint of any animal, including the chairing of non-human primates, should be avoided unless essential to the research objectives. Less restrictive systems, such as the tether system or the pole and collar system should be used when compatible with research objectives.
- c. Following points should be considered during handling and restraining animals:-
 - i. Animals should be handled by competent individuals trained in methods that cause minimal distress and injury (for example, a person with a publication to his/her credit and post/experience in relevant techniques for handling animals is preferable).
 - ii. The use of restraint devices is sometimes essential for the welfare of the animal and safety of the handler. Restraint devices should be used to the minimum
 - iii. extent, for the minimum period required to accomplish the purpose of the experiment and be appropriate for the animal.
 - iv. Tranquilisers or anaesthetics may initially be used to aid restraint but they may prolong recovery from the procedure. When these agents have been used, recovery of the animals should be closely monitored.
- d. The following are important guidelines for the use of restraint equipments:
 - i. Restraint devices cannot be used simply as a convenience in handling or managing animals. The period of restraint should be the minimum required to accomplish the research objectives. Animals to be placed in restraint devices should be given training to adapt to the equipment, prior to initiation of the experimentation.
 - ii. Provision should be made for observation of the animal at appropriate intervals. Veterinary care should be provided if symptoms or illness associated with restraint are observed. The presence of illness, or severe behavioural change should be dealt with by temporary or permanent removal of the animal from restraint related protocol.

12. LOCATION OF ANIMAL FACILITIES TO LABORATORIES

Good animal husbandry and human comfort and health protection require physical separation of animal facilities from personnel areas such as offices, break room, training and education room.

- Laboratory animals are very sensitive to their living conditions. It is important that they shall be housed in an isolated building located as far away from human habitations as possible and not exposed to dust, smoke, noise, wild rodents, insects and birds. The building, cages and environment of animal rooms are the major factors, which affect the quality of animals.
- This separation can be accomplished by having the animal quarters in a separate building, wing, floor, or room. Careful planning should make it possible to place animal housing areas adjacent to

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or near laboratories, but separated from them by barriers such as entry locks, corridors, or floors.

- While planning an animal facility the space should be well divided for various activities. The animal rooms should occupy about 50-60% of the total constructed area and the remaining area should be utilized for services such as stores, washing, office and staff, machine rooms, quarantine and corridors. The environment of animal room (Macro-Environment) and animal cage (Microenvironment) are factors on which the production and experimental efficiency of the animal depends. Since animals are very sensitive to environmental changes, sharp fluctuations in temperature, humidity, light, sound and ventilation should be avoided. The recommended space requirements for animal rooms, for different species are given in (Annexure - 3).

13. FUNCTIONAL AREAS


- a. The size and nature of a facility will determine whether areas for separate service functions are possible or necessary. Sufficient animal area required to:
 - Ensure separation of species or isolation of individual projects when necessary;
 - Receive, quarantine, and isolate animals; and
 - Provide for animal housing.
- b. In facilities that are small, maintain few animals or maintain animals under special conditions (e.g., facilities exclusively used for housing germfree colonies or animals in runs and pens) some functional areas listed below could be unnecessary or included in a multipurpose area. Professional judgement must be exercised when developing a practical system for animal care.
 - Specialized laboratories or
 - Individual areas contiguous with or near animal housing areas for such activities as surgery, intensive care, necropsy, radiography, preparation of special diets, experimental manipulation, treatment, and diagnostic laboratory procedures containment facilities or
 - Equipment, if hazardous biological, physical, or chemical agents are to be used
 - Receiving and storage areas for food, bedding
 - Pharmaceuticals and biologics, and supplies
 - Space for administration, supervision, and direction of the facility
 - Showers, sinks, lockers and toilets for personnel
 - An area for washing and sterilization equipment and supplies,
 - An autoclave for equipment
 - Food, and bedding; and separate areas
 - For holding soiled and cleaned equipment
 - An area for repairing cages and equipment
 - An area to store wastes prior to incineration or removal

14. PHYSICAL FACILITIES

The physical condition and design of animal facility determine, to a great extent, the efficiency and economy of this operation. The design and size of an animal facility depend on the scope of institutional research activities, animals to be housed, physical relationship to the rest of the institution, and geographic location. A well planned, properly maintained facility is an important element in good animal care.

- a. Housing facility should be compatible with the needs of the species to be housed.
- b. Housing Facilities should be designed and operated to facilitate control of environmental factors to exclude vermin and limit contamination associated with the housing of animals, delivery of food, water, bedding, and the entry of people and other animals.

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- c. Housing Facilities should be maintained in good repair. Walls and floors should be constructed of durable materials with surfaces that can be cleaned and disinfected readily.
 - d. Housing Facilities should be kept clean and tidy and operated to achieve maximum possible hygiene.
 - e. There should be a pest control programme to monitor and control vermin.
 - f. There should be adequate and appropriate storage areas for food, bedding and equipment.
 - g. Deodorants designed to mask animal odours should not be used in Housing Facilities as they may expose animals to volatile compounds which can alter metabolic processes. In addition, deodorants must not be used as a substitute for good cage and equipment cleaning practices and good ventilation.
 - h. Cleaning practices should be monitored on a regular basis to ensure effective hygiene and sanitation. This may include visual inspection, monitoring water temperatures and microbiological testing of surfaces after cleaning.
 - i. There should be proper water supply and drainage.
 - j. There should be adequate contingency plans to cover such emergencies as flooding and fire, or the breakdown of lighting, heating, cooling or ventilation.
 - k. In the interest of disease prevention and general animal welfare, access to the Housing Facilities by unauthorised persons should be restricted.
- I. Building Materials should be selected to facilitate efficient and hygienic operation of animal facilities. Durable, moisture-proof, fire-resistant, seamless materials are most desirable for interior surfaces including vermin and pest resistance.
- II. Corridor(s) should be wide enough to facilitate the movement of personnel as well as equipments and should be kept clean.
- III. Utilities such as water lines, drain pipes, and electrical connections should preferably be accessible through service panels or shafts in corridors outside the animal rooms.

IV. Animal Room Doors

Doors should not be rust and should be vermin and dust proof. They should fit properly within their frames and provided with an observation window. Door closures may also be provided. Rodent barriers can be provided in the doors of the small animal facilities.


V. Exterior Windows

Windows are not recommended for small animal facilities. However, where power failures are frequent and backup power is not available, they may be necessary to provide alternate source of light and ventilation. In primate rooms, windows can be provided to have visual access to natural environment.

VI. Floors

Floors should be or either monolithic or epoxy smooth, moisture proof, nonabsorbent, skid-proof, resistant to wear, acid, solvents and adverse effects of detergents/ disinfectants
They should be capable of supporting racks, equipment, and stored items without becoming gouged,

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cracked, or pitted, with minimum number of joints.

VII. Drains

Floor drains are not essential in all rooms used exclusively for housing rodents. Floor in such rooms can be maintained satisfactorily by wet vacuuming or mopping with appropriate disinfectants or cleaning compounds. Where floor drains are used, the floors should be sloped and drain taps kept filled with water or corrosion free mesh. To prevent high humidity, drainage must be adequate to allow rapid removal of water and drying of surfaces. At the inlet and outlets of the drains should be fitted with wire mesh guard to prevent wild rodent entry

VIII. Walls & Ceilings

Walls should be free of cracks, unsealed utility penetrations, or imperfect junctions with doors, ceilings, floors and corners.

Surface materials should be capable of withstanding scrubbing with detergents, disinfectants and the impact of water under high pressure. Materials used for construction of roof should cater needs of local climatic condition to provide comfort to the animals.

IX. Storage Areas

Separate storage areas should be designed for feed, bedding, cages and materials not in use.

Refrigerated storage, separated from other cold storage, is essential for storage of dead animals and animal tissue waste.

X. Facilities For Sanitizing Equipment And Supplies

An area for sanitizing cages and ancillary equipment is essential with adequate water supply

XI. Experimental Area

All experimental procedures in small animals should be carried out in a separate area away from the place where animals are housed. Aseptic surgery for large animals should include separate functional areas for surgical support, like a preparation area, the operating theatre room or rooms, and an area for post-operative care and for treatment of animals.

15. ENVIRONMENT

a. Temperature and Humidity Control

Air conditioning is an effective means of regulating these environmental parameters for laboratory animals. Temperature and humidity control prevents variations due to changing climatic conditions keeping in view of the variations in the number of room occupants the range should be within or approximately between 18 to 29°C (64.4 to 84.2oF) all times.


The relative humidity should be under control within the range of 30% to 70% throughout the year. For larger animals a comfortable zone (18 to 37°C) should be maintained. During extreme summer appropriate methods e.g. sprinklers should be adopted for cooling open enclosures of large animals.

b. Ventilation

In renovating existing or in building new animal facilities, consideration should be given to the ventilation of the animals' primary enclosures.

Heating, ventilation, and air-conditioning systems should be designed with 12-15 air cycles per hour so that operation can be continued with a standby system. The animal facility and human occupancy areas should be ventilated separately.

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c. Power and Lighting

The electrical system should be safe and provide appropriate lighting and with sufficient number of power points lighting system be installed provide adequate illumination for people to work in the animal rooms and a lowered intensity of light for the animals. Fluorescent lights are efficient and less than 400 lux is preferable for rodent facilities.

A time-controlled lighting system should be used if possible to ensure a regular diurnal lighting cycle wherever required. Emergency power should be available in the event of power failure.

d. Noise Control

The facility should be provided with noise free environment. Noise control is an important consideration in designing the animal facility. Concrete walls are more effective than metal or plaster walls because their density reduces sound transmission. Preferably less than 85 dB is desirable for rodents and non-human primates.

16. ANIMAL HUSBANDRY

I. Caging of Housing System

- a. The caging or housing system is one of the most important elements in the physical and social environment of research animals. It should be designed carefully to facilitate animal well being, meet research requirements, and minimize experimental variables.

The housing system should:

- Provide space that is adequate, permit freedom of movement and normal postural adjustments, and have a resting place appropriate to the species;

(Annexure – 3)

- Provide a comfortable environment
➤ Provide an escape proof enclosure that confines animal safety
➤ Provide easy access to food and water;
➤ Provide adequate ventilation
➤ Meet the biological needs of the animals, e.g., maintenance of body temperature, urination, defecation, and reproduction;
➤ Keep the animals dry and clean, consistent with species requirements;
➤ Facilitate research while maintaining good health of the animals.

- b. They should be constructed of sturdy, durable materials and designed to minimize cross- infection between adjoining units. Polypropylene, polycarbonate and stainless steel cages should be used to house small lab animals, Monkeys should be housed in cages made of steel or painted mild steel and for other animals such as sheep, horses, the details can be seen in Annexure - 3.

- c. To simplify servicing and sanitation, cages should have smooth, impervious surfaces that neither attract nor retain dirt and a minimum number of ledges, angles, and corners in which dirt or water can accumulate. The design should allow inspection of cage occupants without disturbing them. Feeding and watering devices should be easily accessible for filling, changing, cleaning and servicing.

- d. Cages, runs and pens must be kept in good condition to prevent injuries to animals, promote physical comfort, and facilitate sanitation and servicing. Particular attention must be given to

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eliminate sharp edges and broken wires, keeping cage floors in good condition. International guidelines can be referred from time to time to improve caging facilities.

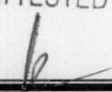
II. Sheltered or Outdoor Housing

- a. When animals are maintained in outdoor runs, pens, or other large enclosures, there must be protection from extremes in temperature or other harsh weather conditions an adequate protective and escape mechanism for submissive animals especially in monkeys by way of providing indoor portion of run. Shelter should have sufficient ventilation, and should be designed to prevent accumulation of waste materials and excessive moisture.
- b. Houses, dens, boxes, shelves, perches, and other furnishings should be constructed in a manner and made of materials that allow cleaning or replacement in accordance with generally accepted husbandry practices when the furnishings are soiled or worn out.
- c. Ground-level surfaces of outdoor housing facilities can be cemented or covered with absorbent bedding, sand, gravel, grass, or similar material that can be removed or replaced when that is needed to ensure appropriate sanitation. Accumulation of animal waste and stagnant water should be avoided by, for example, using contoured or drained surface. Other surfaces should be able to withstand the elements and be easily maintained.
- d. In case of open runs of macaques, it is obvious in our country (unlike others) to have outside animals and local macaques frequenting the colony pens and runs increasing risk of contracting contagious diseases. Hence, it is advisable to cover such open pens with additional layers of materials (double fencing) to separate outside animals physically from the animals belonging to the colony. Initiation of such practices may reduce spread of infectious diseases like TB etc. found more frequently in Indian colonies of macaques in various establishments and thought to be unavoidable.

17. SOCIAL ENVIRONMENT

- a. The social environment includes all interactions among individuals of a group or among those able to communicate. The effects of social environment in caged animals vary with the species.
- b. In selecting a suitable social environment, attention should be given whether the animals are naturally territorial or communal and accordingly they should be housed single or in groups.
- c. When appropriate, group housing should be considered for communal animals. In grouping animals, it is important to take into account population density and ability to disperse; initial familiarity among animals; and age, sex, and social rank.
- d. Population density can affect reproduction, metabolism, immune responses, and behavior. Group composition should be held as stable as possible, particularly for canine, non-human primates, and other highly social mammals, because mixing of groups or introducing new

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members can alter behavioral and physiological functions.

- e. Non-human primates should have a run for free ranging activities:


18. ACTIVITY

- a. Provision should be made for animals with specialized locomotor pattern to express their natural habitat, especially when the animals are held for long periods. e.g., artificial trees, ropes, bars, and perches are appropriate for non-human primates.
- b. Cages are often used for short-term (up to 3 months) housing of dogs and may be necessary for postsurgical care, isolation of sick dogs, and metabolic studies.
- c. Pens, runs, or other out-of-cage space provide more opportunity for exercise, and their use is encouraged when holding dogs for long periods.

19. FOOD

- a. Animals should be fed with palatable, non-contaminated, and nutritionally adequate food daily unless the experimental protocol requires otherwise.
- b. Feeders should allow easy access, while avoiding contamination by urine and faeces.
- c. Food should be provided in sufficient amounts to ensure normal growth in immature animals and to maintain normal body weight, reproduction, and lactation in adults.
- d. Food should contain adequate nutrition, with proper formulation and preparation; and ensure free from chemical and microbial contaminants; bio-availability of nutrients should be at par with the nutritional requirements of the animal. The animal feed should contain moisture, crude fiber, crude protein, essential vitamins, minerals, crude fat and carbohydrate for providing appropriate nutrition.
- e. Laboratory animal diets should not be manufactured or stored in facilities used earlier for farm feeds or any products containing additives such as rodenticides, insecticides, hormones, antibiotics, fumigants, or other potential toxicants.
- f. Areas in which diets are processed or stored should be kept clean and enclosed to prevent entry of insects or other animals.
- g. Precautions should be taken if perishable items such as meats, fruits, and vegetables are fed, because these are potential sources of microbiological and chemical contamination and can also lead to variation in the amount of nutrients consumed.
- h. Diet should ideally be free from heavy metals (e.g., Lead, Arsenic, Cadmium, Nickel, Mercury), naturally occurring toxins and other contaminants. Exposure to extremes of relative humidity, unsanitary conditions, light, oxygen, and insects hasten the deterioration

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of food.

- i. Meats, fruits, vegetables, and other perishable items should be refrigerated if required to be stored. Unused, open food should be stored in vermin proof conditions to minimize contamination and to avoid potential spread of disease causing agents.
- j. Food hoppers should not be transferred from room to room unless cleaned and properly sanitized.

20. BEDDING

- a. Bedding should be absorbent, free from toxic chemicals or other substances that cause irritation, injure animals or personnel, and of a type not readily eaten by animals. Bedding should be used in amounts sufficient to keep animals dry between cage changes without coming into contact with watering tubes.
- b. Bedding should be removed and replaced periodically with fresh materials as often as necessary to keep the animals clean and dry. The frequency is a matter of professional judgement of animal care personnel in consultation with the investigation depending on the number of animals and size of cages. In general, it is ideal to change the bedding twice a week or whenever requires.
- c. The desirable criteria for rodent contact bedding is ammonia binding, sterilizable, deleterious products not formed as a result of sterilization, easily stored, non - desiccating to the animal, uncontaminated, unlikely to be chewed or mouthed, non - toxic, non - malodorous, nestable, disposable by incineration, readily available, remains stable during use, manifests batch uniformity, optimizes normal animal behavior, non - deleterious to cage - washers, non - injurious and non - hazardous to personnel, non - nutritious and non - palatable.
- d. Nesting materials for newly delivered pups should be provided wherever needed (e.g. Paper cuttings, tissue paper, cotton etc.).

21. WATER

- a. Animals should have continuous access to fresh, potable, uncontaminated drinking water, according to their requirements. Periodic monitoring of microbial contamination in water is necessary.
- b. Watering devices, such as drinking nozzles and automatic waterers should be examined routinely to ensure their proper operation. Sometimes it is necessary to train animals to drink water from automatic watering devices.
- c. Animals should receive appropriate, uncontaminated and nutritionally adequate food according to accepted requirements for the species. The food should be in sufficient quantity and of appropriate composition to maintain normal growth of immature animals, normal weight of adult animals or provide for the requirements of pregnancy or lactation.
- d. When animals are fed in groups, there should be sufficient trough space or feeding points to cater to the number and size of animals that eat together at one time so as to avoid

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- undesirable competition for food, especially if feed is restricted.
- e. Uneaten perishable food should be removed promptly unless contrary to the eating habits or needs of the species. Any alteration to dietary regimes should be gradual.

22. SANITATION AND CLEANLINESS

- a. Sanitation is an essential activity in an animal facility. Animal rooms, corridors, storage spaces, and other areas should be properly cleaned with appropriate detergents and disinfectants as often as necessary to keep them free of dirt, debris, and harmful agents of contamination.
- b. Cleaning utensils, such as mops, pails, and brooms, should not be transported between animal rooms.
- c. Where animal waste is removed by hosing or flushing, this should be done at least twice a day. Animals should be kept dry during such procedures. For larger animals, such as dogs, cats, and non - human primates, soiled litter material should be removed twice daily.
- d. Cages should be sanitized before animals are placed in them. Animal cages, racks, and accessory equipments, such as feeders and watering devices, should be washed and sanitized frequently to keep them clean and contamination free. Generally, this can be achieved by washing solid bottom rodent cages and accessories once or twice a week and cages, racks at least monthly.
- e. Wire - bottom cages other than rodent cages should be washed at least every 2 weeks. It is good practice to have extra cages available at all times so that a systematic cage-washing schedule can be maintained. Cages can be disinfected by rinsing at a temperature of 82.2C (180oF) or higher for a period long enough to ensure the destruction of vegetative pathogenic organisms.
- f. Disinfection can also be accomplished with appropriate chemicals. Equipments should be rinsed free of chemicals prior to use. Periodic microbiologic monitoring is useful to determine the efficacy of disinfection or sterilization procedures.
- g. Rabbits and some rodents, such as guinea pigs, mice and hamsters, produce urine with high concentration of proteins ammonia and minerals. Minerals and organic compounds in the urine from these animals often adhere to cage surfaces and necessitate treatment with acid solutions before washing.
- h. Water bottles, sipper nozzles stoppers, and other watering equipment should be washed and then sanitized by rinsing with water of at least 82.2oC (180oF) or appropriated chemicals agents (e.g. Sodium Hyperchlorite) to destroy pathogenic organisms, if bottles are washed by hand, mechanized brushes at the washing sink are useful, and provision should be made for dipping or soaking the water bottles in detergents and disinfectant solutions. A two – compartment sink or tub is adequate for this purpose.
- i. Some means for sterilizing equipments and supplies, such as an autoclave or gas sterilizer, is essential when pathogenic organisms are present. Routine sterilization of cages, feed and bedding is also essential besides care is taken to use clean materials from reliable sources. Where hazardous biological, chemical, or physical agents are used, a system of equipment monitoring might be appropriate.

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- j. Deodorants or chemical agents other than germicidal agents should not be used to mask animal odors. Such products are not a substitute for good sanitation.

23. ASSESSING THE EFFECTIVENESS OF SANITATION

- a. Sanitation practices should be monitored appropriately to ensure effectiveness of the process and materials being cleaned; it can include visual inspection of the materials, monitoring of water temperatures, or microbiologic monitoring.
- b. The intensity of animal odors particularly that of ammonia should not be used as the sole means of assessing the effectiveness of the sanitation program.
- c. A decision to change the frequency of such bedding changes or cage washing should be based on factors such as the concentration of ammonia, appearance of the cage, condition of the bedding and number and size of the animals housed in the cage.
- d. Autoclaving: Chemical Indicator - batch wise assessment; Biological indicator - Periodical assessment.

24. WASTE DISPOSAL

- a. Wastes should be removed regularly and frequently. All waste should be collected and disposed off in a safe and sanitary manner. The most preferred method of waste disposal is incineration. Incinerators should be in compliance with all central, state, and local Public Health and Pollution Control Board regulations.
- b. Waste containers containing animal tissues, carcasses, and hazardous wastes should be lined with leak - proof, disposable liners. If wastes must be stored before removal, the waste storage area should be separated from other storage facilities and free of flies, cockroaches, rodents, and other vermin. Cold storage might be necessary to prevent decomposition of biological wastes. Hazardous wastes should be rendered safe by disinfection, decontamination, or other appropriate means before they are disposed off from an animal facility.

25. PEST CONTROL

Adaptation of Programs designed to prevent, control, or eliminate the presence of or infestations by pests are essential in an animal home environment. Best results can be achieved by giving contracts to people/firm specialized in pest control.

26. EMERGENCY, WEEKEND AND HOLIDAY CARE

There should be an institutional policy to care animals by qualified personnel every day, including weekends and holidays, to safeguard their well - being including emergency veterinary care. In the event of an emergency, institutional security personnel and fire or police officials should be able to reach responsible persons for the animals. That can be enhanced by prominently posting emergency procedures, names, or telephone numbers in animal facilities or by placing them in the security department or near telephone. A disaster plan that takes into account both personnel

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and animals should be prepared as part of the overall safety plan for the animal facility.

27. RECORD KEEPING

It is essential that animal House should maintain following records:

- Animal House plans, which includes typical floor plan, all fixtures etc.
- Animal House staff record - both technical and non - technical
- Health record of staff and animals
- All SOPs relevant to experiments, care, breeding and management of animals
- Breeding, stock, purchase and sales records
- Minutes of institutional Animals Ethics Committee Meetings
- Records of experiments conducted with the number of animals used (copy of Form D)
- Mortality, Post-mortem Record, wherever required.
- Clinical record of sick animals.
- Training record of staff involved in animal activities
- Water, feed and bedding materials analysis report
- Health monitoring Records.
- Rehabilitation Records, wherever required.

28. STANDARD OPERATING PROCEDURES (SOPs) / Guidelines

The Institute should maintain SOPs describing procedures / methods adapted with regard to Animal Husbandry, maintenance, breeding, animal house activities microbial testing and experimentation.

A SOP should contain the following items:

- Name of the Author
- Title of the SOP
- Date of approval
- Reference of previous SOP on the same subject and date (Issue number and Date)
- Location and distribution of SOP's with sign of each recipient.
- Objectives
- Detailed information of the instruments used in relation with animals with methodology (Model no., Serial no., Date of commissioning, etc)
- The name of the manufacturer of the reagents and the methodology of the analysis pertaining to animals
- Normal value of all parameters
- Hazard identification and risk assessment

29. PERSONNEL AND TRAINING

- a. The selection of animal facility staff, particularly the staff working in animal rooms or involved in transportation, is a critical component in the management of an animal facility.
- b. The staff must be provided with all required protective clothing (face masks, head covers, aprons, gloves, gumboots, other footwear etc.) while working in animal rooms. Facilities should

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be provided for change over with lockers, wash basin, toilets and bathrooms to maintain personal hygiene. It is also important a regular medical check-up is arranged for the workers to ensure that they have not picked up any zoonotic infection and also that they are not acting as a source of transmission of infection to the animals. The persons working in animal house should not eat, drink, smoke in animal room and have all required vaccination, particularly against Tetanus and other zoonotic diseases.

- c. Initial in-house training of staff at all levels is essential. A few weeks must be spent on the training of the newly recruited staff, teaching them the animal handling techniques, cleaning of cages and importance of hygiene, disinfection and sterilization. They should also be made familiar with the activities of normal healthy and sick animals so that they are able to spot the sick animal during their daily routine checkup of cages (Annexure - 7).

30. TRANSPORT OF LABORATORY ANIMALS

- a. The transport of animals from one place to another is very important and must be undertaken with care. The main considerations for transport of animals are, mode of transport, containers, animal density in cages, food and water during transit, protection from transit infections, injuries and stress.
- b. The mode of transport of animals depends on the distance, seasonal and climatic conditions and the species of animals. Animals can be transported by road, rail or air taking into consideration of above factors. In any case the transport stress should be avoided and the containers should be of an appropriate size so as to enable these animals to have a comfortable movement and protection from possible injuries. Sometimes injuries can be avoided by reducing space but parallely decreasing time of transportation. The food and water should be provided in suitable containers or in suitable form so as to ensure that they get adequate food and more particularly fluid during transit. The transport containers (cages or crates) should be of appropriate size and only a permissible number of animals should be accommodated in each container to avoid overcrowding and infighting (Annexure - 4)

31. ANAESTHESIA AND EUTHANASIA

- a. The investigators should ensure that the procedures, which are considered painful, are conducted under appropriate anaesthesia as recommended for each species of animals.
- b. It must also be ensured that the anaesthesia is given for the full duration of experiment and at no stage the animal is conscious to perceive pain during the procedure. If at any stage during the experiment the investigator feels that he has to abandon the experiment or he has inflicted irreparable injury, the animal should be humanely sacrificed. Neuromuscular blocking agents must not be used without adequate general anaesthesia (Annexure - 5).
- c. In the event of a decision to sacrifice an animal or termination of an experiment or otherwise an approved method of euthanasia should be adopted (Annexure - 6) and the investigator must ensure that the animal is clinically dead before it is sent for disposal. The data of all the animals, that have been euthanized, should be maintained.

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I. Anaesthesia: -

- a. Unless contrary to the achievement of the results of study, sedatives, analgesics and anaesthetics should be used to control pain or distress under experiment. Anaesthetic agents generally affect cardiovascular, respiratory and thermo-regulatory mechanism in addition to central nervous system.
- b. Before using actual anaesthetics the animals are prepared for anaesthesia by overnight fasting and using pre-anaesthetics, which block parasympathetic stimulation of cardio-pulmonary system and reduce salivary secretion. Atropine is most commonly used anti-cholinergic agent. Local or general anaesthesia may be used, depending on the type of surgical procedure.
- c. Local anaesthetics are used to block the nerve supply to a limited area and are used only for minor and rapid procedures. This should be carried out under an expert supervision for regional infiltration of surgical site, nerve blocks and for epidural and spinal anaesthesia.
- d. A number of general anaesthetic agents are used in the form of inhalants. General anaesthetics are also used in the form of intravenous or intra-muscular injections such as barbiturates. Species characteristics and variation must be kept in mind while using an anaesthetic. Side - effects such as excess salivation, convulsions, excitement and disorientation should be suitably prevented and controlled. The animal should remain under veterinary care till it completely recovers from anaesthesia and postoperative stress.

II. Euthanasia

Euthanasia should be resorted to events where an animal is required to be sacrificed to reduce suffering or to limit spread of infections or for termination of an experiment or for other ethical reasons. The procedure should be carried out quickly and painlessly in an atmosphere free from fear or anxiety. For accepting an euthanasia method as humane it should have an initial depressive action on the central nervous system for immediate insensitivity to pain. The choice of a method will depend on the nature of study, the species of animal to be killed (Annexure - 6). The method should in all cases meet the following requirements:

- a. Death, without causing anxiety, pain or distress with minimum time lag phase.
- b. Minimum physiological and psychological disturbances.
- c. Compatibility with the purpose of study and minimum emotional effect on the operator.
- d. Location should be separate from animal rooms and free from environmental contaminants.

Tranquilizers have to be administered to larger species such as monkeys, dogs and cats before a procedure of euthanasia.

32. LABORATORY ANIMAL ETHICS

All scientists working with laboratory animals must have a deep ethical consideration for the animals they are dealing with. From the ethical point of view, it is important that such considerations are taken care at the individual level, at institutional level and finally at the national


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level. Interaction amongst people working in animal house should be organized once in a while to discuss ethical issues favoring wellbeing of animals.

33. TRANSGENIC ANIMALS

Transgenic animals are those animals, into whose germ line foreign gene(s) have been engineered, whereas knockout animals are those whose specific gene(s) have been disrupted leading to loss of function. These animals can be bred to establish transgenic animal strains. Transgenic animals are used to study the biological functions of specific genes, to develop animal models for diseases of humans or animals, to produce therapeutic products, vaccines and for biological screening, etc. These can be either developed in the laboratory or procured for R&D purpose from registered scientific/academic institutions or commercial firms, generally from abroad with approval from appropriate authorities.

34. MAINTENANCE

Housing, feeding, ventilation, lighting, sanitation and routine management practices for such animals are similar to those for the other animals of the species as given in guidelines. However, special care has to be taken with transgenic/gene knockout animals where the animals can become susceptible to diseases where special conditions of maintenance are required due to the altered metabolic activities. The transgenic and knockout animals carry additional genes or lack genes compared to the wild population. To avoid the spread of the genes in wild population, care should be taken to ensure that these are not inadvertently released in the wild to prevent cross breeding with other animals. The transgenic and knockout animals should be maintained in clean room environment or in animal isolators.


35. DISPOSAL

The transgenic and knockout animals should be first euthanized and then disposed off as described elsewhere in the guidelines. A record of disposal and the manner of disposal should be kept as a matter of routine.

36. BREEDING AND GENETICS

For initiating a colony, the breeding stock must be procured from established breeders or suppliers ensuring that genetic makeup and health status of animal is known. In case of an inbred strain, the characters of the strain with their gene distribution and the number of inbred generation must be known for further propagation. The health status should indicate their origin, e.g. conventional, specific pathogen free or transgenic, genotobiotic or knockout stock.

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