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INSTITUTIONAL ETHICS COMMITTEE BIMS

DR. B.R. AMBEDKAR ROAD, BELGAUM – 590 001

(Autonomous Medical Institution, Government of Karnataka)

Ethics Committee of The Belgaum Institute Of Medical Sciences Belgaum

Standard Operating Procedures

**In Accordance With
The Declaration of Helsinki (2000)**

**&
The ICH GCP (E6) Guideline**

**&
ICMR Guideline for Biomedical Research on Human Participants (2007)**

Issue Date:

Effective Date:

Accepted by:

**Chairman: Ethics Committee (EC) Of the Belgaum Institute Of Medical
Sciences Belgaum**

Signature of Member Secretary: _____

Name: Dr. B. C. Kotinatot

Date:

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Structure of Ethics Committee of the Belgaum Institute of Medical Sciences Belgaum

Establishing and constituting Authority: Director of the Belgaum Institute of Medical Sciences
Belgaum

- **Members of Committee:**

1. Medical/ Biomedical scientists:

1. Dr. Ramaiah, Director of the BIMS, Belgaum - Chairman
2. Dr. B. C. Kotinatot, Prof & HOD, Dept. of Pharmacology - Member Secretary
3. Dr. S. T. Kalsad , Medical superintendent BIMS, Hospital - Member
4. Dr. Rajashekar R. K, Prof & HOD, Physiology, BIMS, Belgaum - Member
5. Dr. A. B. Halappanavar, Prof & HOD, Community Medicine
BIMS, Belgaum - Member
6. Dr. M. M. Umadi, Prof & HOD, Dept of OBG, BIMS, Belgaum - Member
7. Dr. I. B. Havannavar, Prof & HOD, Dept. of Surgery, BIMS, Belgaum - Member

2. Legal Expert

1. Mr. Shrikanth Halbhavi , Advocate - Member

3. Social Worker:

- **Tenure of the Committee:** 3 Years

- **Tenure of Chairperson:** Maximum 2 consecutive Terms of 3 years each

- **Tenure of Member – Secretary :** Maximum 2 consecutive Terms of 3 years each

- **Duties – of the officer bearers -**

- **Chairperson :**

- 1) The chairperson shall be responsible for conducting all committee meeting, and shall lead all Discussion and deliberations pertinent to the review of research proposals.
- 2) The chairperson shall preside over all administrative matters pertinent to the committee's Function.
- 3) In case of anticipated absence, the chairperson shall nominate a committee member as acting Chairperson. The acting chairperson will have all the powers of the chairperson **for that meeting.**

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○ **Member secretary :**

1) In consultation with the chairperson, the member secretary shall be responsible for the following Functions:

- 1 .Receiving all research proposals.
- 2 .Forwarding all materials for review to the committee members
- 3 .Establishing time limits for receipt of reviewer's comments for EC members
- 4 .Preparation and dissemination of agenda and venue for all committee meetings (at least 5day **prior** to the meeting date)
5. Inviting special attendees/experts, from relevant therapeutic areas to the scheduled meetings, if needed.
6. Preparation and circulation of minutes (within 7 days of the meeting).
7. Notification of review outcome to principal investigator of research proposal.
8. Retention and safe keeping of all records and documentation.
9. To perform other duties assigned by the chairperson.

○ **Duties of other member :**

1 .To review research proposals submitted to committee as per the mandate and protect the right and dignity of study participants .All the members shall maintain confidentiality of the deliberations.

All the office bearers of the committee shall execute a confidentiality / conflict of interest agreement prior to discharging their responsibilities.

2. Procedure for Establishing and constituting committee, Responsibility and composition of Committee:

1. Director, Belgaum Institute of Medical Sciences Belgaum will establish and constitute an Ethics committee To ensure a competent review of all ethical aspects of the project proposals forwarded by Institute monitoring committee for clinical research .The committee shall consider the Same free from any bias and influence that could affect their objective.

2. Responsibilities:

- 1 .To protect and safeguard the dignity ,rights , safety and well being of all actual or potential research participants, and vulnerable population.

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2. To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethnic consideration.
3. To advise the researchers on all aspects of the welfare and safety of research participants after ensuring the scientific soundness of the proposed research
4. To ensure that trials are sound in scientific design, have statistical validity and are conducted according to the guidelines ICH-GCP as well as local regulatory requirements
5. To ensure that no participants are admitted into the study without **Committee's written approval** for the conduct of the study.
6. All the members will sign a confidentiality/conflict of interest agreement. One copy of the agreement will be kept with the EC office and another copy will be provided to the members.

Composition:

- **Committee** will Comprise of total Ten (10) members including
 - *6 medical / biomedical scientists
 - *2 non-scientist
 - *1 Social worker
 - *1 legal expert or retired judge.

3. Procedure for Quorum requirement

1. The quorum for conducting the meeting is defined as 50% of the constituent members of the Committee, rounded off to the next higher whole number.
2. No quorum should consist entirely of members of one profession only. Quorum will include at least one member as non-scientist, at least one who is independent of the **Belgaum Institute of medical sciences**, and one medical /biomedical scientist.

4. Review procedure

1. The **Committee** will review all research proposals / studies on human participants.
2. The **Committee** will evaluate the possible risks to the participants with proper justifications benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
3. The Committee review will be done through formal meetings and will not restore to decision through circulation of proposal

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5. Types of Review: The Committee may conduct either expedited review or full board review:

- 1. Expedited Review:** For certain kinds of research involving no more than minimal risk, and for minor changes in approved research, the Committee Chair or a designated voting member or group of voting members shall review the proposed research rather than the entire committee.
- 2. Full Board Review:** When full board review is necessary, the research proposal is presented and discussed at a meeting at which a quorum of Committee members is present.

6. Meeting requirements

- 1.**All the **Committee** meetings will be held when ever a research proposal / study on human Participants are submitted (or once a month). Dates will be announced and notified in advance to all members. Additional review meetings may also be held with short notice as and when required and deemed necessary.
- 2.**Members will be given 5 days time in advance to review study proposal and the relevant Documents
- 3 .Committee** meetings will be recorded and the proceedings and deliberation will be documented and approved by the chairperson –**Ethics committee of the Belgaum Institute of medical sciences, BELGUM .**
- 4 .Independent** expert may be invited to the meeting or to provide written comment. The Invited experts will be required to sign a confidentiality /conflict of interest agreement from Prior to accessing the EC documents.

7. Procedure for submission of application

- 1 .The principal** investigator has to submit an application along with study protocol for the review of the **committee.**
- 2. All the** proposals received at least 7 days in advance from the scheduled meeting will be Included for review, otherwise they will be deferred to the next meeting.
- 3.**Twelve (12) copies of study proposal (with all other essential documents) must be submitted along with application form duly signed and dated by the investigator (s)
- 4 . On** receipt, the application from will be acknowledged (including the completeness of an application) by the office and will be allotted a registration number for all future correspondence and reference.
- 5. The Ethics committee office, Belgaum institute of medical sciences,** shall ensure that the applications are complete in all respects for trials proposed to be implemented at Belgaum institute of medical sciences, Belgaum, prior to their submission to the ethics Committee to expedite the review process

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8. Procedure for decision –making:

In making decision on application for the ethical review of any research proposal, committee

Will consider the following:

1. Member having the conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes.
2. Where there is conflict of interest, member will withdraw from the decision –making Procedure
3. Decision will only be taken at meeting where a quorum is complete
4. Decision will be taken only after reviewing a complete application with required documents Necessary for proposal has been examined by **Committee**
5. Only members who participated in review and discussion will participate in decision
6. Decision procedure will specify through clearance or conditional clearance, with clear suggestions and review procedure
7. Negative decision will be supported by clearly stated reasons and justifications
8. No person, who is not member of the Committee, will be allowed to participate in the proceedings of the meeting

9. Procedure for communicating the decision of Committee to the applicant / Principal Investigator

A decision of the Committee will be communicated to the applicant / principal Investigator in

Writing, within seven working days of the meeting at which the decision was taken.

10. Validity of approval and renewal of approval

1. Approval of the research protocol shall be valid for a period of one year from the date of issue.
2. In case the research project work exceeds one year, the PI shall seek renewal of approval at yearly intervals. The application for renewal of approval shall be submitted to the EC no later than 15 days prior to the expiry of approval.
3. In case of failure to comply with 10.2 above, the PI shall stop the trial and submit an application for approval. The research project will be treated as a fresh proposal.

11. Follow up procedure

1. **Committee** will review the progress of all the studies for which a positive decision has been reached, from the time of approval till the completion / termination of the research.

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2. Progress of all research proposals will be monitored at regular intervals of six months. However, in special situations **Committee** will conduct the follow up review at shorter intervals based on need, nature and events of research project. .
3. Following instance and events will require the **follow –up review**:
 1. Protocol amendment likely to affect , rights, safety or well being of research participants
In conduct of study
 2. Serious Adverse Events (SAEs) related to study or product, action taken by investigator
Sponsor and regulatory authority..
 3. Any events or information that may directly / indirectly affect the benefit /risk ratio of
The study.. .
 4. A decision of a follow up review will be issued and communicated to applicant
Indicating modification/suspension/termination/continuation of the project
 5. In case of premature suspension/termination, the applicant must notify the reasons to the
Committee for suspension/termination with a summary of results

12. Procedure for documentation and archiving:

1. All the documents and communications of **Committee** will be dated filed and archived in a Secured place..
2. Only the person, who is authorized by the chairman of **Committee**, will have the access to the Various documents. Under special circumstances, other person may be provided access to Various documents upon executing a confidentiality/conflict of interest agreement
3. All the documents related to research proposals will be archived for a minimum period of 15 years following the completion of the study. These will be:
 1. The constitution, written standard operating procedure of the **Committee**, and regular (Annual) reports.
 - 2 The curriculum vitae of all **Committee members**.
 3. A record of all incomes and expenses , if any, of the **Committee** , including allowances and reimbursements made to the secretariat and **Committee members**.
 4. The agenda of the **Committee** meetings.
 5. The minutes of the **Committee** meetings.
 6. One copy all materials submitted by an applicant.

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7. The correspondence by **Committee members** with applicants or concerned parties Regarding application, decision and follow-up
8. A copy of the decision and advice or requirements sent to an applicant.
9. The final summary or final report of the study.

13. Investigator's Responsibility

1. Report to the **Committee** any planned change in the study and to implement any changes without Receiving prior approval except to eliminate immediate hazards or when the changes involve Only logistical or administrative aspects of the study.
2. Investigator should promptly report to the **Committee the following:**
 1. Changes/amendment that increase the risk to study participants and/or those significantly affecting the conduct of the study.
 2. All deviations from the approved protocol or changes in the protocol to eliminate immediate hazards to the study participants.
 3. All serious Adverse Events (SAEs) within 72 hours of their occurrence.
 4. New information that may affect adversely the participants or the conduct of the study.
 5. Any changes in the study documents.
 6. Progress of the study once a year and the final report.

14. Dossier of essential documents to be submitted with the proposal

1. Application form.
2. The current version of the protocol of t he proposed research .
3. Case report forms, diary cards and other questionnaires intended for research.
4. Investigator's brochure
5. Investigator (s) curriculum vitae (updated, signed and dated)
6. Material to be used (including advertisements) for the recruitment of potential research participants

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7. A description of the process to be used to obtain and document consent
8. Written and other forms of information for potential research participants (clearly identified and Dated) in the language (s) understood by the potential research participants and, when required, in other languages Viz- Kannada, Marathi, Hindi.
9. Informed consent form understood by the potential research participants and when required in other languages Viz – Kannada, Marathi, Hindi. The document should be customized for the site by including Principal Investigator & chairman name, address & phone number of Belgaum Institute of Medical Sciences Belgaum Ethics committee.
10. Indicate amount of compensation to be paid to study participant/parents/Guardian in Informed consent form.
11. A statement describing any compensation for study participation (including expenses and access to medical care) and medical insurance (negligent and non-negligent) to be given to research participants or institutional policy of medical insurance.
12. All the letters of approval from the concerned regulatory authorities (e.g. Drug Controller General of India) etc.

The Standard Operating procedures will be reviewed / modified from time to time.

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No. BIMS/IEC / 2012-13

Date:27-07-2012

Proceedings of the Institutional Ethics Committee (IEC) meeting held on 25th JULY. 2012 at 2.30 PM in the Director's Chamber, Belgaum Institute of Medical Sciences, Belgaum.

The Member Secretary, IEC welcomed all the members.

The following members of the Ethics Committee were present.

- | | |
|--------------------------------|--------------------|
| 1. Dr. Ramaiah, Director, BIMS | - Chairman |
| 2. Dr. Basavaraj C. Kotintot | - Member Secretary |
| 3. Dr. S.T. Kalsad | - Member |
| 4. Dr. Rajashekar R. K. | - Member |
| 5. Dr. I. B. Havannavar | - Member |
| 6. Dr. M. M. Umadi | - Member |

The following members of the Ethics Committee were present.

The Protocol titled Tinea Capitis: 'A Study on prevalence and its causative agent among paediatric age group' Submitted by Principal investigator presented the study protocol.

- Study protocol reviewed by all members
The protocol was approved by BIMS, IEC committee

Meeting ended with vote of thanks.

**(Dr. Ramaiah)
Chairman, IEC,
BIMS,BELGAUM.**

1. Copy to Director's office for kind information.
2. Copy to All BIMS, IEC Members.

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No. BIMS/IEC

Date:19-11-2012

Proceedings of the Institutional Ethics Committee (IEC) meeting held on 7th Nov. 2012 at 9.30 AM in the MEU hall Belgaum Institute of Medical Sciences, Belgaum.

The Member Secretary, IEC welcomed all the members.

The following members of the Ethics Committee were present.

- | | |
|--------------------------------|--------------------|
| 1. Dr. Ramaiah, Director, BIMS | - Chairman |
| 2. Dr. Basavaraj C. Kotintot | - Member Secretary |
| 3. Dr. S.T. Kalsad | - Member |
| 4. Dr. Rajashekar R. K. | - Member |
| 5. Dr. I. B. Havannavar | - Member |
| 6. Dr. M. M. Umadi | - Member |
| 7. Dr. A. B. Halappanavar | - Member |

The following P. G. student's synopsis reviewed for ethical clearance

Sl. No	Title of the Protocol	Name of Applicant	Department
1.	“Brucellosis Among HIV Infected Patients Reporting to Anti Retro Viral Therapy (ART) Centre, BIMS Hospital, Belgaum – A seroclinic Study”	Dr. Rajalaxmi D.	Microbiology
2.	“Role of Myeloperoxidase and Lipid Peroxidation in Acute Myocardial Infarction”	Dr. Fatima Farheen	Biochemistry
3.	“Comparative Study of Oxidative Stress Antioxidants, HDL and apo A-I in Whisky and Rum Consumers”	Dr. Atteeque ur Rehman. M. Harlapur	Biochemistry
4.	“Prospective drug utilization Study of Corticosteroids in Dermatology Unit of Tertiary Care Hospital”	Dr. Vijaykumar Lakshman Lamani	Pharmacology
5.	“Thyroid Cytology Evaluation Based on Bethesda System – A Two Years Prospective Study at Belgaum Institute of Medical Sciences, Belgaum”	Dr. Gudaganatti Sunil Basappa	Pathology
6.	“Histopathological Spectrum of Lesions in Aorta - AN Autopsy Study”	Dr. Fernandes Baptist Francis Jason	Pathology
7.	“Randomized Controlled Trial of Intravenous Fluid Supplementation on Serum Bilirubin Level During Phototherapy of Term Infants with Severe Hyperbilirubinemia”	Dr. Meenakshi	Paediatrics

Contd...2

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8.	“Profile of Noninfectious Mucocutaneous Manifestations Among HIV Infected Individuals - A Cross Sectional Study at Belgaum Institute of Medical Sciences, Belgaum”	Dr. Pooja Devi Malipatil	Dermatology
9	“Incidence of Poisoning at BIMS Hospital, Belgaum – A Prospective Study”	Dr. Rashmi K. S.	Forensic Medicine & Toxicology
10	“ Pattern of Violent Asphyxial Deaths -A Prospective Study”	Dr. Gopal Govinda Hargi	Forensic Medicine & Toxicology
11	“Regression Equation for Estimation of Total Length of Humerus from its Segments”	Dr. Kirankumar R.	Anatomy
12	“ A Study of Socio-Occupational and Lifestyle Factors Affecting the Health of Bank Employees in Belgaum City”	Dr. Pavithra R.	Community Medicine
13	“Impact of Nutritional Education with or Without Supplementation Through Peer Counselors on Nutritional Status of Malnourished Children Under Five Years of Age-A Community Based Approach to Malnutrition”	Dr. Suresh C. M.	Community Medicine

The necessary corrections are suggested by committee members.

All the protocols approved by IEC, BIMS with subject to incorporation of IEC members suggested modifications.

Meeting ended with vote of thanks.

**(Dr. Ramaiah)
Chairman, IEC,
BIMS,BELGAUM.**

Copy to All BIMS, IEC Members.

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No. BIMS/IEC / 2012-13

Date:08-02-2012

Proceedings of the Institutional Ethics Committee (IEC) meeting held on 7th Feb. 2012 at 03.30 PM in the Director's Chamber, Belgaum Institute of Medical Sciences, Belgaum.

The following Member of the Ethics Committee were present

- | | |
|--------------------------------|--------------------|
| 1. Dr. Ramaiah, Director, BIMS | - Chairman |
| 2. Dr. Basavaraj C. Kotintot | - Member Secretary |
| 3. Dr. S.T. Kalsad | - Member |
| 5. Dr. A. B. Halappanavar | - Member |
| 6. Dr. M. M. Umadi | - Member |

The Member Secretary, IEC welcomed all the members.

The Protocol titled "Study of Cardiovascular Response Cytomorphology of Buccal Mucosa and Psychological Changes in Tobacco Chewers with Correlation to Urine Cotinine" Submitted by Principal investigator presented the study protocol.

- Study protocol reviewed by all members

The protocol was approved by BIMS, IEC committee

Meeting ended with vote of thanks.

**(Dr. Ramaiah)
Chairman, IEC,
BIMS,BELGAUM.**

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O/W NO. /IEC/BIMS/2013-14

Date:21/11/2013

Institutional Ethical Committee meeting held on 19-11-2013 at 9.30 AM in the college MEU hall BIMS, Belgaum to review post graduate student's dissertations protocols. All the following protocols reviewed and cleared by Institutional ethical committee

Sl. No	Title	Name of Applicant & PG Guide	Department
1.	EFFECT OF AUTOLOGOUS SERUM THERAPY IN PATIENTS WITH CHRONIC IDIOPATHIC URTICARIA - A PROSPECTIVE, RANDOMIZED, PLACEBO-CONTROLLED ,SINGLE BLINDED STUDY	Dr. Naveen Kumar.V Guide: Dr. Shilpa V. Dastikoppa. Asso.Prof	Dermatology
2	SERUM ADENOSINE DEAMINASE ACTIVITY IN HIV PATIENTS ON ANTIRETROVIRAL THERAPY	Dr. Sneha Prakash Allavar Guide: Dr. Shashikant V. Nikam Prof. & HOD	Biochemistry
3	LECITHIN CHOLESTEROL ACYL TRANSFERASE (LCAT) ACTIVITY AND APOLIPOPROTEIN A-I (apo A-I) IN HIV PATIENTS	Dr. Akshata Mirajkar Guide: Dr. Shashikant V. Nikam Prof. & HOD	Biochemistry
4	NEONATAL SEPTICEMIA - A CLINICOBACTERIOLOGICAL STUDY	Dr. Deepti R Angadi Guide: Dr. B. G. Mantur. Prof. & HOD	Microbiology
5	SCREENING OF ANTI-ULCER ACTIVITY OF ASPARAGUS RACEMOSUS ROOT EXTRACT ON PEPTIC ULCER MODELS IN ALBINO RATS	Dr. Amardeep Guide: Dr. Basavaraj C K. Prof. & HOD	Pharmacology
6	FINE NEEDLE ASPIRATION CYTOLOGY OF LYMPHNODES IN HIV POSITIVE PATIENTS WITH CD4 COUNT CORRELATION	Dr. Sadia Siddiq Nasser Guide: Dr. Rashmi K. Patil Asst. . Professor	Pathology
7	CORRELATION OF BREAST CARCINOMA AND SERUM HEPATOCYTE GROWTH FACTOR - A PROSPECTIVE STUDY	Dr. Prathiksha Pai. Guide: Dr. S. K. Kittur Prof. & HOD	Pathology
8	DETAILED STUDY OF LEFT CORONARY ARTERY IN CADAVERIC HUMAN HEARTS	Dr. Pratik Khona Guide:	Anatomy
9	ANTHROPOMETRIC STUDY OF PROXIMAL FEMORAL GEOMETRY IN INDIAN POPULATION AND ITS CLINICAL APPLICATION"	Dr. Samita Rani Guide:	Anatomy
10	"STUDY OF OUTCOME OF CHILDREN HOSPITALIZED WITH COMMUNITY ACQUIRED PNEUMONIA TREATED WITH AQUEOUS PENICILLIN G IN BELGAUM INSTITUTE OF MEDICAL SCIENCES (BIMS)	Dr. Udaya K Guide: Dr. Arun S. Desai Prof. & HOD	Paediatrics
11	PROFILE OF SUICIDAL DEATHS AUTOPSIED AT BELGAUM INSTITUTE OF MEDICAL SCIENCES, BELGAUM: A CROSS SECTIONAL STUDY	Dr. Hari Prasad V Guide: Dr. Ashok Kumar Shetty. Asso. Prof I/C HOD	Forensic Medicine & Toxicology

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12	PATTERN OF PEDESTRIAN INJURIES SUSTAINED DURING ROAD TRAFFIC ACCIDENTS IN AUTOPSIEDCASES AT BELGAUM INSTITUTE OF MEDICAL SCIENCES, BELGAUM: A CROSS SECTIONAL STUDY	Dr. Keshava. H. B. Guide: Dr. K. S. Gurudut. Asst. Professor	Forensic Medicine & Toxicology
13	A CROSS SECTIONAL STUDY OF CARDIOVASCULAR AUTONOMIC FUNCTIONS AMONG FIRST YEAR MEDICAL STUDENTS,IN BIMS BELGAUM	Dr. Mahanthes Y D Guide: Dr. Rajashekar R K. Prof. & HOD	Physiology
14	EVALUATION OF RESPIRATORY MORBIDITY AND GENERAL HEALTH PROFILE OF WEAVERS IN URBAN BELGAUM: A CROSS SECTIONAL STUDY	Dr. Fawwad M. Shaikh Guide: Dr.R.G Viveki Asso. Professor	Community Medicine
15	A CROSS SECTIONAL STUDY TO ASSESS RISK FACTORS FOR CARDIOVASCULAR DISEASE AMONG ANGANWADI TEACHERS IN URBAN ICDS BLOCK –BELGAUM	Dr. Varsha M Bhamaikar Guide: Dr. Shobha Karikatti Asso. . Professor	Community Medicine

Dr. Ramaiah
Chairman
Institutional Ethical Committee
BIMS, Belgaum

- Copy to 1. Director BIMS, Belgaum for kind information
2. Copy to IEC members, PG Guides and PG students