

#### || विशे इसे इपरप्रवेहर ||

### ADICHUNCHANAGIRI UNIVERSITY BGS MCH HOSPITAL



BGS Vignatam South Campus, Nagarur, Dasanapur, Bangalore North - 562 123 E-mail : bgsmchhospital@acu.edu.in | Contact : 080-29914404, 9591187490

#### UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and current work place/organization of the Chairman

Dr. Byresh A, Principal, Adichunchungiri Ayurvedic Medical College, Hospital & Research Center Nagarur, Dasanupura Nelamanagala, Bangalore -562123

2. Name and complete address of office of the Ethics Committee

BGS Medical College & Hospital (Affiliated to Adichunchangiri University) BGS Vignatam South Campus Nagarur, Dasanupura Bangalore- 562123

3. Name, address, qualifications (specialization), current work place/organization, designation of the members of the Ethics Committee and affiliation status of each member of Ethics Committee with the Institute/organization that has constituted Ethics Committee.

SI No	Ethical Committee members	Qualificat ion	Designation	Affiliation to BGS	Phone number	Email ID	Member's specialty
1	Dr. Byresh A, Principal, Adichunchungiri Ayurvedic Medical College, Hospital & RC, Nagarur, Blore0562123	BAMS, MD	Chairman	No	9480869982	aamchrcbengaluru @gmail.com	Scientific
2	Dr. Malini. S, Associate Professor, Pharmacology, BGS MCH, Nagarur, Blore-562123	MBBS, MD	Member Secretary	Yes	9886497255	drsmalini@gmail.c om	Scientific
3	Bhante Sugathananda, Member Secretary, Mahabodhi Society, Bangalore	Theology studies	Spiritual Religious	No	9945992082	info@mahabodhi.in fo	Non-scienti fic;
4	Mr. Virupaksha, Law Officer, Adichunchangiri University, BG Nagara, Nagamangala Taluk 571432, Mandya District	BA, LLB(Law)	Legal expert	No	9845460704	h.virupaksha99@ gmail.com	Non-scienti fic
5	Dr. Raghuram v., Professor & Head, Community medicine, BGS MCH, Nagarur, Blore- 562123	MBBS, MD	Member- Clinician (community health)	Yes	9986863110	raghu3873@gmail. com	Scientific
6	Dr. Ashok, Kayachikitsa, Ayurveda College, Nagarur, Blore- 562123	BAMS MD(Ayur veda)	Member- Clinician (Ayurveda)	No	9916077183	drashokmgowder @gmail.com	Scientific
7	Dr. Sushma Krishna, Assistant Professor, Microbiology, BGS MCH, Nagarur, Blore-562123	MBBS, MD, MPH	Member- Medical scientist-	Yes	9740882970	drsushmakrishna1 @gmail.com	Scientific
8	Dr. Ravi, Assisted Professor, Orthopedics, BGS MCH, Nagarur, Blore-562123	MBBS, MS	Member Clinician	yes	9535311740	drraviks@bgsaims. edu.in	Scientific
9	Dr. Bindushree, Dentistry, BGS MCH, Nagarur, Blore- 562123	BDS, MDS	Member-Clinicia n (Dentistry)	Yes	8197716929	bindushreerv@gm ail.com	Scientific
10	Mrs. Jyothi, Old Age Home Social	BA	Member-Social	No	8310812876		Non-scienti





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				04405607777	bgshospital562123	Non-scienti
Mr. Shreyas A Gowda, Bhairavanagar, RV College Post, Bangalore-560059	BSc	Lay person	Yes	9113562727	@gmail.com	fic

#### 4. Commitments.

- I. 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 the New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and well-being of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.
- II. 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 shah 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.
- III. The Ethics Committee shall allow any officer authorized by the Central Licensing 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.

iv. 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.

(Signature of the Chairperson)
Date:

CHAIRMAN

BGS MCH ETHICS COMMITTEE

BGS MCH-HOSPITAL

Nagarur, Bengaluru North - 562 123.

(Signature of the Member Secretary)
Date: 05/03/2024

MEMBER SECRETARY
BGS MCH ETHICS COMMITTEE
BGS MCH-HOSPITAL
Nagarur, Bengaluru North - 562 123.



#### || विशे इसे द्वारायेहर ||

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BGS Vignatam South Campus, Nagarur, Dasanapur, Bangalore North - 562 123 E-mail: bgsmchhospital@acu.edu.in | Contact: 080-29914404, 9591187490

Date: 04/02/2024

From. The Dean's Office, BGS Medical College & Hospital Nagarur, Bangalore

#### **Authority Letter**

Sub: Appointment the Chairman and Member Secretary at the inception of the IEC

The Authority of BGS Medical College & Hospital, Nagarur is pleased to appoint the Chairman and the Member Secretary for the Institutional Ethics Committee.

Sl No	Ethical Committee members	Qualification	Designation
1	Dr. Byresh A, Principal, Adichunchungiri Ayurvedic Medical College, Hospital & RC, Nagarur, Blore-562123	BAMS, MD	Chairman
2	Dr. Malini. S, Associate Professor, Pharmacology, BCS Medical College Hospital, Nagarur, Blore-562123	MBBS, MD	Member Secretary

With Regards,

Copy to Dr. K.S. CAD M.S. (ENT)

Dean cum Principal Instituti**ng ៅក្រុង** ក្រុម្ភារុទ្ធន Committee Office (at Inception)

2. BASiVijnatehu இவர்ப்பெரியூக்கூர், Mandya Nagarur, Dasanapura Bengaluru North - 562 123



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BGS Vignatam South Campus, Nagarur, Dasanapur, Bangalore North - 562 123 E-mail : bgsmchhospital@acu.edu.in | Contact : 080-29914404, 9591187490

Date:29 /02/2024

From, The Dean's Office, BGS Medical College & Hospital Nagarur, Bangalore

#### **Authority Letter**

#### Sub: Appointment the new IEC members at the inception of the IEC

The Authority of BGS Medical College & Hospital, in consultation with Chairman of IEC is pleased to appoint the following members as the Institutional Ethics Committee members. The following members are required to attend the IEC meeting and sign the acceptance of the same.

- Dr. Byresh A, Principal, Adichunchungiri Ayurvedic Medical College, Nagarur, as Chairman
- 2. Dr. Malini. S, Associate Professor, Pharmacology, as Member Secretary
- 3. Mr. Virupaksha, Mandya, as legal expert
- 4. Ven. Bhante Sugathananda, Mahabodhi Society, as Spiritual person
- 5. Dr. Raghuram V, Professor & Head, Community medicine, as Clinician-Community Health
- 6. Dr. Ashok, Kayachiktsa, as Clinician-Ayurveda
- 7. Dr. Sushma Krishna, Assistant Professor, Microbiology, as BioMedical Scientist
- 8. Dr. Ravi, Assistant Professor, Orthopaedics as Clinician
- 9. Dr. Bindushree, Dentist, as clinician- Dentistry
- 10. Mr. Shreyas A Gowda as lay person
- 11. Mrs. Jyothi, Nagarur as Medical Social Worker



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SI No	Ethical Committee members	Qualification	Designation	Acceptance Signatures
1	Dr. Byresh A, Principal, Adichunchungiri Ayurvedic Medical College, Hospital & RC, Nagarur, Blore-562123	BAMS, MD	Chairman	Someth
2	Dr. Malini. S, Associate Professor, Pharmacology, BGS MCH, Nagarur, Blore-562123	MBBS, MD	Member Secretary	
3	Bhante Sugathananda, Member Secretary, Mahabodhi Society, Bangalore	Theology studies	Spiritual person	Sayl- De
4	Mr. Virupaksha, Law Officer, Adichunchangiri University, BC Nagara, Nagamangala Taluk 571432, Mandya, District	BA, LLB(Law)	Legal expert	#
5	Dr. Raghuram , Professor & Head, Community medicine, BGS MCH, Nagarur, Blore- 562123	MBBS, MD	Member- Clinician (community health)	Rashulm V
6	Dr. Ashok, Kayachikitsa, Ayurveda College, Nagarur, Blore- 562123	BAMS MD(Ayurveda)	Member- Clinician (Ayurveda)	distr.
7	Dr. Sushma Krishna, Assistant Professor, Microbiology, BGS MCH, Nagarur, Blore-562123	MBBS, MD, MPH	Member- Bio Medical scientist	Sinhe Kucha
8	Dr. Ravi, Associate Professor, Orthopedics, BGS MCH, Nagarur, Blore-562123	MBBS, MS	Member Clinician	Rosilal
9	Dr. Bindushree, Dentistry, BGS MCH, Nagarur, Blore- 562123	BDS, MDS	Member-Clinician (Dentistry)	Bidaly.
10	Mrs. Jyothi, Old Age Home Social Worker, Kanva Nagar, 562123	ВА	Member-Social Worker	youti-c
11	Mr. Shreyas A Gowda, Bhairavanagar, RV College Post, Bangalore-560059	BSc	Member-Lay person	A Level

Dean & Principal Date:

M.S. (ENT)
Dear cum Principal
BGS MCH,

BGS MCH,
BGS Vijnatam South Campus,
Nagarur, Dasanapura
Bengaluru North - 562 123



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Office Circular No. 36

Date:

From	То
Dean & Principal, BGS Medical College & Hospital, Nagarur, Bangalore	To the inception IEC members

Dear Colleagues,

The 1st Institutional Ethical Committee Meeting is scheduled as below-

Date: 02/02/2024

Time: 11am

Venue: Dean's Office, BGS Medical College & Hospital, Nagarur, Bangalore

Agenda of the 1st IEC meeting -

- 1. Appointment of Chairman and Member Secretary of the IEC
- 2. Issue of authority letter for the composition of members for IEC
- 3. Information to the IEC Members of their designation in IEC.
- Assigning formulation of SOP to Member secretary & 1-2 IEC members (appointed by chairman) in the next 30 days

Regards,

Dr. K.S. GANGADHARA

Dean cum Principal BGS MCH,

BGS Vijnatam South Campus, Nagarur, Dasanapura Bengaluru North - 562 123

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### Minutes of the 1st Institutional Ethics Committee (IEC) Inception Meeting BGS Medical College & Hospital, Nagarur, Bangalore

Ref to. Office Circular No.

Date:

The  $1^{st}$  IEC meeting was conveyed by the Authority on 02/02/2024 at the Dean & Principal's office, BGS MCH, Bangalore.

The following personnel attended the meeting-

- 1. Dr. Byresh, Pricipal, Adichunchangiri Ayurveda College, Nagarur
- 2. Dr. Malini, Pharmacologist, BGS Medical College & Hospital
- 3. Dr. Sushma Krishna, Microbiologist, BGS Medical College & Hospital
- 4. Dr. Ravi, Orthopedician, BGS Medical College & Hospital
- 5. Mr. Shreyas Gowda, Lay Person, Bhairavnagar

The following agenda were put forwards as actions during the meeting-

- Appointment of Dr. Byresh as the Chairman of the IEC and Dr. Malini S as the Member Secretary
- 2. Issue of authority letter for the composition of members for IEC.
- 3. Assigning Member Secretary to carry on the role of Agenda preparation, meeting procedures and minutes of the meeting for subsequent meetings
- 4. Information to the IEC Members, their acceptance of their designation in IEC.
- 5. Assigning formulation of SOP to Member secretary & 1-2 IEC members (appointed by chairman) in the next 30 days.

### Attendance sheet of 1st IEC meeting on 02/02/2024

	Name	Designated role in IEC	Signature
1	DR. BYRESH. A	CHAIRMAN	Partients
2	DR. S. MALINI	Member Secretary	Clap
3	DR, SUSHMA KRISHNA	Bio Medical Scientist	Svohna Cudha
4	Dr. RAVI, G.R.	CLINDUCAN	Kenlak
5			
6			
7			

Meeting proceedings Prepared by

Member Secretary

Date:





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Ref No. BGS MCH/IEC/01/2024-25 27/02/2024 Date:

From	То
Member Secretary IEC	To all the IEC members

Dear Members,

The 2<sup>nd</sup> Institutional Ethical Committee Meeting is scheduled as below-

Date: 29/02/2024

Time: 10am

Venue: Board Room, New Building, BGS Medical College & Hospital, Nagarur,

Bangalore

We humbly invite our Dean & Principal Dr. Gangadhar as our invitee for the meeting.

Agenda of the 2nd IEC meeting -

- 1. To Welcome the new members
- 2. To brief about the member's roles and responsibilities
- 3. To review the Formulated Draft SOP, discussion and approval by the members
- 4. To discuss about the Training programs for the year for the IEC members

Regards,

MEMBER SECRETARY
BGS MCH ETHICS COMMITTEE
BGS MCH-HOSPITAL
Nagarur, Bengaluru North - 562 123.

Member Secretary

Copy to-

- 1. IEC Office
- 2. Dean & Principal's office, BGS MCH





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Ref No. BGS MCH/IEC/01/2024-25

Date: 05/03/2024

To,

The Dean and Principal, BGS Medical College & Hospital, Nagarur, Bangalore

Respected Sir,

The 2<sup>nd</sup> IEC meeting was held on 29/02/2024 at the Board Room, BGS Medical College & Hospital, at 10am.

The meeting was conveyed by the Member Secretary. The following members were present for the 2<sup>nd</sup> IEC-

- 1. Mr. Byresh A, Chairman
- 2. Dr. Malini S, Member Secretary
- 3. Ven. Bhante Sugathananda, Spiritual person
- 4. Dr. Raghuram B, Professor & Head, Community medicine
- 5. Dr. Ashok, Ayurveda
- 6. Dr. Sushma Krishna, Assistant Professor, Microbiology
- 7. Dr. Ravi, Assistant Professor, Orthopaedics
- 8. Dr. Bindushree, Dentistry
- 9. Mr. Shreyas A Gowda, Lay person
- 10. Mrs. Jyothi, Social Worker

Mr. Virupaksha, Legal Expert could not attend the meeting.

The following activities were discussed by the IEC members-

- 1. Minutes of the previous meetings were confirmed
- 2. **Greeting of the new members and welcome addressal:** The authority welcomed the new members with introductory speech
  - A) on the four principles of the IEC operation-autonomy, beneficence, non-maleficence and justice.
  - B) The authority emphasised the role of IEC in the clinical Trials in the coming days.
  - C) The IEC members were guided to strengthen the methodologies of research proposals received with the help of statistician.
  - D) The IEC members were told to be kept informed of all the future research publications coming from the medical college & Hospital.
  - E) The research proposals from Ayurveda College would also be screened by the IEC members after the MOU.
- 3. **Discussion on the roles and responsibilities of IEC members**: was undertaken by the Member Secretary and the members agreed to the same
- Review of the Formulated Draft SOP: All members will be forwarded a copy of drafted SOP- it will open for discussion and approval by the members for the next 15 days and subsequently will be forwarded to Chairman
- Registration of the IEC: The Member Secretary was guided to take note of the regulatory requirements and proceed with the registrations on DHR and CDSCO
- 6. Training programs for the IEC members in 2024-
  - A) NIE-ICMRs Bioethics online course was suggested for the members.
  - B) On-spot in-person training by ICSR training will be held at the campus on 16/03/2024

From,