



SDMVMS

Sou Shantadevi Vedprakash Patil Ayurved College & Research Institute Hatta



Date: 3 Dec 2020

Time: 11.00 am

Venue: CONFERENCE HALL, SSV PAC, HATTA

As per last meeting held on 9 Dec 2019 previous key points were discussed and meeting was proceed further.

As per chairperson suggested standard operative procedures (SOP) were formed by member secretary and were distributed in hard copies to all the IEC members, constituent department of institute. SOP was discussed in meeting and was suggested to follow the same.

Copies enclosed:

1. Slandered operative procedures for IEC



Members	SIGNATURE
Mr. Umesh Jadhav	
Adv. Yogesh Agrawal	
Sharika Siddiqui	
Dr. Deepali Agrawal	
Dr. Vilas Khanapurkar	
Dr. Swami B D	
Dr. Hemant Aderao	
Dr. Snehal Akhare	
Dr. Vijay Maske	

21/12/20

DR KAHALEKAR DHANANJAY
MEMBER SECRETARY

SECRETARY
IEC, SSV PAC & RI
Hatta, Tq. Basmath Dist. Hingoli

DR RAMESH INGOLE
CHAIRMAN

CHAIRMAN
IEC, SSV PAC & RI
Hatta, Tq. Basmath Dist. Hingoli



Shri Dhaneshwari Manav Vikas Mandal's

Sau. Shantadevi Vedprakash Patil Ayurved College & Research Institute

(Recognised by Ayush Ministry-New Delhi, Govt. of
Maharashtra & Affiliated by Maharashtra University of Health Sciences, Nashik)

Dr. V.K. Patil
(President)



Dr. Manikrao Kulkarni
(Principal)



Standard Operating Procedures (SOP) Related to Institutional Ethics Committee


Standard Operating Procedures (SOP) Related to Institutional Ethics Committee

1. Writing, Reviewing, Distributing and Amending Standard Operating Procedures for IECs

The SOP will be written by experts as per the guidelines of ICMR as and when amended. The written copies will be sent for review to the scientific committee of the institution. After approval the document will be digitalized and kept in file for office record. The printed copies of SOP will be distributed to each and every member of newly formed Institutional Ethics Committee every time. The SOPs will be amended as and when required on the basis of issues faced in due course of time.

2. Constituting an Ethics Committee

Institutional Ethics Committee shall be constituted as per ICMR guidelines As per the latest guidelines composition of Institutional Ethics Committee of Sau shantadevi vedprakash patil ayurved college and research institute is as under-



Sr. No.	Member	Qualification	No of Posts
1	Chairperson Non-affiliated	A well-respected person from any background with prior experience of having served/serving in an EC	01
	Vice Chairperson Non-affiliated	A well-respected person from any background with prior experience of having served/serving in an EC	01
	Member Secretary Affiliated	A staff member of the institution Should have knowledge and experience in clinical research and ethics, Be motivated and have good communication skills	01
	Alternate Member Secretary Affiliated	A staff member of the institution Should have knowledge and experience in clinical research and ethics, Be motivated and have good communication skills	01
5	Basic Medical Scientists Non-affiliated	Medical person with qualifications in basic medical sciences (1 each from Ayurveda and Allopathic system of medicine)	02
6	Basic Medical Scientist Non-affiliated	Pharmacologist	01
7	Clinician Non-affiliated	An individual with recognized medical qualification, expertise and training (Allopathic)	01
8	Clinician Affiliated	An individual with recognized medical qualification, expertise and training (Ayurvedic)	01
9	Legal expert Non-affiliated	Basic degree in Law from a recognized university, with experience	01
10	Social scientist/ philosopher/ ethicist/theologian Non-affiliated	An individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	01
11	Lay person Non-affiliated	Literate person who has not pursued a medical science/ health related career in the last 5 years May be a representative of the community and aware of the local language, cultural and moral values of the community Desirable: involved in social and community welfare activities	01

3. Confidentiality Agreements

At the time of every meeting a written confidentiality statement shall be undertaken in relation to the every topic of discussion from the present members of Institutional Ethics Committee

4. Conflict of Interest Agreements

A paper of having conflict of interest shall be undertaken from those members if he or she has any conflict of interest in the topic to be discussed in the meeting. Such members shall remain absent while taking any decision related to that specific topic,

5. Training Personnel and EC Members

All the members of Institutional Ethics Committee shall have to go through training from the Competent Authority from Government as and when specified organized by the authority in case any member has not taken training. At the time of appointment as a member of IEC, an undertaking regarding the willingness of training shall be taken from those members who have not taken the training from government authority.

6. Categorization of Submitted Protocols for Ethics Review

The principal investigator (PI) shall have to submit his/her new or amended research protocol to the member secretary of IEC through head of the institution or Director Ayurved Sanshodhan Vibhag in two hard copies along with application from specified in Annexure. Submitted protocols shall be noted in inward register of IEC office.

The research protocols submitted by Principal Investigator shall be categorized as under-

a) Initial Full Committee Review of New Research Protocols - This category consists of all new clinical study protocols

b) Expedited Review of Research Protocols –

This category consists of all clinical research protocols for renewal of IEC approval within one year. Corrected and amended protocols after suggestions from IEC in its previous meeting.

c) Exemption from Ethics Review of Research Protocols

This category consists of research proposals of retrospective nature

Preclinical study protocols

Laboratory experimental research protocols

7. Agenda Preparation, Meeting Procedures and Minutes

The principal investigator (PI) shall have to submit his/her new or amended research protocol to the member secretary of IEC through head of the institution or Director Ayurved Sanshodhan Vibhag in two hard copies along with application from specified in Annexure.

Submitted protocols shall be noted in inward register of IEC office and sorting shall be done on the basis of nature of the protocol.

The list of received protocols along with one hard copy shall be send to the Chair person of IEC for deciding the date of IEC meeting.

The date of IEC meeting shall be communicated to the principal investigator (PI) within 8 working days from the date of submission of research protocol.

PI of new research protocol shall present his/her research topic physically using PPT a stipulated time before IEC in a meeting for ethical clearance. There shall no need of PPT presentation for the category of Expedited Review protocols.

After every presentation there shall have a discussion regarding the ethical issues related to concerned topic. The remarks of IEC shall be recorded in minutes.

The decision shall be communicated in writing in a specified format (Annexure) within 3 working days to the PI The approval of IEC shall be valid for 6 months.

PI shall submit one hard copy of Final Study Report after completion of the research project.

8. Review of Resubmitted Protocols

Procedure of point no 7 shall be applicable to review of resubmitted new protocols.

9. Review of Protocol Amendments

The procedure shall be applicable to the amended protocols depending upon their classification on the basis of risk factor.

10. Continuing Review of Protocols

All non-exempt long term research protocols shall be reviewed once in a year. The same procedures for ethical clearance shall be applicable as in point no 9, but in such cases the PI shall have to submit annual progress report of his/her research project.

11. Review of Final Reports

As the final reports of research projects are placed in Expedited Review category, there shall have no need of IEC meeting. The remarks of Member secretary and Chair person shall be noted on the report

12. Review of Serious Adverse Events (SAE) Reports

SAE reports received from the PI shall be reviewed by Chair person an decision of keeping the issue on agenda before IEC meeting shall be factor of SAE.

13. Management of Premature Termination, Suspension, and Discontinuity

Considering the documents received from PI the Chair person shall deci on the conduction of research project.

14. Site Monitoring Visits

The monitoring visits shall be arranged once in year for long term researc The decision of visiting the site shall be taken by Chair person depending research protocol in relation with the projects other than long term researc

15. Dealing with Participants' Requests and Complaints

The requests and complaints received from the participants shall be put bef Depending upon the risk factor and seriousness the issue shall be dis meeting

The decision shall be communicated to PI and the concerned participant in working days from the meeting

16. Emergency Meetings

An emergency meetings shall be arranged on the serious issues obtained as and when. An emergency meeting shall be arranged within three working days on digital intimation and the hardcopies of such communication shall be preserved in the office file.

The decision shall be communicated to the PI and concerned in written within two working days from the meeting.

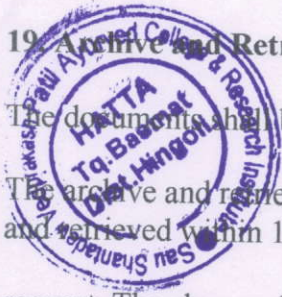
17. Communication Records

The communication record shall be preserved in hard copy at the office of IEC in the college building.

The record shall be preserved for five years after completion of the clinical study.

18. Maintenance of Active Study Files

Files of the active study shall be maintained by a clerk fully or partly dedicated for IEC under the supervision of member secretary if IEC till the completion of clinical study



19. Archive and Retrieval of Documents

The documents shall be archived and retrieved on request of the participant, authority for legal purpose only.

The archive and retrieval of documents shall be limited up to 5 years back. The documents shall be archived and retrieved within 15 working days from the receipt of

request. The charges for archive and retrieval shall be borne by the concerned PI/Institution

20. Maintaining Confidentiality of EC's Documents

For the maintenance of confidentiality the document handling powers of the active study shall be restricted to The chairman, member secretary and concerned clerk of IEC. The document handling powers of completed study shall be restricted to The member secretary of IEC only

21. Reviewing Proposals involving Vulnerable Populations

In case of reviewing proposals involving vulnerable population the informed consent must be obtained from the legal representative of the participant In this regard the PI shall submit three monthly progress report to IEC

22. Review and Inspection of the EC

The review and inspections from Government and Legal authority shall be faced by The chairman and member secretary of IEC as and when required. All the members of IEC shall be present for the review and inspection of Government and legal authority

23. Audio Visual Recording of the Informed Consent Process

Audio Visual recording of the Informed Consent process shall not be mandatory for cache and every clinical study Audio Visual recording of the informed consent process may be applicable on the request of PI or the Government or Legal authority.

The digital data of the same shall be preserved in the separate hard disk secured with password



PRINCIPAL
S.S.V.P. Ayurved College & R.I.
Hattta, Tq. Basmath Dist. Hingoli



Shri Dhaneshwari Manav Vikas Mandal's

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Dr. V.K. Patil
(President)



Dr. Manikrao Kulkarni
(Principal)

Institutional Ethical Committee Members

Date :- 21-2-24

Sr.No.	Name of member	Designation	Role in committee
1	Dr. Ramesh Ingale	Principal college of Pharmacy (B.Pharm) Pathri Dist: Parbhani	Chairperson
2	Dr.Dhananjay N. kahalekar	Professor and HOD Dept Kayachiitsa	Secretary
3	Mr. Umesh Jadhav	Principal,SVP college of Pharmacy Hattat	Expert(Pharmaceutics)
4	Adv.Yogesh Agrawal	Advocate	Legal Advisor
5	Sharika Siddiqui	Social worker	Social worker
6	Ram Kale		Layman

Institutional Members (Clinical/Para-clinical/Non-clinical)

Sr.No.	Name of member	Designation	Role in committee
1	Dr.Deepali Agrawal	Professor Dept Rognidan	Member
2	Dr.Sagar Magar	Associate professor Dept Panchakarma	Member
3	Dr.Yogesh Madgulwar	Assistant Professor Dept RSBK	Member
4	Dr Ashish Zanwar	Assistant Professor Dept Kayachikitsa	Member
5	Dr Rupali patil	Assistant Professor Dept Sharirkriya	Member
6	Dr.Deshmukh P.S	Assistant Professor Dept Samhita	Member



1 of 2

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(President)



Dr. Manikrao Kulkarni
(Principal)

Date: -21-2-24

Copy to:

Dr. Ramesh Ingale	<i>Ramesh Ingale</i>
Dr. Dhananjay N. Kahalekar	<i>Dhananjay N. Kahalekar</i>
Mr. Umesh Jadhav	<i>Umesh Jadhav</i>
Adv. Yogesh Agrawal	<i>Yogesh Agrawal</i>
Sharika Siddiqui	<i>Sharika Siddiqui</i>
Dr. Deepali Agrawal	<i>Deepali Agrawal</i>
Dr. Sagar Magar	<i>Sagar Magar</i>
Dr. Yogesh Madgulwar	<i>Yogesh Madgulwar</i>
Dr. Ashish Zanwar	<i>Ashish Zanwar</i>
Dr. Rupali Patil	<i>Rupali Patil</i>
Dr. Deshmukh P.S.	<i>Deshmukh P.S.</i>



(Signature)

(Dr. Manikrao. H. Kulkarni)

Principal
PRINCIPAL

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(President)

Dr. Manikrao Kulkarni
(Principal)

Institutional Ethical Committee



Date: 10 DEC 2023

Time: 11.00 am

Venue: CONFERENCE HALL, SSV PAC,
HATTA

As per discussion made in college council meeting for new formation of IEC as soon as possible for approving research protocols of the institute. As per ICMR guidelines IEC was made and will be functioning from today onwards.

IEC chairperson, member secretary and members were selected in and out of the institute as per norms. They are as follows.

Members

Sr.No.	Name of member	Designation	Role in committee
1	Dr. Ramesh Ingole	Principal College Of Pharmacy(B.Pharm) Pathri Dist: Parbhani	Chairperson
2	Dr. Dhananjay N. Kahalekar	Professor And HOD Dept Kayachikitsa	Secretary
3	Mr. Umesh Jadhav	Principal, SVP College Of Pharmacy Hattatq. Basmat Dist. Hingoli	Expert (Pharmaceutics)
4	Adv. Yogesh Agrawal	Advocate	Legal Advisor
5	Sharika Siddiqui	Social Worker	Social Worker
6	Ram Kale		Layman

Institutional Members (Clinical/Para-clinical/Non-clinical)

Sr.No.	Name Of Member	Designation	Role In Committee
1	Dr. Deepali Agrawal	Associate Professor Dept Rognidan	Member
2	Dr. Sagar Magar	Associate Professor Dept Panchkarma	Member
3	Dr. Yogesh Mudgulwar	Assistant Professor Dept Rsbk	Member
4	Dr. Ashish Zanwar	Assistant Professor Dept Kayachikitsa	Member
5	Dr. Rupali Patil	Assistant Professor Dept kriya sharir	Member
6	Dr. Priyanka Deshmukh	Assistant Professor Dept Samhita	Member



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Points discussed in IEC meeting held.

- Encouraging for research protocols through the faculty members.
- Encouraging students for student teacher research protocol.
- Ensuring working efficiency and confidentiality to be maintained by all IEC members.



Members	SIGNATURE
Mr. Umesh Jadhav	
Adv. Yogesh Agrawal	
Sharika Siddiqui	
Dr. Deepali Agrawal	
Dr. Ashish Zanwar	
Dr. Sagar Magar	
Dr. Yogesh Mudgalwar	
Dr. Rupali Patil	
Dr. Priyanka Deshmukh	

10/12/25

DR KHALEKAR DHANANJAY

MEMBER SECRETARY

SECRETARY

IEC, SSVPAC & RI

Hatta, Tq. Basmath Dist. Hingoli

DR RAMESH INGOLE

CHAIRMAN

CHAIRMAN

IEC, SSVPAC & RI

Hatta, Tq. Basmath Dist. Hingoli

Address : Dr. Vedprakash Patil Educational Campus At. Hatta Tq. Basmat Dist. Hingoli - 431 705 Contact : Ph.02454-244257

web : www.svpayurvedhatta.in ♦ Email ID : svpayurvedhatta@gmail.com



SDMVMS

Sou Shantadevi Vedprakash Patil Ayurved College & Research Institute, Hattatq.Basmat, Dist.Hingoli



Institutional Ethical Committee

Date: 1AUG 2023

Time: 11.00 am

Venue: CONFERENCE HALL, SSV PAC, HATTA

With the permission of chairmen of IEC meeting were started with IEC members, previous key points and today's agenda of meeting were discussed and proceeded to forward

- Total number of research protocol revised and were listed as per categories
- Date of this meeting was inform to principal investigators 8 days prior
- Through PowerPoint presentation research protocols were presented in front of IEC by PI
- cosequessences and positive outcomes of research protocol were discussed
- Total 1 protocol was resived after last meeting held and research protocol was approved by IEC.

Titles approved by IEC

1. Name of pi – dr vijay maske (pi)

Name to title of study – a randomized controlled open label clinical trial of asparagus racemosus (shtavari), abultion indicum(atibala) in patients with sandhigata vata (janu sandhigata) w.s.r.t., osteoarthritis of knee joint.



Members	SIGNATURE
Mr. Umesh Jadhav	
Adv. Yogesh Agrawal	
Sharika Siddiqui	
Dr. Deepali Agrawal	
Dr. Vilas Khanapurkar	
Dr. Swami B D	
Dr. Hemant Aderao	
Dr. Snehal Akhare	
Dr. Vijay Maske	

11/4/23

DR KAHALEKAR DHANANJAY
MEMBER SECRETARY

SECRETARY
IEC, SSV PAC & RI
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DR RAMESH INGOL
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(President)

Dr. Manikrao Kulkarni
(Principal)



Institutional Ethical Committee

Date: 9 DEC 2019

Time: 11.00 am

Venue: CONFERENCE HALL, SSVAC, HATTA

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2	Dr. Vilas Kahanpurkar	Associate ProfessorDeptDravyaguna	Member
3	Dr. Aderao Hemant	Assistant Professor Dept RSBK	Member
4	Dr Maske Vijay	Assistant ProfessorDeptKayachikitsa	Member
5	DrAkhare Snehal	Assistant ProfessorDeptStrirog Prasuti	Member
6	Dr. Swami B D	Assistant ProfessorDept Samhita	Member



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Points discussed in IEC meeting held.

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- Encouraging students for student teacher research protocol.
- Ensuring working efficiency and confidentiality to be maintained by all IEC members.



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Date: 10AUG 2022

Time: 11.00 am

Venue: CONFERENCE HALL, SSVAC, HATTA

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- Date of this meeting was inform to principal investigators 8 days prior
- Through PowerPoint presentation research protocols were presented in front of IEC by PI
- cosequessences and positive outcomes of research protocol were discussed
- Total 3 protocols were received and 1 were selected and approved by IEC.

Titles approved by IEC

1. Name of PI – DR Nagola Ajay Virswami

Name to Title of study – IN VITRO ASSESEMENT OF SHILA SINDUR RAS AND IT'S ANTIPROLIFERATIVE ACTION ON BREAST CANCER CELL LINES.



Members	SIGNATURE
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Adv. Yogesh Agrawal	
Sharika Siddiqui	
Dr. Deepali Agrawal	
Dr. Vilas Khanapurkar	
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Date: 3 Dec 2020

Time: 11.00 am

Venue: CONFERENCE HALL, SSV PAC, HATTA

As per last meeting held on 9 Dec 2019 previous key points were discussed and meeting was proceed further.

As per chairperson suggested standard operative procedures (SOP) were formed by member secretary and were distributed in hard copies to all the IEC members, constituent department of institute. SOP was discussed in meeting and was suggested to follow the same.

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1. Slandered operative procedures for IEC



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Sou Shantadevi Vedprakash Patil Ayurved College & Research Institute, Hattatq.Basmat, Dist.Hingoli



Institutional Ethical Committee

Date: 3 AUG 2021

Time: 11.00 am

Venue: CONFERENCE HALL, SSVFAC, HATTA

With the permission of chairmen of IEC meeting were started with IEC members, previous key points and today's agenda of meeting were discussed and proceeded to forward

- Total number of research protocol revised and were listed as per catagaries
- Date of this meeting was inform to principal investigators 8 days prior
- Through power point presentation research protocols were presented in front of IEC by PI
- ADR and adverse effects of research protocol were discussed and corrected by members
- Total 3 protocols were resived after last meeting held out of which 1 research protocol was approved by IEC and remaining were send for corrections

TITLES APPROVED BY IEC

Name Of Principal Investigator- Dr Deepali Agrawal

Name Of Title – Role Of Sphatik Bhasma As Haemostatic Drug In The Management Of Raktapradar W.S.T.Heavy Mentrual Bleeding



Members	SIGNATURE
Mr. Umesh Jadhav	
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Dr. Vilas Khanapurkar	
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Dr. Vijay Maske	

31/5/21

DR KAHALEKAR DHANANJAY
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SECRETARY

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**Sou Shantadevi Vedprakash Patil Ayurved College &
Research Institute, Hattatq.Basmat, Dist.Hingoli**

Institutional Ethical Committee



Date: 17 March 2020

Due to Pandemic exposure of COVID – 19 IEC meeting was not held.

[Signature]
17/3/20

DR KHALEKAR DHANANJAY
MEMBER SECRETARY

SECRETARY
IEC, SSVAC & RI
Hatta, Tq. Basmath Dist. Hingoli

[Signature]

DR RAMESH INGOLE
CHAIRMAN

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Hatta, Tq. Basmath Dist. Hingoli