



Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 10/11/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 11/11/2021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.


Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



Godavari Foundation's
(Registered under the Bombay Public Trusts Act, 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 11/11/2021

Location:

Dean's Office

Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To discuss the research study of Dr. RANJANA C. SHINGNE, Associate Professor, Department of PHYSIOLOGY -

"EFFECT OF E-LEARNING DURING COVID - 19 PANDEMIC ON UNDERGRADUATE MEDICAL STUDENTS."

4.1

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from DECEMBER 2021 to JANUARY 2022.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm



Dr. RAHUL PRAKASH BHAVASAR.
Member Secretary
DUPMCH



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-236657 (Fax) 0257-236648 Website: <http://www.dupmc.ac.in/>

Covering letter

Through Proper Channel Only

Date - 01/11/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. Ranjana C. Shingnehereby
submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it
for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my
aforesaid Guide.

Title of Synopsis

Effect of lockdown on E-learning during COVID-19
Pandemic on undergraduate medical students

Kindly do the needful.

REA

Dr. Ranjana C. Shingne

(Principal Investigator name and signature)

(Guide name and signature)

Dr. Shivanand S Rathod
(HOD name and Signature with Dept. seal)

PROFESSOR & HOD
Dept. of Physiology
Dr. Ulhas Patil Medical College
and Hospital, Jalgaon Kh.




INSTITUTIONAL ETHICS COMMITTEE
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Phone, No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmrc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)
OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.: * To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

		Signature
1.	Title of the Research Project/ Dissertation Effect of lockdown on E-learning during COVID-19 Pandemic on undergraduate medical Students	
2.	Name of the Principal Investigator/ Under/Post graduate student: Dr. Ranjana C. Shingre	Rsa
3.	Name of the co-Investigator/s (if applicable) i) Santosh Kumar Jha ii) Shivanand S Rathod iii) iv)	Santosh Shivanand
4.	Name of UG/PG guide	NO
5.	Name of Trial monitor / co-guide	NO
6.	HOD of Principal Investigator/UG/PG student:	(With seal)  PROFESSOR & HOD Dept. of Physiology Dr. Ulhas Patil Medical College and Hospital, Jalgaon Kt
7.	HOD of other Departments involved	(With seal) NO

8.	Place where research work will be carried out	Yes / No
	a. At DUPMC&	<input checked="" type="checkbox"/>
	b. Outside DUPMC&H.	<input type="checkbox"/>
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	Time period required for completion of research project and it's analysis (Approximately)	From -To (Date) DEC 2021 - Jan 2022
10.	Risk factor for the patient (give details): A) Procedural NA B) Adverse drug reaction (ADRs) NA C) Invasive investigations (if any) NA D) Explain the measures to counter the above risk factors. NA	

11.	Details about research project must include	Yes	No
	(a) Project title	<input checked="" type="checkbox"/>	
	(b) Aims and objectives:	<input checked="" type="checkbox"/>	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	<input checked="" type="checkbox"/>	
	(d) Materials and methods (Research plan and its implications)	<input checked="" type="checkbox"/>	
	(e) Statistical analysis	<input checked="" type="checkbox"/>	
	(f) Conflict of interest:	<input checked="" type="checkbox"/>	
	(g) Risk factors:		<input checked="" type="checkbox"/>
	(h) List of references:	<input checked="" type="checkbox"/>	



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12.	Details of financial burden involved and how it will be met:	N/O	
13.	Whether the research project is sponsored:		Yes / No <input checked="" type="checkbox"/>
14.	Sponsoring authority: (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).		
15.	Any other relevant information:	N/O	

16. Enclosures:

	Attached	Not attached	Not applicable
1			✓
2	✓		
3			✓
4			
5			✓
6			✓
7			✓
8			✓
9			✓
10			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and international Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

R. S. A.

Signature

Principal Investigator.

- 1) Principal investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-Investigator for research on Traditional Medicine.



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
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(For IEC Office use only)

1	Sr. No given to project	20
2	Department	Physiology
3	Date of Receipt by IEC (submission of application)	01/11/21
4	Date of resubmission to IEC	10/11/21
5	Date of IEC meeting	11/11/21
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	12/11/21


CHAIRPERSON
IEC, DUPMCH


MEMBER SECRETARY
IEC, DUPMCH

Research Protocol

Project Title- Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students.

Aims and Objectives –

1. To assess effectiveness of E-learning classes as compared to conventional classroom teaching-learning method.
2. To assess perceptions of medical students on the role of E-learning in facilitating medical education during COVID-19 pandemic.
3. To evaluate knowledge of electronic gadgets used during E-learning activities.

Introduction – COVID-19 viral infection started in December 2019, Wuhan, China and spread rapidly throughout the globe. As the infection spread throughout the world rapidly, on March 11, 2020 World Health Organization (WHO) declares it as pandemic [1]. As the infection spreads rapidly, government of India announces nation wise lockdown on 25th March 2020 for 21 days [2]. Pandemic imposed lockdown in all areas, including educational institutions. In the wake of institute shutdown, this was challenging time for professional education which combated through introduction of E-learning through online classes so as to ensure continuation of teaching-learning process for medical students. Our institute started online classes from 20th April 2020 and continued till the end of academic year. Again, we continued e-learning process ON and OFF as per the guidelines of government of India. We did E-learning total of 5 months i.e. from March 2021- July 2021. Present study is conducted to investigate perception of medical students on the role of online teaching in facilitating medical education during the COVID-19 pandemic.

Materials and Methods – This online study will be done on 1st year MBBS students (total of 150 students), who have already completed online classes from March 2021 to July 2021. A set of self-designed questionnaire will be given to assess the effectiveness of learning through online classes and their understanding with satisfaction level on various parameters.

Statistical Analysis – After completion of study, it will be analysed by using Students T-test.

Conflict of interest – None

References

1. WHO Director-General's opening remarks at the media briefing on COVID-19 -March 2020
2. Newspaper- THE HINDU , March 25, 2020. <https://www.thehindu.com/news/national/pm-announces-21-day-lockdown-as-covid-19-toll-touches-10/article61958513.ece>

Questionnaires

1. Are you willing to participate in this study?
Yes / No
2. On which device you are attending online lectures?
Smart phone/ Laptop /Tablets
3. Whether online teaching was good decision to continue your education during lockdown?
a) Yes b) No c) Can not say
4. Does pandemic has increased your stress?
a) Yes b) No c) Can not say
5. Are you feeling anxious during lock down?
a) Yes b) No c) Can not say
6. Duration of screen use before pandemic COVID-19
a) < 2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs
7. Duration of screen use during pandemic COVID-19
a) < 2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs
8. Do you have technophobia before joining the online session?
Yes / No
9. Do you like online teaching over classroom teaching?
Yes / No
10. Do you like online exams?
Yes / No

11. Do you like classroom exam?

Yes / No

12. Do you feel that pandemic has affected your academic performances?

Yes / No

13. Do you face internet error while connecting for online class?

a) Yes b) No c) Sometimes d) Never

14. Do you like open book exam?

Yes / No

15. Do you feel flexibility while attending online lecture?

Yes / No

16. Which type of online lecture is good - live or recorded?

17. Disturbances while attending online session

a) Yes b) No c) Sometimes d) Never

18. What will you prefer in future?

a) E-learning b) Class room teaching

19. To improve online lecture effectiveness any suggestion -

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

Dr. Ranjana C. Shingne
Dept. of Physiology, Dr. Vhas Patil Medical College and Hospital,
Talgaon Khurd, Talgaon, Maharashtra, India

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

Dr. Vhas Patil Medical College and Hospital
Talgaon Khurd, Talgaon, Maharashtra, India

3. Name and address of all clinical laboratory facilities to be used in the study.

NA

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

TEC, DUPMCH, Talgaon

5. Names of the other members of the research team (Co-or. sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

Dr. Santosh Kumar Jha

Dr. Shivanand S Rather

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

Effect of lockdown on E-learning during COVID-19
pandemic on undergraduate medical students

7. Commitments:

- i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
- ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment.

except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

- iii. I agree to personally conduct or supervise the clinical trial at my site.
- iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
- v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
- vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.
- x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event
- xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
- xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.
- xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

PSA
01.11.21

8. Signature of Investigator with date.



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.duipmc.ac.in/>
Covering letter

Through Proper Channel Only

Date: 01/11/21

To
The Chairperson,
IEC DUMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. Ranjana C. Shingnehereby
submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it
for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my
aforesaid Guide.

Title of Synopsis

Effect of lockdown on E-learning during COVID-19
pandemic on undergraduate medical students

Kindly do the needful.

Dr. Ranjana C. Shingne

(Principal Investigator name and signature)

PROFESSOR & HOD
Dept. of Physiology

Dr. Ulhas Patil Medical College
and Hospital, Jalgaon Kh.

(Guide name and signature)

Dr. Shivanand S Rathod





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APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)
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N.B.: * To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(* To be preserved by IEC for minimum 15 years.)

		Signature
1.	Title of the Research Project/ Dissertation Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students	
2.	Name of the Principal Investigator/ Under/Post graduate student: Dr. Ranjana C. Shingne	PSA
3.	Name of the co-investigator/s (if applicable) i) Santosh Kumar Jha ii) Shivanand S Rathod iii) iv)	bantesh 
4.	Name of UG/PG guide	NA
5.	Name of Trial monitor / co-guide	NA
6.	HOD of Principal Investigator/UG/PG student:	(With seal)  PROFESSOR & HOD Dept. of Physiology Dr. Ulhas Patil Medical College
7.	HOD of other Departments involved	(With seal) and Hospital, Jalgaon Kh. NA

8.	Place where research work will be carried out	Yes / No
	a. At DUPMC&	✓
	b. Outside DUPMC&H.	Yes / No
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	Time period required for completion of research project and its analysis (Approximately)	From -To (Date)
		Dec 2021 - Jan 2022
10.	Risk factor for the patient (give details):	
	A) Procedural	NA
	B) Adverse drug reaction (ADRs)	NA
	C) Invasive investigations (if any)	NA
	D) Explain the measures to counter the above risk factors.	NA

11.	Details about research project must include	Yes	No
	(a) Project title	✓	
	(b) Aims and objectives:	✓	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	✓	
	(d) Materials and methods (Research plan and its implications)	✓	
	(e) Statistical analysis	✓	
	(f) Conflict of interest:	✓	
	(g) Risk factors:		✓
	(h) List of references:	✓	



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12.	Details of financial burden involved and how it will be met:
13.	Whether the research project is sponsored: Yes / No <input checked="" type="checkbox"/>
14.	Sponsoring authority: (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).
15.	Any other relevant information:

16. Enclosures:

	Attached	Not attached	Not applicable
1			✓
2	✓		
3			✓
4			✓
5			✓
6			✓
7			✓
8			✓
9			✓
10			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

DeA

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- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-Investigator for research on Traditional Medicine.



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(For IEC Office use only)

1	Sr. No given to project	20
2	Department	Physiology
3	Date of Receipt by IEC (submission of application)	01/11/21
4	Date of resubmission to IEC	10/11/21
5	Date of IEC meeting	11/11/21
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	12/11/21


CHAIRPERSON
IEC/DUPMCH


MEMBER SECRETARY
IEC, DUPMCH

Research Protocol

Project Title- Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students.

Aims and Objectives –

1. To assess effectiveness of E-learning classes as compared to conventional classroom teaching-learning method.
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Statistical Analysis – After completion of study, it will be analysed by using Students T-test.

Conflict of interest – None

References

1. WHO Director-General's opening remarks at the media briefing on COVID19 -March 2020
2. Newspaper- THE HINDU , March 25, 2020. <https://www.thehindu.com/news/national/pm-announces-21-day-lockdown-as-covid-19-toll-touches-10/article61958513.ece>

Questionnaires

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Yes / No

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a) Yes b) No c) Can not say

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a) Yes b) No c) Can not say

5. Are you feeling anxious during lock down?

a) Yes b) No c) Can not say

6. Duration of screen use before pandemic COVID-19

a) <2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs

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17. Disturbances while attending online session

a) Yes b) No c) Sometimes d) Never

18. What will you prefer in future?

a) E-learning b) Class room teaching

19. To improve online lecture effectiveness any suggestion -

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)
Dr. Ranjana C Shingne
Dept. of Physiology, Dr. Vilhas Patil Medical College and Hospital, Jalgaon Khurd, Jalgaon, Maharashtra, India
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
Dr. Vilhas Patil Medical College and Hospital
Jalgaon Khurd, Jalgaon, Maharashtra, India
3. Name and address of all clinical laboratory facilities to be used in the study.
NA
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
TEC, DUPMCH, Jalgaon
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
Dr. Santosh Kumar Jha
Dr. Shivanand S Rathod
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students
7. Commitments:
 - i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
 - ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment.

except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

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- v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
- vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.
- x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event
- xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
- xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.
- xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

DSA
01.11.21

8. Signature of Investigator with date.



Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon - Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2058557 Fax : 2366648
E-Mail Id : dupmcj@yahoo.in
2366657

Date:- 30/09/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 04/10/2021 to 09/01/2021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar,

Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 04/10/2021

Location:
Dean's Office
Recorded By: Dr. Rahul P.B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of medicine PGs-

1	Dr. KAMELI MOHAMMAD JUNAID RAFEIQUE AHMAD	COMPARATIVE STUDY OF ECG AND CORONARY ANGIOGRAPHIC FINDINGS WITH ACUTE CORONARY SYNDROME IN DIABETIC AND NON-DIABETIC PATIENTS IN TERTIARY CARE CENTRE
2	Dr. KOTECHE TEJAS KUNDAN	STUDY OF CLINICAL PROFILE OF PATIENTS WITH HYPONATREMIA IN TERTIARY CARE HOSPITAL
3	Dr. NANDEDKAR ADITYA MAHADEV	THE STUDY OF SERUM MAGNESIUM AND VITAMIN D3 IN TYPE 2 DIABETES MELLITUS AND ITS CORRELATION WITH CORONARY ARTERY DISEASE
4	Dr. PRIYANKA ASHOK BHALKE	BACTERIAL SPECTRUM OF ASCITIC FLUID IN ALCOHOLIC LIVER DISEASE PATIENT ON ADMISSION AND ITS CORRELATION WITH SERUM ASCITIC ALBUMIN GRADIENT.
5	Dr. WAGAJ SUSHANT PRAKASH	A STUDY TO ESTIMATE PREVALENCE OF ANAEMIA IN ACUTE AND CHRONIC INFLAMMATION IN PATIENTS ATTENDING TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm



Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

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Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 05/10/2021

Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09:00 am

Meeting Actual Start: 09:05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of Surgery PGs-

1	Dr. ANISH AVINASH JOSHI	COMPARATIVE STUDY OF EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA WITH SALINE DRESSING IN DIABETIC FOOT ULCER BY EXAMINING NEOVASCULARIZATION ON BIOPSY
2	Dr. FARKE VAIBHAV BALASAHEB	STUDY OF ETIOLOGY AND MANAGEMENT OF PERITONITIS AT TERTIARY CARE HOSPITAL
3	Dr. MANKAR SHUBHAM SHRIKRUSHNA	SPECTRUM OF DISEASES MANAGED BY LAPAROSCOPY AND ITS OUTCOME AT TERTIARY CARE CENTRE
4	Dr. SHRIYASH KONDIBA SONAWANE	STUDY OF MANAGEMENT AND OUTCOME OF ACUTE OBSTRUCTIVE UROPATHY DUE TO CALCULUS IN A TERTIARY CARE CENTRE
5	Dr. SIRPURAM VARUNDEV ASHOK	EFFECT OF FLAP FIXATION TECHNIQUE ON SEROMA FORMATION AND ITS COMPLICATIONS IN PATIENTS UNDERGOING BREAST CANCER SURGERY AT A TERTIARY CARE CENTER.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm



Dr. Rahul Prakash Bhavasar,
Member Secretary
DUPMCH



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

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Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 06/10/2021

Location:

Dean's Office
Recorded By: Dr. RAHUL P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

- 4.1 To discuss the 6 monthly report of research study of Anesthesia and Pathology PGs-

1	Dr. DESHPANDE HARSHA SANJAY	TO STUDY THE EFFECT OF INTRAVENOUS MAGNESIUM SULPHATE IN ATTENUATING THE HEMODYNAMIC RESPONSE DURING LARYNGOSCOPY AND INTUBATION IN PATIENTS REQUIRING GENERAL ANAESTHESIA AT A TERTIARY CARE CENTRE.
2	Dr. KELGAONKAR VIJAYA VIVEK	A COMPARATIVE STUDY OF DEXAMETHASONE AS AN ADJUVANT TO LOCAL ANAESTHETIC DRUG FOR SUPRACLAVICULAR BLOCK WITH PLACEBO IN A TERTIARY CARE CENTER
3	Dr. PRAJAKTA PRAKASH SHILAHAR	COMPARATIVE STUDY BETWEEN FENTANYL AND BUPRENORPHINE AS AN ADJUVANT TO HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK FOR INFRA UMBILICAL SURGERIES
4	Dr. SONONE SHIVAJI DILIP	TO COMPARE EFFECT OF 0.75% ROPIVACAINE WITH 0.5% BUPIVACAINE IN EPIDURAL ANAESTHESIA IN LOWER LIMB SURGERIES IN TERTIARY CARE CENTRE.
5	Dr. KAMBLE PRIYANKA SHASHIKANT	THE STUDY OF FINE NEEDLE ASPIRATION CYTOLOGY OF HEAD AND NECK REGION LYMPHADENOPATHY WITH ITS HISTOPATHOLOGIC CORRELATION IN TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 07/10/2021

Location:

Dean's Office

Recorded By: Dr. RAHUL. P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

- 4.1 To discuss the 6 monthly report of research study of three OBGY and two Pediatrics PGs-

1	Dr. DONGARWAR AKASHKUMAR SHALIKRAM	AN OBSERVATIONAL STUDY OF INTRAOPERATIVE DIFFICULTIES IN REPEAT CAESAREAN SECTION COMING TO TERTIARY CARE HOSPITAL
2	Dr. MAHESH GAJANAN DESHMUKH	TRANSABDOMINAL ULTRASOUND ASSESSMENT OF FETAL OCCIPUT - SPINE ANGLE TO PREDICT THE MODE OF DELIVERY
3	Dr. YASHASHREE PRADIP DESHMUKH	A STUDY OF UTERINE ARTERY DOPPLER FOR PREDICTION OF PREECLAMPSIA FROM 12 TO 26 WEEKS OF GESTATION IN TERTIARY CARE CENTER.
4	Dr. RANGNEKAR PRADNIL KISHOR	CLINICAL PROFILE OF LOW BIRTH WEIGHT NEONATES ADMITTED IN NICU AT TERTIARY CARE CENTER
5	Dr. SHUKLA SURUCHI RAMPRASAD	PROSPECTIVE STUDY OF CLINICAL OUTCOME OF EARLY DISCHARGED VERY LOW BIRTH WEIGHT BABIES FROM NICU AT WEIGHT BETWEEN 1300GMS TO 1800GMS.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm



Dr. Ranul Prakash Bhavasar.
Member Secretary
DUPMCH



Godavari Foundation's
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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 08/10/2021

Location:

Dean's Office
Recorded By: Dr. Rahul P.B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

- 4.1 To discuss the 6 monthly report of research study of three Ophthalmology and two ENT PGs-

1	Dr. AKASH UTTAMRAO MALVI	A STUDY TO EVALUATE AND COMPARE VISUAL OUTCOMES AFTER CATARACT SURGERY IN DIABETICS COMPARED TO NONDIABETIC PATIENTS AT A TERTIARY CARE CENTRE.
2	Dr. ANUJA VINAYAK GADGIL	A CLINICAL STUDY OF SUTURELESS GLUEFREE CONJUNCTIVAL AUTOGRAFT REPAIR IN PTERYGIUM SURGERY.
3	Dr. DESHMUKH KALPANA ARJUNRAO	STUDY OF EFFECT OF MYOPIA AND AXIAL LENGTH ON PERIPAPILLARY RETINAL NERVE FIBRE LAYER USING SPECTRAL DOMAIN OPTICAL COHERENT TOMOGRAPHY
4	Dr. HARSHAL VASUDEO MAHAJAN	A COMPARATIVE STUDY OF ENDOSCOPIC SEPTOPLASTY OVER CONVENTIONAL SEPTOPLASTY IN TERTIARY CARE CENTER.
5	Dr. KHANDAGALE SHRUTI SHAILENDRA	A COMPARATIVE STUDY BETWEEN GRAFTS OF TRAGAL CARTILAGE, TEMPORALIS FASCIA LATA IN PATIENTS POSTED FOR REVISION TYMPANOPLASTY.

Minutes of meeting:-

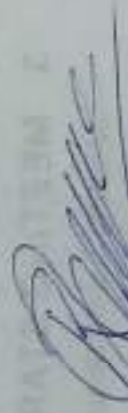
1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm



Dr. Rahul Prakash Bhavasar,
Member Secretary
DUPMCH



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 09/10/2021
Location:

Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

- 4.1 To discuss the 6 monthly report of research study three Orthopedics, two Skin and one Chest and TB PGs-

1	DR. JAMBANDHU RAHUL SHANTILAL	COMPARATIVE STUDY OF FUNCTIONAL OUTCOME OF FIXATION BY OPEN AND CLOSED METHODS IN DISTAL END RADIUS FRACTURE IN TERTIARY CARE HOSPITAL.
2	DR. PATIL PARIKSHIT PRATAP	TO STUDY FUNCTIONAL OUTCOME OF SURGICAL DECOMPRESSION IN LUMBAR SPINAL STENOSIS IN A RURAL HOSPITAL
3	DR. VELANKAR SUNEET NITIN	STUDY ON EFFICACY AND FUNCTIONAL OUTCOME OF AUTOLOGOUS PLATELET RICH PLASMA INJECTION IN ADHESIVE CAPSULITIS, LATERAL EPICONDYLITIS AND PLANTAR FASCIITIS.
4	DR. KALBANDE PRAJAKTA PRAKASH	STUDY OF VARIOUS CLINICAL PATTERNS OF ADVERSE CUTANEOUS DRUG REACTIONS AT DERMATOLOGY OUT PATIENT DEPARTMENT IN A TERTIARY CARE CENTRE
5	DR. SHAIKH MUBINA IRFAN	CLINICO EPIDEMIOLOGICAL STUDY OF HERPES ZOSTER AND POST HERPETIC NEURALGIA AND ITS IMPACT ON QUALITY OF LIFE
6	DR. SAMADHAN DATTATRAYA BAHEKAR	STUDY OF POST COVID 19 PULMONARY COMPLICATIONS AT A TERTIARY CARE CENTER - PROSPECTIVE OBSERVATIONAL STUDY.

Minutes of meeting :-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm



Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmch.ac.in>

Ref. No. IEC/GCON/2021/1

Date: 19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Puja c. waghmare (Ms. Vishakha Granvir)	Child Health Nursing.	Approved	"A study to assess the knowledge, attitude, anxiety and coping strategies of students (16 to 18 years) during COVID - 19 epidemic in selected urban area."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Puja C. Waghmare Dept. of Child Health Nursing.
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. [Office] 0257-2386657 (Fax) 0257-2386648 Website. <http://www.dipmch.ac.in/>

Ref.No. IEC/GCON/2021/2

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

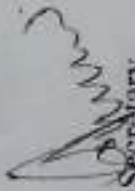
This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	MS. Utkarsha Gawande (Mrs. Ganvir) Vishakha	Child Nursing Health	Approved	Study to assess the physical and psychological impact of lockdown during covid-19 pandemic on school age children, in view to develop the information booklet on how to mitigate its effect in selected urban area.

Copy W/C to:-

1. Ms. Utkarsha Dhanraj Gawande Dept. of Child Health Nursing
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon


Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone: No. (Office) 0257-2356657 (Fax) 0257-2366648 Website, <http://www.dupmch.ac.in>

Ref. No. IEC/GCON/2021/4

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Shital Umate (Mrs. Vishakha Ganvir)	Child Health Nursing	Approved	"A descriptive study to assess the attitude & behavioural changes in primary school children regarding unplanned school closure during covid-19 pandemic in selected urban area."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Shital Umate Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone No. (Office) 0257-236657 (Fax) 0257-236648 Website: <http://www.dupmch.ac.in>

Ref. No. IEC/GCON/2021/5

Date: 19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Shilpa Vairagade (Mrs. Vishakha Ganvir)	Child Health Nursing	Approved	"Study to assess the challenges faced by village parents of primary school children regarding online education during lockdown in selected rural area."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Shilpa Vairagade Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. <http://www.dupmic.ac.in>

Ref. No. IEC/GCON/2021/6

Date: 19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Kirti Patil (Mrs. Jacinth Dhaya)	Community health nursing	Approved	"A true experimental study to assess the effectiveness of kriya yoga in reduction of anxiety level among the nursing staff at selected COVID hospitals."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Kirti Patil Dept. Community health Nursing
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 / (Fax) 0257-2366648 Website: <http://www.dupmch.ac.in/>

Date: 19/07/2021


Ref. No. IEC/GCON/2021/7

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Dipali Gote Mrs Manorama Kashyap	Medical Surgical Nursing- (Neurosciences nursing)	Approved	"A study to assess the effectiveness of self instructional module on knowledge regarding prevention of early complication following stroke among staff nurses working at selected hospital."


Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms Dipali Gote Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dipmmc.iec.jh>

Ref.No. IEC/GCON/2021/8

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms.Snehal Diwakar Kshirsagar (Mrs.Manorama Kashyap)	Medical Surgical Nursing-(Neurosciences nursing)	Approved	"A quasi experimental study to assess the effectiveness of Backward Walking Training to improve gait among stroke patient admitted at selected rehabilitation center."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms.Snehal Kshirsagar Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmch.jalgaon.edu>

Ref. No. IEC/GCON/2021/9

Date: 19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing Research** Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Mr.Chinmay Prakash Chopade (Mrs.Manorama Kashyap)	Medical Surgical Nursing- (Neurosciences nursing)	Approved	"A quasi experimental study to assess the effectiveness of structured teaching programme on knowledge regarding lumbar puncture, its complication and prevention of complication among staff nurses working at selected hospital."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Mr. Chinmay Chopade Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone, No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmch.org.in>

Ref. No. IEC/GCON/2021/10

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.


This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Priti Gaikwad (Mrs. Manorama Kashyap)	Medical Surgical Nursing- (Neurosciences nursing)	Approved	"A pre experimental study to assess the effectiveness of video assisted teaching programme on knowledge regarding swallowing therapy for dysphagia in patient with stroke among staff nurses working at selected hospital"

Copy W/C to:-

1. Ms. Priti Gaikwad Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon


Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone, No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmch.ac.in/>

Ref. No. IEC/GCON/2021/11

Date: 19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Priyanka G. Gadekar (Ms. Ashwini Vaidya)	Mental Health Nursing.	Approved	"A quasi experimental study to assess the effectiveness of self- instructional module on knowledge regarding management of client with mania among staff nurses at selected hospitals."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Priyanka G. Gadekar Dept., of Mental Health Nursing.
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmch.ac.in>

Ref.No. IEC/GCON/2021/12

Date: 19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following Msc 1st Year Nursing Research Project were discussed and given approval.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Mr. Akshay Wankhede (Ms. Ashwini Vaidya)	Mental Health Nursing	Approved	"A Quasi-experimental study to assess the effectiveness of structured teaching programme on knowledge regarding prevention of complications of electroconvulsive therapy among the staff nurses at selected hospitals."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Mr. Akshay Wankhede Dept. Mental Health Nursing
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon



Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon

Ph. No. (0257) 3058557 Fax : 3058548 E-Mail Id : dupmcj@yahoo.in

Date:- 26/09/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 29/09/2021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 29/09/2021

Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Rahul Prakash Bhavasar.	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the new members of IEC

Minutes of meeting:-

1. According to the criteria of SOP'S of IEC, during re-registration of IEC some members should be changed.
2. So by taking this into consideration member secretary is been changed from Dr. Amrut Mahajan to Dr. Vaishali Nagose and member Dr. Milind Joshi to Dr. Shivaji Sadulwad.
3. Appointment letter will be given to newly appointed members and secrecy and one page CV will be filled from them.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm



Dr. Rahul Prakash Bhavasar.

Member Secretary

DUPMCH



DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Godavari Foundation's

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,

Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013

Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]

Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309

Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648

Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date – 29.09.2021

To,

The Concern authority,
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Subject: Constitution of Institutional Ethics Committee is under my guidance

Respected sir,

I, **Dr. Narayan Arvkar, Dean of Dr.Ulhas Patil Medical College & Hospital, Jalgaon** has constituted this Institutional Ethics Committee is under my guidance

Sr. No.	Member Name	Designation
1.	Dr. Parag Patil	Chairman
2.	Dr. Rahul P. Bhavasar	Member Secretary
3.	Dr. Shubhangi D. Chaudhari	Member
4.	Dr. Vaishali Nagose	Member
5.	Dr. Shivaji Sadulwad	Member
6.	Dr. Nilesh Bendale	Member
7.	Prof Girish A. kulkarni	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10	Mrs.Swara J.Waghodkar	Member

Thanking you.



Dean

Dr. N. S. Arvkar sir



Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon-Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 18/08/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 20/08/2021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.


Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 20/08/2021

Location:

Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

- 4.1 To discuss the new members of IEC

Minutes of meeting:-

1. According to the criteria of SOP'S of IEC, during re-registration of IEC some members should be changed.
2. So by taking this into consideration member secretary is been changed from Dr. Devendra Chaudhari to Dr. Rahul Prakash Bhavasar and member Dr. Maya Arvikar to Dr. Shubangi Devendra Chaudhari.
3. Appointment letter will be given to newly appointed members and secrecy and one page CV will be filled from them.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm



Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH



Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013

Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309

Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648

Email ID : dupmci@yahoo.in Web Site : www.dupmci.ac.in

Date – 20.08.2021

To,

The Concern authority,
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Subject: Constitution of Institutional Ethics Committee is under my guidance

Respected sir,

I, **Dr. Narayan Arvikar, Dean of Dr.Ulhas Patil Medical College & Hospital, Jalgaon** has constituted this Institutional Ethics Committee is under my guidance

Sr. No.	Member Name	Designation
1.	Dr. Parag Patil	Chairman
2.	Dr. Rahul P. Bhavasar	Member Secretary
3.	Dr. Shubhangi D. Chaudhari	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Nilesh Bendale	Member
7.	Prof Girish A. kulkarni	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10	Mrs.Swara J.Waghodkar	Member

Thanking you.




Dean

Dr. N. S. Arvikar sir

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi - 110 002, India
Dated: 30/09/2016

To

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

SUB: - Ethics Committee Registration No. ECR/852/Inst/MH/2016 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the **INSTITUTIONAL ETHICS COMMITTEE**, situated at **DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, 1st FLOOR, COLLEGE BUILDING, DUPMCH, JALGAON-425309, MAHARASHTRA, INDIA** with Registration number **ECR/852/Inst/MH/2016** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

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



Dr. Jihvas Patil Medical College
and Hospital, Jalgaon Kh.
Inward No.: 248

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

(Dr. G. N. Singh)
Drugs Controller General (I) & Licensing Authority

Drugs Controller General (I)
Dir. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi - 110002

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi - 110 002, India
Dated: 30/09/2016

To,

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

Subject: Ethics Committee Registration No. ECR/852/Inst/MH/2016 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. ECR/852/Inst/MH/2016 with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Ravindrakumar L. Bakal	M.Pharm, PhD	Chairman
2.	Dr. Devendra R. Chaudhari	MD (Pharmacology)	Member Secretary
3.	Dr. Maya N. Arvikar	MD (Obst & Gyane)	Clinician
4.	Dr. Milind P. Joshi	MCH, Pediatric Surgery	Clinician
5.	Dr. Rahul P. Bhavasar	MD (Pharmacology)	Basic Medical Scientist
6.	Dr. Sandeep V. Pakhale	MS (Anatomy)	Basic Medical Scientist
7.	Dr. Smita C. Pathade	MD (Pathology)	Basic Medical Scientist
8.	Adv. Satish G. Gadge	LLM	Legal Expert
9.	Mr. Prabhakar M. Jangale	MA, B.Ed	Lay Person
10.	Dr. Prashant S. Warke	BE, MBA (Marketing), PhD (Business Adm.)	Social Scientist
11.	Mr. Sandesh Yashwant Patil	12 th Pass	Non Scientific Member

(Dr. G. N. Singh)

Drugs Controller General (D) & Licensing Authority
Dir. General of Health Services
Ministry of Health & Family Welfare
FDA P.O.

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi - 110 002, India
Dated: 30/09/2016

To,

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

Subject: Ethics Committee Registration No. ECR/852/Inst/MH/2016 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. ECR/852/Inst/MH/2016 with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Ravindrakumar L. Bakal	M.Pharm, PhD	Chairman
2.	Dr. Devendra R. Chaudhari	MD (Pharmacology)	Member Secretary
3.	Dr. Maya N. Arvikar	MD (Obst & Gyane)	Clinician
4.	Dr. Milind P. Joshi	MCH, Pediatric Surgery	Clinician
5.	Dr. Rahul P. Bhavasar	MD (Pharmacology)	Basic Medical Scientist
6.	Dr. Sandeep V. Pakhale	MS (Anatomy)	Basic Medical Scientist
7.	Dr. Smita C. Pathade	MD (Pathology)	Basic Medical Scientist
8.	Adv. Satish G. Gadge	LLM	Legal Expert
9.	Mr. Prabhakar M. Jangale	MA, B.Ed	Lay Person
10.	Dr. Prashant S. Warke	BE, MBA (Marketing), PhD (Business Adm.)	Social Scientist
11.	Mr. Sandesh Yashwant Patil	12 th Pass	Non Scientific Member

(Dr. G. N. Singh)

Drugs Controller General (I) & Licensing Authority

Dir., General of Health,
Ministry of Health,
FDA



Godavari Foundation's

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Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon-Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 20/07/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 21/07/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

SrNo	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvkar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.


Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



Godavari Foundation's
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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 21/07/2021

Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

- 4.1** To discuss the CASE REPORT of 3RD YR STUDENT
"GULLIAN BARRE SYNDROME IN A 3 YEAR OLD CHILD".

Minutes of meeting:-

1. **CASE REPORT** was discussed under – title of the **CASE REPORT, CASE DETAILS REPORTED**, any sponsorship by the committee members.
2. It was ensured that **CASE REPORT** was undertaken as per ICE guidelines.
3. The permission was granted to **PUBLIUSH** the **CASE REPORT** by the committee members.
4. Application form for permission of **CASE REPORT** was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm



Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH



Appendix II

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-236657 (Fax) 0257-236648 Website. <http://www.dupmc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE) OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation

Guillain Barre Syndrome in a 34 year old child: A Rarity

2. Name of the Principal Investigator/
Under/Post graduate student:

Prakash Paidisetty

3. Name of the co-investigator/
UG/PG guide/Trial monitor
(if applicable)

Neel Navya S. Motamary

4. i) Signature of Principal Investigator/
UG/PG student:

Prakash

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:

Neel

iii) Signature of HOD of Principal Investigator/UG/PG student:

(with seal)

Dr. Ulhas Patil
Professor & HOD
Dept. of Pediatrics
Dr. Ulhas Patil Medical College &
Hospital Jalgaon K.B. Jalgaon.



iv) Signature of HOD of other Departments Involved (with seal):

(For IEC Office use only)

Sr. No _____

Dept.....

- 1) Date of Receipt by IEC (submission of application) _____
- 2) Date of resubmission to IEC _____
- 3) Date of IEC meeting _____
- 4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED. _____
- 5) IEC decision conveyed on date: _____


CHAIRPERSON
I.E.C.


MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

- (A) At DUPMC&H (B) Outside DUPMC&H.
(Permission letter to be submitted if outside DUPMC&H)
(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

1 month _____

7) Risk factor for the patient (give details):

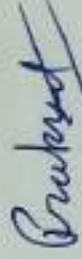
A) Procedural: None.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.
- (a) Patient information sheet.
- (b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
- (c) Case Record Form (CRF)
- (d) Undertaking by the investigator (Appendix VII)
- (e) Stability testing of new drug (Appendix IX)
- (f) Content of the proposed protocol for conducting clinical trial (Appendix X)
- (g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
- (h) Study Flow Chart if any.
- (i) News paper publication matter for subject recruitment if any.
- (j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature of Principal Investigator.

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

B) Adverse drug reaction (ADRs):

N/A

C) Invasive investigations (if any):

N/A

D) Explain the measures to counter the above risk factors:

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

YES/NO

10) Whether the research project is sponsored:

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical

Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Prakruti Paudisetty.....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis

Guillain Barre Syndrome In A 3 Year Old Child: A Rarity.

Kindly do the needful.

Prakruti Paudisetty
Prakruti
(Candidate name and signature)
Dr. Anant G. Bendale.

Dr. Anant G. Bendale

(Guide name and signature)

Professor & HOD
Dept. of Pediatrics
(HOD name and Signature with Dept. seal)
Hospital Jalgaon K.B. Jalgaon.





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Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in
Date:- 20/05/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 21/05/2021 at 3.00 pm

All members are requested to attend meeting
Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 21/05/2021

Location:

Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Millind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To discuss the research study of 3RD YR STUDENT

"Mucourmycosis in covid and non-covid patients, a Tertiary Care Centre study"

4.1

Minutes of meeting:-


1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from June 2021 to November 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm



Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH



Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretary-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website, <http://www.dupmc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
*Covid and
Mucormycosis in post-Covid patients, a
tertiary care centre study.*

2. Name of the Principal investigator/

Under/Post graduate student:

Chakrut Pachyally

3. Name of the co-investigator/
UG/PG guide/Trial monitor

(if applicable)

Dr. Vaishali Nagare Rathod.

4. i) Signature of Principal investigator/

UG/PG student:

Chakrut

ii) Signature of co-investigator/

UG/PG guide/Trial monitor:

Vijay

iii) Signature of HOD of Principal Investigator/UG/PG student:

(with seal)

Apamala
~~Professor & HOD~~

Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only)

Sr. No _____

Dept. _____

- 1) Date of Receipt by IEC (submission of application) _____
- 2) Date of resubmission to IEC _____
- 3) Date of IEC meeting _____
- 4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED. _____
- 5) IEC decision conveyed on date: _____


CHAIRPERSON
I.E.C.


MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

At DUPMC&H

(B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Uhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

6 Months

7) Risk factor for the patient (give details):

A) Procedural: _____

N.A

B) Adverse drug reaction (ADRs):

N.A

C) Invasive investigations (if any):

N.A

D) Explain the measures to counter the above risk factors:

N.A

8) Details about research project : *Submitted in synopsis*

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met: *Cost of investigation* YES/NO *of serum iron & HbA, C*

10) Whether the research project is sponsored:

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR

(5) Any other (give details).

(DUPMC)

11) Any other relevant information:

—

—

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

- (a) Patient information sheet.
- (b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
- (c) Case Record Form (CRF)
- (d) Undertaking by the investigator (Appendix VII)
- (e) Stability testing of new drug (Appendix IX)
- (f) Content of the proposed protocol for conducting clinical trial (Appendix X)
- (g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
- (h) Study Flow Chart if any.
- (i) News paper publication matter for subject recruitment if any.
- (j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature of Principal Investigator.

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Prabhakar Laidinethy hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis	<i>Covid and</i>
	<i>Muscomyosis in post-COVID patients: A tertiary care center study.</i>

Kindly do the needful.

Prabhakar Laidinethy

Prabhakar

(Candidate name and signature)

Pradyumn

(Guide name and signature)

Pradyumn
(HOD name and signature with Dept. seal)
PROFESSOR & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kti, Jalgaon



Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

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and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon-Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmc@yahoo.in

Date:- 08/05/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 10/05/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Millind P. Joshi
6	-Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.


Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 10/05/2021

Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Millind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office



3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dipmc.ac.in/>
Covering letter

Through Proper Channel Only

Date- 25/04/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/Mrs.....SHWETA A. MANDLIK.....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis

PREVALENCE OF RISK FACTORS FOR KIDNEY STONE
PATIENTS IN TERTIARY CARE CENTRE IN JALGAON,
MAHARASHTRA, INDIA.

Kindly do the needful.

SHWETA A. MANDLIK

(Principal Investigator name and signature)

Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh., Jalgaon

(Guide name and signature)

(HOD name and Signature with Dept. seal)

Dept. of Gen. Surgery

Professor & Head



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.diprnc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)
OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.: To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	Title of the Research Project/ Dissertation PREVALENCE OF RISK FACTORS IN KIDNEY STONE PATIENTS IN TERTIARY CENTRE IN JALGAON, MAHARASHTRA, INDIA	Signature
2.	Name of the Principal Investigator/ Under/Post graduate student: SHWETA A. MANDLIK	
3.	Name of the co-investigator/s (if applicable) i) DR. SHREYASH SOMAWANE ii) iii) iv)	
4.	Name of UG/PG guide	
5.	Name of Trial monitor / co-guide DR. SHIVAJI P. SABULWAD	 M.D. Department of Surgery Dr. Ulhas Patil Medical College (With seal) Jalgaon, Maharashtra
6.	HOD of Principal Investigator/UG/PG student: DR. SHIVAJI P. SABULWAD	 Dept. of Gen. Surgery Dr. Ulhas Patil Medical College (With seal) Jalgaon, Maharashtra
7.	HOD of other Departments involved	(With seal)

8.	Place where research work will be carried out	Yes / No
	a. At DUPMC&	Yes
	b. Outside DUPMC&H.	Yes / No
9.	(Permission letter to be submitted if outside DUPMC&H) Time period required for completion of research project and it's analysis (Approximately)	Yes / No From -To (Date) 29/04/21 - 30/05/22
10.	Risk factor for the patient (give details): A) Procedural B) Adverse drug reaction (ADRs) C) Invasive investigations (if any) D) Explain the measures to counter the above risk factors.	

11.	Details about research project must include	Yes	No
	(a) Project title	yes	
	(b) Aims and objectives:	yes	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	yes	
	(d) Materials and methods (Research plan and its implications)	yes	
	(e) Statistical analysis	yes	
	(f) Conflict of interest:	yes	
	(g) Risk factors:	yes	
	(h) List of references:	yes	



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupatc.ac.in/>

12.	Details of financial burden involved and how it will be met:	
13.	Whether the research project is sponsored:	Yes / No
14.	Sponsoring authority: (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).	
15.	Any other relevant information:	

16. Enclosures:

	Attached	Not attached	Not applicable
1	✓		
2	✓		
3	✓		
4	✓		
5			✓
6			✓
7			✓
8	✓		
9			✓
10			✓

[Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.]

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.


Signature

Principal Investigator.

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmch.ac.in/>

(For IEC Office use only)

1	Sr. No given to project	95. 04. 2021
2	Department	G. Surgery
3	Date of Receipt by IEC (submission of application)	25.04.2021
4	Date of resubmission to IEC	10.05.2021
5	Date of IEC meeting	10.05.2021
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved.
7	IEC decision conveyed on date	10.05.2021


CHAIRPERSON
IEC, DUPMCH




MEMBER SECRETARY
IEC, DUPMCH

1. Title: Prevalence of risk factors in kidney stone patients in tertiary care centre in Jalgaon, Maharashtra, India

2. Introduction

- Kidney stone disease is a common clinical problem worldwide. It is the formation of stones in kidney by the successive physicochemical events of supersaturation, nucleation and aggregation, which eventually culminates in retention of stone.
- The epidemiology of nephrolithiasis differs according to geographical area in terms of prevalence and incidence, age and sex distribution, eating habits, sources of drinking water etc. Data studies show rising global prevalence of nephrolithiasis. Risk of developing nephrolithiasis in adults appears to be higher in the West (4% in Germany, 5-9% in Europe, 10-12% in Canada and 13-15% in US) than in the East. Nephrolithiasis is common in ages of 40-49 years in the US; 50-59yrs in Japan. High risk of nephrolithiasis has also been found in Asian and third world countries such as Saudi Arabia, India, Malaysia, Thailand etc.
- In India, urolithiasis affects 2 million people every year. The "stone belt" occupies parts of Maharashtra, Gujarat, Rajasthan, Punjab, Haryana, Delhi and states of North east. Stone patients from North India were found to have a high rate of consumption of oxalate rich foods, dairy products, and alcohol. In India, 12% of population is estimated to have renal stones, out of which 50% may progress to renal damage or loss of renal function. Nearly 15% of people from Northern India are affected with kidney stones. Prevalence of nephrolithiasis in Indian males is 10.60% while that in females is 7.10%.
- Kidney stone disease has gained increasing significance because of its rising prevalence, and also due to its tendency to recur within 5 to 10 years. Epidemiological studies indicate that factors like age, sex, race, ethnicity, geography, climate, occupation, socioeconomic status, daily water intake and dietary habits of an individual influence kidney stone formation and recurrence.
- Food patterns are among the major factors for renal stone formation. In the context of Indian diet, there is a collection of different tastes and food products. Several communities in the country are vegetarian, although there is still a large range of non-vegetarian recipes. Increased urinary

calcium excretion is attributed to animal proteins. Oxalate stones are a result of diets rich in spinach, tomatoes, beetroot, sweet potatoes and almonds. This food pattern in Indian culture attributes to high incidence of nephrolithiasis specially in the "stone belt". An equally crucial factor is the frequency or amount of water consumption, hard/soft water and the sources from which these populations obtain drinking water.

3. OBJECTIVE

- Primary objective:
- The aim of the study is to determine the prevalence of risk factors in kidney stone patients in our hospital-a tertiary care centre in Jalgaon.
- Secondary objective:
- To provide evidence for the formulation of evidence-based changes in lifestyle and eating habits, as well as creating awareness regarding preventive measures.
- To update an essential database with details of patients with kidney stones, highlighting the risk factors which attribute to the condition.

4. METHODOLOGY:

- The type of study is Cross-sectional type of epidemiological study.
- Study setting- The data will be collected from patients who are currently admitted to the Surgery ward of our hospital with diagnosis of renal calculi.
- Study period- Total of 9 months from May 2021 to February 2022.
- Study population- All voluntary symptomatic patients diagnosed with kidney stones and admitted to our hospital.
- All patients in the sample of 100 are given self-administered questionnaire and relevant information is obtained by medical case history.

5. METHOD OF COLLECTION OF DATA

- This is a hospital-based study conducted in Department of Surgery, DUPMC&H, Jalgaon, Maharashtra, India.

- After taking written informed consent, patients with clinical features of nephrolithiasis and radiological confirmation of obstructive calculus will be included.
- Information regarding residential address, daily volume of water consumption, eating habits, and source of drinking water will be collected from 100 patients with obstructive kidney stones.
- Some of the relevant information about the patients will be obtained from medical case history.
 - Inclusion Criteria:
 - Age between 10 and 80 years
 - Temperature- afebrile or below 37 C/98.4 F
 - Pulse between 60 to 100 beats per minute
 - History of vaccination
 - Exclusion Criteria:
 - Age less than 10 and more than 80 years
 - Previously operated for renal stones
 - Temperature- above 37.5 C/ 99.5 F

6. Data collected which will be coded, entered, validated and analysed using Microsoft Excel.

7. ETHICAL APPROVAL

The current study will be carried after approval by ethical committee of hospital. The study involves analyses of available data. The study maintains confidentiality of all the patients involved.

8. IMPLICATIONS

- Data obtained from this study can be utilized for screening larger population for better public health.
- To review the trends of nephrolithiasis in our hospital as this study has not been conducted previously.
- To create awareness among the local population regarding risk factors and possible preventive measures.

9. REFERENCES

1. Prakash R, Arunachalam, Narayanasamy. Prevalence and socio-demographic status on kidney stone patients in Thanjavur district, Tamil Nadu, India. *Int J Community Med Public Health* 2019;6:1943-7..
2. Faridi MS, Singh KS. Preliminary study of prevalence of urolithiasis in North-Eastern city of India. *J Family Med Prim Care*. 2020;9(12):5939-5943. Published 2020 Dec 31. doi:10.4103/jfmpe.jfmpe_1522_20.
3. Mitra, Pubali & Pal, Dilip & Das, Madhusudan. (2018). Does quality of drinking water matter in kidney stone disease: A study in West Bengal, India. *Investigative and Clinical Urology*. 59. 158. 10.4111/icu.2018.59.3.158..
4. Sofia, H.Nalini & Manickavasakam.K, & Walter, Thomas M. (2016). PREVALENCE AND RISK FACTORS OF KIDNEY STONE. *Global journal for Research Analysis*. volume 5. page 183-187.
5. Khalili P, Jamali Z, Sadeghi T, Esmaeili-Nadimi A, Mohamadi M, Moghadam-Ahmadi A, Ayoobi F, Nazari A. Risk factors of kidney stone disease: a cross-sectional study in the southeast of Iran. *BMC Urol*. 2021 Oct 8;21(1):141. doi: 10.1186/s12894-021-00905-5. PMID: 34625088; PMCID: PMC8499392.
6. Shah P, Baral R, Agrawal CS, Lamsal M, Baral D, Khanal B. Urinary Calculi: A Microbiological and Biochemical Analysis at a Tertiary Care Hospital in Eastern Nepal. *Int J Microbiol*. 2020 Sep 12;2020:8880403. doi: 10.1155/2020/8880403. PMID: 33005194; PMCID: PMC7503111.

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

SHWETA A. MANDLIK

T-1, 904, CAPITOL HEIGHTS

MEDICAL SQUARE, NAGPUR - 440003

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL

NH-6, BHUSANJAL ROAD

JALGAON - 425309

3. Name and address of all clinical laboratory facilities to be used in the study.

NIL

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

IEC, DUMCH, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

NIL

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.


PREVALENCE OF RISK FACTORS FOR KIDNEY
STONE PATIENTS IN TERTIARY CARE CENTRE
IN JALGAON, MAHARASHTRA, INDIA

7. Commitments:

- i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
- ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate

- hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
- iii. I agree to personally conduct or supervise the clinical trial at my site.
 - iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
 - v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
 - vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
 - vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
 - viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
 - ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.
 - x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event
 - xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
 - xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with date.


25/04/27



INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA

OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone: No. (Office) 0257-2366657 (fax) 0257-2366648 Website: <http://www.dugimc.ac.in/>
Covering letter

Through Proper Channel Only

Date: 25/08/24

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. SHWETA A. MANDLIK hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

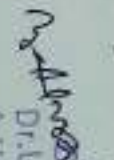
Title of Synopsis

PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN TALWADN MAHARASHTRA, INDIA.

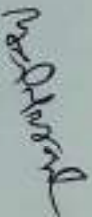
Kindly do the needful.


SHWETA A. MANDLIK

(Principal Investigator name and signature)
Professor & Head


Dr. Ulhas Patil, of Gen. Surgery
& Hospital, Jalgaon Kh., Jalgaon
(HOD name and Signature with Dept. seal)

(Guide name and signature)





RESEARCHES IN MEDICINE




INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone: No. (Office) 0257-236657 (Fax) 0257-236648 Website: <http://www.dpmc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE) OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.: * To be submitted in TRIPPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	Title of the Research Project/ Dissertation PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CENTRE IN JALGAON, MAHARASHTRA, INDIA.	
2.	Name of the Principal Investigator/ Under/Post graduate student: SHWETA A. MANDLIK	Signature 
3.	Name of the co-investigator/s (if applicable) i) DR. SHRIYASH SONAWANE ii) iii) iv)	
4.	Name of UG/PG guide DR. SHIVAJI P. SADDULWANI	
5.	Name of Trial monitor / co-guide	
6.	HOD of Principal Investigator/UG/PG student: DR. SHIVAJI SADDULWANI	 Department of Surgery Dr. Ulhas Patil Medical College (With seal) Jalgaon Kh. Jalgaon Professor & Head of Gen. Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh., Jalgaon
7.	HOD of other Departments involved	(With seal)

8.	Place where research work will be carried out	Yes / No
		Yes / No
9.	Time period required for completion of research project and it's analysis (Approximately)	Yes / No
		From -To (Date) 29.04.21 - 30.05.21
10.	Risk factor for the patient (give details): A) Procedural B) Adverse drug reaction (ADRs) C) Invasive investigations (if any) D) Explain the measures to counter the above risk factors.	

11.	Details about research project must include	Yes	No
	(a) Project title		
	(b) Aims and objectives:		
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic		
	(d) Materials and methods (Research plan and its implications)		
	(e) Statistical analysis		
	(f) Conflict of interest:		
	(g) Risk factors:		
	(h) List of references:		



INSTITUTIONAL ETHICS COMMITTEE

DR. USHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone: No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dipmc.ac.in/>

12.	Details of financial burden involved and how it will be met:	
13.	Whether the research project is sponsored:	Yes / No
14.	Sponsoring authority: (mention the name)	
	(1) Industry	
	(2) Government	
	(3) University	
	(4) ICMR	
	(5) Any other (give details).	
15.	Any other relevant information:	

16. Enclosures:

	Attached	Not attached	Not applicable
1	✓		
2	✓		
3	✓		
4	✓		
5			✓
6			✓
7			✓
8	✓		
9			✓
10			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.


Signature

Principal Investigator.

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-Investigator for research on Traditional Medicine.



INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON, 425309 MAHARASHTRA

OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone: No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmc.ac.in/>

(For IEC Office use only)

1	Sr. No given to project	
2	Department	General Surgery
3	Date of Receipt by IEC (submission of application)	25.04.2019
4	Date of resubmission to IEC	10.05.21
5	Date of IEC meeting	10.05.21
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	10.05.21

CHAIRPERSON
IEC, DUPMCH



MEMBER SECRETARY
IEC, DUPMCH

1. Title: Prevalence of risk factors in kidney stone patients in tertiary care centre in Jalgaon, Maharashtra, India

2. Introduction

- Kidney stone disease is a common clinical problem worldwide. It is the formation of stones in kidney by the successive physicochemical events of supersaturation, nucleation and aggregation, which eventually culminates in retention of stone.
- The epidemiology of nephrolithiasis differs according to geographical area in terms of prevalence and incidence, age and sex distribution, eating habits, sources of drinking water etc. Data studies show rising global prevalence of nephrolithiasis. Risk of developing nephrolithiasis in adults appears to be higher in the West (4% in Germany, 5-9% in Europe, 10-12% in Canada and 13-15% in US) than in the East. Nephrolithiasis is common in ages of 40-49 years in the US; 50-59yrs in Japan. High risk of nephrolithiasis has also been found in Asian and third world countries such as Saudi Arabia, India, Malaysia, Thailand etc.
- In India, urolithiasis affects 2 million people every year. The "stone belt" occupies parts of Maharashtra, Gujarat, Rajasthan, Punjab, Haryana, Delhi and states of North east. Stone patients from North India were found to have a high rate of consumption of oxalate rich foods, dairy products, and alcohol. In India, 12% of population is estimated to have renal stones, out of which 50% may progress to renal damage or loss of renal function. Nearly 15% of people from Northern India are affected with kidney stones. Prevalence of nephrolithiasis in Indian males is 10.60% while that in females is 7.10%.
- Kidney stone disease has gained increasing significance because of its rising prevalence, and also due to its tendency to recur within 5 to 10 years. Epidemiological studies indicate that factors like age, sex, race, ethnicity, geography, climate, occupation, socioeconomic status, daily water intake and dietary habits of an individual influence kidney stone formation and recurrence.
- Food patterns are among the major factors for renal stone formation. In the context of Indian diet, there is a collection of different tastes and food products. Several communities in the country are vegetarian, although there is still a large range of non-vegetarian recipes. Increased urinary

calcium excretion is attributed to animal proteins. Oxalate stones are a result of diets rich in spinach, tomatoes, beetroot, sweet potatoes and almonds. This food pattern in Indian culture attributes to high incidence of nephrolithiasis specially in the "stone belt". An equally crucial factor is the frequency or amount of water consumption, hard/soft water and the sources from which these populations obtain drinking water.

3. OBJECTIVE

- Primary objective:

- The aim of the study is to determine the prevalence of risk factors in kidney stone patients in our hospital-a tertiary care centre in Jalgaon.

- Secondary objective:

- To provide evidence for the formulation of evidence-based changes in lifestyle and eating habits, as well as creating awareness regarding preventive measures.
- To update an essential database with details of patients with kidney stones, highlighting the risk factors which attribute to the condition.

4. METHODOLOGY:

- The type of study is Cross-sectional type of epidemiological study.
- Study setting- The data will be collected from patients who are currently admitted to the Surgery ward of our hospital with diagnosis of renal calculi.
- Study period- Total of 9 months from May 2021 to February 2022.
- Study population- All voluntary symptomatic patients diagnosed with kidney stones and admitted to our hospital.
- All patients in the sample of 100 are given self-administered questionnaire and relevant information is obtained by medical case history.

5. METHOD OF COLLECTION OF DATA

- This is a hospital-based study conducted in Department of Surgery, DUPMC&H, Jalgaon, Maharashtra, India.

- After taking written informed consent, patients with clinical features of nephrolithiasis and radiological confirmation of obstructive calculus will be included.
- Information regarding residential address, daily volume of water consumption, eating habits, and source of drinking water will be collected from 100 patients with obstructive kidney stones.
- Some of the relevant information about the patients will be obtained from medical case history.
- Inclusion Criteria:
 - Age between 10 and 80 years
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 - Pulse between 60 to 100 beats per minute
 - History of vaccination
- Exclusion Criteria:
 - Age less than 10 and more than 80 years
 - Previously operated for renal stones
 - Temperature- above 37.5 C/ 99.5 F

6. Data collected which will be coded, entered, validated and analysed using Microsoft Excel.

7. ETHICAL APPROVAL

The current study will be carried after approval by ethical committee of hospital. The study involves analyses of available data. The study maintains confidentiality of all the patients involved.

8. IMPLICATIONS

- Data obtained from this study can be utilized for screening larger population for better public health.
- To review the trends of nephrolithiasis in our hospital as this study has not been conducted previously.
- To create awareness among the local population regarding risk factors and possible preventive measures.

9. REFERENCES

1. Prakash R, Arunachalam, Narayanasamy. Prevalence and socio-demographic status on kidney stone patients in Thanjavur district, Tamil Nadu, India. *Int J Community Med Public Health* 2019;6:1943-7..
2. Faridi MS, Singh KS. Preliminary study of prevalence of urolithiasis in North-Eastern city of India. *J Family Med Prim Care*. 2020;9(12):5939-5943. Published 2020 Dec 31. doi:10.4103/jfmpe.jfmpe_1522_20.
3. Mitra, Pubali & Pal, Dilip & Das, Madhusudan. (2018). Does quality of drinking water matter in kidney stone disease: A study in West Bengal, India. *Investigative and Clinical Urology*. 59. 158. 10.4111/icu.2018.59.3.158..
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5. Khalili P, Jamali Z, Sadeghi T, Esmaceli-Nadimi A, Mohammadi M, Moghadam-Ahmadi A, Ayooobi F, Nazari A. Risk factors of kidney stone disease: a cross-sectional study in the southeast of Iran. *BMC Urol*. 2021 Oct 8;21(1):141. doi: 10.1186/s12894-021-00905-5. PMID: 34625088; PMCID: PMC8499392.
6. Shah P, Baral R, Agrawal CS, Lamsal M, Baral D, Khanal B. Urinary Calculi: A Microbiological and Biochemical Analysis at a Tertiary Care Hospital in Eastern Nepal. *Int J Microbiol*. 2020 Sep 12;2020:8880403. doi: 10.1155/2020/8880403. PMID: 33005194; PMCID: PMC7503111.

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

SHWETA A. MANDLIK

T-1, 904, CAPITOL HEIGHTS
MEDICAL SQUARE, NAGPUR - 440003

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL

NH-6, BHUSANVAL ROAD

JALGAON - 425309

3. Name and address of all clinical laboratory facilities to be used in the study.

NIL

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

IEC, DUMC&H, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

NIL

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

PREVALENCE OF RISK FACTORS FOR KIDNEY
STONE PATIENTS IN TERTIARY CARE CENTRE
IN SALGAON, MAHARASHTRA, INDIA.

7. Commitments:

- i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
- ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate

hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.



25/04/21

3. Signature of Investigator with date.



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmc.ac.in>
Covering letter

Through Proper Channel Only

Date: 25/04/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. SHWETA A. MANDLIK.....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis

PREVALENCE OF RISK FACTORS FOR KIDNEY STONE
PATIENTS IN TERTIARY CARE CENTRE IN JALGAON,
MAHARASHTRA, INDIA.

Kindly do the needful.

SHWETA A. MANDLIK

(Principal Investigator name and signature)

Professor & Head

Dept. of Gen. Surgery
Dr. Ulhas Patil Medical College
Jalgaon, Dist. Jalgaon, Maharashtra

(Guide name and signature)

(HOD name and Signature with Dept seal) Kh., Jalgaon



INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone: No. (Office) 0257-2366657 [Fax] 0257-2366648 Website: <http://www.ulhaspatil.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE) OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.: * To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	Title of the Research Project/ Dissertation PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CENTRE IN JALGAON, MAHARASHTRA, INDIA	
2.	Name of the Principal Investigator/ Under/Post graduate student: SHWETA A. MANDLIK	Signature
3.	Name of the co-investigator/s (if applicable) i) DR. SHRIYASH SONAWANE ii) iii) iv)	
4.	Name of UG/PG guide	
5.	Name of Trial monitor / co-guide DR- SHIVAJI SADBULWAD	 Department of Surgery Dr. Ulhas Patil Medical College
6.	HOD of Principal Investigator/UG/PG student: DR. SHIVAJI SADBULWAD	(With Seal) Head, Jalgaon, Kh. Jalgaon Principal & Head Department of Gen. Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh., Jalgaon
7.	HOD of other Departments involved	(With seal)

8.	Place where research work will be carried out	Yes / No
	a. At DUPMC&H	Yes / No
	b. Outside DUPMC&H.	Yes / No
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	Time period required for completion of research project and it's analysis (Approximately)	From -To (Date) 29/04/2021 - 30/05/2022
10.	Risk factor for the patient (give details):	
	A) Procedural	
	B) Adverse drug reaction (ADRs)	
	C) Invasive investigations (if any)	
	D) Explain the measures to counter the above risk factors.	

11.	Details about research project must include	Yes	No
	(a) Project title	yes	
	(b) Aims and objectives:	yes	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	yes	
	(d) Materials and methods (Research plan and its implications)	yes	
	(e) Statistical analysis	yes	
	(f) Conflict of interest:	yes	
	(g) Risk factors:	yes	
	(h) List of references:	yes	



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dipmc.ac.in/>

12.	Details of financial burden involved and how it will be met:
13.	Whether the research project is sponsored: Yes / No
14.	Sponsoring authority: (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).
15.	Any other relevant information:

16. Enclosures:

	Attached	Not attached	Not applicable
1	✓		
2	✓		
3	✓		
4	✓		
5			✓
6			✓
7			✓
8	✓		✓
9			✓
10			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature

Principal Investigator.


- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-Investigator for research on Traditional Medicine.



INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON, 425309 MAHARASHTRA
OFFICE: Member Secretary-IEC, Dept. of Pharmacology
Phone: No. (Office) 0257-236657 (Fax) 0257-236648 Website: <http://www.dupmc.ac.in/>

(For IEC Office use only)

1	Sr. No given to project	
2	Department	G. Surgery
3	Date of Receipt by IEC (submission of application)	25.04.24
4	Date of resubmission to IEC	10.05.24
5	Date of IEC meeting	10.05.24
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	10-05-24


CHAIRPERSON
IEC, DUPMCH




MEMBER SECRETARY
IEC, DUPMCH

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

SHWETA A. MANDLIK
T-1, 304, CAPITOL HEIGHTS
MEDICAL SQUARE, WASHINGTON - 440003

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

DR ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
NH-6, BHUSAWAL ROAD
SALGAON - 425309

3. Name and address of all clinical laboratory facilities to be used in the study.

NIL

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

IEC, DOPMCH, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

NIL

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.


PREVALENCE OF RISK FACTORS FOR KIDNEY
STONE PATIENTS IN TERTIARY CARE CENTRE
IN SALGAON, MUMBAI RAJSHTRA, INDIA

7. Commitments:

i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate

- hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
- iii. I agree to personally conduct or supervise the clinical trial at my site.
 - iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
 - v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
 - vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
 - vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
 - viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
 - ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.
 - x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event
 - xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
 - xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.



25/04/21

8. Signature of Investigator with date.



Godavari Foundation's

Dr. Uhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon-Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmc@yahoo.in

Date:- 17/02/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 18/02/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvkar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean

Dr. Uhas Patil Medical
College & Hospital, Jalgaon
kh.



Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 18/02/2021

Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	X
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvkar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of Dr. Vaishali Nagose (Prof. Department of Pathology, DUPMCH)

“Effect of recent IAC guidelines for serous fluid cytology reporting, repeat sampling and cell block on atypical cell categories in serous fluid cytology”.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from March 2021 to April 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm


Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II



INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretary-IEC, Professor, Dept. of Pharmacology

Phone: No. (Office) 0257-236657 Fax) 0257-236648 Website: <http://www.dipmc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.: * To be submitted in TRIPPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
Effect of Ketansin-like Guidelines for Snows Fluid Cytology Reporting, Repeat Sampling and Colloidal block in Atypical cells categories in snows Fluid cytology.

2. Name of the Principal Investigator
Under/Post graduate student
Dr. Yashwantrao. Patil

3. Name of the co-investigator/
UG/PG guide/Trial monitor
(if applicable)
Dr. Shilpa Gondane

4. i) Signature of Principal investigator/
UG/PG student:
Patil

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:
Patil

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)
Patil

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):


(For IEC Office use only)

Sr. No _____

Dept.....

- 1) Date of Receipt by IEC (submissi-----on of application) _____
- 2) Date of resubmission to IEC _____
- 3) Date of IEC meeting _____
- 4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED. _____
- 5) IEC decision conveyed on date: _____


CHAIRPERSON
I.E.C.


MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

✓
(A) At DUPMC&H

(B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Uhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 months

7) Risk factor for the patient (give details):

A) Procedural:

None

B) Adverse drug reaction (ADRs):

C) Invasive investigations (if any):

D) Explain the measures to counter the above risk factors:

8) Details about research project

- (a) Objectives:
- (b) Current knowledge about the research subject:
- (c) Research plan:
- (d) Implications:
- (e) Conflict of interest:
- (f) Risk factors:
- (g) Bibliography/List of references:

As mentioned in
syllabus.

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: YES/NO YES NO

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

- (a) Patient information sheet.
- (b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
- (c) Case Record Form (CRF)
- (d) Undertaking by the investigator (Appendix VII)
- (e) Stability testing of new drug (Appendix IX)
- (f) Content of the proposed protocol for conducting clinical trial (Appendix X)
- (g) Data elements for reporting Serious ADR/ADE occurring in clinical trial (Appendix XI)
- (h) Study Flow Chart if any.
- (i) News paper publication matter for subject recruitment if any.
- (j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature of Principal Investigator.

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Clearance.
Sub: Submission of Synopsis of research protocol for Ethical

Respected Sir/Madam,

I the undersigned, Dr. Vaidali Nagose hereby submitting synopsis of my research protocol/ ~~PG~~ ^{PG} dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis

Effect of Recent IAC guidelines for Serum Fluid cytology Reporting, Repeat sampling & cell block on Atypical Cells Categorized in serum fluid cytology.

Kindly do the needful.



Co Investigator

(Candidate name and signature)

Dr. Shivish Gondane,

(HOD name and signature with Dept. seal)



Dr. Anagha Anand Chopade

Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kti, Jalgaon

Effect of Recent IAC Guidelines for Serous Fluid Cytology Reporting, Repeat Sampling and Cell Block on Atypical Cells Categories in Serous Fluid Cytology.

Cytological examination of body fluids has increasingly gained acceptance in clinical medicine to such extent that once positive diagnosis is made often considered definitive diagnosis and it is paramount important to identify primary site and type of malignancy. This can help to obviate the proper surgical management, chemotherapy and radiotherapy so as to increase patients' survival rate [1,2].

Established international reporting terminology systems are already in place for cervical,[3] urinary tract,[4] thyroid,[5] salivary gland,[6] pancreatico-biliary,[7] and pulmonary cytology.[8] As of now, there is absence of a globally accepted and widely used reporting terminology system for serous effusion cytology samples. However, for reporting effusion cytology specimens, there was no consistent and reproducible reporting system until recently. Not long ago, the international system for reporting serous fluid cytopathology was announced.[9] In the beginning of year 2020. Also, Recently the Indian Academy of Cytologists (IAC) has published the guidelines for interpretation and reporting of serous effusions [10]. Till date, there are only occasional studies on its applicability. However, the criteria for diagnosis of the atypical cells if strictly followed, promise to reduce the number of entries in this group.

A major diagnostic challenge lies in the distinction of atypical/reactive mesothelial cells from malignant adenocarcinoma cells. Smears may be reported initially as atypical on cytology, probably misinterpreted due to overlapping cytomorphological features. Both architecturally and cytologically reactive mesothelial cells may pose a diagnostic challenge. Detection of malignant cells on effusion cytology in these patients becomes at times difficult.

Conventional smear is a much simpler procedure than that of cell block technique, it has lower sensitivity in these cases because of overcrowding of cells, cell loss, lack of architecture and also, abundance of inflammatory cells and paucity of representative cells contribute to considerable difficulties in making conclusive diagnosis on conventional smears [11,12]. Cell block technique is one of the oldest method has advantages like it concentrates minimal amount of cellular material in one small area that can be evaluated at a glance with all cells lying in the same focal plane of the microscope, and as it uses of histological techniques it gives better cellular morphology better nuclear and cytoplasmic preservation, intact cell membrane and crisp chromatin details , preservation of architectural pattern like cell balls, papillae, acini, rosettes and individual cell characteristic, representing its primary site of malignancy, fragment of this tissue can easily interpreted in a biopsy-like fashion [11,12]. On the other hand as multiple section of same material can be obtained for special stains and immunohistochemistry. And also the possibility of storing slides for retrospective studies also done , as storage of the conventional smears is a practical problem [1,2] . These advantages of the CB can give the advent of sorting the atypical cells into the malignant or benign group upto a certain extent.

If there is a suspicion of malignancy on clinical/imaging grounds, a repeat cytology evaluation has been proven to be of use. It is also known to have a potential to change the categories such as atypical /suspicious of malignancy to move them into clear cut benign and malignant categories on repeat sampling and/or ancillary testing.[13]

Aims:

1. To assess the feasibility of applying the IAC reporting categories to effusions, determine the frequency of various categories including atypical cases.
2. To compare the categorization after the repeat sampling in these atypical category cases.
3. To compare the categorization after the study of cell block prepared from these cases.

Materials and Methods: The study will be carried out in accordance with the standards laid down in the Helsinki Declaration. Relevant details will be noted from the sample requisition forms. Medical records will be searched for the clinical, radiological, and histopathological follow-up. Cases with no hospital record of malignancy in one year will be presumed to have a benign course. Categorization of cases as per the recent IAC Guidelines for interpretation and reporting of serous effusion samples will be done.[10] Papanicolaou smears of fluid cytology samples received over calendar years January 2018 to June 2021 will be reviewed retrospectively by an expert in cytopathology blinded to the final clinical and/or histopathological diagnoses. Cases with discrepancies after review will be noted. Data were analyzed using SPSS version 16.

References:

1. Koss LG et al: Effusions in the presence of cancer. In Koss' Diagnostic Cytology and its Histopathologic Bases, 5th edition. Edited by Koss LG, Melamed MR, Vol 2, Philadelphia :Lippincott, Williams & wilkins 2006, 950-951.
2. Dekker A, Bupp PA. Cytology of serous effusions. An investigation into the usefulness of cellblocks versus smears. Am J Clin Pathol 1978;70 (6):855-860.
3. Nayar R, Wilbur DC. The Bethesda system for reporting cervical cytology: A historical perspective. Acta Cytol 2017;61:359-72.
4. Barkan GA, Wojcik EM, Nayar R, Savic-Prince S, Quek ML, Kurtycz DF, et al. The Paris system for reporting urinary cytology: The quest to develop a standardized terminology. Acta Cytol 2016;60:185-97.
5. Cibas ES, Ali SZ. The 2017 Bethesda system for reporting thyroid cytopathology. Thyroid 2017;27:1341-6.
6. Rossi ED, Faquin WC, Baloch Z, Barkan GA, Foschini MP, Pusztaszeri M, et al. The Milan system for reporting salivary gland cytopathology: Analysis and suggestions of initial survey. Cancer Cytopathol 2017;125:757-66.
7. Pitman MB, Layfield LJ. Guidelines for pancreaticobiliary cytology from the Papanicolaou society of cytopathology: A review. Cancer Cytopathol 2014;122:399-411.



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Dr. Ulhas Patil Medical College & Hospital

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and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jaalgaon-Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 07/01/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 08/01/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr.No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.


Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)

Jalgaon Khurd (Dist. Jalgaon) M. S.

Pin - 425 309

Phone: (0257) 2366657

Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 08/01/2021

Location:

Dean's Office

Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvkar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of three OBGY and two Pediatrics PGs-

1	Dr. DONGARWAR AKASHKUMAR SHALIKRAM	AN OBSERVATIONAL STUDY OF INTRAOPERATIVE DIFFICULTIES IN REPEAT CAESAREAN SECTION COMING TO TERTIARY CARE HOSPITAL
2	Dr. MAHESH GAJANAN DESHMUKH	TRANSABDOMINAL ULTRASOUND ASSESSMENT OF FETAL OCCIPUT - SPINE ANGLE TO PREDICT THE MODE OF DELIVERY
3	Dr. YASHASHREE PRADIP DESHMUKH	A STUDY OF UTERINE ARTERY DOPPLER FOR PREDICTION OF PREECLAMPSIA FROM 12 TO 26 WEEKS OF GESTATION IN TERTIARY CARE CENTER.
4	Dr. RANGNEKAR PRADNIL KISHOR	CLINICAL PROFILE OF LOW BIRTH WEIGHT NEONATES ADMITTED IN NICU AT TERTIARY CARE CENTER
5	Dr. SHUKLA SURUCHI RAMPRASAD	PROSPECTIVE STUDY OF CLINICAL OUTCOME OF EARLY DISCHARGED VERY LOW BIRTH WEIGHT BABIES FROM NICU AT WEIGHT BETWEEN 1300GMS TO 1800GMS.

Minutes of meeting:-


1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr Devendra R. Chaudhari,
Member Secretary
DUPMCH



Appendix II

INSTITUTIONAL ETHICS COMMITTEE

**DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA**

OFFICE: Member Secretary-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. <http://www.dupmc.ac.in>

**APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)
OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)**

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project: Study of Association of E-Selectin and Hematological Parameters In Patients of Sickle Cell Disease.

2. Name of the Principal Investigator

**Dr .Anagha Amale (Chopade), Professor, Pathology Department
DUPMC, Jalgaon.**

3. Name of the co-investigator

**Dr. Uditkumar Agrawal, Associate Professor, Biochemistry Department, GMC,
Khandwa.**

4. i) Signature of Principal Investigator

Anagha

ii) Signature of co- investigator/

Udit

iii) Signature of HOD of Principal Investigator (with seal)

Anagha

Professor & HOD

Dept. of Pathology

Dr. Ulhas Patil Medical College & Hospital

Jalgaon Kh, Jalgaon

(For IEC Office use only)


Sr. No _____

Dept......

- 1) Date of Receipt by IEC (submission of application) _____
- 2) Date of resubmission to IEC _____
- 3) Date of IEC meeting _____
- 4) Decision of IEC: APPROVED/REJECTED _____

5) IEC decision conveyed on date:


CHAIRPERSON
I.E.C.


MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out
At DUPMC&H

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:
3 months.

7) Risk factor for the patient (give details): None.

5) Details about research project-Synopsis Attached

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

8) Details of financial burden involved and how it will be met: No financial burden.

9) Whether the research project is sponsored: Yes.
Sponsoring authority: Self.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

- (a) Patient information sheet.
- (b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
- (c) Case Record Form (CRF)
- (d) Undertaking by the Investigator (Appendix VII)
- (e) Stability testing of new drug (Appendix IX)
- (f) Content of the proposed protocol for conducting clinical trial (Appendix X)
- (g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
- (h) Study Flow Chart if any.
- (i) News paper publication matter for subject recruitment if any.
- (j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

मनामो
शान्त अर्जुन च
I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

मनामो
Signature of Principal Investigator.

Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh., Jalgaon

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jaigaon.

Sub: Submission of Synopsis of research protocol for Ethical

Clearance.

I the undersigned, Dr Anagha Amale (Chopade) hereby submitting synopsis of my research protocol for ethical clearance. Kindly consider it for approval from ethics committee.
I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis: Study of Association of E-Selectin and Hematological parameters in patients of Sickle Cell Disease.

Kindly do the needful.

Anagha
Dr Anagha Amale
(Candidate name and signature)

Anagha
Dr Anagha Amale
(HOD name and Signature with Dept. seal)

(Guide name and signature)

CASE RECORD FORM

1. Full name of the Subject
2. Age
3. Gender
4. Height
5. Weight
6. Blood Pressure
7. Pulse
8. Pallor
9. Icterus
10. Family History
11. History of Present Illness

12. Any other associated Disorders/Diseases:

Informed Consent Form

I (the undersigned), am willingly ready to participate in the study titled "**Study of Association of E-Selectin, Hematological and Biochemical Parameters in patients of Sickle Cell Disease**". I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

I (the undersigned), am willingly ready to participate in the study titled **"Prevalence of Sickle Cell Disorders in patients visited to Tertiary Care Hospital"**. I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

I (the undersigned), am willingly ready to participate in the study titled **"Hematological indices, electrolyte status & effect of micronutrients and vitamins on polymerization in sickle cell disease at rural based tertiary care hospital"**. I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Research Protocol

Title of the Research Project: Study of Association of E-Selectin and Hematological Parameters in Patients of Sickle Cell Disease.

Introduction: In patients of sickle cell disease, there was statistically significant variation in the red cell indices. Very few studies have been shown less commonly determined variables such as erythrocyte indices like MCV, MCH, MCHC width in this region of India.(1-6)

Aim: To find the association of E-Selectin and Hematological Parameters In Patients of Sickle Cell Disease.

Objectives: 1.To find relationship between E-selectin and hematological parameters.

2. to find relationship between E-selectin and other biochemical parameters.

Materials and methods:Invasive investigations: The parameters analyzed will be plasma soluble E selectin, hemoglobin, total RBC Count, total leukocyte count(TLC), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration(MCHC) and other parameters like serum SGPT, SGOT, RBS, Creatinine, Urea parameters. Observations will be analyzed statistically by SPSS version 20.

Study type: Prospective study

Study duration: 3 months

Place of study: DUPMC hospital

Statistical Analysis: SPSS version 20.

Implications: Early assessment of risk of hemolysis with the evaluation of routine parameters. Better services will be timely provided to the patients.

Conflict of interest: None

Risk factors: None

Bibliography/List of references:

1. Deore A.U.and Zade S.B. Epidemiology of sickle cell disorder: The urban scenario in Maharashtra, India, International Journal of Public Health and Epidemiology, 2013; 2(5) 101-107.
2. Kamble M. and Chatruvedi P.Epidemiology of sickle cell disease in a rural hospital of central India, Indian Pediatrics, 2000;37: 391-396.
3. Ahmed SG, Bukar AA,Jolayemi B Hematological Indices of Sickle Cell Tuberculosis in Northern Nigeria. Medit J Hemat Infect Dis 2010;Vol2(1):1-5
4. Omoti CE Haematological Values In Sickle Cell Anaemia In Steady State And During Vaso- Occlusive Crisis In Benin City, Nigeria Annals of African Medicine, 2005: Vol. 4(2); 62 – 67
5. Chiklikar K,Wilkinson A A Study of Red Cell Parameters in Patients of Sickle Cell Trait IOSR Journal of Dental and Medical Sciences,2014; Vol.13(3):pp 46-50
6. Tedder TF, Steeber DA, Chen A, Engel P. The selectins: vascular adhesion molecules.FACEB J, 1995Vol; 9(10):866-73.



Appendix II

INSTITUTIONAL ETHICS COMMITTEE

**DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA**

OFFICE: Member Secretary-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: <http://www.dupmc.ac.in/>

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project: PREVALENCE OF SICKLE CELL DISORDERS IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL

2. Name of the Principal Investigator

**Dr .Anagha Amale (Chopade), Professor, Pathology Department
DUPMC, Jalgaon.**

3. Name of the co-investigator

**Dr. Uditkumar Agrawal, Associate Professor, BiochemistryDepartment, GMC,
Khandwa.**

4. i) Signature of Principal investigator

Anamala

ii) Signature of co- investigator/

gms

iii) Signature of HOD of Principal Investigator (with seal)

Anamala

**Professor & HOD
Dept. of Pathology**

**Dr. Ulhas Patil Medical College & Hospital,
Jalgaon, Gujarat**


Sr. No _____

(For IEC Office use only)

Dept.....

- 1) Date of Receipt by IEC (submission of application)
- 2) Date of resubmission to IEC
- 3) Date of IEC meeting
- 4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
- 5) IEC decision conveyed on date:


CHAIRPERSON
I.E.C.


MEMBER SECRETARY
I.E.C.

- 5) Place where research work will be carried out
At DUPMC&H
(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)
- 6) Time period required for completion of research project and it's analysis:
3 months.
- 7) Risk factor for the patient (give details): None.
- 5) Details about research project-Synopsis Attached
- (a) Objectives:
 - (b) Current knowledge about the research subject:
 - (c) Research plan:
 - (d) Implications:
 - (e) Conflict of interest:
 - (f) Risk factors:
 - (g) Bibliography/List of references:
- 8) Details of financial burden involved and how it will be met: No financial burden.
- 9) Whether the research project is sponsored: Yes.
Sponsoring authority: Self.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

- (a) Patient information sheet.
- (b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
- (c) Case Record Form (CRF)
- (d) Undertaking by the investigator (Appendix VII)
- (e) Stability testing of new drug (Appendix IX)
- (f) Content of the proposed protocol for conducting clinical trial (Appendix X)
- (g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
- (h) Study Flow Chart if any.
- (i) News paper publication matter for subject recruitment if any.
- (j) Funding details of sponsor or permission letter of other institutions if any.
- (j) Regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

Dr. Umashankar
Dr. Umashankar
Dr. Umashankar

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Dr. Umashankar
Signature of Principal Investigator.

Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jaigaon Kh, Jalgaon

- 1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
- 2) Involved Traditional Medicine Doctor as Co-Investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical

Clearance.

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I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis: PREVALENCE OF SICKLE CELL DISORDERS IN PATIENTS VISITED TO

TERTIARY CARE HOSPITAL.

Kindly do the needful.

Dr Anagha Amale
(Candidate name and signature)

Dr Anagha Amale
(HOD name and Signature with Dept. seal)

(Guide name and signature)

CASE RECORD FORM

1. Full name of the Subject

2. Age

3. Gender

4. Height

5. Weight

6. Blood Pressure

7. Pulse

8. Pallor

9. Icterus

10. Family History

11. History of Present Illness

12. Any other associated Disorders/Diseases:

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I (the undersigned), am willingly ready to participate in the study titled "**Study of Association of E-Selectin, Hematological and Biochemical Parameters in patients of Sickle Cell Disease**". I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

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Name:

Date:

Signature:

Informed Consent Form

I (the undersigned), am willingly ready to participate in the study titled **"Hematological indices, electrolyte status & effect of micronutrients and vitamins on polymerization in sickle cell disease at rural based tertiary care hospital"**. I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Research Protocol

Title of the Research Project: Haematological indices ,electrolyte status & effect of micronutrients and vitamins on polymerisation in sickle cell disease at rural based tertiary care hospital.

Introduction: Sickling is accompanied by an intra-erythrocytic loss of potassium and gain of sodium, thus creating disequilibrium in the ionic strength across the cell membrane. Biochemical abnormalities have been associated with sickle cell disease. However, there is a paucity of information on the roles of these ions in the pathogenesis and management of sickle cell disease. Delicate balance of micronutrients and vitamins is required to maintain hydration and membrane integrity.(1-5)

Aim: To find the Haematological indices ,electrolyte status & effect of micronutrients and vitamins on polymerisation in sickle cell disease at rural based tertiary care hospital.

Objectives: 1.To determine the haematological values & electrolyte status that can be used in monitoring the status and management of sickle cell anaemia patients .

2. To demonstrate in practical terms, the antisickling effectiveness of some micronutrients and vitamins in inhibiting sickle cell hemoglobin polymerization.

Material and methods: Invasive investigations: The parameters will be analyzed in sickle cell patients and controls in a steady state, at DUPMC Hospital, Jalgaon Maharashtra, India. The complete blood counts (CBC) and serum electrolytes will be analyzed and compared.

The antisickling effectiveness of crude extracts of copper, cobalt, magnesium, two fat soluble vitamins(A,E) and one water soluble vitamin (C) will be investigated to ascertain the ability of ions to inhibit sickle cell hemoglobin polymerisation process. Mineral samples of concentration 1.0x10⁻¹ mM, Vitamin A of concentration 100 IU and 1 mg/ml for each of vitamins C and E will be prepared and HbSS polymerization experiment will be carried out. Data will be analyzed using SPSS version 20.0. P value \leq 0.05 will be considered to be significant.

Study type: Prospective study

Study duration: 3 months

Place of study: DUPMC hospital

Statistical Analysis: SPSS version 20.

Implications: Early assessment of risk of hemolysis with the evaluation of routine parameters. Better services will be timely provided to the patients.

Conflict of interest: None

Risk factors: None

Bibliography/List of references:

1. Meshram AW, Bhatkulkar PA, Khare R, Pazare K. Haematological indices & electrolyte status in sickle cell disease at rural hospital of Central Maharashtra. *Int J Med Sci Public Health* 2014;3:1410-1412.
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Appendix II

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OFFICE: Member Secretary-IEC, Professor, Dept. of Pharmacology

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N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

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2. **Name of the Principal Investigator**
Dr .Anagha Amale (Chopade), Professor, Pathology Department
DUPMC, Jalgaon.
3. **Name of the co-investigator**
Dr. Uditkumar Agrawal, Associate Professor, Biochemistry Department, GMC,
Khandwa.
4. i) **Signature of Principal investigator** *Amale*
ii) **Signature of co- investigator/** *gms*
iii) **Signature of HOD of Principal Investigator (with seal)**

Amale
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

(For IEC Office use only)

Sr. No _____

Dept.....

- 1) Date of Receipt by IEC (submission of application) -----
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CHAIRPERSON

I.E.C.


MEMBER SECRETARY
I.E.C.

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I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.


Signature of Principal Investigator.

PROFESSOR & HOD

Dept. of Pathology

Dr. Ulhas Patil Medical College & Hospital

Jaigaon Rd., Jalgaon

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Dr Anagha Amale
(Candidate name and signature)

Dr Anagha Amale
(HOD name and Signature with Dept. seal)

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Study duration: 3 months

Place of study: DUPMC hospital

Statistical Analysis: SPSS version 20.

Implications: Early assessment of risk of hemolysis with the evaluation of routine parameters. Better services will be timely provided to the patients.

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Risk factors: None

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2. Bunn, H. F., and Forget, B. G. (1986) Hemoglobin: Molecular, Genetic and Clinical Aspects, Saunders, Philadelphia, 2 –Serjant, G. R. (1992) Sickle Cell Disease, OUP, Oxford.
3. Francis, R. B., and Johnson, C. S. (1991) Vascular occlusion in sickle cell disease: current concepts and unanswered questions. *Blood* **77**, 1405–1414.
4. Malik P (1999). Nutrition and hemato poiesis: An overview. Workshop on Nutrient Metabolism in genetic Anemias, NHLBI, May 24-25, Bethesda MD,USA.
5. Al-Saqladi AWM, Cipolotti R, Fijnvandraat K, Brabin BJ. Growth and nutritional status of children with homozygous sickle cell disease. *Annals of Tropical Paediatrics: International Child Health*. 2008;28:165–189. doi: 10.1179/146532808x335624.



Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 15/01/2021

Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

- 4.1 To discuss the research study of three Orthopedics, two Skin and one Chest and TB PGs-

1	DR. JANBANDHU RAHUL SHANTILAL	COMPARATIVE STUDY OF FUNCTIONAL OUTCOME OF FIXATION BY OPEN AND CLOSED METHODS IN DISTAL END RADIUS FRACTURE IN TERTIARY CARE HOSPITAL
2	DR. PATIL PARIKSHIT PRATAP	TO STUDY FUNCTIONAL OUTCOME OF SURGICAL DECOMPRESSION IN LUMBAR SPINAL STENOSIS IN A RURAL HOSPITAL
3	DR. VELANKAR SUNEET NITIN	STUDY ON EFFICACY AND FUNCTIONAL OUTCOME OF AUTOLOGOUS PLATELET RICH PLASMA INJECTION IN ADHESIVE CAPSULITIS, LATERAL EPICONDYLITIS AND PLANTAR FASCIIITIS.
4	DR. KALBANDE PRAJAKTA PRAKASH	STUDY OF VARIOUS CLINICAL PATTERNS OF ADVERSE CUTANEOUS DRUG REACTIONS AT DERMATOLOGY OUT PATIENT DEPARTMENT IN A TERTIARY CARE CENTRE
5	DR. SHAIKH MUBINA IRFAN	CLINICO EPIDEMIOLOGICAL STUDY OF HERPES ZOSTER AND POST HERPETIC NEURALGIA AND ITS IMPACT ON QUALITY OF LIFE
6	DR. SAMADHAN DATTATRAYA BAHEKAR	STUDY OF POST COVID 19 PULMONARY COMPLICATIONS AT A TERTIARY CARE CENTER - PROSPECTIVE OBSERVATIONAL STUDY.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ~~EC~~ guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH



Godavari Foundation's
(Registered under the Bombay Public Trusts Act, 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 13/01/2021

Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar,	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

- 4.1 To discuss the research study of three Radiology, two Psychiatry and one Chest and TB PGs-

1	DR. BHARAPURIA KANISHKA RAVI	STUDY OF VARIOUS PATTERNS MANIFESTED BY COVID 19 INFECTION ON CHEST CT SCAN AND IMPORTANCE OF EARLY CHEST CT SCAN IN COVID 19 IN TERTIARY CARE HOSPITAL
2	DR. BHOSALE ABHIJEET DNYANESHWAR	TO STUDY THE ROLE OF MAGNETIC RESONANCE IMAGING IN DIAGNOSIS OF SPINE DISORDERS IN FARM WORKERS ATTENDING TERTIARY CARE HOSPITAL IN JALGAON KH.
3	DR. SHEIKH MOHAMMAD ZAINUL	TO STUDY THE ROLE OF ULTRASONOGRAPHY IN THE DIAGNOSIS OF BLEEDING PER VAGINUM, IN THE FIRST TRIMESTER OF PREGNANCY.
4	DR. SHAIKH MUJAHID KHADARSAB	A STUDY OF ASSOCIATION OF SERUM MAGNESIUM LEVELS WITH THE SEVERITY OF ALCOHOL WITHDRAWAL SYNDROME IN HOSPITALISED PATIENTS IN A TERTIARY CARE HOSPITAL
5	DR. YADAV GOVIND UDHAVRAO	STUDY OF PREVALENCE AND CHARACTERIZATION OF DEPRESSION IN SCHIZOPHRENIA IN A TERTIARY CARE CENTER.
6	DR. LANGADE SUSHIL SURESH	THE STUDY OF CORRELATION OF C- REACTIVE PROTEIN , LACTATE DEHYDROGENASE, SERUM FERRITIN AND D - DIMER WITH CT SCORE OF COVID PATIETS AND OUTCOME IN DEDICATED COVID HOSPITAL

Minutes of meeting:-

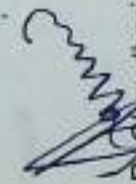
1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH



Godavari Foundation's
(Registered under the Bombay Public Trusts Act, 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 11/01/2021

Location:

Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvkar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of three Ophthalmology and two ENT PGs-

1	Dr. AKASH UTTAMRAO MALVI	A STUDY TO EVALUATE AND COMPARE VISUAL OUTCOMES AFTER CATARACT SURGERY IN DIABETICS COMPARED TO NONDIABETIC PATIENTS AT A TERTIARY CARE CENTRE.
2	Dr. ANUJA VINAYAK GADGIL	A CLINICAL STUDY OF SUTURELESS GLUEFREE CONJUNCTIVAL AUTOGRAFT REPAIR IN PTERYGIUM SURGERY.
3	Dr. DESHMUKH KALPANA ARJUNRAO	STUDY OF EFFECT OF MYOPIA AND AXIAL LENGTH ON PERIPAPILLARY RETINAL NERVE FIBRE LAYER USING SPECTRAL DOMAIN OPTICAL COHERENT TOMOGRAPHY
4	Dr. HARSHAL VASUDEO MAHAJAN	A COMPARATIVE STUDY OF ENDOSCOPIC SEPTOPLASTY OVER CONVENTIONAL SEPTOPLASTY IN TERTIARY CARE CENTER.
5	Dr. KHANDAGALE SHRUTI SHAILENDRA	A COMPARATIVE STUDY BETWEEN GRAFTS OF TRAGAL CARTILAGE, TEMPORALIS FASCIA LATA IN PATIENTS POSTED FOR REVISION TYMPANOPLASTY.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm



Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH



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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

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Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 08/01/2021

Location:

Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of Dr. Anagha Amale (Prof. Department of Pathology, DUPMCH) and Dr. Uditkumar Agrawal (Associate Professor, Biochemistry Department, GMC Khandwa)

I. PREVALENCE OF SICKLE CELL DISORDER IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL.

II. STUDY OF ASSOCIATION OF E-SELECTIN AND HEMATOLOGICAL PARAMETERS IN PATIENTS OF SICKLE CELL DISEASE

III. HEMATOLOGICAL INDICES, ELECTROLYTE STATUS AND EFFECT OF MICRONUTRIENTS AND VITAMINS ON POLYMERIZATION IN SICKLE CELL DISEASE AT RURAL BASED TERTIARY CARE HOSPITAL.

Minutes of meeting:-

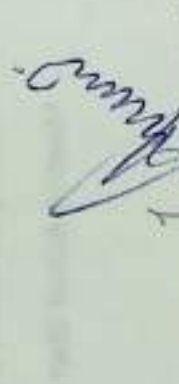
1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm



Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH



Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 07/01/2021

Location:

Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvkar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Millind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of Anesthesia and Pathology PGs-

1	Dr. DESHPANDE HARSHA SANJAY	TO STUDY THE EFFECT OF INTRAVENOUS MAGNESIUM SULPHATE IN ATTENUATING THE HEMODYNAMIC RESPONSE DURING LARYNGOSCOPY AND INTUBATION IN PATIENTS REQUIRING GENERAL ANAESTHESIA AT A TERTIARY CARE CENTRE.
2	Dr. KELGAONKAR VIJAYA VIVEK	A COMPARATIVE STUDY OF DEXAMETHASONE AS AN ADJUVANT TO LOCAL ANAESTHETIC DRUG FOR SUPRACLAVICULAR BLOCK WITH PLACEBO IN A TERTIARY CARE CENTER
3	Dr. PRAJAKTA PRAKASH SHILAHAR	COMPARATIVE STUDY BETWEEN FENTANYL AND BUPRENORPHINE AS AN ADJUVANT TO HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK FOR INFRA UMBILICAL SURGERIES
4	Dr. SONONE SHIVAJI DILIP	TO COMPARE EFFECT OF 0.75% ROPIVACAINE WITH 0.5% BUPIVACAINE IN EPIDURAL ANAESTHESIA IN LOWER LIMB SURGERIES IN TERTIARY CARE CENTRE.
5	Dr. KAMBLE PRIYANKA SHASHIKANT	THE STUDY OF FINE NEEDLE ASPIRATION CYTOLOGY OF HEAD AND NECK REGION LYMPHADENOPATHY WITH ITS HISTOPATHOLOGIC CORRELATION IN TERTIARY CARE HOSPITAL

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr Devendra R Chaudhari.
Member Secretary
DUPMCH



Godavari Foundation's
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DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)

Jalgaon Khurd (Dist. Jalgaon) M. S.

Pin - 425 309

IEC/ 2021/ Minutes of Meeting

Phone: (0257) 2366657

Fax: (0257) 2366648

DATE: 04/01/2021

Location:

Dean's Office

Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvkar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar,	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of Surgery PGs-

1	Dr. ANISH AVINASH JOSHI	COMPARATIVE STUDY OF EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA WITH SALINE DRESSING IN DIABETIC FOOT ULCER BY EXAMINING NEOVASCULARIZATION ON BIOPSY
2	Dr. FARKE VAIBHAV BALASAHEB	STUDY OF ETIOLOGY AND MANAGEMENT OF PERITONITIS AT TERTIARY CARE HOSPITAL
3	Dr. MANKAR SHUBHAM SHRIKRUSHNA	SPECTRUM OF DISEASES MANAGED BY LAPAROSCOPY AND ITS OUTCOME AT TERTIARY CARE CENTRE
4	Dr. SHRIYASH KONDIBA SONAWANE	STUDY OF MANAGEMENT AND OUTCOME OF ACUTE OBSTRUCTIVE UROPATHY DUE TO CALCULUS IN A TERTIARY CARE CENTRE
5	Dr. SIRPURAM VARUNDEV ASHOK	EFFECT OF FLAP FIXATION TECHNIQUE ON SEROMA FORMATION AND ITS COMPLICATIONS IN PATIENTS UNDERGOING BREAST CANCER SURGERY AT A TERTIARY CARE CENTER.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr Devendra R. Chaudhari,
Member Secretary
DUPMCH



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Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 02/01/2021

Location:

Dean's Office

Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of medicine PGs-

1	Dr. KAMELI MOHAMMAD JUNAID RAFEEQUE AHMAD	COMPARATIVE STUDY OF ECG AND CORONARY ANGIOGRAPHIC FINDINGS WITH ACUTE CORONARY SYNDROME IN DIABETIC AND NON-DIABETIC PATIENTS IN TERTIARY CARE CENTRE
2	Dr. KOTECHE TEJAS KUNDAN	STUDY OF CLINICAL PROFILE OF PATIENTS WITH HYPONATREMIA IN TERTIARY CARE HOSPITAL
3	Dr. NANDEDKAR ADITYA MAHADEV	THE STUDY OF SERUM MAGNESIUM AND VITAMIN D3 IN TYPE 2 DIABETES MELLITUS AND ITS CORRELATION WITH CORONARY ARTERY DISEASE
4	Dr. PRIYANKA ASHOK BHALKE	BACTERIAL SPECTRUM OF ASCITIC FLUID IN ALCOHOLIC LIVER DISEASE PATIENT ON ADMISSION AND ITS CORRELATION WITH SERUM ASCITIC ALBUMIN GRADIENT.
5	Dr. WAGAJ SUSHANT PRAKASH	A STUDY TO ESTIMATE PREVALENCE OF ANAEMIA IN ACUTE AND CHRONIC INFLAMMATION IN PATIENTS ATTENDING TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
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Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm


Dr Devendra H. Chaudhari.
Member Secretary
DUPMCH



Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmc@yahoo.in

Date:- 30/12/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 02/01/2021 to 15/01/2021 from attached circular at 9.00 am

All members are requested to attend meeting

Copy to all members

Sr.No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.


Dean

Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.



Godavari Foundation's Dr. Ujhas Patil Medical College & Hospital

Recognized by Medical Council of India, Approved by Central Board of India, New Delhi
and Affiliated to Maharashtra's University of Health Sciences, Nashik
N.M.H. (Jalgaon - Bhamburda Road), Jalgaon (K.) - 425 308 Tel & Dist - Jalgaon
Ph. No. (0267) 2364007 Fax - 2364008 E-Mail: drupmcd@vsnl.in

DATE - 24/12/2020

Circular

For all PG students and PG guides

All PG students are requested to present their thesis topic in front of IEC, DUPMCH, Jalgaon, in PPT format initially on following respective dates to finalize the topic:

All PG guides of respective department must attend the session on respective dates of presentation. After that the final submission will be taken in proper protocol format.

Time table is as follows...

TIMING - 2 TO 4 PM

SN	Department	Date
1	Medicine (5)PGs	02/01/2021
2	Surgery (5) PGs	04/01/2021
3	Anesthesia (4) & Pathology (1) PGs	07/01/2021
4	OBGY (3) & Pediatrics (2) PGs	08/01/2021
5	Ophthalmology (3) & ENT (2) PGs	11/01/2021
6	Radiology (3), Psychiatry (2) & Chest TB (any one out of TWO) PGs	13/01/2021
7	Skin (2), Ortho (3) & Chest TB (remaining one PG) PGs	15/01/2021

R

Prof. Dr. Manoj Kumar
By: Prof. Dr. Manoj Kumar

Dean

DUPMCH, JALGAON