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:- 26/12/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 28/12/2020 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/ 2020/ **Minutes of Meeting**

DATE: 28/12/2020

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: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the case report of Dr. Vaishali Nagose titled "the first case of proliferative fasciitis of tongue coexistent with squamous cell carcinoma case report of a rare lesion."

Minutes of meeting:-

1. Case report was discussed under – title, introduction, case history, discussion and conclusion, and consent form.
2. As per guidelines for publication of case report only the consent of patient is sufficient and that has been taken by the case reporter.
3. The permission was granted to publish the case report by the committee members.
4. Application form for publication 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: 4.00 pm

Meeting Actual End: 4.30 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
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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:- 21/12/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 22/12/2020 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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INSTITUTIONAL ETHICS COMMITTEE

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

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

IEC/ 2020/ Minutes of Meeting

DATE: 22/12/2020

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: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the SOP's to introduce it to all new IEC members.

4.2 To prepare the time table for PG students for presentation of their thesis topic.

Minutes of meeting:-

1. All SOP's were distributed to all present IEC Members.
2. All members presented their respective SOP's and stated the importance of that SOP.
3. In this way the SOP's discussed among all present members.
4. Finalization of SOP's done in the meeting.
5. All members finalized the date of presentation of thesis topics of PG students and prepared the time table for them.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 4.00 pm

Meeting Actual End: 4.30 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 Secretory-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

The First case of Proliferative Verrucous Leukoplakia of Tongue Coexistant with Squamous cell Carcinoma: Case report of a rare lesion.

2. Name of the Principal Investigator/
~~Under/Post graduate student~~
Dr. Vaishali Nagose
Professor Pathology.

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

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

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

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

Professor & Head
Department of Pathology
D.U.P.M.C.,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. Ulhas Patil Medical College & Hospital)

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

2 moths.

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

A) ProceduraIL: No.

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 in synopsis.

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

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

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

11) **Any other relevant information:** 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.

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. Vaishali Nagose. 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
The first case of Proliferative fasciitis of tongue coexistant with SCC. - Case report of a rare lesson. (squamous cell carcinoma)

Kindly do the needful.

Dr. Vaishali Nagose.
(Candidate name and signature)

Dr. Vaishali Nagose.
(Guide name and signature)

(HOD name and Signature with Dept. seal)

Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-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

The First case of Proliferative Fasciitis of Tongue Coexistant with squamous cell Carcinoma: Case report of a rare lesion.

2. Name of the Principal Investigator/
~~Under/Post graduate student:~~
Dr. Vaishali Nagore
Professor Pathology.

3. Name of the Co-investigator/
~~UG/PG Guide/Trial monitor~~
~~(if applicable)~~

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

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

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

Professor & Head
Department of Pathology
D.U.P.M.C., 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. Ulhas 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) ProceduraIL: No.

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 in Synopsis

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

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

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

11) Any other relevant information: 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.

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. Vaishali Nagose. .....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
The first case of proliferative fasciitis of tongue coexistant with SCC. - Case report of a rare lesion. (squamous cell carcinoma)

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose

(Candidate name and signature)

Nagose. Dr. Vaishali Nagose

(Guide name and signature) (HOD name and Signature with Dept. seal)

Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-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

The First case of Proliferative Fasciitis of tongue Coexistant with squamous cell Carcinoma: Case report of a rare lesion.

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

Dr. Vaishali Nagose
Professor Pathology.

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

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

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

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

Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

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

(For IEC Office use only) Sr. No_____

Dept.....

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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:

2 moths.

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

A) ProceduralL: No.

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 in Synopsis.

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

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

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

11) Any other relevant information: 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).
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(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.

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To
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IEC DUPMCH,
Jalgaon.

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

Title of Synopsis
The first case of Proliferative fasciitis of tongue coexistant with SCC. - Case report of a rare lesion. (squamous cell carcinoma)

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose
(Candidate name and signature)

Nagose. Dr. Vaishali Nagose
(Guide name and signature)

(HOD name and Signature with Dept. seal)
Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

Godavari Foundation's
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Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmci@yahoo.in

Date:- 06/01/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 07/01/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

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/ 2020/ Minutes of Meeting

DATE: 07/01/2020

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

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	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.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	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 associate professor of pathology Dr. Vaishali Baburao Nagose, titled **'Case based learning as a means of reforming Pathology Teaching in second MBBS (Undergraduate Students)'**

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 10th Jan 2020 to 10th March 2020. 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 Secretory-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

Case Based learning as a means of reforming Pathology Teaching in second MBBS (Undergraduate students)

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

Dr. Vaishali Baburao Nagose.

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

Dr. Vipin Todase.

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

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

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

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. Ulhas 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: Not applicable.

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 as per 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:

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

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

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

11) Any other relevant information: ____

_____

_____

Enclosures: Not applicable.

- 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.

Thagore.

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. Vaishali Baburao Nagose 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
Case Based Learning as a means of reforming Pathology Teaching in second MBBS (Undergraduate) Students.

Kindly do the needful.

Dr. Vaishali Nagose.
(Candidate name and signature)

—
(Guide name and signature)

(HOD name and Signature with Dept. seal)
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh. 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) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 16/09/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 17/09/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

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/ 04 / 2020/ **Minutes of Meeting**

DATE: 17/09/2020

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

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	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.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

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

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the research study of **DR MILIND B. NIKUMBH** titled **"A CLINICAL EVALUATION OF EFFICACY OF SPECIFICALLY DESIGNED INNOVATION AURVEDIC TREATMENT REGIMEN FOR SUSPECTED HIGH RISK ADULTS AND FIELD WORKERS IN PREVENTION OF COVID -19: A RANDOMIZED CONTROLLED PROSPECTIVE CLINICAL TRIAL ."**

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 October 2020 to December 2020 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

4 AGENDA

4.1 To discuss the research study of **DR MILIND B. NIKUMBH** titled **"A CLINICAL EVALUATION OF EFFICACY OF SPECIFICALLY DESIGNED INNOVATION AURVEDIC TREATMENT REGIMEN FOR SUSPECTED HIGH RISK ADULTS AND FIELD WORKERS IN PREVENTION OF COVID -19: A RANDOMIZED CONTROLLED PROSPECTIVE CLINICAL TRIAL ."**

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 October 2020 to December 2020 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 Secretory-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** - Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults And Field Workers In Prevention Of Covid-19: A Randomized Controlled Prospective Clinical Trial

2. **Name of the Principal Investigator:** Dr. Milind B. Nikumbh, Dean, Government Ayurved College, Jalgaon

3. **Name of the co-investigator** –Dr. Sandeep V. Binorkar, Assistant Professor, Government Ayurved College, Jalgaon

4. **i) Signature of Principal investigator:**

   ii) Signature of co-investigator:

   iii) Signature of HOD of Principal Investigator:

   iv) Signature of HOD of other Departments involved (if any):

Dr. Milind B. Nikumbh
M.D. (Ayu.), Ph.D.
Dean, Govt. Ayurved College
Jalgaon

(For IEC Office use only) Sr. No_____

Dept .....

1) Date of Receipt by IEC (submission of application) 12.09.2020
2) Date of resubmission to IEC .....
3) Date of IEC meeting 17.09.2020
4) Decision of IEC: APPROVED
5) IEC decision conveyed on date: 17.09.2020

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 its analysis:** - 3 Months from the date of allotment of first subject

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

A) Procedural L: None

B) Adverse drug reaction (ADRs): Trial drugs are all Herbal Medicine. ADR Not reported so far.

C) Invasive investigations (if any): - None

D) Explain the measures to counter the above risk factors: Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

8) **Details about research project**

(a) Objectives:

1. To study the efficacy of specifically designed innovative ayurvedic treatment regimen in suspected high-risk adults and field workers.
2. To create awareness among the subjects regarding Ayurveda and Yoga in preventing COVID-19.

(b) Current knowledge about the research subject: The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities.

(c) **Research plan:** The total cases of COVID warriors turned positive or symptomatic on 17th Sept 2020 from Jalgaon city is around 1500 which includes, doctors, nurses, police officers, paramedical staff etc. Considering this as a population, the sample size for the present research can be calculated as 383 using Raosoft® online sample size calculator [5] with 5% margin of error and 95% confidence level. So, to avoid further bias and errors, the sample size for the present study will be 300 (150 in each group).

Selection of subjects: - The individuals who were at high risk and in immediate contact with the COVID-19 subjects, do or **do not show any signs and symptoms of flu** will be the population for the current study. 300 such healthy individuals will be selected randomly and will be divided into two groups (A-Trial & B-Control group 150 each).

After procuring the informed written Consent, first group-A (Trial group;

n=150) will be managed with specifically designed innovative ayurvedic treatment regimen and the other group -B (Control group; n=150) will be kept under observation. The trial will be conducted for the 30 days. And the entire duration of the study including the allotment and analysis of the results will be 3 months.

(d) Implications: None

(e) Conflict of interest: None Declared

(f) Risk factors: Stated in the Research Protocol.

(g) Bibliography/List of references:

1. Cyranoski D. "We need to be alert": scientists fear second coronavirus wave as China's lockdowns ease. Nature 2020 [Epub ahead of print]. DOI: 10.1038/d41586-020-00938-0
2. World Health Organization. Off label use of medicines for COVID 19. WHO reference number: WHO/2019-nCoV/Sci_Brief/Off-label_use/2020.1 Online document at: https://apps.who.int/iris/bitstream/handle/10665/331640/WHO-2019-nCoV-Sci_Brief-Off-label_use-2020.1-eng.pdf, accessed May 8, 2020.
3. World Health Organization. WHO SOLIDARITY Clinical trial for COVID 19 treatments. Online document at: https://www.who.int/solidarity-clinical-trial-for-covid-19-treatments, accessed April 8, 2020
4. https://icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf (Accessed on 27.04.2020)
5. http://www.raosoft.com/samplesize.html (Accessed on 27.04.2020)

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

Sr. No.	Expenditure	Justification	Approximate Amount
1	Raw Drugs & Medicine	The contents of Innovative Ayurveda Medicines (IAM-Dip bags) will cost around Rs 15/3gm. Therefore, for approximate cost of total medicine per subject will be around Rs. 1100 and for 150 subjects will be Rs 2 Lakh	200000
2	Preparation of Medicines	Preparation of the specified coarse powder and inner and outer packaging.	50000
3	Purchasing Poly-propylene non-woven material	Size of dip bag will be 5.5x6cm. Approximate costs per dip bag will be around Rs 1.5/ bag.	15000
4	Lab Investigations including RT-PCR (in case if the subject is positive for Rapid antigen test.)	RT-PCR is conducted only if the patient is showing the signs and symptoms of COVID-19. The cost decided by Government of Maharashtra for private laboratories is Rs. 1200 per subject.	360000
5	Stationary	A4 size papers for Case Research form (20 pages each), information leaflets, Test reports etc.	50000
6	Printing	Printing of Case Research form (20 pages each), information leaflets, Test reports etc.	50000
7	Travelling	Petrol expenditure for first and last personal visit to the subjects at their respective offices and work places.	35000
8	Liability Insurance	Liability Insurance for 800 subjects in case of any ADR (Approximately Rs. 175 per subject)	140000
9	Miscellaneous	For sudden and unexpected expenditure during the research in case if the budget of above 8 heads is exhausted.	30000
	Total		**930000**

The financial support will be provided by the Maharashtra University of Health Sciences, Nashik under the Extra Mural Research Scheme.

10) **Whether the research project is sponsored:** YES
Sponsoring authority: Maharashtra University of Health Sciences, Nashik

11) **Any other relevant information: Attached herewith is Detail Research Protocol**

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) Newspaper 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.

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

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. Milind B. Nikumbh 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
Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers In Prevention Of Covid-19: A Randomized Controlled Prospective Clinical Trial

Kindly do the needful.

Government Ayurved College • Jalgaon •

Dr. Milind. B. Nikumbh
Dean
Government Ayurved College,
Jalgaon

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

TO BE PRINTED ON OFFICIAL LETTER-HEAD OF OFFICE

TO WHOM SO EVER IT MAY CONCERN

CONSENT LETTER

We have no objection to conduct clinical trials of the trial drugs under the studytitled **"Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial"** on COVID patients admitted in ourcentre for the purpose of research sponsored by Maharashtra University of Health Sciences Nashik.

The investigators will have full access to the patients in our centre for examination of the patientunder the trial in the proposed study.

We hereby give consent to **Dr. Milind B. Nikumbh, Dean, Government Ayurved College& Hospital, Jalgaon,**the PrincipalInvestigator of the Research project titled**"Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial"** for the same.

In-charge
COVID Hospital/ Center

TO BE PRINTED ON IEC LETTERHEAD

Institutional Ethics Committee (IEC) Report

OutwardNo.: IECDUPMCH/04/2020 Date: 17/09/2020

Dr Milind B. Nikumbh
Dean,
Government Ayurved College& Hospital,
Jalgaon

Reference: The Research project entitled **Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial**

Dear Researcher,

The meeting of the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) [please state the name of the IEC] .....IEC DUPMCH..... was held on .....17/09/2020 at (time) ..3:00 P.M.. in the (Venue) ....DUPMS Jalgaon....with(Name).Dr. Ravindra Kumar Bakal as Chairperson.

The following members attended the meeting.

Sr. No.	Name	Position on IRB/IEC	Designation and Affiliation	Qualification
01	Dr Ravindra kumar Bakal	Chairman	Principal	
02	Dr Devendra R. Chaudhari	Member Secretary	Prof & Head	M.D.
03	Dr(Mrs) M. N. Avhikar	Member	Prof & Head	M.D.
04.	Dr Nilesh Bendale	Member	Asso. Prof	M.D.
05.	Adv Satish Gadge	Member	Legal Adv. Sor	LLM
06.	Dr. Prashant S. Wanke	Member	Principal MBA	MBA

It is hereby confirmed that, neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
The IRB/IEC has reviewed and approved the following documents submitted for the above- mentioned Researchproject.

1. Research Proposal.
2. Consent form
3. Case Record Form

The IRB/IEC approves the project entitled **Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial**

It is understood that the research project will be conducted under your direction, in a total of 300 (150 each in two groups) research participants, at Department of ***Government Ayurved College& Hospital, Jalgaon*** (Institute) as per the submitted protocol.

This approval is valid for the entire duration of the project. It is the policy of IRB/IEC that it be informed about any serious adverse event (SAE) occurring during the course of the research project within seven working days of the occurrence of the adverse event; It'Death' is a SAE, it should be reported to the IRB/IEC within 24 hours of its occurrence via an e-mail.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IRB/IEC of an appropriate amendment. The IRB/IEC expects that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

The EC functions in accordance with ICH GCP and ICMR guidelines.

Sincerely yours,

Member Secretary/Chairperson IRB/IEC
(Signed and dated by the
IRB/IEC
Chairperson or Member Secretary)

Date of approval of the Research project:

It is understood that the research project will be conducted under your direction, in a total of 300 (150 each in two groups) research participants, at Department of ***Government Ayurved College& Hospital, Jalgaon*** (Institute) as per the submitted protocol.

This approval is valid for the entire duration of the project. It is the policy of IRB/IEC that it be informed about any serious adverse event (SAE) occurring during the course of the research project within seven working days of the occurrence of the adverse event; It'Death' is a SAE, it should be reported to the IRB/IEC within 24 hours of its occurrence via an e-mail.

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The EC functions in accordance with ICH GCP and ICMR guidelines.

Sincerely yours,

Member Secretary/Chairperson IRB/IEC
(Signed and dated by the
IRB/IEC
Chairperson or Member Secretary)

Date of approval of the Research project:

CLINICAL EVALUATION OF EFFICACY OF SPECIFICALLY DESIGNED INNOVATIVE AYURVEDIC TREATMENT REGIMEN FOR SUSPECTED HIGH-RISK ADULTS AND FIELD WORKERS IN PREVENTION OF COVID-19: A RANDOMIZED CONTROLLED PROSPECTIVE CLINICAL TRIAL

CLINICAL TRIAL PROTOCOL

Submitted to Maharashtra University of Health Sciences, Nashik

Principal Investigator	Co-investigator(s)	AYUSH Associate
Dr. Milind B. Nikumbh Dean, Government Ayurved College, Jalgaon	Dr. Sandeep V. Binorkar Assistant Professor Government Ayurved College, Jalgaon	Dr. Leena Badgujar, MO, NRHM, AYUSH, Jalgaon Dr. Bhushan Deo CHO, NHM, Jalgaon

Government Ayurved College & Hospital, Jalgaon

Introduction:

The coronavirus disease 19 (COVID-19) pandemic is exceptional and unprecedented in several aspects and has challenged health care systems all over the world. At present, the global momentum is unrelieved and further catastrophe is still anticipated.[1] The outbreak of this virus was primarily reported in Wuhan, China in December 2019 [2] The principal cause behind this pandemic is newly identified sever acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The experiences and lessons learnt from the earlier severe acute respiratory syndrome (SARS) epidemics appear inadequate and resulted in call for better approaches and strategies in public health and medical care. Contemporary mainstream medicine is the vanguard and struggling to rheostat the menace. The existing prophylactic measures are inadequate, and suggested possibilities such as hydroxychloroquine (HCQ) are still under investigation. [3]

Globally mortality rates and sever complications have been high among those with hypertension, cardiovascular disease or type 2 diabetes. However, COVID-19 infection exhibits a wide clinical course affected by lower respiratory tract infection and gastrointestinal system. The role of the immune response in COVID-19 infection disease is under study but there is evidence suggesting that lung damage could be more immune-mediated rather than directly virus-induced. In adding, recent data from various laboratories suggest that SARS maybe a systemic disease with widespread extrapulmonary dissemination.

The prophylactic and therapeutic potential of traditional and complementary medicine systems such as Ayurveda and Yoga is not really being considered during this crisis and global hunt for effective preventive and treatment measures.

Therefore, the present study is being attempted to evaluate the knowledge and practices from Ayurveda that might be effectively utilized in the prophylaxis and adjuvant therapy of COVID-19 which may support the quarantined patients of COVID-19 and field workers including doctors, paramedical staff, Police staff, municipal corporation and other related personals in preventing the disease thereby improving the quality of standard care.

AIM & OBJECTIVES:

To study the efficacy of specifically designed innovative ayurvedic treatment

regimen in suspected high-risk adults and field workers in preventing the disease.

Objectives:

1. To study the efficacy of specifically designed innovative ayurvedic treatment regimen in suspected high-risk adults and field workers.
2. To create awareness among the subjects regarding Ayurveda and Yoga in preventing COVID-19.

Research Question

Is specifically designed innovative ayurvedic treatment regimen is effective in preventing suspected high-risk adults and field workers turning positive?

Research Hypothesis

The specifically designed innovative ayurvedic treatment regimen is effective in preventing suspected high-risk adults and field workers turning positive.

Review of Literature:

Innovative Ayurveda Medicines (IAM-Dip bags):

This preparation is combination of various herbs which are proven to exhibit immuno-modulator properties, as well as their effects on various respiratory disorders. Dip bags are the innovative methods to server the medicine in required quantity and also easy to carry at workplace thereby avoiding the laborious and tedious method of preparing a decoction.

Material and Methods:

The specifically designed innovative ayurvedic treatment regimen includes following combination of Ayurveda drugs treatment.

Particular	Details
Innovative Ayurveda Medicines (IAM-Dip bags)	Each 3 gm Dip Bags containing – 1. Shunthi (*Zingiber officinale*) 1 part, 2. Hingu (Ferula assafoetida) 1 part, 3. Maricha (*Piper nigrum*) ¼ part, 4. Twak (*Cinnamomum zeylanicum*) 1part, 5. Tulasi (*Ocimum sanctum*) 1part, 6. Amalaki (*Emblica officinalis*) 1part, 7. Haridra (*Curcuma longa*) 1/10th part, 8. Lavang (*Syzygium aromaticum*) 1part, 9. Jatiphal (*Myristica fragrans*) 1/20th part, 10. *Nimbu satwa* (Citrus limon) 1/20th part 11. Saindhava (Rock salt) 1/5th part

	All herbs packed in dip bag boiled at 100°C for 3 minutes in 200 ml of water and reduced to half. 100 ml BID After breakfast 8:00 am and in the evening at 5:00pm
Duration of the Treatment	30 days
Follow up	Day -0, 7, 15, 22 and 31st

The raw drugs for innovative dip tea bags will be procured from the GMP certified Yugandhar Pharma from Nashik and a certification for authentication and standardization will be obtained from them.

The standard Poly-propylene non-woven material with the permeance (23.9×10^{-5}m/s) will be used for the preparation of dip tea bags containing 3 gm of combination of the contents stated above. The coarse powder of the content (40 mesh size) will be used to fill in the tea bags (5.5x6cm).

Methodology:

It is known fact under the Drugs and Cosmetics Rules of 1945, that there is no regulatory provision for clinical trials in alternative medicine. Therefore, the clinical research in Ayurveda should also be conducted as per AYUSH guidelines and clinical research or ICMR guidelines. Consequently, after acquiring the approval by the scientific advisory bodies and Institutional Ethics Committee, the research protocol will also be registered with the CTRI, the Clinical Trials Registry of India.[4]

Sample Size: -

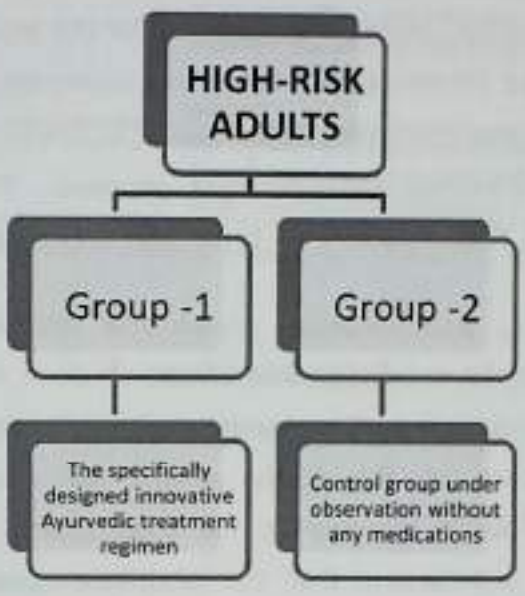
The total cases of COVID warriors turned positive or symptomatic on 17th Sept 2020 from Jalgaon city is around 1500 which includes, doctors, nurses, police officers, paramedical staff etc. Considering this as a population, the sample size for the present research can be calculated as 383 using Raosoft® online sample size calculator [5] with 5% margin of error and 95% confidence level. So, to avoid further bias and errors, the sample size for the present study will be 300 (150 in each group).

Selection of subjects: -

The individuals who were at high risk and in immediate contact with the COVID-19 subjects, do or **do not show any signs and symptoms of flu** will be the population for the current study. 300 such healthy individuals will be selected

randomly and will be divided into two groups (A-Trial & B-Control group 150 each).

After procuring the informed written Consent, first group-A (Trial group; n=150) will be managed with specifically designed innovative ayurvedic treatment regimen and the other group -B (Control group; n=150) will be kept under observation. The trial will be conducted for the 30 days. And the entire duration of the study including the allotment and analysis of the results will be 3 months.



Time schedule:

First two months will be utilized for the allotment and selection of the subjects for the study and the 3rd month will be utilized for the assessment of the results.

Inclusion criteria: -

1. High risk individuals such as doctors, paramedical staff, police staff, municipal corporation staff and other suspected personals who were in contact with the COVID-19 subjects.
2. Individuals who do not show any signs and symptoms of flu.
3. Individuals who shows Negative rapid antigen / Negative RT-PCR test for COVID-19.
4. Individuals between the Age- above 18 years below 50 years

Exclusion criteria: -

1. Subjects who are COVID 19 positive and in critical stage.
2. Subjects below 18 years above 50 years of age.
3. Pregnant and lactating women.
4. Subjects having an active malignancy

5. Subjects giving history of significant cardiovascular event < 12 weeks prior to randomization
6. Subjects having a chronic disease such as active tuberculosis, Hepatitis B or C, or HIV

Institutional Ethics Committee & Scientific Advisory Approval: -

The necessary approval from Institutional Ethics Committee (IEC) of Dr. Ulhas Patil Medical College & Hospital, Jalgaon is obtained for the study via vide letter No. IEC, DUPMCH/04/20, dated 17.09.2020. This Ethics committee is registered under rule 122DD of the Drugs and Cosmetic Rules 1945 (ECR/852/Inst/MH/2016). The copy of IEC approval is attached herewith the proposal. The research will also be registered to Clinical Trial Registry of India and CTRI no. will be obtained in due course.

Clinical Trial Insurance coverage benefits: -

As per the recommendation and suggestion of the Institutional Ethics Committee (IEC), each participant of the study should be insured against the harms experienced by him/her if any during the trial, mainly Adverse Drug Reactions (ADR). Therefore, it is proposed that the insurance coverage will be obtained for the participants from appropriate insurance agency supporting bulk general insurance for such clinical trials.

OBSERVATIONS: -

Observations and responses of the participants will be collected through google forms on daily basis until the day of completion of duration of research project.

EXPECTED BUDGET ALLOCATIONS:

Sr. No.	Expenditure	Justification	Approximate Amount
1	Raw Drugs & Medicine	The contents of Innovative Ayurveda Medicines (IAM-Dip bags) will cost around Rs 15/3gm. Therefore, for approximate cost of total medicine per subject will be around Rs. 1100 and for 150 subjects will be Rs 2 Lakh	200000
2	Preparation of Medicines	Preparation of the specified coarse powder and inner and outer packaging.	50000
3	Purchasing Poly-propylene non-woven material	Size of dip bag will be 5.5x6cm. Approximate costs per dip bag will be around Rs 1.5/ bag.	15000
4	Lab investigations including RT-PCR (in case if the subject is positive for Rapid antigen test.)	RT-PCR is conducted only if the patient is showing the signs and symptoms of COVID-19. The cost decided by	360000

		Government of Maharashtra for private laboratories is Rs. 1200 per subject.	
5	Stationary	A4 size papers for Case Research form (20 pages each), information leaflets, Test reports etc.	50000
6	Printing	Printing of Case Research form (20 pages each), information leaflets, Test reports etc.	50000
7	Travelling	Petrol expenditure for first and last personal visit to the subjects at their respective offices and work places.	35000
8	Liability Insurance	Liability Insurance for 800 subjects in case of any ADR (Approximately Rs. 175 per subject)	140000
9	Miscellaneous	For sudden and unexpected expenditure during the research in case if the budget of above 8 heads is exhausted.	30000
	Total		930000

The above proposed budget is showing approximated values. In case if any amount remained in the account after the completion of the research, the same will be highlighted and reimbursed while submitting the audit report and utilization certificate.

Results and Conclusions: -

The results will be obtained based on observations after applying Paired and Unpaired 't' test and other statistical tools; conclusions will be drawn accordingly.

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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:- 22/09/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 23/09/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

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

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INSTITUTIONAL ETHICS COMMITTEE

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

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

IEC/ 05 / 2020/ **Minutes of Meeting**

DATE: 23/09/2020

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

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	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.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

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

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the research study of **DR MILIND B. NIKUMBH** titled **"A CLINICAL EVALUATION OF EFFICACY OF AYURVEDIC TREATMENT REGIMEN AS AN ADD-ON THERAPY WITH MODERN MEDICINE IN COVID 19 - A RANDOMIZED, MULTI-CENTER, SINGLE BLIND, PROSPECTIVE CLINICAL 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 October 2020 to December 2020. 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 Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2356657 (Fax) 0257-2356648 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** - A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study

2. **Name of the Principal Investigator/ Under/Post graduate student:** Dr. Milind B. Nikumbh, Dean, Government Ayurved College, Jalgaon

3. **Name of the co-investigator/ UG/PG guide/Trial monitor –**Dr. Sandeep V. Binorkar, Assistant Professor, Government Ayurved College, Jalgaon

4. **i) Signature of Principal investigator:**

   ii) Signature of co-investigator:

   iii) Signature of HOD of Principal Investigator:

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

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

(For IEC Office use only) Sr. No_____

Dept .....

1) Date of Receipt by IEC (submission of application) 17.09.2020
2) Date of resubmission to IEC .....
3) Date of IEC meeting 23.09.2020
4) Decision of IEC: APPROVED
5) IEC decision conveyed on date: 23.09.2020

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 its analysis: -** 3 Months from the date of allotment of first subject

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

A) Procedural L: None

B) Adverse drug reaction (ADRs): Trial drugs are all Herbal Medicine. ADR Not reported so far.

C) Invasive investigations (if any): - None

D) Explain the measures to counter the above risk factors: Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

8) Details about research project

(a) Objectives:

Primary Objectives:

- To assess the efficacy of Ayurvedic treatment regimen in the patients of positive coronavirus Disease. (Laboratory confirmation + Patients with uncomplicated respiratory tract infection which may have non-specific symptoms such as fever, fatigue, cough, anorexia, malaise, muscle pain, sore throat, dyspnoea, nasal congestion, or headache)

Secondary Objectives

- To assess the clinical safety of Ayurvedic treatment regimen in the patients of positive coronavirus Disease.

(b) Current knowledge about the research subject: The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities.

(c) Research plan: **Number of Patients to be completed in the clinical trial (Sample Size)** : 380 (190 Patients in each group) The total active cases all over India on 27th April 2020 are around 27,000. Considering this as a population, the sample size for the present research can be calculated as 380 using Raosoft® online sample size calculator [9] with 5% margin of error and 95% confidence level.

Groups: -The subjects will be divided randomly in two groups (190 Patients in each group), viz. Trial and Control. The Trial group (Group -1) will be administered with Ayurvedic treatment regimen for COVID-19 along with the standard modern medicines and control group (Group-2) will be provided with the standard treatment protocol only which is followed in the modern medical hospitals.

(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 its analysis: -** 3 Months from the date of allotment of first subject

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

A) Procedural L: None

B) Adverse drug reaction (ADRs): Trial drugs are all Herbal Medicine. ADR Not reported so far.

C) Invasive investigations (if any): - None

D) Explain the measures to counter the above risk factors: Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

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(d) Implications: None

(e) Conflict of interest: None Declared

(f) Risk factors: Stated in the Research Protocol.

(g) Bibliography/List of references:

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

Sr. No.	Expenditure head	Amount in Rupees
1	Raw Drugs (Medicine)	500000

2	Preparation of Medicines	200000
3	Remuneration	100000
4	Stationary	30000
5	Contingency	35000
6	Printing	50000
7	Travelling	35000
8	Liability Insurance	50000
	Total	10,00,000

The financial support will be provided by the Ministry of AYUSH, Government of India, New Delhi under the Extra Mural Research Scheme.

10) **Whether the research project is sponsored:** YES
Sponsoring authority: Ministry of AYUSH, Government of India, New Delhi

11) Any other relevant information: Attached herewith is Detail Research Protocol

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) Newspaper 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.

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
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 researchon 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. Milind B. Nikumbh 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
A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study

Kindly do the needful.

Dr. Milind. B. Nikumbh
Dean
Government Ayurved College,
Jalgaon

Government Ayurved College Jalgaon

Dr.Milind B.Nikumbh
Dean,Govt.Ayurved College
Jalgaon

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Phone: (0257) 2366657
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Institutional Ethics Committee (IEC) Report

OutwardNo.:IEC / DUPMCH / 05 / 20

Date:23.09.2020

Dr Milind B. Nikumbh
Dean,
Government Ayurved College& Hospital,
Jalgaon

Reference: The Research project entitled **"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"**

Dear Researcher,

The meeting of the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) IEC, DUPMCH, was held on 23/09/2020 at (time) 3 PM in the (Venue) DUPMC, JALGAON with DR. RAVINDRAKUMAR BAKAL as Chairperson.

The following members attended the meeting.

Sr. No.	Name	Position on IRB/IEC	Designation and Affiliation	Qualification
1.	Dr. Ravindrakumar. L. Bakal	Chairman	Principal	M pharm PHD
2.	Dr. Devendra R. Chaudhari	Member Secretary	Prof. & head	MD
3.	Dr. (Mrs) Maya N. Arvikar	Member	Prof. & head	MD
4	Dr. Nilesh Bendale	Member	Associate prof	MD
5	Adv. Satish Gadge	Member	Legal advisor	LLM
6	Dr. Prashant S. Warke	Member	Principal MBA	MBA, PhD

It is hereby confirmed that, neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
The IRB/IEC has reviewed and approved the following documents submitted for the above- mentioned Researchproject.

1. Research Proposal.
2. Consent form
3. Case Record Form

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INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
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Institutional Ethics Committee (IEC) Report

OutwardNo.:IEC / DUPMCH / 05 / 20

Date:23.09.2020

Dr Milind B. Nikumbh
Dean,
Government Ayurved College& Hospital,
Jalgaon

Reference: The Research project entitled "**A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study**"

Dear Researcher,

The meeting of the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) IEC, DUPMCH, was held on 23/09/2020 at (time) 3 PM in the (Venue) DUPMC, JALGAON with DR. RAVINDRAKUMAR BAKAL as Chairperson.

The following members attended the meeting.

Sr. No.	Name	Position on IRB/IEC	Designation and Affiliation	Qualification
1.	Dr. Ravindrakumar. L. Bakal	Chairman	Principal	M pharm PHD
2.	Dr. Devendra R. Chaudhari	Member Secretary	Prof. & head	MD
3.	Dr. (Mrs) Maya N. Arvikar	Member	Prof. & head	MD
4	Dr. Nilesh Bendale	Member	Associate prof	MD
5	Adv. Satish Gadge	Member	Legal advisor	LLM
6	Dr. Prashant S. Warke	Member	Principal MBA	MBA, PhD

It is hereby confirmed that, neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
The IRB/IEC has reviewed and approved the following documents submitted for the above- mentioned Researchproject.

1. Research Proposal.
2. Consent form
3. Case Record Form

The IRB/IEC approves the project entitled **A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study**

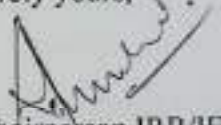
It is understood that the research project will be conducted under your direction, in a total of 380 (190 each in two groups) research participants, at Department of ***Government Ayurved College& Hospital, Jalgaon*** (Institute) as per the submitted protocol.

This approval is valid for the entire duration of the project. It is the policy of IRB/IEC that it be informed about any serious adverse event (SAE) occurring during the course of the research project within seven working days of the occurrence of the adverse event; It 'Death' is a SAE, it should be reported to the IRB/IEC within 24 hours of its occurrence via an e-mail.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IRB/IEC of an appropriate amendment. The IRB/IEC expects that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

The EC functions in accordance with ICH GCP and ICMR guidelines.

Sincerely yours,



Member Secretary/Chairperson IRB/IEC
(Signed and dated by the
IRB/IEC
Chairperson or Member Secretary)

Date of approval of the Research project:

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:-23/09/2020

TO WHOM SO EVER IT MAY CONCERN

CONSENT LETTER

We have no objection to conduct clinical trials of the trial drugs under the studytitled **"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"** on COVID patients admitted in ourcentre for the purpose of research sponsored by Ministry of AYUSH, Government of India, under Extra Mural Research.

The investigators will have full access to the patients in our centre for examination of the patientunder the trial in the proposed study.

We hereby give consent to **Dr. Milind B. Nikumbh, Dean, Government Ayurved College& Hospital, Jalgaon,**the PrincipalInvestigator of the Research project titled**"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"** for the same.

In-charge
COVID Hospital/ Center
Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Confidential and Restricted Circulation
Among identified experts

"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"

Clinical Research Proposal

Submitted to The Ministry of AYUSH, Government of India, New Delhi

Principal Investigator	Co-investigator	AYUSH Associate
Dr. Milind B. Nikumbh Dean, Government Ayurved College, Jalgaon	Dr. Sandeep V. Binorkar, Assistant Professor, Government Ayurved College, Jalgaon	Dr. Leena Badgujar, MO, NRHM, AYUSH, Jalgaon Dr. Subhash Wadodkar Dr. Narendra Gujarati Ayurved Practitioners, Jalgaon

"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"

Background:

Corona virus disease 2019 is an ongoing pandemic disease, abbreviated as COVID 19, causes by newly identified sever acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The outbreak of this virus was primarily reported in Wuhan, China in December 2019 [1] and on 30th of January 2020 World Health Organization declared the to be Public Health Emergency of International Concerned and labeled it as Pandemic on 11th March 2020. [2,3] This condition, in general is characterized by fever, dry cough, fatigue and headache.

In a very short period of just four months, this disease has tolled approximately 3 million cases with more than 206000 deaths and have been reported in 185 countries. [4] In India, the first COVID 19 case was identified on 30th January 2020 in Kerala and by the end of April 2020, 27892 cases are confirmed with death of 872 infected patients.[5]

This viral pandemic has caused severe global socioeconomic disruption [6] having the potential equivalent to that of 'The Great Depression 'that occurred in 1930's. [7] This socioeconomic disruption has affected both poor and rich countries and had adversely affected personal income, tax revenue, large and small-scale industries, infrastructure and development field, education system, entertainment and agriculture industry.

As far as treatment is concerned, till date no specific antiviral agent is approved for COVID-19. Over the counter preparations for common cold, fluid intake and rest have shown to alleviate the symptoms. Depending upon the severity, oxygen supplement, breathing support or ventilation, intravenous fluids and usage of various pharmacological agents as per the requirement are the only available options left with the physicians and intensivist treating COVID-19 patients.

Considering the magnitude of this pandemic it is the need of the hour to develop a standardize approach and remedy for COVID-19. In Ayurveda, although no specific condition is described having exact resemblance with COVID-19 but few diseases have a comparable presentation with the same. Hypothetically it can be stated that, a good number of

classical drug preparations can be used against the COVID-19. In current clinical trials, a specially designed drug regime based on classical Ayurvedic text have been proposed depending on the present clinical presentation of COVID-19. All these classical presentations are used by Ayurvedic physicians since ages and have shown very promising results in various conditions resembling with the signs and symptoms of COVID-19.

METHODS

It is known fact under the Drugs and Cosmetics Rules of 1945, that there is no regulatory provision for clinical trials in alternative medicine. Therefore, the clinical research in Ayurveda should also be conducted as per AYUSH guidelines and clinical research or ICMR guidelines. Consequently, after acquiring the approval by the scientific advisory bodies and Institutional Ethics Committee, the research protocol will also be registered with the CTRI, the Clinical Trials Registry of India. [8]

Study Type	: Interventional
Purpose	: Treatment
Masking	: Nil
Control	: Controlled
Timing	: Prospective
No. of Groups	: Two

Number of Patients to be completed in the clinical trial (Sample Size) : 380 (190 Patients in each group) The total active cases all over India on 27th April 2020 are around 27,000. Considering this as a population, the sample size for the present research can be calculated as 380 using Raosoft® online sample size calculator [9] with 5% margin of error and 95% confidence level.

Groups: -

The subjects will be divided randomly in two groups (190 Patients in each group), viz. Trial and Control. The Trial group (Group -1) will be administered with Ayurvedic treatment regimen for COVID-19 along with the standard modern medicines and control group (Group-2) will be provided with the standard treatment protocol only which is followed in the modern medical hospitals.

TIMELINES:

- **Study duration** : 3 months
- **Pre-trial preparation & medicine procurement** : 15 days
- **Duration of intervention** : 15 days
- **Follow-up** : 30th and 45th day
- **Statistical analysis** : 1 month

Inclusion criteria:

1. All hospitalized cases above 18 years of age, clinically diagnosed with corona virus disease 2019 and presenting with mild to moderate signs and symptoms of COVID-19, quarantined at identified hospital set up.
2. Participants who can take medicines orally.
3. Patients willing to provide signed informed consent.

Exclusion criteria:

1. Cases of severe vomiting which would affect oral administration of medicine difficult.
2. Cases of respiratory failure and requiring mechanical ventilation.
3. Combined organ failure requiring ICU monitoring.
4. Pregnant and lactating women.
5. Subjects having an active malignancy.
6. Subjects giving history of significant cardiovascular event < 12 weeks prior to randomization.
7. Subjects having a chronic, contagious infectious disease, such as active tuberculosis, Hepatitis B or C, or HIV.
8. Subjects having active metabolic or gastrointestinal diseases that may interfere with nutrient absorption, metabolism, or excretion, excluding diabetes
9. Any other condition, which as per the investigator would jeopardize the outcome of the trial.

Withdrawal Criteria

a) The participant may be withdrawn from the trial if there is

- Any major ailment which necessitating the institution of new modalities of treatment.

OR

- Non-compliance of the treatment regimen (minimum 80% compliance is essential to continue in the study).

b) Such cases will be immediately referred to the appropriate health authorities for further management.

**The decision to withdraw a participant from the trial would be taken only by the Principal Investigator, who will then have to set out a detailed justification and also indicate the line of further management-if needed. The same needs to be informed to the Sponsor and the Ethics Committee within two working days.

Interventions

Group I: (Ayurveda as add-on to standard care as per guidelines)

Name of the drug	Particulars	Details
Bilwadi Yog [10] (Ashtang Hridya Uttara tantra/35)	**Dose**	1 gm B.I.D.
	Dosage form	Tablet
	Route of Administration	Oral
	Time of Administration	After food
	Anupana	Shadangodak
	Duration of therapy	15 days
Kantakaryavaleha [11] Sharangdhar Samhita Madhyama khanda, 8; 5-8	**Dose**	3 gm B.I.D.
	Dosage form	Avaleha
	Route of Administration	Oral
	Time of Administration	Before food
	Anupana	Shadangodak
	Duration of therapy	15 days
Shadangodak [12] Charaka Samhita Chikitsa Sthana 1/15	**Dose**	40 ml B.I.D.
	Dosage form	Phant
	Route of Administration	Oral
	Time of Administration	As Anupana with other medicine
	Anupana	--
	Duration of therapy	15 days

Group-II: Conventional standard therapy

Authentication and Standardization of Research Medicines:

Raw drugs procured from the market will be authenticated by the experts from the Department of Dravyaguna and Rasashastra be authenticated as per the guidelines of the

Ayurvedic Pharmacopoeia of India (API) and compound formulation, will be prepared and standardized as per the guidelines of Ayurvedic Formulary of India (AFI).

RATIONALE BEHIND THE SELECTION OF DRUGS:

The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities. [13-48]

OBJECTIVES

Primary Objectives:

- To assess the efficacy of Ayurvedic treatment regimen in the patients of positive coronavirus Disease. (Laboratory confirmation + Patients with uncomplicated respiratory tract infection which may have non-specific symptoms such as fever, fatigue, cough, anorexia, malaise, muscle pain, sore throat, dyspnoea, nasal congestion, or headache)

Secondary Objectives

- To assess the clinical safety of Ayurvedic treatment regimen in the patients of positive coronavirus Disease.

OUTCOMES

Primary Outcome Measure

1. Clinical cure rate: Time to negative conversion of severe acute respiratory syndrome corona-virus 2 (defined as viral load of respiratory specimen negative for two consecutive times when tested in an interval of two days)

Secondary Outcome Measures:

1. Length of stay in hospital
2. Duration of fever and respiratory symptoms
3. Improvement in hematological and laboratory parameters (Hs-CRP, ESR, TC, DC, Absolute lymphocyte count, LFT, RFT, IL-6, Ig E, Ig-G,Ig-M, LDH, Creatine Kinase, Platelet count),
4. Frequency of ADR/AE
5. Number of cases that required oxygen therapy during the intervention.

Method of Randomization: Subjects will be randomized into either the interventional drug group or placebo using a computer-generated table.

OBSERVATIONS: -

Observations will be taken on daily basis until the day of discharge.

Grading of Signs and Symptoms: -

1. Temperature: - Temperature will be recorded by means of Infrared thermometer (Temperature Gun).
2. Cough: - Cough will be graded by using Cough Severity Score and Frequency Score. Cough Severity Score will be obtained by using visual analog scale and cough frequency score will be graded as follows: -

Grade	Sign
0	No Cough at all
1	Occasional Hems
2	Mild isolated cough without associated or additional symptoms.
3	Moderate paroxysmal cough with additional symptoms.
4	Sever strenuous cough accompanied by chest discomfort.

3. Shortness of Breath: - SOB will be graded by using Five-point Likert scale: -

Grades	Signs
1	Not Short of breath
2	Mildly short of breath
3	Moderately short of breath
4	Severely short of breath
5	Severely short of breath requiring external assistance.

4. Headache: - Headache will be graded by using Visual Analog Scale.
5. Sore Throat: - This will be graded by using Visual Analog Scale.
6. Hemoptysis: -

Grade	Sign
Mild	< 50ml
Moderate	50 to 200 ml
Severe	>200ml
Massive	>600ml

SAFETY RECORDING

a. Adverse Events

All adverse events observed or reported by patients will be recorded in the CRF with information about severity (i.e., whether mild, moderate or severe) and possible relation to the study medication. Any serious adverse effects will be notified immediately to the study monitor. Such cases will be immediately referred to the appropriate health authorities for further management.

b. Clinical Laboratory Parameters

The following laboratory tests will be performed as per the study schedule.

The laboratory tests include:

Hs-CRP, ESR, TC, DC, Absolute lymphocyte count, LFT, RFT, IL-6, Ig E, Ig-G, Ig-M, LDH, Creatine Kinase, Platelet count). The laboratory test results will be recorded in CRF.

STATISTICAL METHODS

Clinical symptoms, Subjective parameters and Laboratory parameters will be subjected to Univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) 15.0 version with appropriate statistical methods.

DEVIATION FROM THE PROTOCOL:

The trial will be conducted in compliance with the protocol. Deviations from the protocol will not be made except when necessary to alleviate an immediate hazard to trial patients. All the deviations from the protocol, including unplanned changes to interventions, examinations, data collection and method of analysis will always be reported to sponsors and IEC at the earliest along with the exact reason for that deviation.

ADVERSE EVENTS

Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

ADVERSE DRUG REACTION (ADR)

Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

DRUG COMPLIANCE

If there is more than or equal to 80% compliance, the participant would be continued in the trial. The compliance will be assessed at each follow-up by investigator on the admitted patients.

CONCOMITANT MEDICATION

Participants registered under the trial will be issued treatment cards with the entire treatment regimen written on it. They will be instructed to avoid the use of any other drugs on their own for any ailment and will be clearly instructed to consult the treating Investigating physician

for any symptom or complaint, or if they feel anything unusual. The Investigating physician will record any medication(s) he / she may prescribe to alleviate their ailments.

RESCUE MEDICATION

To alleviate any emergency and to relieve symptoms immediately, the use of rescue medication is permitted as per the wisdom / discretion of the Principal Investigator. However, the same will be documented in appropriate column in the Case Record Form.

DROP-OUTS

An attempt shall be made to record the reason for drop outs, if any during the clinical trial.

ETHICS

The trial will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), and that are consistent with Indian / ICH Good Clinical Practice (GCP) guidelines.

INSTITUTIONAL ETHICS COMMITTEE:

Institutional Ethics Committee (IEC) Scientific advisory committee approval is already procured from the Institutional Ethics Committee (IEC) of Government Medical College, Jalgaon. (IEC Approval No. 3536/20 dt. 29.04.2020 – Annexure-1) The research will also be registered to Clinical Trial Registry of India after the final approval for the EMR from Ministry of AYUSH and CCRAS.

PATIENT INFORMATION AND CONSENT FORM:

Written informed consent will be obtained from the subjects before the actual allocations in the study. Those who are not willing to participate in the study will be referred to appropriate health authorities for further treatment. The consent will be procured in the vernacular language. The format of the consent is attached herewith the proposal. (Annexure -2)

DATA DOCUMENTATION AND ANALYSIS

Clinical symptoms, Subjective parameters and Laboratory parameters will be subjected to univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) 15.0 version with appropriate statistical methods. All information regarding clinical trial should be properly documented, carefully handled and meticulously stored in order to ensure its accurate interpretation and verification.

Study Schedule

Particular	Screening (Before Intervention)	Day 1	Day 7	Day 15	Day 30	Day 45
Informed consent & PIS	Y	--	--	--	--	--
Medical history	Y	--	--	--	--	--

for any symptom or complaint, or if they feel anything unusual. The Investigating physician will record any medication(s) he / she may prescribe to alleviate their ailments.

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Study Schedule

Particular	Screening (Before Intervention)	Day 1	Day 7	Day 15	Day 30	Day 45
Informed consent & PIS	Y	--	--	--	--	--
Medical history	Y	--	--	--	--	--

Laboratory Investigations	Y	--	--	Y	--	--
Chest Xray	Y	--	--	Y	--	--
Clinical Examination	Y	Y	Y	Y	Y	Y
Concomitant Medication	--	Y	Y	Y	--	--
Assessment of ADRs	--	Y	Y	Y	Y	Y
Assessment of Medication compliance	--	Y	Y	Y	Y	Y
Temperature Chart/Blood Gas analysis	Daily thrice					

Laboratory Examination:

- **Hematology**
  - Haemoglobin : _____ g/dl
  - T.L.C.: _____ / cu.mm.
  - D.L.C. : N ____ % E ____ % B ____ % L ____ % M ____ %
  - Absolute lymphocyte count _____
  - E.S.R.: _____ mm (at the end of 1st hour)
  - Blood Sugar: Fasting _____ mg%
  - HbA1c: _____ %
- **Bio-chemistry:**
  - Blood Urea: _____ mg/dL
  - Serum Uric Acid: _____ mg/dl.
  - Serum Creatinine: _____ mg/dL
  - S.G.O.T.(A.S.T.): _____ IU/L
  - S.G.P.T. (A.L.T.): _____ IU/L
  - Total protein: _____ gm/dl
  - S.Albumin: _____ gm/dl
  - S.Globulin: _____ gm/dl
  - A/G ratio: _____
  - Serum Bilirubin:
    - Conjugated bilirubin _____ mg/dl
    - Unconjugated bilirubin _____ mg/dl
  - Serum Alkaline Phosphatase: _____ IU/L
  - Hs-CRP
  - IL-6
  - Ig E
  - Ig-G
  - Ig-M
  - LDH,
  - Creatine Kinase
- Chest X-Ray-PA view _____
- USG-whole abdomen _____
- Blood gas analysis [pH (normal range 7.35-7.45), PCO2 (kPa, normal range 4.65-6.0), PO2 (kPa, normal range 10.6-13.3)]

Budget

The expenses associated with the proposal of the research project submitted herewith would be approximately Rs. 10,00,000 (Rupees Ten Lakh only). The details of expenditure head and the amount required to respective head is provided in the table below.

Sr. No.	Expenditure head	Amount in Rupees
1	Raw Drugs (Medicine)	500000
2	Preparation of Medicines	200000
3	Remuneration	100000
4	Stationary	30000
5	Contingency	35000
6	Printing	50000
7	Travelling	35000
8	Liability Insurance	50000
	Total	10,00,000

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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:- 23/10/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 24/10/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

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/ 06 / 2020/ **Minutes of Meeting**

DATE: 24/10/2020

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

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	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.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

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

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the research study of **MISS. DHARMISHTHA N. SONI** titled **"COVID - 19 IMPACT ON MENTAL HEALTH OF STUDENTS – MEDICAL AND NON MEDICAL – INDIAN SCENARIO."**

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 October 2020 to December 2020 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 Secretory-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 19 Impact on Mental Health of student - Medical & Non Medical - Indian Scenario.

2. Name of the Principal Investigator/ Under/Post graduate student:
Miss Dharmishtha Soni
FINAL MBBS - I student

3. Name of the co-investigator/ ~~UG/PG guide/Trial monitor~~ (if applicable)
Dr. Vaishali Nagose Rathod
(Dr. Vaishali Babbarao Nagose)
Asso. Prof. Pathology.

4. i) Signature of Principal investigator/ UG/PG student:
D.N. Soni

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

iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)
for. Upadhyay

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: ----------

for 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:

2 months

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

A) ProceduraIL:

_____

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 – 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:

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

10) Whether the research project is sponsored: ~~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 investigatidgal 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.

D.N. Soni

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. Dhanishtha Soni 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
COVID-19 impact on Mental Health of students - Medical & Non Medical - Indian scenario.

Kindly do the needful.

D.N. Soni
(Candidate name and signature)
Dhanishtha Soni

Co-investigator/ ~~Guide~~ name and signature)
Dr. Vaishali Nagose

for. Ujjwala
(HOD name and Signature with Dept. seal)
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon