Maratha Mandal's
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3.3.1

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1	Ethical committee members
2	Research publication ethics guidelines
3	Ethical committee minutes of meeting
4	Ethical committee policy booklet

Maratha Mandal's
Nathajirao G. Halgekar
Institute of Dental Sciences
& Research Centre.
BELAGAVI

Dr. Ramakant Nayak
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3.3.1 Course content and ethical committee members

2016-17 and 2017-18

COMPOSITION OF ETHICAL COMMITTEE – 2016-2018		
1	DR. ANJANA BAGEWADI	CHAIRMAN
2	DR. RENUKA AMMANAGI	MEMBER SECRETARY
3	DR. VIKRAM PAI	MEMBER
4	DR.KISHORE BHATT	MEMBER
5	DR. VIJAYLAKSHMI K	MEMBER
6	DR.VINAYAK JOSHI	MEMBER
7	DR. MANOHAR KUGAJI	MEMBER
8	DR. PRAVEEN MANDROLI	MEMBER
9	DR. PREETI KUSUGAL	MEMBER
10	DR. POOJA DESAI	MEMBER
11	DR.RAVI SHIRAHATTI	BIOSTATISTICIAN

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2018-19 and 2019-20

COMPOSITION OF ETHICAL COMMITTEE 2018-2019		
1	DR. ANJANA BAGEWADI	CHAIRMAN
2	DR. RENUKA AMMANAGI	MEMBER SECRETARY
3	DR. VIKRAM PAI	MEMBER
4	DR.KISHORE BHATT	MEMBER
5	DR. VIJAYLAKSHMI K	MEMBER
6	DR.VINAYAK JOSHI	MEMBER
7	DR. MANOHAR KUGAJI	MEMBER
8	DR. PRAVEEN MANDROLI	MEMBER
9	DR. PREETI KUSUGAL	MEMBER
10	DR. POOJA DESAI	MEMBER
11	DR.RAVI SHIRAHATTI	BIOSTATISTICIAN

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2020-21

COMPOSITION **OF ETHICAL COMMITTEE – 2020-2021**		
1	DR. ANJANA BAGEWADI	CHAIRMAN
2	DR. HARSHADA HALGEKAR	MEMBER SECRETARY
3	DR. RENUKA AMMANAGI	MEMBER
4	DR.RAJENDRA HALLIKERIMATH	MEMBER
5	DR. CHETNA B	MEMBER
6	DR.RANGNATH NAYAK	MEMBER
7	DR. CHANDRASHEKAR. Y	MEMBER
8	DR. PRAVEEN MANDROLI	MEMBER
9	DR. PRACHI SHIVAPUJE	MEMBER
10	DR. BABU METGUD	MEMBER
11	DR.RAVI SHIRAHATTI	BIOSTATISTICIAN

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2021-22

COMPOSITION OF ETHICAL COMMITTEE - 2021-22		
1	DR. ANJANA BAGEWADI	CHAIRMAN
2	DR. SANDEEP KATTI	MEMBER SECRETARY
3	DR. RENUKA AMMANAGI	MEMBER
4	DR. HALIKERIMATH	MEMBER
5	DR. VIJAYLAKSHMI K	MEMBER
6	DR.CHANDRASHEKAR .Y	MEMBER
7	DR. CHETANA. B	MEMBER
8	MR. VIJAY MORE	SOCIAL WORKER
9	ADV. YARADAL	LAWYER
10	MRS. ASHA RUTTONJI	LAYMAN
11	DR.ANURADHA. B	BIOSTATISTICIAN

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Research publication / presentation ethics guidelines at the Institute

These guidelines are applicable to all the research work carried out at the Institute including main dissertation, term papers, short research, case reports, original articles, reviews and meta-analysis conducted by faculty, Post graduate or undergraduate students at the Institute.

- All the research work conducted in the Institute has to mention in any subsequent publication or presentation the name of the Institute and the concerned department's name in the methods section. Such details also need to be mentioned in description of author affiliations.
- Decision regarding 'First Author'
    1. Publications related to main dissertation/ thesis should have PG student as 'First Author' and the staff who has guided the dissertation should be the 'Corresponding Author'. The remaining authors can be choosen based on the substantial contribution to the research and the manuscript.
    2. Publications related to Non-dissertation for example, short studies, surveys, case reports, case Scenarios, Reviews, Meta analysis etc can have the first author whoever conceptualized the 'Primary Idea' to do the study or present the finding into a Publication. The Primary Idea can be from staff, PG or UG student or staff of other department.
- The Institution's name should be as "Maratha Mandal's Nathajirao G. Halgekar Institute of Dental Science & Research Centre, Belagavi."
- Kindly publish articles in the Journals which are from SCOPUS, Web of Science, UGC care or PUBMED.
- All such completed research must first be submitted to the Head of the department seeking permission for publishing and may proceed with submission only after due approval.
- The Document should contain the final manuscript ready for submission with the title page including authors' names, Institutional affiliations and acknowledgements.
- The authorship guidelines (See link below) of the ICMJE should be followed for deciding authorship, conflicts of interest and other related issues: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
- The following ICMJE recommended authorship criteria must be strictly adhered to. For being considered as an author, the author must satisfy all the criteria below:
    - Each author should have made "Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work"; **AND**
    - Each author should have contributed in "Drafting the work or revising it critically for important intellectual content"; **AND**
    - Author shouldcertify "Final approval of the version to be published"; **AND**

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- Each author must sign an "Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."
- In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

❖ All who meet the above criteria should be identified as authors. Those who do not meet the authorshipcriteria should be acknowledged appropriately after obtaining written or by email permission for placing their names in acknowledgements.

❖ Each post –graduate student and any undergraduate student involved in research should submit the following:

- Submit a declaration to the head of the department (of all concerned departments where the research will take place) stating that she has read and will adhere to the institutional guidelines for Publication ethics (As stated in this document) during his tenure at the Institute. Student should also declare that she/he will apply these guidelines while publishing all research conducted in this institution, even after completion of post-graduation and moving to subsequent institutions.
- On completion of research, submit a declaration that the integrity, originality, truthfulness and authenticity of data were duly ensured to while collecting and analyzing data. The student also needs to name one person from the Institute (with most substantial contribution to the particular work like Guide or co-guide) as "Corresponding author" for that research work for use in subsequent submission for publication.

❖ The institution holds the authority to take disciplinary action if any of the aforementioned aspects are not followed. Such disciplinary action may involve informing the concerned journal editor for retraction or informing the University or Council for further disciplinary action.

❖ All the research work conducted in the Institute has to mention in any subsequent publication or presentation the name of the Institute and the concerned department's name in the methods section. Such details also need to be mentioned in description of author affiliations.

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Student declaration form

(To be submitted to the HOD of departments where the research is being carried out)

- I have read and am aware of the publication ethics guidelines of the Institute and declare that I will adhere to it during my tenure here. I will also be liable to apply those guidelines to all the research carried out in this Institute even if subsequent publication / presentation is made after I leave the Institution after my post-graduation.
- I will adhere to and will strictly follow the authorship guidelines (See link below) of the ICMJE for deciding authorship, conflicts of interest and other related issues: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
- I will also adhere to all the research guidelines issued by ICMR and any such competent authority of our nation or state.
- All those who meet the authorship criteria will be identified as authors. Those who helped me with research but do not meet the authorship criteria will be acknowledged appropriately after obtaining written or by email permission for placing their names in acknowledgements. This includes the data processing work, data analysis carried out inside or outside of the Institute.
- I shall NOT include anyone as author who has NOT substantially contributed to the manuscript as stated in the authorship criteria.
- I will assure the integrity, originality, truthfulness and authenticity of data collecting and analyzing in my research.
- I shall name one person from the Institute (with most substantial contribution to the particular work like Guide or co-guide) as "Corresponding author" for that research work for use in subsequent submission for publication.
- On completion of my research, I shall submit a document containing the final manuscript ready for submission with the title page including authors' names, institutional affiliations and acknowledgements.
- For my research work conducted in the Institute, I will mention in any subsequent publication or presentation the name of the Institute and the concerned department's name and names of all substantial contributors in the methods section and affiliations of such presentations/ publications.
- I hold myself accountable for all the above.
- I know that the institution holds the authority to take disciplinary action if any of the aforementioned aspects are not followed. Such disciplinary action may involve informing the concerned journal editor for retraction or informing the University or Council for further disciplinary action.

Signature

Name of the student and department name

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(4)

6/07/2017.

Ethical Committee Meeting to discuss Research Grants applied for RGUHS Bengaluru for the year 2017-18.

All the committee members are requested to attend the meeting at 9.30 a.m on 07/07/17 at HOD Chamber, Dept of OMDR.

Dr Renuka. A

1. Dr Kishore Bhat
2. Dr Praveen Mendoncelli
3. Dr Vijayalakshmi K.
4. Dr Vikram Pai
5. Dr Ravi Shirahatti - Kindly avail me a leave since we have BDS final exam.
6. Dr Preethi Kusugal
7. Dr Pooja Desai
8. Mr. Manohar S Kugaji

Dr. Ramakant Nayak
Principal
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(1)

31/07/2017

Ethical Committee Meeting to discuss Research Grants applied for SERB (Proposal)

All the committee members are requested to attend the Meeting at 11.30 am on 31/07/2017 at HOD Chamber, Dept of OMDR

1. Dr Kishore Bhat
2. Dr Praveen Mendoolli
3. Dr Vijayalakshmi K.
4. Dr Vikram Pai
5. Dr Ravi Shirhatti
6. Dr Preeti Kusugal
7. Dr Pooja Desai.
8. Mr. Manohar S. Jugaji

1) A collective decision was made to write a letter to the Principal's office to request to depute a member (staff) to IRB to the position vacated by Dr Vinayak Joshi

2) A decision was also made to reconstitute the Research Committee which was headed by Dr Vinayak Joshi with the consent of higher authority.

3) The members went through various research proposals submitted to the Committee.

[a] UG Research Topic by Kiran Lamba & Onkar Pawar was approved without any changes.

[b] Research Proposal by Dr Manisha Hosekar was approved without any changes

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3] Research Proposal by Dr Sujatha Byrakatti → Suggested changes in Title, Aims & objectives, Review of literature & Methodology
- To make it more evidence based & to have logical explanation

The changes will be conveyed to the Staff.

4] A letter/circular from Ethical Committee to be ~~Submitted~~ sent to all the departments to submit the Proposals to the committee well in advance of the deadline so as to give time to committee to scrutinize the Proposals properly.

5] The Minor Research Proposals to be discussed by Subcommittee, Other members will be contacted in case of need.

Dr Renuka Ammanagi

Subcommittee,

1) Dr Renuka A
2) Dr Vijaylakshmi K
3) Dr Praveen M
4) Dr Ravi S.

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Ref.No.MM/BDS/MDS/2017-18/ 1019 Date:08/09/2017

INSTITUTIONAL REVIEW BOARD

CIRCULAR

The Institutional Review board (IRB) of the college has scheduled the PG dissertation synopsis presentation for I MDS on 24th and 25th October at 9:30 am (timing 9:30 am onwards).

All PG departments are requested to go through the following guidelines

1) All Postgraduate students should submit the hard copy of their dissertation synopsis to Dr. Renuka Ammanagi on or before 17th October 2017.
2) All the HOD's, PG guides & Co-guides and IRB Committee members are requested to compulsorily attend the entire presentation on both the days.
3) Time for power point presentation should not exceed 8 min followed by discussion.(Review of literature to be skipped)
4) Changes recommended should be incorporated and submitted to the committee on or before 02-11-2017.
5) For information on ethical guidelines PG's are directed to refer WHO consortium and ICMR guidelines for ethics in conducting biomedical research.
6) Department of OMDR, Prosthodontics and Periodontics will have their presentations on 24th and Department of Pedodontics, Conservative and Orthodontics will have it on 25th.

Copy to:-

1) Principals office
2) Dept of Oral Medicine
3) Dept of Prosthodontics 8/9/17
4) Dept of Periodontics 8/9/17
5) Dept of Pedodontics 8/9/17
6) Dept of Conservative 8/9/17
7) Dept of Orthodontics 8/9/17
8) IRB Members

Ashwini to note.

8/9/17

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23/10/2017

Ethical Committee Meeting is conducted to discuss the PG Synopsis Presentations to be held on 24th & 25th of Oct 2017.

1. Dr Kishore Bhat
2. Dr Parveen Mandrolli — 23.10.17
3. Dr Vijayalakshmi K.
4. Dr Vikram Pai — Vehar 23.10.17
5. Dr Ravi Shirhatti — 23.10.17
6. Dr Preeti Kusugal — 23/10/17
7. Dr Pooja Desai — 23/10/17.
8. Mr. Manohar S. Kugaji
9. Dr Renuka Annarao

1. Dr Pooja to welcome

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PG Synopsis Presentation For the
Year 2017-18 24/10/2017

The 1st year MDS Students of OMDR, Periodontics and Prosthodontic departments Presented the Synopsis for the dissertation.

The proposals were discussed at length for the Scientific as well as Ethical issues.
The suggestions & changes were conveyed to the PG's.
The PG's are asked to make the changes in the Synopsis & Submit one hard copy to the committee by 20th November.

The Following members were present for the same.

1. Dr Anjana Bagewadi
2. Mr Vijay More
3. Mr Umesh Yardal Achrekar
4. Dr Kishore Bhat.
5. Dr Praveen Mandrolli
6. Dr Vijaylakshmi. k.
7. Dr Rao Shirahatti
8. Dr Vikram Pai
9. Dr Preethi Kusugal
10. Dr Pooja Desai.
11. Dr Renuka Annanagi
12. Mr. Manohar S. Kugaji

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20/12/2017

A Meeting was called of the Subcommittee of IRB to discuss a few research proposals submitted to the committee.

Research Proposals were submitted by following Students.

1. Dr Shruti Paradkar,
2. Dr Madhukar Nayaka
3. Dr Yashashree Pawaskr
4. Dr Nikita Burde
5. Dr Dr Neha Naince

Went through the proposals & Suggested Changes to the Students.

* To add consent form
* To mention the Surce of samplel. etc.

The following members were Present

1. Dr Ravi Shirahatti
2. Dr Vijaylakshmi K.
3. Dr Ramesh Annaraegi.
4. Mr. Manohar S. Jugaji
5. Dr. Vikram Pai

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17/01/2018.

A meeting was called of the Subcommittee of IRB to discuss the research proposals submitted by ~~the~~ various students & also a PhD candidate.

Following ~~8~~ students/ phD candidate submitted the proposals.

1. Dr Sneha Gade
2. Dr Swetalina Das
3. Dr Prabhadeep Kour
4. Dr Madhura MG.

The proposals were studied at length & were discussed for the ethical issues.
All the studies had the Informed consent form
The committee approved all the four proposals with minor changes which was conveyed to the students.

1. Dr Praveen Mantralli
2. Dr Vijaylakshmi K.
3. Dr Renuka Annemagi
4. Mr. Manohar S. Kugaji
5. Dr Vikram. bai

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24/2/18 -

The Following committee members (Subcommittee) are requested to attend a meeting on 26/2/18 at 11.00 AM in OMDR Dept.

1. Dr Vijayalakshmi K.
2. Dr Praveen Kumar M
3. Dr Ravi Surhatti.
4. Dr. Vikram Pai

Discussed Dr Sheetal Kubsad's PhD Synopsis.

Suggested Corrections

1. Methodology & Objectives to be modified.
2. Consent to be done in local Languages.
3. To Re-Submit the Corrected Copy.

Dr RENUKA ANGADAGI

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The Following Committee members are requested to attend a meeting on 10/04/18 at 10.00 AM. in OMDR Dept

1. Dr Praveen Mandrekli — 9.4.18
2. Dr Ravi Shirahatti — 9/4/18
3. Dr Vijayalakshmi K — 9/4/18
4. Dr Vikram Pai — 9/4/18
5. Dr Preethi Kusugal — 9/4/18
6. Dr Pooja Desai — Absent.
7. Mr. Manohar S. Jugaji

Discussed 3 TOPICS.

(1) Dr Sheetal's PhD topic.
↓
Minor corrections to Writing Objectives.
↓
Conveyed to Dr Sheetal.

(2) UG Research Project → Survey among Dental Practioners.
↓
Modified Questionnaire.
Suggested to maintain Confidentiality (To remove name)
To Re-Submit after doing changes.

(3) Dr Sucheta → Short study.
- To modify Title.
- To elaborate methodology
- To change Statistical tests.
- To add Consent form in local languages.

Conveyed the Changes to her & to Re-Submit.

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27/09/18

The following Committee members (subcommittee) are requested to attend a meeting on 28/9/18 at 10.00 AM in Dept of OMDR to discuss a few short studies submitted by PG's.

1. Dr Praveen Mandroli
2. Dr Vijaylakshmi. k
3. Dr Ravi Shirahatti
4. Dr Renuka Annanagi.
5. Dr Vikram Pai.
6. Mr. Manohar S. Jugaji

The following study protocols were discussed.

1.

2. Evaluation of antimicrobial effect of Aloe vera gel & Tulsi gel & its combination on periodontal pathogens. – An in-vitro study
   PI → Dr Neha D Sugandhi

3. Assessment of antimicrobial activity of Carica papaya leaf & Raw fruit extract on Periodontal pathogens — An In-vitro Study
   PI → Dr Abhilasha Jha.

4. ~~Perceptions~~ Clinical experience by Interns – A Survey
   PI Miss Jyotishi Kumbar

5. Master rhythm therapy – A novel effective treatment option for treating fibrosis in OSMF — A pilot study
   PI – Dr Ashwini H.

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The studies were evaluated for ethical Concessons.

Dr Hameeda Bee was asked to change the title for In-vitro to Ex-vivo as the tissue samples were taken from patients.

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16/10/2018

The Synopsis Presentation of I St MDS Students has been Planned & arranged on 16/10/18 in College auditorium for the following Students.

1. Dr Umesh Bhosle
2. Dr Madhuri Nikam
3. Dr Akshaya Lal

} Pedodontics

4. Dr Ashwin Pradeep - Periodontics
5. Dr S Rakendu - Oral Pathology

The above mentioned Students are attending Conference or are having some personal issues hence can not attend on 25th, 26th October 2018.

The following Committee members are Present.

1. Dr Anjana Bagewadi
2. Dr Ramakant Nayak.
3. Dr Praveen Mondrolli.
4. Dr Vijaylakshmi. K.
5. Dr Ravi Shirhatti
6. Dr Chandrashekhar Yavagal
7. Dr Preeti Kusugal.
8. Dr Vikram Pai.
9. Dr Keshal Bhuva
10. Dr Renuka Annanagi
11. Mr. Manohar S. Tugaji

The Study Proposals were discussed in length & the corrections were told to the Students.

Dr Akshaya was asked to Prepare a time table for follow-up.

Dr Ashwin was asked to consider changing objectives of the Study.

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25/10/18.

1st MDS Students Synopsis Presentation.

Following committee members attended the PG Synopsis presentation. The research proposals were discussed in length & the suggestions were conveyed to the students. PGs were asked to do modifications in the synopsis & to re-submit 5th November

1. Dr Anjana Bageradi
2. Mr Vijay More
3. Mr. Vinesh Yardal.
4. Dr Ramakant Nayak.
5. Dr Kishore Bhat
6. Dr Parveen Mendroli
7. Dr Vijaylakshmi K.
8. Dr Vikram Pai
9. Dr Ravi Shirhatti
10. Dr Preethi Kusugal.
11. Dr Pooja Desai 25/10/18
12. Dr Ramka Annarago
13. Dr Madhu. Pujar
14. Dr Viraj Patil.
15. Dr Sheetal K.
16. Mr. Manohar S. Jugaji

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15. Dr Veerendra VPPIS

16. Dr Preeti Astagi

17. Dr Zarir Ruttonji

18. DR R B. Hallikeremath BDT

19. Dr. Pallavi. Gopushetti

20. Dr. Pushpa. S. P

21 Dr Hemanth. T. Vagarali 25/10/18

22 Mr. Manohar S. Jugji

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26/10/18

I MDS SYNOPSIS PRESENTATION

I MDS - Post graduate students presented their respective synopsis from the dept. of Orthodontics & Periodontology in front of Ethical committee members. Suggestions and modifications were conveyed to the students and they were asked to re-submit by 5th Nov. 2018. The following committee members and PG guides and other faculty members were present

1) Dr Anjana Bagewadi
2) Dr Renuka Annanagi
3) Mr Vijay More
4) Mr Umesh Yadal
5) Dr Praveen Mandeoli
6) Dr Ravi Shivahatti
7) Dr Aarati Nayak
8) Dr Pushpa S. Pudakalkatti
9) Dr. Vikram. Rai
10) Dr Madhu Priya
11) [illegible]
12) Dr. Sheetal Sanchy
12) Dr. Suvarna Patil
13 Mr. Manohar S. Pujari

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A meeting of Subcommittee called to 10/12/18 discuss the following Agenda,

1. To design & Prepare Protocols for Waiver for Consent form in cases of retrospective studies.

2. To go through the research Proposals Submitted by Conservative PG's (Short study).

↓

- Research Proposal by Dr Nikita Kapshe, PG Conservative → To follow ICMR Consent form & to include all three languages (Kannada, Marathi).

- Studies which have less than minimal risk like retrospective studies, interviews ... etc to be considered for waiver...

1. Dr Vijaylakshmi Kotrashetti
2. Dr Ravi Sirsalatti
3. Dr Romika Annanagi
4. Mr. Manohar S. Jangaji
5. Dr. Vikram Rao

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A meeting of subcommittee to discuss the following research proposals on 23/2/19 is called.

(1) • Effect of Cold Saline irrigation on Post operative pain – A RCT
P.I → Dr Satyam Jaiswal.
Corrections told by the committee were incorporated.

(2) Assessment of antimicrobial activity of murraya Koenigij on Periodontal pathogens – An in-vitro Study.
P.I → Dr Sreeshma Padmanabhan

(3) Comparative evaluation of collection, cultivation & identification of not yet cultivated oral anaerobic bacteria by using innovative culture methods.
PI → Dr Preethi Kasugal
ICMR grant Proposal
correction were communicated & the same are incorporated in the amended copy.

(4) Ex-vivo Culture of Oral keratinocytes using Direct explant cell culture technique
PI — Dr Vijaylakshmi Katanshetti

(5) Comparative evaluation of smear layer removal efficacy of 2.5% Sodium hypochlorite mixed with 18% HEBP using two different irrigation techniques — A SEM Study
PI → Dr Bheemreddy Vivek Reddy.

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The above mentioned research Proposal were scrutinized & discussed at length, suggestions were told.

The Revised copies were approved.

(1) Dr Ravi Shirahatti

(2) Dr Vijaylakshmi Kotrashetti

(3) Dr Renuka Annaraegi

(4) Dr. Vikram Kr.

Scholar

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
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02/03/2019

A Subcommittee Meeting is called to discuss the following research Proposals which have been submitted to the Research Committee.

(1) A research Proposal title "Isolation, Identification & Characterisation of Aggregatibacter actinomycetemcomitans from Patients with aggressive Periodontitis" submitted by Dr Kishore Bhat. The selection of patients & sample collection will be done at Kamineni Institute of Dental Sciences - Andhra Pradesh. The laboratory procedures will be carried out in CRL MMNGH IDS. For the lab procedures the ethical certificate has been given.

(2) A research proposal submitted by Dr Swapnali B Ghumare was evaluated Title - A kaleidoscopic vision towards conservation. The following corrections were communicated.

- The title is inappropriate, does not reflect the study design.
- Objectives need to be reframed.
- Methodology need to be more clear.
- Statistic → Sample size estimation is not clear.
- It appears that two different studies have been combined.

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① Dr Ravi Shirahatti

② Dr Vijaylakshmi K.

③ Dr Pooja Kasugar, Prof

④ Dr Renuka Annaiger

⑤ Dr. Vikram Rao

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

12/11/19

1st MDS SYNOPSIS PRESENTATION.

BATCH – 2019 - 2022.

1st MDS / Post Graduate Students presented their Synopsis for the dissertation to the Ethical Committee.

Suggestions & modifications were conveyed to the Students & they were asked to Re-submit the same by 18th Nov 2019

The following Committee members, PG guides & Faculty members were present.

1. Dr Anjana Bagewadi 12/11/2019
2. Dr Kishore Bhat
3. Dr Ramakant Nayak.
4. Mr Vijay More
5. Mr Umesh Yardal
6. Dr Vijaylakshmi K
7. Dr Vikram Pai
8. Dr Preethi kusugal
9. Dr Ravi Shirahatti
10. Dr Praveen Mandrali
11. Dr. Shrikant Kulkarni
12. Dr Madhu Rajan
13. Dr Hemant Vaijapurkar

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

14) Dr. Pallavi. G

15) Dr. Siddharth. Ravalkar

16) Dr Vijay Naik

17) Dr Halikerimath.

18) Dr Renuka Annamanagi

19) Dr Vinay N Patil

20) Manohar S. Kugaji

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
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(20)

DATE 13 11 13

TSL MDS SYNOPSIS PRESENTATION.

The Synopsis ~~~~ Presentation Conducted.

Department of Periodontics, Prosthodontics & Pedodontics PG's ~~~~ Presented the Synopsis.

Suggestions & Modifications were conveyed to the PG's.

Following members attended the meeting.

1. Dr. Arjuna Bugewadi
2. Mr Vijay More
3. Mr Umesh Yardal
4. Dr Kishore Bhat
5. Dr Urooj Patil
6. Dr Praveen M.
7. Dr Ravi Shirhatti
8. Dr Vijalakshmi
9. Dr Preethy Venugopal
10. Dr Ramakant Nayak
11. Dr Ranganath Nayak 13/11/13
12. Dr Ajaykumar Nayak
13. DR R B Hallikerimath

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences & Research Centre, Belagavi-590010.

09/12/19 (21)

Meeting of Subcommittee to Discuss Research Proposals.

Two research Proposals are Submitted by Mr Vijay Kumbar Research officer CRL.

The research Proposals were discussed in length & the Candidate was asked to Submit the copy of a Letter Submitted by ~~to~~ the Institute to the SDM College for sample collection

The CRL ~~was~~ will be conducting

In-vitro Procedures of cancer cell Line (oral & head & neck cancer) Preperation.

The research Proposal by a PG Dr ATHUL CHANDRA was discussed.

The change in Title for Dr Deepa Babji's request was considered with declaration & Submission of Old Certificate.

1. Dr Vijaylakshmi K
2. Dr Ravi S
3. Dr Renuka Annanagi
4. Mr. Manohar S. Kugaji

9/12/19

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences & Research Centre, Belagavi-590010.

NOTICE

The research and Ethical committee meeting will be held on 9.1.2020 at 10.30am to discuss a research project for ICMR grant. All the members are requested to make it convinient to attend the same. The meeting will be held at Seminar room, Department of Periodontology.

Member	Signature
1. Dr. Ranganath Nayak	06/01/2020
2. Dr. Renuka Ammanagi	6/1/2020
3. Dr. Praveenkumar Mandroli	6.1.19
4. Dr. Ravi Shirahatti	4.1.19.
5. Dr. Rajendra Hallikerimath	
6. Dr. Chandrashekar Yavagal	7/1/2020
7. Dr. Prachi Shivpuje	6/1/2020
8. Dr. Babu Metgud	9/1/2020
9. Dr. Chetana Bagar	6/1/2020

Dr. Harshada Hulyekar

The synopsis for research project is not yet submitted. Dr. Madhu Pujar has informed that the synopsis will be submitted by 12.1.2020 and has requested to postpone the

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meeting. So, the meeting will be held at 1.30 pm on 9.1.2020.

9.1.2020
9.50 am.

Meeting was conducted at 1.30pm. The following points were discussed

1. Seperate outward numbers to be given for ethical clearance certificate issued for MDS / BDS / Staff research.
2. Sub-committee can be formed to discuss U.G research projects.
3. The research project submitted by CRL and Dept of conservative dentistry was discussed
   Topic - Development, Characterization, Evaluation, Validation of ex-vivo Endodontic Biofilm Models.
   - Statistical tests for all research variables should be mentioned
   - Details of Laser tip that will be used should be written.
   - Details of equipments used - Technicals, manufacturer and country to be mentioned.
   - Turbidity ~~stand~~ standard to be mentioned.

Meeting was attended by -

1. Dr. Renuka A.
2. Dr. Praveenkumar M.
3. Dr. Ravi S.
4. Dr. Rajendra H.
5. Dr. Chandrashekar Y.
6. Dr. Prachi
7. Dr. Harshada.

9.1.20.
9/1/2020
9/1/2020

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

The research and Ethical committee meeting will be held on 7.2.2020 at 9.30am to discuss short study research proposals submitted by PGs. (Dr. Rajesh and Dr. Raghavendra)

The agenda for meeting is also to discuss about registration of Ethical committe with National ethics Committe Registry for Biomedical and Health research, DHR.

The meeting will be held at seminar room, Dept of Periodontology.

	Member	Signature
1.	Dr. Ranganath Nayak	03/02/2020
2.	Dr. Renuka Ammanagi	
3.	Dr. Praveenkumar Mandroli	(OUT OF STATION)
4.	Dr. Ravi Shirahatti	
5	Dr. Rajendra Hallikeinmath	
6.	Dr. Chandrashekhar Yavagal	(UNAVAILABLE)
7.	Dr. Prachi Shivpuje	
8.	Dr. Babu Metgud.	—
9.	Dr. Chetana Bogar.	

3.02.2020

Dr. Harshada Halgekar

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

7.02.2020

Meeting was conducted at 10:00am in the Conference hall of the college. The following points were discussed.

① Total 7 members were present in the meeting.
② minutes of meeting of previous meeting were read out in which two alteration were made
① No sub committee should be formed. MMNGHIDS IEC members will overlook all the ethical proposals.
② Only one outward and inword registe and file will be maintain.

③ IEC members have to be trained in good clinical practical Practice and ethical guidelines, so the member secretatory interacted with principal sir on 6/2/2020 regarding the training proposal. Principal sir assured that training will be conducted.

④ Dr. Renuka maam suggested that members should be trained by ICMR.
⑤ Dr. Ravi Sir suggested to invite as a guest speaker for training program – Dr. Roli mathur

⑥ The new email id account will be open for IEC. All communications by IEC will be done in writing or email.
⑦ A Circular has to be sent to all the departments regarding –
ⓐ Proposal should be submitted to the committe before 15th of every month.
ⓑ Pro A format for submission of research proposal will be provided (According to ICMR guidelines)
ⓒ Proposals received after 15th will be discussed in subsequent month.
ⓒ The proposal should be submitted in the hard copy format to member secretatory and Soft copy should be sent to id-mail to IEC.

⑧ Member Secretary will forward the research proposal to all the IEC members via email. members Should review the research proposal within 7 days and reply at earliest.
⑨ Seperate file/folder will be maintain for each research proposal and IC number will be provided. All research proposals will be saved in the hard disk.
⑩ updated CV of all IEC members should be submitted.
⑪ Committee should include Legal expert, social scientist, Layman and Pharmacist.
⑫ Need for having audit committee to audit the work of IEC was discussed. Dr. Hallikeramath will provide a format in which ethical committee is audited.

Meeting was attended by :-

1. Dr. Ranganath Nayak – 7/2/2020
2. Dr. Renuka Ammangi – 7/2/2020
3. Dr. Ravi Shirahatti –
4. Dr. Rajendra Hallikerimath –
5. Dr. Chetana Bagar –
6. Dr. Prachi Kati – 7/2/2020
7. Dr. Harshada Halgekar –

Dr. Ramakant Nayak
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The research and Ethical Committee meeting will be held on 2.3.2020 at 9.30 am to discuss research proposals for start studies submitted by P.G. students. All the members are requested to make it convinient to attend the same. The meeting will be held at Conference room in the college office

Members	Sign
1. Dr. Ranganath M.	26/2/2020
2. Dr. Renuka A.	
3. Dr. Praveenkumar M.	(Have seminar at 9.30 am)
4. Dr. Rani S.	26/2/2020
5. Dr. Rajendra H.	26/02/20
6. Dr. Chandrashekhar Y.	—
7. Dr Prachi S.	26/2/2020
8. Dr. Babu Metgud.	
9. Dr. Chetana Bogar.	26/2/2020

26.2.2020
Dr. Harshada H.
Member Secretary

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2.3.2020

Meeting was conducted at 9.30 am in the conference room of the college office. Total 7 members were present for the meeting. The following points were discussed.

1. It was decided that the secretary is authorised to request for relevant missing documents and information as per comments / suggestions of individual IEC members before the study is reviewed in the IEC meeting.

2. It was decided that a circular to be sent to all departments informing them that Ethical clearance by IEC is mandatory before commencement of any study / research. The CRL has to be informed to not accept any request ~~with~~ or commence the study without ethical clearance certificate.

3. Member secretary informed that auditing of Ethical committee is not mandatory for registration for IEC with ~~Health~~ ministry DHR - Member secretary had a telephonic conversation with help center at natik.gov.in.

4. The secretary had discussed with the Principal ~~sir~~ on 7.2.2020 regarding training of IEC members. The Principal suggested that Dr. Subarna Roy, JCMR, Belgavi could be contacted through Dr. Kishore Bhat, CRL.

5. Circular to be sent to all the departments - that the Principal investigators of research proposals submitted to IEC ~~should be present~~ could be called for during IEC meeting. along with the study details. and replies to queries set by IEC ~~if~~ any.

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6. The research proposal should be submitted with corrections after the meeting. The corrections ~~were~~ should be highlighted.

7. 7 research proposal were discussed and comments/ suggestions given accordig to the attachment.

Members

1- Dr. Rangenath M.

2- Dr. Renuka A.

3. Dr Pravan Kumar

4, Dr Ravi S,

5. Dr Hallikeemath

6 Dr. Chetana B.

7. Dr. Hanchate H,

8 Dr. Prachi. K

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Principal
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The research and Ethical committee meeting will be held on 13.3.2020 at 9.30am. at conference room in the college office. All the members are requested to make it convinient to attend the same.

Members.	Sign.
1. Dr. Ranganath H.	11/03/20
2. Dr. Renuka A.	11.03.20
3. Dr. Praveenkumar M.	11/3/2020
4. Dr. Ravi S.	
5. Dr. Rajendra H.	—
6. Dr. Chandrashekhar Y.	11/3/2020
7. Dr. Prachi S.	
8. Dr. Babu Metgud	11/3/2020
9. Dr. Chetana Bogar.	

Dr. Harshada H.
Member Secretary.

Dr. Ramakant Nayak
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...n Centre, Belagavi-590010

The research and ethical committe meeting will be held on 16th sept 2020 at 10.00am. at conference room in the college office. All the members are requested to make it convinient to attend the same. Revised synopsis of short studies submitted by PGs will be discussed.

Members:	Sign
1. Dr. Ranganath N.	14/9/20
2. Dr. Renuka A.	14/9/20
3. Dr. Praveen Kumar M.	12.9.20
4. Dr. Ravi S.	16/9/20 OPD Duty
5. Dr. Rajendra H.	12/09/20
6. Dr. Chandrashekhar Y. (On leave)	15/09/2020
7. Dr. Prachi S.	Leave
8. Dr. Babu Metgud	
9. Dr. Chetana Bugar.	14/9/2020

Dr. Harshada H.
Member secretary

Dr. Ramakant Nayak
Principal
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16.09.2020

Meeting was conducted at 10.am in the conference room of college office. Total 6 members attended the meeting. The following points were discussed -

① Revised Synopsis and corrections submitted by post-graduate and undergraduate students were discussed. (3 studies)

② Dr. Chetana Bogar had requested the IEC in writing on 12.3.2020 regarding need for the publications and ~~athour~~ authorship guidelines for various research work that was carried out at the institute.

③ A document regarding 'Research publication / presentation ethics guidelines at the Institute' was discussion and few suggestions were given.
- College name can be written in materials and methods section of article if the Journal permits doing so.
- Disciplinary Action would be taken by IEC.
- For publications of case reports the student along with the staff who guided / monitored the case will be main authors.
- Guide will be the corresponding author for publication of thesis / dissertation work.

④ A staff member will have to inform the ethical committee in writing if any unethical research is being done and noticed by the staff in the department / institute.

Attended by -

Dr. Ranganath N
Dr. Renuka A.
Dr. Praveenkumar N
Dr. Rajendra H
Dr. Chetana B.
Dr. Harshada H.
Dr. Pooja K

Dr. Ramakant Nayak
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The research and ethical committee meeting will be held on 19 oct 2020 at 10.00 am at conference room in the college office All the members are requested to make it convinient to attend the same. Synopsis of Short studies submitted by PGs will be discussed.

Members

Dr. Rangenath H. — 15/10/20

Dr Renuka A. — 15/10/20

Dr Praveen Kumar M. — 15.10.20

Dr. Ravi S — 15/10/20

Dr. Rajendra H. — 16/10/20

Dr. Chandrashekhar Y. — Leave

Dr. Prachi S.

Dr. Baby Metgud. —

Dr. Chetana B.

Dr. Harshada H.
Member Secretary

Dr. Ramakant Nayak
Principal
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19.9.2020

The research and ethical committee meeting was conducted at 10 am in the conference room in college office. Total 5 members attended the meeting. The following points were discussed.

1. Revised synopsis of short studies submitted by PGs were discussed (2 studies) and approved.
2. Short study synopsis submitted by Dr Bhakti was received and by suggestions were given.

Attended by

- Dr. Hallikeremath
- Dr. Renuka A.
- Dr Praveenkumar M.
- Dr. Ravi S.
- Dr Harsheda H.
- Dr. pracci K

19.10.20

19/10/20

Dr. Ramakant Nayak
Principal
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4.11.2020

The research and ethical committee meeting will be held on 10.11.2020 at 10:00am at the conference room in the college office. All the staff members are requested to make it convinient to attend the same. Revised synopsis of short study submitted by P.G student will be discussed.

Members: Sign.

Dr. Ranganath N. 04/11/2020

Dr. Renuka A.

Dr. Prabeen Kumar M. 5.11.20

Dr. Ravi S.

Dr Rajendra H.

Dr Chandrashekhar Y.

Dr. Prachi S. - madam, i am on OPD duty on 10/11/2020 Prachi.

Dr. Babu Metgud

Dr. Chetana B.

Dr. Harshada H.
Member Secretary

Dr. Ramakant Nayak
Principal
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10.11.2020

The research and ethical committee meeting was conducted at 10:00 am in the conference room in the college office. Total 6 members attended the meeting. The following points were discussed.

① Short study Synopsis submitted by Dr. Bhakti was approved for ethical clearance.

② All IEC committee members should register for Certified online Training program on Research ethics, ~~review committee in India~~ GCP and current regulations on 12.11.2020 Conducted by Dayanand Sagar College of dental science.

③ Synopsis presentation ~~for~~ of Dissertation / Thesis will be organised in the month of January.

Attended by —

Dr. Ranganath N. 10/11/2020

Dr. Hallikeimath 10/11/20

Dr. Renuka A.

Dr. Ravi S. 10/11/20

Dr. Harshada H.

Dr. Praveen M 10.11.20

Dr. Pravin. K

Dr. Ramakant Nayak
Principal
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Ethical committee meeting will be held on 12.2020 at 10.00 am at the conference room the college office. All the staff members are requested make it convinient to attend the same. NAAC criteria 3.3.1 which is regarding IEC has to be discussed.

Members :	Signature
Ranganath N.	02/12/2020
Renuka A.	
Praveen Kumar M.	07.12.20
Ravi S.	
Rajendra H.	
Chandrashekhar Y.	
Prachi S.	
Babu Matgud.	
Chetana B.	

Dr. Harshada H.
Member Secretary

Dr. Ramakant Nayak
Principal
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& Research Centre, Belagavi-590010.

The research and Ethical committee meeting was held on 9.12.2020 at the conference room in the college office. Total 6 members attended the meeting. The following points were discussed.

1. Post graduate thesis synopsis presentation will be held on 3rd and 4th Feb 2021.
2. The last date for submission of Synopsis is 18 Jan 20
3. The last date for submission of revised synopsis will be 10 Feb 2021.

Attended by -

Dr. Ranganath Nayak — 09/12/20

Dr. Renuka. A — 9/12/20

Dr. Ravi S — 9/12/20

Dr. Prachi K — 9/12/2020

Dr. Chetana B — 9/12/2020

Dr. Harshada H

Dr Rajendra L

BL

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

The institutional Ethical committee meeting will be held on 18.1.2021 at 9.00 am at Conference room in the college office. All the committee members are requested to make it convinient to attend the same. Synopsis of thesis study submitted by PG student has to be discussed. P.G. dissertation Synopsis presentation has to be planned.

Members -

Dr. Rayanath H.

Dr. Renuka A.

Dr. Rajendra H.

Dr. Chandrashekhar Y.

Dr. Prachi S. - 13/1/2021

Dr. Babu Metgud

Dr. Chetana Bogar 13/1/21

Dr. Vikram Pai 13/1/21

Dr. Kolvekar.

Dr. Harshada H.
Member Secretary

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences & Research Centre, Belagavi-590010.

18.1.2024

The IEC meeting was held on 18.1.2024 at the conference room in the college office. Total 7 members attended the meeting. The following points were discussed -

1. Principal had suggested that PGs should not be given NOC till they submit the manuscript copy of Dissertation work. This does not ~~come~~ fall under the purview of IEC. The above practice should be mandated by individual departments or the administrative office.

2. Dr. Krushika Kadam to submit the consent for her short study.

3. Remuneration for the other participating members to be arranged.

4. welcome address to be given by Dr. Harshada

5. Dr. Renuka will give vote of thanks.

6. Corrections / suggestions will be noted by Dr Prachi

7. Suggestion was made by Dr. Renuka to include a pharmacist in the committee, Dr. Mallesh's name was suggested and approved by the committee members.

8. Refreshments - Tea / biscuits to be arranged by Dr. Chetan.

Attended by -

Dr. Ranganath N. — 18/1/24
Dr. Renuka A. =
Dr. Vikram P.
Dr. Mallikarjunaiah
Dr. Chetan
Dr. Prachi -
Dr. Harshada

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

The IEC meeting will be held on 29.1.2021 at 9.00am at conference room in college office. All the Comittee members are requested to make it convinient to attend the same. Synopsis of P.G dissertation have to be discussed.

Members :

Dr. Ranganath N. — Leave

Dr. Ramika A.

Dr. Rajendra H. — Lecture.

Dr. Prachi K. — (on Leave on 29/1/2021)

Dr. Chetana B.

Dr. Vikram P. — Leave (Soon leave on 29/1/21)

Dr. Kolvekar

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

Dr. Hemshede H.

3.2.2021

P.G. Dissertation synopsis presentation for year 2020-21

The 1st year MDS students of department of Prosthodontics and Crown & Bridge presented the synopsis of their Dissertation.

The proposals were learned at length for the methods as well as ethical issues. The suggestions and changes advised were conveyed to the P.G students.

- The PGs were asked to submit the revised synopsis copy to the IEC on or before 8th Feb 2021.

Attended by :

1. Dr Anjana Bagewadi
2. Dr Roopal Sankeshwari - 3/2/21
3. Mr Umesh Yardal
4. Mr Vijay More
5. Dr Ranganath Nayak
6. Dr Ramakant Nayak
7. Dr Roshan Annaraya
8. Dr Harshada Kalgekar
9. Dr. Chetana Bagade
10. DR R B Hallikerimath

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

4.2.2021

P.G Dissertation synopsis presentation for year 2020-21

- The 1st year M.D.S students of department of Conservative dentistry, Orthodontics and Pedodontics presented the synopsis of their dissertation.
- The proposals were discussed at length for the scientific as well as ethical issues. The suggestions and changes advised were conveyed to the P.G students.
- The P.Gs were asked to submit the revised synopsis copy to the IEC on or before 8th Feb 2021

Attended by -

1. Dr. Anjana Bagewadi
2. Dr. Roopali Sankeshwari
3. Mr. Umesh Yardal
4. Dr. Ranganath Nayak 4/2/21
5. Dr. Renuka Ammangi
6. Dr. Chetana Bogar
7. Dr. Hallikeri math 4/2/21
8. Dr ~~Hallikeri~~ Hanchate M
9. Dr Madhu Rijan
10. Dr. Pallavi G

Dr. Ramakant Nayak
Principal
M M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

(11) Dr. Prachi Katti - Prachi 4/2/2021

12 Dr Virendra Uppin

13 Dr Hemant Vagarali

14 Dr Chetan Patil 4/2/21

15 Dr Asim Jamadar

16 Dr. Ramakant Nayak

17 Dr [illegible] Naik

18 Dr. Siddharth Revankar.

19. Dr Bhakti Halappanavar

20. Dr. Vikram Kori. Vikram

21. Dr. Chandrashekar Yavagal Chavagal

Dr. Ramakant Nayak
Principal
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9.2.2021

IEC meeting was held on 9.2.2021 at the conference room in college office. Total 6 members attended the meeting. Following points were discussed.

- Revised synopsis of P.G dissertation were discussed.
- Short study submitted by Dr. Krutika Kadam was discussed and approved.
- Short study submitted by Dr. Harish and Dr. Soumya was approved.
- Dr. Ranganath Nayak suggested that the constitutes of IEC members be changed as follows.
  The following members are not the part of IEC as of today —
  1. Dr. Chandrashekhar Yavagal
  2. Dr. Praveenkumar Mandroli
  3. Dr. Babu Metgud
  4. Dr. Ravi Shirahatti
- Two new members are appointed as members of IEC. from 1
  1. Dr. Vikram Puri
  2. Dr. Kolvekar.
- This is done in consultation with Principal.
- Publication ethics document was approved.

Attended by —

1. Dr. Ranganath Nayak
2. Dr. Rajendra Hallikeremath
3. Dr. Renuka A.
4. Dr. Prachi Kotli

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

P.T.O

5. Dr. Chetana Bogar

6. Dr. Harshada Halgekar

4/10/2021

IEC Meeting

01. An ethical comittee meeting was conducted in the dept. of Periodontology with the new members of the comittee and the following points were discussed

→ Whenever a synopsis is presented to the comittee (UG / PG), the synopsis will be mailed to each & every member of comittee. Any changes in the synopsis should be done via mail.

→ It is also suggested by Dr. Kothrashetty to take list of external members from Dr. Renuka.

→ It is also suggested in the meeting to form an institutional policy for UG students with Dr. Anuradha. for the purpose of research.

→ It is also suggested to take a note on renewal of college ethical comittee and any necessary advise to be taken from Dr. Diwan

→ All the email id's of all the college ethical comittee members was collected

Attended by :

1. Dr. Sandeep

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences & Research Centre, Belagavi-590010.

2. Dr Chandrashekar
3. Dr Hallikerimath
4. Dr Kotrashetty
5. Dr Chetana
6. Dr Renuka Annaraya

24/11/2021

IEC Meeting

01. In the meeting, the renewal process of the institutional ethical comittee was discussed. There were various inputs from the comittee members. Dr Vijayalaxmi suggested that the renewal process for the new ethical comittee could take some time, ~~so,~~ hence and as the institute is going for NAAC accreditation, the chairman & the member secretary of the registered comittee to continue. Dr Vikram who was the member secretary during the registration of institutional ethical comittee said that, 2 years of his 10 year is over. It was also said by Dr Vikram that ethical comittee is not registered for clinical trials.

02. Dr. Hallikerimath suggested to continue the same comittee with Dr Anjana Bageevadi as chair person & Dr. Vikram as member secretary.

03. It was also discussed that all the mails to be sent to mmdcethicalcomittee@gmail.com. Any correspondence of ~~through~~ the ethical comittee will be through mail.

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

04. It was also discussed about the new ICMR gurdelines. All the members of the comittee were asked to go through the ICMR gurdelines and also to find out the ~~and~~ CDESCO gurdelines

05. Ethical clearance to be given to all the short study submitted after doing necessary changes by Dr. Anukumar, Dr. Haripriya & Dr. Ekta.

06. Dr. Yavgal ~~was~~ ~~asked~~ to submitted the synopsis of hrs study.

07. All the members also discussed about the plagia software for the institute.

08. Dr. Anuradha suggested 'checker X' as a software for plagarism

09 'Turnitin' was suggested by Dr. Vijaylaxmi

10. Dr. Hallikeremath suggested 'Viper'

11. Dr. Renuka said that that soft wares needs to be subscribed & renewed yearly.

Attended by :

1. Dr. Sandeep — 24/11/21
2. Dr. Chandrashekar — 24/11/21.
3. Dr. Vijay laxmi — 24/11/21
4. Dr. Renuka — 24/11/21.
5. Dr. Hallikeremath — 24/11/21.
6. Dr. Anuradha — 24/11/21.
7. Dr. Chetna — 24/11/2021
8. Dr. Vikram — 24/11/21

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

13.1.2021

The institutional Ethical committee meeting will be held on 18.1.2021 at 9:00 am at Conference room in the college offices. All the committee members are requested to make it convinient to attend the same. Synopsis of Case Study submitted by the student has to be discussed. The dissertation synopsis presentation has to be planned.

Members :-

Dr. Ranganath N.

Dr. Renuka A.

Dr. Rajendra H. BJ

Dr. Chandrashekhar Y.

Dr. Prachi S. 13/1/2021

Dr. Babu Metgud

Dr. Chetana Bogar 13/1/21

Dr. Vikram Pai 13/1/21

Dr. Kolvekar.

Dr. Harshada H.
Member Secretary

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences & Research Centre, Belagavi-590010.

18.1.2024

The IEC meeting was held on 18.1.2024 at the conference room in the college office. Total 7 members attended the meeting. The following points were discussed -

1. Principal had suggested that PGs should not be given NOC till they submit the manuscript copy of Dissertation work. This does not come fall under the purview of IEC. The above practice should be mandated by individual departments at the administrative office.

2. Dr. Krutika Kadam to submit the consent form for her short study.

3. Remuneration for the other participating members to be arranged.

4. welcome address to be given by Dr Harshada

5. Dr. Renuka will give vote of thanks.

6. Corrections / suggestions will be noted by Dr Prachi

7. Suggestion was made by Dr Renuka to include a pharmacist in the committee, Dr. Mallesh's name was suggested and approved by the committee members.

8. Refreshments - Tea / biscuits to be arranged by Dr. Chetana.

Attended by -

Dr. Ranganath N. — 18/1/24
Dr. Renuka A. — 18/1/24
Dr. Vikram P. — 18/1/24
Dr. Mallikarjunth — 18/1/24
Dr. Chetana — 18/1/24
Dr. Prachi — 18/1/24
Dr. Harshada — 18/1/24

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

29/1/2024

The IEC meeting will be held on 29.1.2021 at 9.00am at conference room in college office. All the Committee members are requested to make it convinient to attend the same. Synopsis of I-G dissertation have to be discussed.

Members :

Dr. Ranganath N. — Leave

Dr. Renuka A.

Dr. Rajendra H. — Lecturer

Dr. Prachi K. — Resident → (on Leave on 29/1/2021)

Dr. Chetana B.

Dr. Vikram P. — Tutor (on leave on 29/1/21)

Dr. Kolvekar

Dr. Harshada H.

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

3.2.2021

P.G. Dissertation Synopsis presentation for year 2020-21.

- The 1st year MDS students of department of Prosthodontics and Periodontology presented the synopsis of their Dissertation.

- The proposals were discussed at length for the scientific as well as ethical issues. The suggestions and changes advised were conveyed to the P.G students.

- The PGs were asked to submit the revised synopsis copy to the IEC on or before 8th Feb 2021.

Attended by :

1. Dr Anjana Bagewadi
2. Dr Roopali Sankeshwari - 3/2/21
3. Mr Umesh Yardal.
4. Mr Vijay More
5. Dr Ranganath Nayak.
6. Dr Ramakant Nayak.
7. Dr Renuka Annanagi
8. Dr Harshada Halgekar
9. Dr. Chetana Bagad
10. DR R B Hallikerimath

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi 590010.

(11) Dr. VIKRAM PAI

(12) Dr. Pushpa S. P

(13) Dr Sanjeevini. A. H

14. Dr. Sachin Shivanalkar

15. Dr Virendra Uppin

(16) Dr Aarati Nayak

17) Dr. Vijayalakshmi K

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

4.2.2021

P.G. Dissertation synopsis presentation for year 2020-21

- The 1st year M.D.S students of department of Conservative dentistry, Orthodontics and Pedodontics presented the synopsis of their dissertation.
- The proposals were discussed at length for the scientific as well as ethical issues. The suggestions and changes advised were conveyed to the P.G students.
- The P.Gs were asked to submit the revised synopsis copy to the IEC on or before 8th Feb 2021

Attended by -

1. Dr Anjana Bagewadi
2. Dr Roopali Sankeshwari
3. Mr. Umesh Yardal
4. Dr. Ranganath Nayak 4/2/21
5. Dr. Renuka Ammanagi
6. Dr. Chetana Bugar
7. Dr Hallikeerimath 4/2/21
8. Dr ~~Harshita~~ Harshita H
9. Dr Madhu Pujar
10. Dr. Pallavi G

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

(11) Dr. Prachi Katti Prachi 4/2/2021

12 Dr Virendra Uppin

13 Dr Hemant Vageesh

14 Dr Chetan Patil 4/2/21

15 Dr Asim [illegible]

16 Dr. Ramakant Nayak

17 Dr [illegible] Naik

18 Dr. Siddharth Revankar

19. Dr Bhakti Halappanavar

20. Dr. Vikram Rao

21. Dr. Chandrashekar Yavagal

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

9.2.2021

IEC meeting was held on 9.2.2021 at the conference room in college office. Total 6 members attended the meeting. Following points were discussed.

- Revised synopsis of P.G dissertation were discussed.
- Short study submitted by Dr. Krutika Kadam was discussed and approved.
- Short study submitted by Dr. Harish and Dr. Sowmya was approved.
- Dr. Ranganath Nayak suggested that Dr. the constitutes of IEC members be changed and as follows. The following members are not the part of IEC as of today —
  1. Dr. Chandrashekhar Yavagal
  2. Dr. Praveenkumar Mandreli
  3. Dr. Babu Metgud
  4. Dr. Ravi Shirhatti
- Two new members are appointed as members of IEC. from :
  1. Dr. Vikram Pai
  2. Dr. Kalvekar.
- This is done in consultation with Principal.
- Publication ethics document was approved.

Attended by —

1. Dr. Ranganath Nayak
2. Dr. Rajendra Hallikeerimath
3. Dr. Renuka A.
4. Dr. Prachi Katti

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

P.T.O

5. Dr Chetana Bogar

6. Dr Hemchede Halgekar

4/10/2021

IEC Meeting

01. An ethical comittee meeting was conducted in the dept. of Periodontology with the new members of the comittee and the following points were discussed:

→ Whenever a synopsis is presented to the comittee (UG / PG), the synopsis will be mailed to each & every member of comittee Any changes in the synopsis should be done via mail.

→ It is also suggested by Dr. Kothrashetty to take the list of external members from Dr Renuka.

→ It is also suggested in the meeting to form an institutional policy for UG students with Dr. Anuradha for the purpose of research.

→ It is also suggested to take a note on renewal of college ethical comittee and any necessary advise to be taken from Dr Diwan

→ All the email id of all the college ethical comittee members was collected.

Attended by :

1. Dr Sandeep

Dr. Ramakant Nayak
Principal
M M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

2 Dr Chandrashekar
3 Dr Hallikerimath
4 Dr Kollooshelly
5. Dr Chetana
6 Dr Renuka Ammenagi

24/11/2021

IEC Meeting

01. In the meeting, the renewal process of the institutional ethical comittee was discussed. There were various inputs from the comittee members. Dr. Vijayalaxmi suggested that the renewal process for the new ethical comittee could take some time, so, hence and as the institute is going for NAAC accrediation, the chairman & the member secretary of the registered comittee to continue. Dr. Vikram who was the member secretary during the registration of institutional ethical comittee said that, 2 years of his 10 years is over. It was also said by Dr. Vikram that ethical comittee is not registered for clinical trials.

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Dr. Ramakant Nayak
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04. It was also discussed about the new ICMR guidelines. All the members of the committee were asked to go through the ICMR guidelines and also to find out the ~~and~~ CDESCO guidelines.

05. Ethical clearance to be given to all the short study submitted after doing necessary changes by Dr. Anukumar, Dr. Hanpriya & Dr. Ekta.

06. Dr. Yavgal was ~~asked to~~ submitted the synopsis of his study.

07. All the members also discussed about the plagarism software for the institute.

08. Dr. Anuradha suggested 'checker X' as a software for plagarism.

09. 'Turnitin' was suggested by Dr. Vijaylaxmi.

10. Dr. Hallikiremath suggested 'Viper'.

11. Dr. Renuka said that that software needs to be subscribed & renewed yearly.

Attended by :

1. Dr. Sandeep. 24/11/21
2. Dr. Chandrashekar. 24/11/21.
3. Dr. Vijaylaxmi 24/11/21
4. Dr. Renuka 24/11/21.
5. Dr. Hallikiremath
6. Dr. Anuradha 24/11/21.
7. Dr. Chetna 24/11/2021
8. Dr. Vikram. 24/11/21

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
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IEC Meeting 31/01/2022

Agenda

01. Ethical comittee meeting was arranged for the discussion of short study synopsis by the PG students. All studies were recommended for the issue of ethical clearance certificate with minor changes.

02. For the new batch of post graduate, joining in the month of February, the synopsis presentation will be tentatively held in the month of July / August.

03. It was also discussed that, there was no requirement of re-registration of the ethical comittee.

04. Dr. Vijaylaxmi suggested 2 plagarism software along with quatation. She also suggested to ask for the following:
→ Whether there were limited or unlimited uploads with the software.
→ Single or multiple user.
→ Limited or unlimited package.

05. Dr. Anuradha suggested a plagarism software 'ITHENTIC' costing around 30.000 - 60.000/-

06. Dr. Renuka suggested one plagarism software can be purchased for the entire Maratha Mandal group.

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

Attended by :

1. Dr Sandeep
2. Dr Chandrashekar
3. Dr. Vijaylaxmi
4. Dr. Renuka
5. Dr. Hallikeremath
6. Dr Anuradha
7. Dr. Chetna
8. Dr. Vikram

31/1/22

ON LEAVE

Dr. Ramakant Nayak
Principal
M M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

IEC Meeting 07/05/22

Agenda

1. An institutional IEC Meeting was held in the Dept Of Periodontology and the following was discussed:

a) The date for the institutional Synopsis presentation by the PG's of the academic year 2021-22 was discussed.
Dr. Hallikerimath suggested 16th/05/22 - 21/05/22 would be the ideal time. Also it was suggested by Dr Anuradha that 24/05/22 - 28/05/22 would also be a good time to present the PG synopsis before the institutional comitte.

b) Dr Chetana Bogar voluntarily agreed to write down the changes suggested during the PG synopsis presentation during the set dates

c) The above points are yet to finalized and discussed with principal.

Attended by :-

- Dr. Sandeep
- Dr. Chandrashekar
- Dr Vijaylaxmi
- Dr. Renuka
- Dr Hallikerimath
- Dr. Anuradha
- Dr. Chetana

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

IEC Meeting 1/6/2022

Agenda -

An IEC meeting was organised in the Dept of Periodontology to discuss on the following points:

1) The PG synopsis prescutation dates were finalised on the 4th of June 2022. The Synopsis presentation was decided to be held for only one day.

2) The hard copy of the submitted synopsis were circulated amongst the ethical committee members for suggested corrections

3) It was decided that the IEC Synopsis presentation will begin with Informal introduction of the members.

4) The timing for the synopsis presentation for each PG student was decided as 8mins & 2mins for suggested corrections.
The same was discussed with the Principal for approval

Attended by

Dr Sandesh 1/6/22
Dr Chandrashekar Y 1/6/22
Dr Amrendha. B 1/6/22
Dr Vijay Lakshmi K 1/6/22
Dr Chetna B. 1/6/22

Dr. Ramakant Nayak
Principal
M/s. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

SYNOPSIS PRESENTATION 4/6/2022

IEC Synopsis Presentation

Agenda:

As decided earlier in the IEC meeting dated 1/6/2022 the "PG Synopsis presentation" was held on 4/6/22 in the college audio torium.

- All the members of the IEC were present for the Synopsis presentation
- Total of 15 synopsis were presented infront of the IEC members which were scrutinized for correction.
- A total of 8 minutes were alloted for each presenter [PG student] to present the Synopsis & later on followed by questions
- The suggested corrections were noted as remarks in the "remarks Registrar" which was written by Dr Chetana Bagar.
- All the members present for the Synopsis presentation, signatures were duely taken.

[P.T.O]

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010

Maratha Mandal's NGH Institute of Dental Sciences & Research Centre, Belagavi.

DATE : 04/06/2022

INSTITUTIONAL ETHICAL COMMITTEE – P.G SYNOPSIS PRESENTATION 2022

NAME	DESIGNATION	SIGN
DR. ANJANA BAGEWADI	CHAIRMAN	4/6/22
DR. SANDEEP KATTI	MEMBER SECRETARY	4/6/22
DR. RENUKA AMMANAGI	MEMBER	On Leave.
DR. HALIKERIMATH	MEMBER	04/06/22
DR. VIJAYLAKSHMI K	MEMBER	4/6/22
DR.CHANDRASHEKAR. Y	MEMBER	4/6/22
DR. CHETANA. B	MEMBER	4/6/22
DR.ANURADHA. B	BIOSTATISTICIAN	4/6/22
ADV. UMESH YARADAL	LAWYER	4/6/22
MR. VIJAY MORE	SOCIAL WORKER	4/6/22
MR. Nikhil Kadrolkar	LAY MEN	4/6/22

Participants attended the Presentation :-

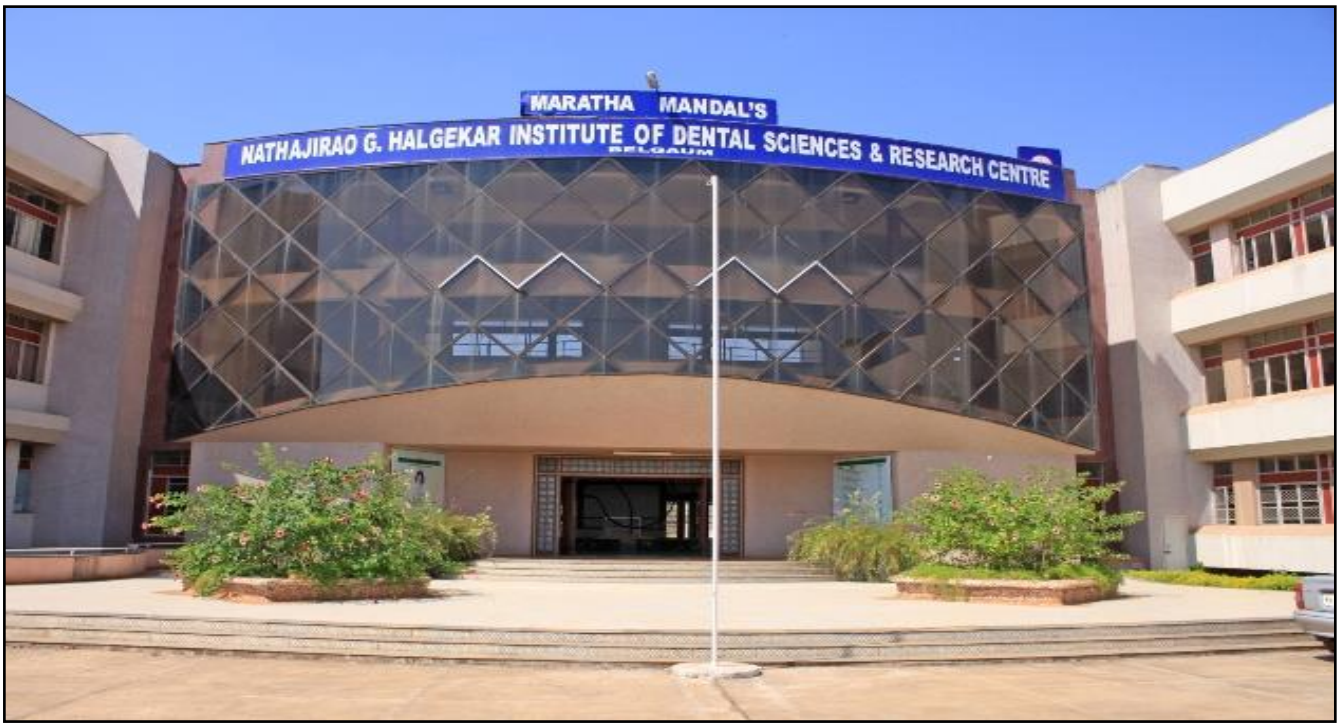
Sl no	name	signature.
1)	Dr Preethi Kurugal	
2)	Dr Madhu Puja	
3)	Dr. Smital Kulkarni	
4)	Dr. Reshma Faras	
5)	Dr. Pallavi G	
6	Dr Veerendra Uppin	
7	Dr. Ruthuluce Theresa	
8.	Dr. Deepa. K	
9	Dr Chetan Patil	
10	Dr Suprit Pawar	
11	Dr. Sachin Bhavanavar	
12)	Dr Hemant. T. V	

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences & Research Centre, Belagavi-590010.

13) Dr Vidyavani Charan-Patil
14) Dr Ramya Pai
15) Dr. Shruti Virupaxi
16) Dr. Pooja Mastanmaravar 4/6/22
17) Dr. Siddharth. Revankar.
18) Dr. Vikram Rao
19) Dr Vijay Patil
20) DR R B Hallikerimath
Dr Aarati Nayak
22) Dr. Preeti Hiraj 4/6/2022
22) Dr Ajay Kumar. Nayak

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

INSTITUTIONAL ETHICAL COMMITTEE POLICY DOCUMENT



Maratha Mandal's NGH Institute of Dental Sciences & Research Centre

RS. No. 47A/2, Bauxite Road,

Belgaum- 590010 Karnataka State.

Contact phone: 91-831- 2477682

Email: mmnhgids@gmail.com

Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
& Research Centre, Belagavi-590010.

Contents

I. Short Description of SOP

The following are called as "Standard Operating Procedures for the Institutional ethics committee (IEC) of Maratha Mandal's NGH Institute of Dental Sciences & Research Centre, Belgaum".

II. Adoption of SOP

Maratha Mandal's NGH Institute of Dental Sciences & Research Centre, Belgaum herein after referred to as "MMNGHIDS" has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at MMNGHIDS.

III. Objectives of SOP

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of Maratha Mandal's NGH Institute of Dental Sciences & Research Centre, Belgaum is to maintain effective functioning of the MMNGHIDS-IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

IV. Authority for constituting the MMNGHIDS IEC

The Principal in consultation with the Chairperson, MMNGHIDS will appoint the Committee Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter Members will confirm their acceptance to the Principal by providing all the required information for membership. The Committee Chairperson will furnish any information or report to the Principal, MMNGHIDS when required.

V. Role and Responsibilities of MMNGHIDS IEC

The MMNGHIDS-IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well being of the human participants.

The MMNGHIDS-IEC will ascertain whether all the cardinal principles of research ethics viz., *Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice* are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of *protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations*. It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.

The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency.

MMNGHIDS IEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

In case MMNGHIDS IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and immediately communicate such a decision to the Investigator as well as to the Licensing Authority.

In case of serious adverse event or death occurring to the clinical trial participant, the MMNGHIDS IEC shall forward it's report on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert committee constituted by the Licensing authority under Appendix XII (gazette notification 30th January 2013) with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death. In case of serious adverse event, other than death occurring to the clinical trial subject, the

MMNGHIDS IEC shall forward it's report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor of his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the licensing authority within twenty one calendar days of the occurrence of the serious adverse event.

VI. Composition of MMNGHIDS-IEC

MMNGHIDS-IEC will be a multidisciplinary and multisectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the different points of view.

There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

The MMNGHIDS-IEC will include

1. Chairperson –from outside the institute
2. One or more persons from basic medical science area (One pharmacologist compulsorily, one female member compulsory)
3. One or more clinicians
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary organization/agency
6. One philosopher/ ethicist/ theologian
7. One lay person (non-medical background) from the community
8. Member Secretary – from within the institute

A Sub-Board of the main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, an IEC may be separately constituted for the purpose, which will review proposals in the same manner as described above.

VII. Requirements for IEC Membership

1. All members will serve for a period of 2 years on renewable basis. New members will be Included in the IEC in such a way that there will be a mix of recently included

members and members with some years of experience.

2. During the term, Principal in consultation with the Chairperson can disqualify any member if, the contribution is not adequate and/or there is long period of non-availability.
3. A member can tender resignation of his office of membership from the IEC to the Principal through the Committee Chairperson after serving one month advance notice.
4. Principal can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities
6. Conflict of interest should be declared by members of the MMNGHIDS-IEC prior to review meeting.

VIII. Quorum requirements

Minimum of 50% of committee strength and not less than 6 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 6 members with following representations:

(a) Basic medical scientists (preferably one pharmacologist).
(b) Clinician
(c) Legal expert
(d) Social scientist/ representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(e) Lay person from the community.

IX. Conduct of MMNGHIDS IEC meetings

The Committee Chairperson will conduct all meetings of the MMNGHIDS IEC. In the absence of the Committee Chairperson an alternate Committee Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get it approved by the Committee Chairperson and circulate among the members.

XI. Independent consultants

The MMNGHIDS IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the MMNGHIDS IEC.

XII. Application procedures

1. All proposals should be submitted on any working day 2 weeks in advance of scheduled meeting in the prescribed application form, the details of which are given under "XII Documentation". The applicant may ask for copy of SOP from the IEC, if the same has not been circulated earlier or not available on the website.

2. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, MMNGHIDS IEC and Institutional Website (www.mmdc.edu.in).

3. Required number of copies of the proposal along with the application and documents in prescribed Copy format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson MMNGHIDS IEC, through member secretary. In his absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office.

4.Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5%. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc.

XIII. Documentation

All Research proposals (6 copies along with 1 CD/DVD) shall be submitted along with the information and documents as specified.

XIV. Review procedures

1.The meeting of the IEC will be held on periodic intervals, i.e. 1st Monday of Jan , March , May, July, Sep, Nov, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load. Provision will be made to call an emergency meeting on the advice of the Chairperson.

2.The proposals will be sent to the IEC at least 2 weeks in advance of scheduled meeting.

3.The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review (as described below).

4.Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of committee chairperson will be final.

5. Researchers will be invited for clarifications if need be. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.

6. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.

7. The decisions will be minuted and Committee Chairperson's approval taken in writing.

1.Exemption from review

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

•Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Exceptions:

1.When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

2.When interviews involve direct approach or access to private papers.

3.Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Committee Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1.Minor deviations from originally approved research during the period of approval.

2.Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

3.Research activities that involve only procedures listed in one or more of the following categories:

•Clinical studies of drugs and medical devices only when -

1.Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

2.Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4.Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

5.When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices / vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

i.When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should Copy be given to the relative/ legal guardian when available later;

ii.When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii.Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv.If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i.Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii.Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii.Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv.Protection must be ensured so that only minimal additional risk is imposed.

v.The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.

vi.All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii.Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

6. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

3. Full Review

All research presenting with *more than minimal risk*, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:
   i. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;
   ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week.
   iii. From neonates depending on the hemodynamic, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
   iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. Excreta and external secretions (including sweat);
4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
5. Placenta removed at delivery;
6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance
   i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
   ii. Weighing or testing sensory acuity;
   iii. Magnetic resonance imaging;
   iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,
   v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
d. Collection of data from voice, video, digital, or image recordings made for research purposes.
e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

XV. Aspects considered during review of research proposal

1. Scientific design and conduct of the study.
2. Approval by appropriate scientific review committees / Research committee, if any.
3. Examination of predictable risks/harms
4. Examination of potential benefits.
5. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
6. Management of research related injuries, adverse events.

7. Compensation provisions.
8. Justification for placebo in control arm, if any
9. Availability of products, benefits to subjects after the study is completed if applicable.
10. Patient information sheet, informed consent form in English and in local languages.
11. Protection of privacy and confidentiality.
12. Involvement of the community, wherever necessary
13. Plans for data analysis and reporting.
14. Adherence to all regulatory requirements and applicable guidelines.
15. Competence of investigators, research and supporting staff.
16. Facilities and infrastructure of study sites.
17. Criteria for withdrawal of patients, suspension or premature termination of a study in MMNGHIDS.

XVI. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decision will be made only in meetings where quorum is complete.
4. Only the members can make the decisions. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific *suggestions for modifications and reasons for modifications and reasons for rejection* will be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. *Modified proposals will be reviewed by an expedited review* through identified members.
8. Procedures for appeal by the researchers will be clearly defined.

XVII. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member

Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

2. The communication of the decision will include:
    a. Name and address of IEC.
    b. The date, place and time of decision.
    c. The name and designation of the applicant.
    d. Title of the research proposal reviewed.
    e. The clear identification of protocol no., version no., date, amendment no., date.
    f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
    g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.
    h. A clear statement of decision reached.
    i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the MMNGHIDS IEC
    j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
    k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
    l. Signature of the member secretary with date.

XVIII. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified, based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.

4. Final report should be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
    b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
    c. Any event or information that may affect the benefit/risk ratio of the study.
6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.

8.Premature termination of study shall be notified with reasons along with summary of the data obtained so far.

9.Change of investigators/sites must be informed to the office of IEC.

10.Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.

Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

XIX. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

(i)The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

(ii)Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.

(iii)In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be

submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions, if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;

(iv)Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee and chairman of the expert committee constituted by the licensing authority as defined under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct.

(i) Of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.

(ii) The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s)

(i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification

30th January 2013), the sponsor or his representative, whosoever had obtained permission from the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(ii) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

XX. Record keeping and archiving at the office of MMNGHIDS IEC

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the CD/DVD containing all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.
6. Following documents will be filed and archived with proper label on the top of file for easy identification
    a. Constitution and composition of MMNGHIDS IEC
    b. Curriculum Vitae (CV) of all members of MMNGHIDS IEC with records of training in Human ethics if any.
    c. Standard Operating Procedures of MMNGHIDS IEC.
    d. Annual reports
    e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
    f. The published guidelines for submission established by the EC.
    g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
    h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
    i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
    j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
    k. Record of all notification issued for premature termination of a study with a summary of the reasons;
    l. Final report of the approved projects, including microfilms, CDs and Video recordings.

XXI. Updating MMNGHIDS IEC members

1. All relevant new guidelines should be brought to the attention of the members.
2. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

XXII. Terms of reference

Terms of reference will be maintained in the office of MMNGHIDS IEC. This includes

A. Membership Requirements
B. Terms of Appointment with reference to the duration of the term,
C. The policy for removal, replacement, resignation procedure,
D. Frequency of meetings, and
E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined term and a defined percentage of members could be changed on regular basis. Preferably, IECwould appoint persons or persons

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons or persons with trained in bioethics conversant ethical guidelines and laws of the country. Substitute member may be nominated if been continuously missed by a member due to illness or other unforeseen circumstances.

XXIII. Administration and Management

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by MMNGHIDS) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

XXIV. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

Annexure 1A

Maratha Mandal's NGH Institute of Dental Sciences & Research Centre, Belgaum
Institutional Ethics committee

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Guide in case of thesis proposals.
6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants, precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational,
   experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, plan to withdraw or withhold standard therapies in the course of research, plan for statistical analysis of the study, ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any. Informed consent process, including patient information sheet and informed consent form in English and local language(s) are mandatory. Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances should be attached. Source of funding and financial requirements for the project has to be detailed.
8. For any drug / device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country / other countries, if available.
9. Usefulness of the project / trial
10. Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any
11. Explain all anticipated (Adverse events, injury, discomfort) of the project. 'risks' Efforts

taken to minimize the 'risks'. trials , proposed compensation and reimbursement of For incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable

12. Agreement to report all Serious Adverse Events (SAE) to MMNGHIDS -IEC.
13. Other financial issues including those related to insurance.
14. An account of storage and maintenance of all data collected during the trial.
15. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
16. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
17. Statement of conflicts of interest, if any.
18. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
19. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
20. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
21. Curriculum vitae of all the investigators with relevant publications in last five years.
22. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
23. Any other information relevant to the study.
24. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

Annexure 1B

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF MMNGHIDS, BELGAUM

Submit six (6) hard copies of the Research Proposal along with Covering letter, a CD/DVD of the proposal and a 'soft copy' along with the following information to the Member Secretary, Institution Ethics Committee at the IEC office, MMNGHIDS.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given,** before it can be considered for placing before the IEC. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all working days. Proposals received till 15th of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible on first Monday of Jan, March, May, July, September, and November. The

frequency will change depending upon the number of proposals and will be updated on the website: **www.mmdc.edu.in**.

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC), MMNGHIDS

(For attachment to each copy of the proposal)

Serial No of IEC Management Office:

Proposal Title:

	Name, Designation, Department & Qualifications	**Address Tel & Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI / Collaborators 1.				
2.				
3.				
4.				
5.				
6.				
	Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐
2. Private ☐
3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget:

Who will bear the cost of investigation / implants drugs / contrasts? ☐ Patients ☐ Project ☐ Exempted ☐ Other Agencies

1. **Type of Study:** Cross Sectional ☐ Case Control Cohort ☐ Clinical Trial ☐ Review ☐

Sponsor Information :													
1. Indian a) Government				Government		Central		State		Institutional			
b) Private													
2. International Government						Private		UN Agencies					

Tick appropriately

Sponsor Information :

1 Indian a) Government ☐ Central ☐ State ☐ Institutional ☐

b) Private ☐

2 International Government ☐ Private ☐ UN Agencies ☐

3 Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget:

Who will bear the cost of investigation / implants drugs / contrasts? ☐ Patients ☐ Project ☐ Exempted ☐ Other Agencies

Tick appropriately

Sponsor Information :

1 Indian a) Government ☐ Central ☐ State ☐ Institutional ☐

b) Private ☐

2 International Government ☐ Private ☐ UN Agencies ☐

3 Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget:

Who will bear the cost of investigation / implants drugs / contrasts? ☐ Patients ☐ Project ☐ Exempted ☐ Other Agencies

Tick appropriately

Sponsor Information :					
1.	Indian	a) Government	Central	State	Institutional
		b) Private			
2.	International	Government	Private	UN agencies	
3.	Industry	National	Multinational		
Contact Address of Sponsor:					
Total Budget :					
Who will bear the cost of investigation / implants drugs / contrasts?			1. Patient 2. Project 3. Exempted 4. Other Agencies		
1.Type of Study :					
Participating Centre :	Cross sectional	case control	cohort	Clinical Trial	Review
	Single center	Multi-centric	Others (Specify)		
2. Status of Review:	New		Revised		

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of:

Drug	Devices	V
Indian Systems of Medicine/ Alternate System of Medicine	Any other	a

ii. Is it approved and marketed In India UK & Europe USA Other countries, specify		
iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I Phase II Phase III Phase IV		

e). Are you aware if this study/similar study is being done elsewhere? **If Yes**, attach details	Yes	No

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects :

ii. Duration of study :

iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)

pregnant women	☐	children	☐	elderly	☐
fetus	☐	illiterate	☐	handicapped	☐
terminally ill	☐	seriously ill	☐		
	☐		☐	me ntal	

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

captives	☐	institutionalized	☐	employees	☐
students	☐	nurses/dependent	☐	armed	☐
any other	☐	staff	☐	forces	

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ ☐

ii.	Confidential handling of data by staff	Yes	No

7. Use of biological/ hazardous materials i. Use of fetal tissue or abortus		Yes	No
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
	If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No

vi. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad?	Yes	No

If Yes, justify with details of collaborators

a) Is the proposal being submitted for clearance from Ministry's Screening Committee (HMSC) for International collaboration?	Yes No Health	

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. If so, reasons… ☐

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	
Compensation for study related injury		eg. genetic basis for drug development	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐ Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort?	Yes	No

If Yes, Minimal or no risk ☐
More than minimum risk ☐
High risk ☐

Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ■ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

Conflict of interest for any other investigator(s) (if yes, please explain in brief	1_____ Yes No 2_____ Yes No
15. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Hindi version is a true translation of
16. **Participant Informed Consent Form** *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Hindi version is a true translation of
17. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no) (Please enclose a separate certificate to this effect).*
18. In case of clinical trials CTRI status	

Annexure 2A

Maratha Mandal's NGH Institute of Dental Sciences & Research Centre, Belgaum

Institutional Ethics Committee

Ongoing Approved Research Review Submission Form

1. Reference number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed to No:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 2B

Institute Ethics Committee, MMNGHIDS- Belgaum

Format for ***submission of revised/additional documents, protocols and information regarding already approved projects*** to be submitted by the Principal Investigator (PI) (Two copies of this form along with the revised documents to be submitted)

1. IEC Reference No:

2. Approval Date and Number:

3. Title:

4. Principal Investigator:

5. Purpose of this submission:

6. **New documents being submitted:** Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:
Date:

Signature PI/Collaborator_____
Name:

Annexure 2C

Six monthly progress of Project

Institute Ethics Committee Reference No. _____

Study title: _____

Name of the Principal Investigator _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from _____to _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____

Date:_____

Annexure3

PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in **English and Hindi, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points**:

1. Study Title

2. Aims and methods of the research study

3. Expected duration of participation

4. The benefits to be expected from the research to the participant or to others

5. Any risk or discomfort to the participant associated with the study

6. Maintenance of confidentiality of records

7. Provision of free treatment for research related injury

8. Compensation of subjects for disability or death resulting from such injury

9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise

10. Amount of blood sample (quantity in tea spoon full) to be taken

11. Costs and source of investigations, disposables, implants and drugs/ contrast media

12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page

13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided

14. Self-certification should be given that the translation to vernacular language is correct

Annexure 4

PARTICPANT INFORMED CONSENT FORM (PICF)

Protocol Study number: _____

Patient identification number for this study: _____

Title of the project: _____

_____

Name of Principal investigator: _____Tel. No (s). _____

The contents of the information sheet dated_____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from MMNGHIDS. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signatures / Left Thumb Impression) Place:

Name of Participant: _____Son/Daughter/spouse of: _____

Complete postal address:_____

This is to certify that the above consent has been obtained in my presence.

---------- Date:
Signatures of the Principal Investigator Place:

1) Witness – 1

Signature

Name:

Address:

2) Witness – 2

Signature

Name:

Address:

NB: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)*
Gender Age and/or date of birth Weight Height

2. Suspected Drug(s)

Generic name of the drug*
Indication(s) for which suspect drug was prescribed or tested Dosage form and strength
Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) Route of administration
Starting date and time of day Stopping date and time, or duration of treatment

3. Other Treatment(s)

Provide the same information for concomitant drugs (including nonprescription /OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*
Start date (and time) of onset of reaction Stop date (and time) or duration of reaction Dechallenge and rechallenge information Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.
Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

*6. Details about the Investigator**

Name
Address
Telephone number
Profession
(specialty)

Date of reporting the event to Licensing Authority:

Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

*Note: Information marked * must be provided."*

Member Secretary

SL No.	Name of the staff	Qualification	Organizational Title	Telephone Number	FAX No.	Email Id	Address
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Members:

Sl.NO	Name of the staff	Qualification	Organizational Title	Telephone Number	FAX No.	Email Id	Address
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1) Mrs. Vaishali Halgekar

Administrative assistant,

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Dr. Ramakant Nayak
Principal
M.M's. N.G. Halgekar Institute of Dental Sciences
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