

Chapter 6 Bibliography

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Appendix A Plagiarism Report

DrillBit
The Report is Generated by DrillBit Plagiarism Detection Software

Submission Information

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Appendix B Publications

1. Mashru R, Banerjee D*, Parmar D*, Popat V, Parmar M & Tanna D, Cervical cancer screening and its outcome – an observational study, IJBPAS, October, Special Issue, 2023, 12(10): 577-584

IJBPAS, October, Special Issue, 2023, 12(10): 577-584
ISSN: 2277-4998



**International Journal of Biology, Pharmacy
and Allied Sciences (IJBPAS)**
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CERVICAL CANCER SCREENING AND ITS OUTCOME - AN OBSERVATIONAL STUDY

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2. Mashru R, Parmar D*, Banerjee D* And Popat V, An observational study of correlation between menopause and early HPV infection, IJBPAS, October, Special Issue, 2023, 12(10): 585-595

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AN OBSERVATIONAL STUDY OF CORRELATION BETWEEN MENOPAUSE AND EARLY HPV INFECTION

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Appendix C Ethical Committee's Approval

 <p>Institutional Ethics Committee M.P. Shah Govt. Medical College & Guru Gobind Singh Hospital, Jamnagar (EC/NEW/INST/2021/1896, Ministry of Health & Family Welfare Department of Research)</p>																																																																																
<p>APPROVAL LETTER</p> <p>Date: 13/09/2022</p> <p>To, MS RIYA MASHRU Laboratory Technician, Multi-disciplinary Research Unit, M P Shah Govt. Medical College, Jamnagar-361008.</p> <p>Ref: Project No. 157/04/2022 titled "MOLECULAR MARKERS OF CERVICAL CANCER AND ITS CLINICAL APPLICATIONS"</p> <p>Sub: Ethics committee approval for the conduct of the referred study at "M P Shah Govt Medical College, Jamnagar", and approval of the study related documents.</p> <p>Dear MS RIYA MASHRU,</p> <p>Institutional ethics committee reviewed and discussed your application for Project proposal dated 3/09/2022 to conduct the study entitled "MOLECULAR MARKERS OF CERVICAL CANCER AND ITS CLINICAL APPLICATIONS" during the Institutional ethics committee meeting held on 13/09/2022.</p> <p>Following documents were reviewed and approved:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>No</th> <th>Item</th> <th>No</th> <th>Item</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Signature of PI and CO-PI on each page in original</td> <td>9</td> <td>Protocol <ul style="list-style-type: none"> * Introduction * Aims and objectives * Material and methods </td> </tr> <tr> <td>2</td> <td>Application</td> <td>10</td> <td>Description of study with study plan</td> </tr> <tr> <td>3</td> <td>Recent photograph pasted on application only of PI</td> <td>11</td> <td>Statistical analysis</td> </tr> <tr> <td>4</td> <td>CV of PI & CO-PI</td> <td>12</td> <td>Reference Article of one relevant article</td> </tr> <tr> <td>5</td> <td>ICMR Form-Principal Investigator form</td> <td>13</td> <td>UNDERTAKING form of M. P. Shah Medical College and GGG Hospital, Jamnagar</td> </tr> <tr> <td>6</td> <td>CRF: Case Record Form</td> <td>14</td> <td>Department Approval</td> </tr> <tr> <td>7</td> <td>Patient information sheet Hindi-Gujarati-English</td> <td></td> <td></td> </tr> <tr> <td>8</td> <td>Consent Form Hindi-Gujarati-English</td> <td></td> <td></td> </tr> </tbody> </table> <p>At the Institutional ethics committee meeting held on 13/09/2022 these documents were examined and discussed. After due consideration, the committee has decided to approve the submitted documents and the proposed methods for patient accrual.</p> <p>The following are members of Institutional Ethics Committee. The meeting was conducted at Meeting room, Department of Pharmacology, 5th floor, New College Building, M P Shah Govt Medical College, Jamnagar-361008</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Sr. No</th> <th>Name</th> <th>Post in the committee</th> <th>Affiliation to institute</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Dr. Nayabben G. Patel</td> <td>Chairperson</td> <td>No</td> </tr> <tr> <td>2</td> <td>Dr. Dinesh. M. Parmar</td> <td>Member Secretary</td> <td>Yes</td> </tr> <tr> <td>3</td> <td>Dr. Jyendra H. Vaghani</td> <td>Basic Medical Sciences</td> <td>Yes</td> </tr> <tr> <td>4</td> <td>Dr. Maulik Shah</td> <td>Clinician</td> <td>Yes</td> </tr> <tr> <td>5</td> <td>Dr. Hitesh Shingra</td> <td>Member</td> <td>Yes</td> </tr> <tr> <td>6</td> <td>Dr. Shilpa P. Jadev</td> <td>Member</td> <td>Yes</td> </tr> <tr> <td>7</td> <td>Dr. Mukeshkumar Nariyu</td> <td>Member</td> <td>No</td> </tr> <tr> <td>8</td> <td>Mr. Kishor L. Bhatt</td> <td>Legal Expert</td> <td>No</td> </tr> <tr> <td>9</td> <td>Mr. Bhavesh Harilal Bhatt</td> <td>Social Scientist</td> <td>No</td> </tr> <tr> <td>10</td> <td>Mr. Girish Gunatra</td> <td>Lay Person</td> <td>No</td> </tr> </tbody> </table> <p>It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee. The project is approved in its present form. For</p>	No	Item	No	Item	1	Signature of PI and CO-PI on each page in original	9	Protocol <ul style="list-style-type: none"> * Introduction * Aims and objectives * Material and methods 	2	Application	10	Description of study with study plan	3	Recent photograph pasted on application only of PI	11	Statistical analysis	4	CV of PI & CO-PI	12	Reference Article of one relevant article	5	ICMR Form-Principal Investigator form	13	UNDERTAKING form of M. P. Shah Medical College and GGG Hospital, Jamnagar	6	CRF: Case Record Form	14	Department Approval	7	Patient information sheet Hindi-Gujarati-English			8	Consent Form Hindi-Gujarati-English			Sr. No	Name	Post in the committee	Affiliation to institute	1	Dr. Nayabben G. Patel	Chairperson	No	2	Dr. Dinesh. M. Parmar	Member Secretary	Yes	3	Dr. Jyendra H. Vaghani	Basic Medical Sciences	Yes	4	Dr. Maulik Shah	Clinician	Yes	5	Dr. Hitesh Shingra	Member	Yes	6	Dr. Shilpa P. Jadev	Member	Yes	7	Dr. Mukeshkumar Nariyu	Member	No	8	Mr. Kishor L. Bhatt	Legal Expert	No	9	Mr. Bhavesh Harilal Bhatt	Social Scientist	No	10	Mr. Girish Gunatra	Lay Person	No
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Institutional Ethics Committee

M.P. Shah Govt. Medical College & Guru Gobindsingh Hospital, Jamnagar
(EC/NEW/INST/2021/1896, Ministry of Health & Family Welfare Department of Health Research)



renewal/extension of the study you are requested to submit a written application along with the submission of annual status report.

Conditions of approval:

1. The Project hereby granted an approval valid for two years.
2. The committee has approved the ethical aspects of the proposed work. However, all other concerns related to the work (e.g., scientific, procedural, legal, financial, regulatory etc.) remain the sole responsibility of the Principal Investigator and /or the Co-Principal Investigator.
3. This committee is working in accordance to the ICH-GCP, New Drugs and Clinical Trial Rules-2019, ICMR guidelines and other applicable regulations.
4. Institutional ethics committee should be informed of the yearly progress in the form of annual report of the study.
5. Institutional ethics committee approved recruitment of 150 number of patients on this study.
6. It is essential that all the patients included in study should have an indoor number. They could, if necessary be registered as Free OPD patients.
7. At the end of the study all the documents are to be preserved and maintained at your respective department for at least not less than five years.
8. As required by ICH-GCP, ICMR guidelines for good clinical practice and "New Drugs and Clinical Trials Rules-2019", study monitor designated by Institutional ethics committee will periodically visit the study site with prior intimation to you to review the projects.
9. In case of PI's retirement/leaving the institute, study responsibility should be transferred to the Co-investigator after obtaining clearance from Institutional ethics committee.
10. In case of any new information or an "Serious Adverse Event" (SAE), which could affect the study, it must be informed to Institutional ethics committee. The PI should inform within 24 hours of occurrence of Serious Adverse Event with appropriate report format.
11. In the event(s) of any protocol amendments, Institutional ethics committee must be informed and only after approval, the amendment(s) then can be implemented. Amendments should be highlighted in clear terms as follows:
 - a. The exact amendment/alteration should be specified and indicated where the amendment occurred in the original proposal (Page no, Clause no etc.)
 - b. Alteration in the budgetary status should be clearly indicated and the revised consent form should be submitted.
 - c. If the amendments require a change in the consent form, the copy of revised consent form should be submitted to Institutional ethics committee for approval.
 - d. If there are any amendments in the study design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval to the Institutional ethics committee.
 - e. Approval of amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the Institutional ethics committee.
 - f. Any deviation/violation/waiver in the protocol must be informed to the Institutional ethics committee.
 - g. Kindly contact ethical committee through mail mpsgmcie.protocolsubmissions@gmail.com

All the above instructions/procedure should be followed strictly without exception. Please feel free to contact the undersigned if you have any queries concerning the study.

Thanking you,
Yours sincerely,

Dr. D. M. Parmar
Member Secretary
Institutional Ethics Committee
M.P. Shah Govt. Medical College
Shree M. P. Shah Govt. Hospital, Jamnagar
and G. G. Govt. Hospital, Jamnagar
Ref No: EC/NEW/INST/GUJ/2013

Appendix D Informed Consent Form

INFORMED CONSENT FORM

MOLECULAR MARKERS OF CERVICAL CANCER AND ITS CLINICAL APPLICATIONS

Mrs/Miss _____

Give consent to participate in the study. I have read and understood the information sheet for the above study. I am allowed to ask question during this study. I have been explained about its objective research status, study design, time, benefit, risks and inconveniences. I have been informed about my right to withdraw from the study without giving any reason at any point of time with full right to available regular treatment. NO RENUMERATION OR COMPENSATION WILL BE GIVEN FOR THE SAME.

After understanding all things I sign here voluntarily with full consciousness and without any pressure for participating in the study.

Name and sign of participant:

Date:

Name and sign of witness:

Name and sign of investigator:

Ms. Riya R. Mashru
Laboratory Technician,
Multi-Disciplinary Research Unit
Shri M.P. Shah Medical College, Jamnagar
Mo. 9429941141

Dr. Dinesh Parmar
(Member Secretary - Ethics Committee)
Shri M.P. Shah Medical College, Jamnagar
Mo. No. 9898345543

Appendix E Case Record Form

CASE RECORD FORM MOLECULAR MARKERS OF CERVICAL CANCER AND ITS CLINICAL APPLICATIONS	
1. Personal details	
Name:	Age:
Mobile no.:	Marital status:
Age of marriage:	Occupation:
Urban/Rural:	Community
2. Clinical history	
Complaint and duration:	
Menstrual history:	
Obstetrics history:	
Contraception history:	
Medication history:	
Past history:	
Personal history:	
Family history:	
3. Date & time of sample collection:	
4. Types of smear: Cervical / Endocervical / Vaginal / others	