APPENDIX 1:
INFORMED CONSENT FORM
PARTICIPANT INFORMATION SHEET
You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

STUDY INFORMATION

<table>
<thead>
<tr>
<th>Protocol Title: Development and Validation of Immunoassays and an Algorithm for Efficient Diagnosis of Ulcerative Colitis</th>
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<tr>
<td>Principal Investigator: Dr. Chander Puri, Pro-Vice Chancellor (Research), MGM Institute of Health Sciences, Navi-Mumbai.</td>
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PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study of Inflammatory Bowel Disease (IBD). We hope to discover a novel biomarker for the early diagnosis and prognosis of IBD. You are selected as a possible subject in this study because you,

a) Have already been diagnosed with the disease. Hence your specimen will be used as a positive test sample.

b) Are a healthy individual. Hence your specimen will be used as a control sample.

This study will recruit 100 healthy and 100 IBD positive subjects from Mumbai over a period of 3 years.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be asked to donate 5ml of your blood for the experimental purpose. Your participation in the study will last for 3 years. You will need to visit the doctor’s office once in the course of the study.

Additional Study Procedures:
A copy of the results of the tests performed during the diagnosis of IBD will be maintained for the records.

Additional Blood Tests
Specimen Requirement- 5 mL whole blood.
**WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY**

The study is being conducted because a single serological biomarker is not yet proven to be a standard diagnostic test in subjects with IBD. We hope that your participation will help us to determine whether a new biomarker can be discovered which can aid or is superior to existing modes of diagnosis of IBD.

Although diagnostic investigation may be part of standard medical care, in this study the tests are being performed for the purposes of the research.

**POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES**

- One-time withdrawal of blood via venipuncture in vacutainers may discomfort and inconvenience the subject.

**POTENTIAL BENEFITS**

If you participate in this study you may reasonably expect to benefit from the study in the following way:

The blood test carried out as an experimental procedure will second or enhance the diagnosis of the disease.

Your participation may contribute to the medical knowledge about the discovery of novel non-invasive techniques for the diagnosis of IBD.

**CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS**

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator will have access to the confidential information being collected.

However, the Sponsoring company, Regulatory Agencies, Institution Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you or your legal representative is authorizing such access to your study and medical records.

Data collected and entered into the Case study form is the property of MGMIMS and Yashraj Biotech Ltd. In the event of any publication regarding this study, your identity will remain confidential.
**RESEARCH RELATED INJURY AND COMPENSATION**

The Hospital does not make any provisions to compensate study subjects for research related injury. However, compensation may be considered by the investigator on a case-by-case basis for unexpected injuries due to non-negligent causes.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

**WHOM TO CONTACT IF YOU HAVE QUESTIONS**

If you have questions about this research study and your rights or in the case of any injuries during the course of this study, you may contact the Investigator,

Mr. Allan Rodrigues
‘Shaila Smruti’,
Vishramwadi, Holi,
Vasai West,
Ph. 9823988360

If you have questions about the study or your rights as a participant, you can contact the MGM Institute of Health Sciences, the Centralized Institutional Review Board, which is the committee that reviewed and approved this study, MGMIHS, Sector 22, Kamote, Navi Mumbai, during office hours (9:30 am to 4:30pm).

**CONSENT BY RESEARCH SUBJECT**

<table>
<thead>
<tr>
<th>Subject’s Particulars</th>
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<tbody>
<tr>
<td>Name:</td>
<td>Patient ID No.:</td>
</tr>
<tr>
<td>Address:</td>
<td>Contact No.</td>
</tr>
<tr>
<td>Gender: Female/Male</td>
<td>Date of birth</td>
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<td>dd/mm/yyyy</td>
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**Part I – to be filled by participant**
I, _____________________________________  
(Name of patient) 
agree / do not agree to participate in the research study as described and on the terms set out in the Patient Information Sheet. The nature of my participation in the proposed research study has been explained to me in 

English/ Hindi/ Marathi by Mr. Allan Rodrigues  
(Language / Dialect) (Name of the Investigator) 

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information. 

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected. 

I also give permission for information in my medical records to be used for research. In any event of publication, I understand that this information will not bear my name or other identifiers and that due care will be taken to preserve the confidentiality of this information. 

____________________________________                        ________________________  
[Signature/Thumbprint (Right / Left) of participant] (Date of signing) 

Part II– Investigator’s Statement  
I, the undersigned, certify to the best of my knowledge that the patient signing this informed consent form had the study fully explained to him/ her and clearly understands the nature, risks and benefits of his/her participation in the study. 

____________________________________   ________________________   ______________  
Name of Investigator Signature Date