KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

FORM TO BE FILLED BY THE PRINCIPAL INVESTIGATOR (PI) FOR SUBMISSION TO INSTITUTIONAL ETHICS COMMITTEE (IEC)

(for attachment to each copy of the proposal)

* **Ref.** Code No. of IEC:	

* to be filled by Office of IEC

Proposal Title:

_____

_____

_____

_____

_____

	Name, Designation & Qualifications	Departmental Tel Nos. email ID	Signature
PI			
Co-PI/Collaborators 1.			
2.			
3.			

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at KGMU. The investigators should sign their CV.

_____

Sponsor Information

1. Indian	a) Government☐ b) Private ☐	Central☐	State ☐	Institutional ☐
2. International	a) Government☐	Private☐		UN Agencies☐
3. Industry	a) National☐	Multinational☐		
4. Contact address of sponsor				
5. Budget				

1. Type of study	Epidemiological☐ Clinical ☐	Basic Sciences ☐ Single Centre ☐	Behavioral ☐ Multicentric☐
2. Status of review	New☐ Revised☐		
3. Clinical Trials Drug/Vacancies/Device/Herbal Remedies i. Does the study involve use of Drugs ☐ Devices☐ Vaccines☐ Indian systems of Medicines / or Alternate systems of Medicine ☐Any other☐ None☐			
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? **if yes**, whether DCGI's/Any other Regulatory Authority's permission obtained? **If yes,** copy of permission attached.			Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
iv. Is it an Investigational New Drug? **If yes,** a. Investigator's Brochure enclosed b. Preclinical studies data available (if yes, provide summary) c. Clinical studies data available (if yes, provide summary) d. Clinical study is Phase I☐Phase II ☐Phase III ☐Phase IV ☐ N/A ☐ e. DCGI's permission obtained **If yes,** copy of letter enclosed			Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐

4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and 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 a) Study: b) Subject participation

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 ☐	Mentally Challenged ☐
Economically & socially backward ☐	Any other ☐	

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

Captives ☐	Institutionalized ☐	Employees ☐
Students ☐	Nurses / Dependent ☐	Armed Forces ☐
Any other ☐	Staff ☐	

6. Privacy and confidentiality

i. Study Involves
- Direct Identifiers ☐
- Indirect Identifiers/Coded ☐
- Completely Anonymised / Delinked ☐

ii. Confidential handling of data by staff Yes ☐ No☐

7. Use of biological / hazardous materials

i. Use of fetal tissue of aborts. If yes provide details Yes ☐ No☐

ii. Use of organs or body fluids. If yes provide details Yes ☐ No☐

iii. Use of recombinant / gene therapy products Yes ☐ No☐

if yes, has Institutional Biosafety Committee 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 Institutional Biosafety Committee approval for Radioactive Isotopes been obtained? Yes ☐ No☐

vii. Use of Infectious / biohazardous specimens Yes ☐ No☐

viii. Proposal disposal of material Yes ☐ No☐

ix. Will any sample collected from the patients be sent abroad? Yes ☐ No☐
If yes, give details and address of collaborators

a. 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

b. Has necessary clearance been obtained Yes ☐ No☐

8. **Consent** *** Written** ☐ **Oral**☐ **Audio-Visual** ☐

i. Patient Information Sheet attached: (Tick the included elements) Yes ☐ No☐

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 material biological	☐
Compensation for participation ☐	☐Benefits if any on future commercialization e.g. Genetic basis for drug development	
Compensation for study related injury ☐		

Translation of information sheet in local language☐

ii. If healthy volunteers will be included, information sheet for them attached Yes ☐ No☐

iii. Consent form in English	☐	Hindi	☐
iv. Who will obtain consent (PI/Co-PI)	☐	Nurse / Cousellor	☐
Research Staff	☐	Any other	☐

* If written consent is not obtained, giver reasons:

9. **Will any advertising be done for recruitment of Subjects?**
(Posters, flyers, brochure, websites – if so 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 benefit	a) to the subject?	Yes ☐ Direct☐	No☐ Indirect☐
	b) to the society?	Yes ☐	No☐

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? Yes ☐ No☐

if yes, reporting will be done to

Sponsor ☐ IEC ☐ DSMB ☐

iii. Is there a plan for interim analysis of data? Yes ☐ No☐

12. Is there compensation for injury? Yes ☐ No☐

If yes, by

Sponsor	☐	Investigator	☐
Insurance Company	☐	Any other	☐

13. Do you have conflict of interest? Yes ☐ No☐

(Financial / Non financial) If yes**,** specify
Check list for attached documents:
Project proposal – 05 copies
Curriculum Vitae of non KGMU Investigators
Brief description of proposal/summary
Copy of the Protocol / Project and questionnaire (if any)
Investigator's Brochure
Copy of Patient information sheet & Consent form in local language
Copy of Advertisements/Information brochures
DCGI/DBT/BARC clearance if obtained
Copy of Insurance Policy
Copy of Clinical trial agreement
Copy of IEC proforma
Copy of PI undertaking
Copy of Case Report Form

Signature of PI with stamp

Date

Signature of HOD with stamp

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1 **NAME OF THE PROJECT**

2 **NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR**

3 **OTHER MEMBERS OF THE RESEARCH TEAM**

4 **NAME AND ADDRESS OF ANY OTHER MEDICAL INSTITUTE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**

5 **NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI.**

- I confirm that I will initiate the study only after obtaining all regulatory clearances.
- I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
- I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them
- I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
- I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives.
- I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
- I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
- I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
- I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Signature of Principal Investigator **Date**

ANNEXURE: 3-RV-1/2019 (SOP-IEC-KGMU)

ONE PAGE CV FOR NON-KGMU INVESTIGATORS

Last Name	First Name	Middle Initial
Date of Birth (dd/mm/yy):		**Sex**
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordination		
Professional Mailing Address (Include institution name)	**Study Sited Address (Include institution name)**	
Telephone (office):	**Mobile Number:**	
Telephone (Residence):	**Email:**	
Academic Qualifications (Most current qualification first)		
Degree / Certificate	**Year**	**Institution, Country**
Current and Previous Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year	**Title**	**Institution / Company, Country**
Brief Summary of Relevant Clinical Research Experience:		
Signature: **(Signature Required)**	**Date:**	

ANNEXURE: 4-RV-1/2019 (SOP-IEC-KGMU)

FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR BY THE MEMBER SECRETARY, INSTITUTIONAL ETHICS COMMITTEE

Dated: _____

To,
Prof./Dr. _____

_____

Dear Prof./Dr. _____

The Institutional Ethics Committee in its meeting held on _____, has reviewed and discussed your application. submitted vide letter no. _____ dated _____, to conduct the clinical trial/project entitled "_____
_____"
sponsored by _____ Ref. Code no._____

The following documents were reviewed:

a. Trial protocol (including protocol amendments/project) dated _____ Version no (s) _____
b. Investigator's Brochure, dated _____, Version no. _____
c. Patient information Sheet and Information Consent Form (including updates if any) in Hindi, English and/or vernacular language.
d. Proposed methods for patient accrual including advertisement (s) proposed to be used for the purpose.
e. Current CV of investigator from outside KGMU.
f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking.
i. Ethics Committee Proforma.
j. DCGI approval letter/ submission letter.
k. Case Report Form
l. Any other/additional documents

Comments of Committee:

Decision of Committee:

Member Secretary
Institutional Ethics Committee

ANNEXURE: 5-RV-1/2019 (SOP-IEC-KGMU)

INTIMATION OF START OF STUDY

1. Project/Trial Reference Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start

(Signature of Principal Investigator)

Date:

ANNEXURE: 6-RV-1/2019 (SOP-IEC-KGMU)

PROGRESS REPORT (ANNUAL)/FINAL REPORT

1. Project/Trial Reference Code Number
2. Title of the Research Project/drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start
8. Objectives of the study
9. Progress report as per objectives (attach separate sheet)
10. Serious Adverse Events if any with details (in summary form)
11. Protocol deviation if any with reasons/justifications
12. Report/publications/conference presentation
13. Awards/recognition

Date: **(Signature of Principal Investigator)**

(Signature of Head of the Department)

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

GUIDELINES FOR PATIENT INFORMATION SHEET

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. Study Title

Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

2. Invitation Paragraph

You should explain that the patient is being asked to take part in a research/trial study. The following is an example:

"You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The background and aim of the study should be given here

4. Why have I been chosen?

You should explain how and why the patient was chosen and how many other patients will be studied.

5. Do I have to take part?

You should explain that taking part in the research/trial is entirely voluntary. You could use the following paragraph:

"It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. What will happen to me if I take part?

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 9.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use – the following simple definitions may help.

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual – i.e. by

chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you not your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.
Placebo: A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research/trial the patient should be told what other treatment options are available.

10. What are the side effects of taking part?

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

“It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

We hope that (all the treatments will help you. However, this can not be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better.

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should

explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

"If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to inpatients what will happen to the results of the research trial. You might add that they will not be identified in any report publication.

18. Who is organizing and funding the research/trial?

The answer should include the organization or company sponsoring or funding the research/trial

(e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

19. Who has reviewed the study?

You may wish to mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

20. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **(Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers)**

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.

21.Legally authorized representative

Legally authorized representative (LAR), under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the ethics committee.

Date **Signature of PI**

किंगजार्जचिकित्साविष्वविद्यालय, उ0प्र0, लखनऊ

सूचितसहमतिपत्र

अध्ययनका शीर्षक----------
अध्ययनकानम्बर----------
अन्वेषककासम्पर्कविवरण----------

सहभागीकापूरानाम----------
जन्मतिथि/उम्र----------
पता ----------

भाग–1

अध्ययन काउद्देश्यः–

अध्ययन की प्रक्रियाएंः–

अध्ययन सेजोखिमः–

अध्ययन सेलाभः–

सम्भावितजटिलताएंः–

क्षतिपूर्तिः–

गोपनियताः–

प्रतिभागी के अधिकारः–

अध्ययन मेभागीदारी के विकल्पः–

भाग–2

1. मेरीपुष्टिहैकिमैनेउपरोक्तपरीक्षणहेतुजानकारीपत्र दिनांक----------कोपढ़ व समझलियाहै, तथामुझे प्रश्नपूछने के अवसरप्रदानकियेगये।

   अथवा

   मुझे अध्ययन अन्वेषक ने विस्तारसेसबतथ्योंको समझा दियाहैतथामुझे प्रश्नपूछनेकाअवसरप्रदानकिया।

2. मैंने समझलियाहैकिइस अध्ययन मेंमेरीप्रतिभागितास्वैच्छिकहै, तथा यह किमैबिनाकोईकारणबताए किसीभी समय अपनीचिकित्सीय देखभाल या कानूनीअधिकारोंपरप्रभावपडेबिनाहटजाने के लिए स्वतंत्र हूं।

3. मैंने समझलियाहैकिचिकित्सीय प्रायोजक की ओरसेकामकरनेवालेअन्य, नैतिकतासमितितथाविनियामकप्राधिकारियोंकाचालू अध्ययन तथाइससेसम्बन्धितहोसकनेवालेकिसीअनुसंधानसेसम्बन्धितमेरेस्वास्र्यें अभिलेखोंको देखने के लिए मेरीअनुमतिकीआवश्यकता नही होगी, भलेहीमैंइसपरीक्षणसेहटहीक्यों न जाऊं।तथापिमैंने समझलियाहैकितृतीय पक्ष कोदीगई या प्रकाषित की गईकिसीजानकारीमेंमेरीपहचानकोउजागर नही कियाजाएगा।

4. इस अध्ययन मेंप्राप्तकिन्हीआकडों या परीक्षणों के प्रयोगपरपाबंदी न लगाने के लियेमैसहमतहूंबशर्तेकि ऐसेप्रयोगमात्र वैज्ञानिकप्रयोजन/नों के लियेहीहों।

5. उपर्युक्त अध्ययन मेंभागलेने के लियेमैंसहमतहूं।

सहभागी के हस्ताक्षर या अगूंठेकानिशान/कानूनी रूपसेस्वीकार्यप्रतिनिधि----------

हस्ताक्षरकरनेवालेकानाम---------- दिनांक----------

सहभागीसेसम्बन्ध ----------

मैं, अधोहस्ताक्षरी ने सहभागी/कानूनी रूपसेस्वीकार्यप्रतिनिधिकोसरल, उनको समझमेआनेवालीभाषामे, अध्ययनमेंपालनहोनेवालीप्रक्रियायेंऔरजोखिम एवंलाभोंसेअवगतकरादियाहै।

अध्ययन अन्वेषक के हस्ताक्षर---------- दिनांक----------

अध्ययन अन्वेषककानाम---------- दिनांक----------

गवाह के हस्ताक्षर ---------- दिनांक----------

गवाह के हस्ताक्षर---------- दिनांक----------

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

INFORMED CONSENT FORM

Study Title_____

Study Number_____

Contact details of Principal-Investigator: _____

Subject's Full Name _____

Date of Birth/Age_____

Address _____

PART 1

1. Purpose of the study:
2. Study procedures:
3. Risk from the study:
4. Benefits from the study:
5. Complications:
6. Compensation:
7. Confidentiality:
8. Rights of the participants:
9. Alternatives to participation in the study:

PART 2

Consent

1 I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.

OR

I have been explained the nature of the study by the Investigator and had the opportunity to ask questions

2 I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3 I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4 I agree not to restrict the use of any data or results that arise from this study provided such a use is

only for scientific purpose(s)

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Signatory's Name:_____

Date:_____

Relationship with subject:_____

Investigator's statement:-

I, the undersigned have explained to the parent/guardian in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signature of the Investigator: ***Date:***

Name of the Investigator:

Signature of the Witness: ***Date:***

Name of the Witness: