**Format recommended for submitting the Informed Consent Document for an interventional research study proposal to the Institutional Ethics Committee of IPGME&R, Kolkata**

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## Part I
## Information to be provided to participants / legally acceptable representative of participants in case they are minor or likely to be deemed incompetent to consent on their own.

1. Statement that the study involves research and explanation of the purpose of the research.
2. Trial treatment schedules and the probability for random assignment to each treatment (for randomized trials).
3. Expected duration of the subject's participation.
4. Description of the procedures to be followed, including all invasive procedures and identification of procedures that are clearly experimental.
5. Disclosure of specific appropriate alternative procedures or therapies, if any, available to the subject.
6. Subject's responsibilities on participation in the trial.
7. Description of any reasonably foreseeable risks or discomforts to the subject.
8. Description of any benefits to the subject (or others) reasonably expected from research. If no benefit is expected subject is to be made aware of this.
9. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's records.
10. A description of any compensation or reimbursement for travel, time spent or other costs to the subject and the manner of disbursement of such compensation.
11. Treatment and compensation available to the subject in the event of a trial-related injury and the manner in which such treatment can be availed and such compensation will be disbursed.
12. An explanation about whom to contact for trial related queries, the rights of subjects, and in the event of any injury. This is generally to be the PI or another staff member closely associated with the study. A separate contact may be named for questions concerning the subject's rights;
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate or withdrawal will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
14. Any other pertinent information.

15. Additional information which may need to be provided
    (a) Additional costs to the subject that may result from participation in the study.
    (b) Statement of foreseeable circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.
    (c) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.
    (d) Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue to participate.
    (e) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
    (f) Approximate number of subjects to be enrolled in the study, including the number to be enrolled at the site.

## Part 2
## Informed Consent Form

Please see following page.

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## Informed consent form

**Title of study**
**Informed Consent Document Version No. and Date**

**Subject's: Name: _____ ID No. _____ Age _____ Sex _____**

Please tick if you agree

1. I confirm that I have read and understood the information sheet for the above study dated _____ and have 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 having to give a reason, and without my rights and privileges being affected. ❒
3. I understand that the sponsor of the clinical trial, 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, I agree to this access. However, I understand that my identity will not be revealed and confidentiality of information will be maintained. ❒
4. I agree not to restrict the use of any data or results that arise from this study for academic purpose. ❒
5. I agree to voluntarily take part in the above study. ❒

**Signature / Thumb impression of the subject or a legally acceptable representative (LAR)**: _____ Date: _____

**Signatory's name**: _____

**Study investigator's signature**: _____ Date: _____

**Study investigator's name**: _____

**Mandatory where subject or LAR has provided thumb impression:**

Signature of the witness: _____ Date: _____

Name & Address of the witness: _____

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Relation to the subject, if any: _____