Format recommended for submitting the Informed Consent Document for an observational 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.

- Title of the study
- What is the purpose of this study?
- Who are the participants and how many participants are likely to be there?
- Why have I been chosen?
- Do I necessarily have to take part?
- What happens during the study / What do I have to do? (the procedures, such as answering a questionnaire, which the participant will have to undergo)
- What are the possible benefits of taking part?
- Are there any possible disadvantages of taking part?
- Are there are any monetary costs involved in participation?
- Will my taking part in this study be kept confidential?
- What will happen to the results of the study?
- Any other information relevant to participation in the study such as sponsorship.
- Contact for further information (the name designation and contact numbers of Principal Investigator and / or Co-Investigators)
- A statement thanking the participant for going through the informed consent document.

Part 2
Informed Consent Form

Please see following page.

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 my data would be kept confidential but individuals authorized by the Principal Investigator, the ethics committee of the institute where the study will be conducted and government regulatory authority will have access to my records both in respect of the current study and 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: _____