

## **Participant/Patient/Volunteer Information Sheet (Updated 27.06.2020)**

### **Instructions**

This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form (Form 3A or 3B) for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Hindi/Other local language(s) which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide and Address and telephone number (IEC office, Room no 2103, Academic section, 2nd floor, Medical College Building, AIIMS, Raipur, Phone : 0771-2577231) of the Institute Ethics Committee for any complaint or clarifications should be clearly mentioned in the end of the PIS.

The patient information sheet must be duly signed by the investigator