**Annexure-5**

# Information for research participants

*This form contains all the information that a person could reasonably need to know in order to decide whether or not to participate in a research project. The written information is a complement to the information that is to be given orally. There should always be an opportunity to ask questions. The consent form may be separate, but a copy of it, as well as a copy of the information form and any annexes, is to be kept by the person participating in the research.*

*It is important that the information for a person participating in the research is given in a simple and clear language and does not include words that could be interpreted as coercive or exaggerating the possible worth of the study. The information should be adapted to the age of the person and other general circumstances or any other grounds that would constitute a diminished ability to make a decision. When the research involves children, the information is to be addressed both to the child (if he/she can read) and to the custodian of the child.*

*The information should not be too long and should only exceed 3-4 A4-sized pages in exceptional circumstances. If, for some reason, the information sheet needs to be considerably longer, a shorter version (1-2 A4 pages), should be supplied as an annex to the longer version, containing the most important information needed by the person participating in the research (see below). If necessary, detailed instructions can be supplied in an annex.*

*The example below is designed to be suitable for both medical research and other research. The relevant parts may be used.*

| Heading | Comment |
|---|---|
| ***1.*** **Background and purpose** | Give a brief but clear description with respect to the background and the general purpose of the study. |
| ***2.*** **Inquiry concerning participation** | Here it should be stated clearly why this particular person was asked to participate and how information about the person was obtained. (For example: ”We found your name in the population register.") |
| ***3.*** **How will the study be conducted?** | This should be a general description of: what will be required; the methods used; the number of visits to a clinic; samples that will be taken and the quantity; interviews; tests, in what manner the examination procedures are different from a patient's/client's routine treatment. It should also be clear how tests and the results of analyses will be dealt with and if they will be sent abroad for analysis or storage. If the analyses concern genes, it should be clear what diseases or other attributes are considered to be linked to genes. |
| ***4.*** **Biobank samples** | If samples are to be stored in a biobank, how and where the samples are stored, that they are coded and cannot be traced to any individual by anyone without access to the code key, the samples are only to be used in the manner to which participants in the research have given their consent to. It should also be made clear if samples will be used for future research; that in such cases a new ethical vetting will be carried out and that in some cases those participating in the research may be contacted again. |
| ***5.*** **What are the risks?** | Here it should be clearly stated if discomfort, pain, adverse reactions, long-term effects, and predictable emotional effects can occur after treatment. In appropriate cases it should also be clearly stated how those who are responsible for the research will deal with problems such as the interruption of procedures, follow-up talks etc. |

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| ***6.*** **Are there any benefits?** | Here there should be a clarification, without any embellishments, of any possible benefits for the patient. With respect to research concerning treatment, it should be clarified that the possible effects of the new treatment (in this particular context) are unknown or need to be verified. |
| ***7.*** **Dealing with data and confidentiality** | Here the manner in which data will be dealt with should be clearly stated and whether it is according to the Personal Data Protection Act: how and what personal information (i.e. information that can be directly or indirectly traced to a particular individual) will be dealt with, how long the personal information will be kept, will it be computerised, who is responsible for personal data, if it will be made available to pharmaceutical companies or other universities in India or abroad, the entitlement of participants to have access to information from the records; and their right to demand the correction of any incorrect information. The wording concerning confidentiality should read: "Your answers and your results will be dealt with in such a way that no unauthorised person will have access to them". There should also be information about how the results of the study will be presented and how personal identity will be protected. |
| ***8.*** **How do I obtain information about the result of the study?** | Here it should be clearly stated in what manner those participants can have access to their personal data (the results of their own analyses) or the results of the entire study (e.g. publication in a journal; information given verbally to a group, etc). It should also be made clear that participants can also ask not to be told the results of any analysis if they so wish. |
| ***9.*** **Voluntariness** | It must be clarified that participation in research projects is voluntary and that one is entitled to withdraw at any moment without giving any explanation. It can also be clarified what items/information are then destroyed. Participants are entitled to demand that samples are destroyed or marked in such a way that it is no longer possible to trace them to a particular individual. If participants in the research who are patients/clients do not wish to participate or wish to end their participation, this will not affect their treatment or the care given to them. |
| ***10.*** **Responsibility** | Here information about those responsible for the completion of the study viz. the PI and researchers (address, telephone number, e-mail addresses etc.) shall be provided. If a representative has been appointed by the PI, it is appropriate to provide contact information for this representative. |
| **11. Consent form** | Details about the project shall be explained to the participants before obtaining their consent in the prescribed format as given in Annexure-VII. |