INFORMATION FOR PARTICIPANTS OF THE STUDY [SAMPLE]

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 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 participant's language which can be understood by the participant:

- Title of the project
- Name of the investigator
- 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
- 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
- The patient information sheet must be duly signed by the investigator

PARTICIPANT CONSENT FORM [SAMPLE]

Participant's name:
Address:
Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. 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). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Note: Consent form II should be appropriately worded for adults and children (less than 18 years) e.g. If the participant is less than 18 years of age, instead of my participation my child's /ward's participation needs to be replaced.

*(In English and patient's language)

भारतीय प्रौद्योगिकी संस्थान हैदराबाद
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This memorandum made on _____ by and between, IIT Hyderabad and

_____Hyderabad.

1. This memorandum is made for carrying out basic research, medically and socially relevant research.
2. Research will be carried out under defined project titles, which will have one PI from _____and one PI and co-PI from Indian Institute of Technology-Hyderabad (IITH)
3. Projects involving human subjects/samples will commence after Institutional Ethical clearance from_____.
4. Intellectual property rights will be decided on individual projects among the partnering institutions. There will be a separate agreement for each project.
5. Paper published in International, and national journals and International and national conferences will be shared by investigators and researchers from both institutes.
6. This understanding is valid for a period of three years and will be extended based on mutual understanding.
7. Either party agrees to provide three month advance notice before terminating this memorandum of understanding and all data available from ongoing projects will be shared in a mutually agreeable manner.

For _____ For IIT, Hyderabad

Name: Name:

Designation: Designation: (Registrar/Dean R&D)

Policy on Blood Withdrawal for Research Purposes

APPLICABILITY: For many studies where the only research intervention is the collection of blood for analysis, the IEC/ICSCR at IITH categorizes the following procedures for obtaining blood from children and adults as minimal risk:

A. General Requirements

- There are no special health reasons (e.g., anemia) to contraindicate blood withdrawal.
- In patients from whom blood is already being drawn for clinical purposes, there are no other health reasons to preclude additional blood collection.
- In subjects from whom blood is not already being drawn for clinical purposes, the withdrawal method is by cutaneous sticks (e.g., heel or finger) or by standard venipuncture in a reasonably accessible peripheral vein, and the frequency of punctures does not exceed two per week.
- The volume of blood drawn from lactating or known pregnant subjects does not exceed 20 ml per week.
- All blood withdrawals and collections are carried out by experienced professional or technical personnel.

B. Additional Requirements for Adults (Subjects over 18 years of age)

- If less than 50 ml is being collected, there are no additional restrictions with regard to hemoglobin or hematocrit.
- If a volume greater than 50 but less than 200 ml is being collected for “no-benefit” studies, hemoglobin levels should be >11.0 g/dl for males and >9.5 g/dl for females with MCVs >85 fl (These restrictions would not apply if iron deficiency anemia or other forms of anemia were critical for inclusion in the study.).
- The cumulative volume withdrawn or collected may not exceed 450 ml per twelve-week period (this maximum includes blood being drawn for clinical purposes) from patients 18 years of age or older in good health and not pregnant.

C. Additional Requirements for Children (Subjects under 18 years of age

- No more than three (3) skin punctures are to be made in any single attempt to draw blood, and the frequency of punctures does not exceed twice per week.
- The volume of blood withdrawn, including blood for clinical purposes, does not exceed the lesser of 50 ml or 3 ml/kg in an eight-week period and collection may not occur more frequently than 2 times per week.
- The cumulative volume of clinical and research blood withdrawn per eight-week period does not exceed six per cent (6.0%) of the child's total blood volume.
- In patients from whom blood is already being drawn for clinical purposes and when the research is directly related to the child's condition, there is no maximum number of extra volume specimens which can be collected as long as the preceding requirements are met.
- In subjects from whom blood is not already being drawn for clinical purposes, the maximum number of allowable separate specimens (again, within the limits of the preceding restrictions) depends upon the child's age and whether the research is directly related to the child's condition.

D. Cord Blood Cord blood from newborns can be used without restrictions when blood is extracted from the placental side of the cord, after it has been clamped and severed.

E. Consent Oral consent is generally sufficient to collect additional volume (within the limits specified above for minimal risk) from patients in whom blood is being drawn for clinical purposes.