RESEARCH UNIT

INFORMED CONSENT

What is Informed Consent

An informed consent is a voluntary aggrement to the participants to participate in a research study after being fully informed about it by the researcher/ study staff followed by its documentation in a written, signed and dated informed consent form.

Informed consent document

The informed consent document/Information sheet should include the following information:

- That the study involves research.
- Purpose of the research.
- Methods of the research(including all invasive procedures)
- Expected duration of the participant's involvement and frequency of the contact.
- The probability of randomization to each treatment (if it is a RCT)
- Any forseeable risks, inconveniences or any discomfort to the participant and when applicable to an embryo, fetus or nursing infant.
- The expected benefits, both direct and indirect to the participant, community or other. When there is no benefit, the participant must be aware of this.
- The alternative procedures or course of the treatment available to the participant including the benefits and the risks.
- Payments/compensation/ free treatment/reimbursement/insurance coverage/ incidental expenses for the particpiants depending upon the type of the study.
- Participation is voluntary and the participant can withdraw from the trial at any time without any penalty or loss of benefits.
- The monitor, auditors, IRB, Research team and the regulatory authorities will have direct access to the participant's original medical records for verification without exploiting/ violating the confidentiality of the participant.

- The records showing the identity of the participant will be kept confidential and will not be made publicly available. (even after the publishment of the results of the trial)
- The participant/participant's legally acceptable representative will be informed timely if information becomes available that may be relevant to the participant's willingness to continue participation in the trial.
- Participant's signature will indicate that he/she has decided to participare in the study, having read and discussed the information presented to him/her about the research.

PROCESS OF OBTAINING THE CONSENT

1. Written
2. Verbal
3. E consent : Online, Audio, Video

VULNERABLE POPULATIONS/GROUPS

1. Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individulas, persons below the poverty line, ethnic minorities, bisexual/transgender etc.
2. Unduly influenced either by expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.
3. Children (upto 18 years)
4. Women in special situations (pregnant or lactating women, or those who have poor decision making powers/poor access to health care)
5. Tribal and marginalized communities
6. Refugees, migrants, homeless persons, population in conflict zone, riot areas or disaster situations.
7. Afflicted with mental illness and cognitively impaired individuals
8. Terminally ill

1. Consent of Pregnant Women

- Both the mother and father must be informed about the potential impact of research on the fetus.
- Both mother and father must give consent to women's participation in the research. However, the father's consent is not required in the following circumstances:
    1. Father's identity not known

2. Father not available
3. Pregnancy resulted from rape
4. Purpose of the research is to meet the health needs of the mother.

2. Consent of Children:

Consent from parents/ Legal representative is necessary.

Assent: In addition to consent from parents/ legal representative, verbal/oral or written assent should be obtained from children 7-18 year of age.

Consideration for assent:

- There is no need to document assent for children below 7 years of age.
- For children between 7-15 years of age, verbal/oral assent must be obtained in the presence of parents/ legal representative and should be recorded.
- For children between 12-18 years of age, written assent must be obtained. This ssent form also has to be signed by the parents/ legal representative.

Informed Consent Form :

I understand that I am being asked to participate in a research study titled "**……** to be conducted at Shahid Gangalal national heart center . The study proposal and procedures have been explained to me clearly. There are no risks associated with this study.
I understand that my privacy will be maintained during the study. I understand that I will be given a copy of this signed consent form.

I realize that the knowledge gained from this study may help either me or other people in the future.

I realize that my participation in this study is entirely voluntary and I will not receive any financial contribution to participate in the study. I may withdraw from the study at any time I wish. If I decide to discontinue my participation in this study, I will continue to be treated in the usual and customary fashion.

I give consent for the study.

Consent given by: Name:…… Age:…… Sex: …… Address:…… Signature: Date:	Consent taken by : Name:…… Designation:…… Address:…… Signature: Date :