E. INFORMED CONSENT (ENGLISH)

IEC NUMBER: IEC=NI/09/DEC/13/38

Description of the Study:

The purpose of this study is to evaluate the role of mutation of genes in congenital heart diseases and study the genotype-phenotype correlation**.** Your child has been selected as a participant based on the inclusion and exclusion criteria of the proposed study. If you agree to participate you will be administered a structured questionnaire by a trained field investigator. The questionnaire will have questions related to the clinical findings of your child and family history. The participation in this study for answering the questionnaire will require approximately 15 min of your time. A **trained and authorized** hospital employee will collect 5-6ml of blood from your infant.

Design of the Study: This is a study on mutation of genes in congenital heart diseases and genotype-phenotype correlation. Probands are initially evaluated by a local physician. A clinical diagnosis is made based on clinical information and echocardiography, and the blood collected will be subjected to cytogenetic and molecular genetic studies.

Possible Risks to the participant: There are NO risks involved in the study. Blood collected will be performed by **trained and authorized** hospital personnel.

Possible Benefits to the participant: It is expected that once we identify a specific genetic basis for cardiac defects it should be possible to identify and appropriately treat individuals who might be at risk at an early stage

Cost and Payments to the participant: There is no cost for participation in this study. Participation is completely voluntary and no payment will be provided.

Confidentiality: Information obtained in this study is strictly confidential. The volunteer will be assigned a specific code and his/her name will not be used in reporting of information in publications or conference presentations.

Participants' right to withdraw from the study: The volunteer has the right to refuse to participate in this study, the right to withdraw from the study and the right to have his/her data destroyed at any point during or after the study, without penalty.

Voluntary consent by the participant: PARTICIPATION IN THIS STUDY IS COMPLETELY VOLUNTARY, AND YOUR CONSENT IS REQUIRED BEFORE YOU CAN PARTICIPATE IN THIS STUDY.

Storage of Samples: The samples processed for this study will be fixed and stored in micro-centrifuge tubes, appropriately labeled with the patients ID no and stored at -50°C. The samples may be used for statistical analysis and research purposes other than the proposed research work in the institute.

I have read this consent form (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate in the study. All of my questions concerning this study have been answered. If I have any questions in the future about this study they will be answered by the investigators listed below. I understand that this consent ends at the conclusion of this study.

By signing this form, I agree to participate in this study. A copy of this form has been given to me.

Date: Participant's signature

Place: Name:

For any further queries please contact:

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CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this study to the above-named individual, and I have discussed the potential benefits of this study participation. The questions the individual had about this study have been answered, and we will always be available to address future questions.