APPENDIX - II

INFORMED CONSENT

Title of the Project: “Investigation of Folate Pathway Gene Polymorphisms in non-syndromic cleft lip with or without cleft palate in South Indian Population”.

Name of the Principal Investigator:
Dr. Jyotsna Murthy,
Prof. Dept of Plastic Surgery,
Sri Ramachandra University, Chennai.

Description of the study:
The risk of recurrence of a cleft condition in the family depends upon a number of factors. These include the number of affected members in the family, the proximity of the affected relatives, the race and sex of all affected person, and the severity of cleft. If one family member is affected, roughly 5-10% chances that next baby will have cleft. If two members of family are affected, roughly 15% chances that next baby will have cleft. DNA contains the code for inherited traits (genes) passed from parents to their children. A genetic counsellor provides information about the risk of having other children with the same defect. We are trying study the causes of non-syndromic clefts or isolated clefts. This includes studies to understand why some children are having this anomaly, but not others. We would like to invite you to take part in this study and this brochure will give you the details about the additional investigations. If you have any doubts you can discuss with any member of our research team to clarify the same. If you agree for you or your son/daughter to take part in the study we will ask you to donate a sample of blood (3-5 ml) to investigate genetic markers. This will help the researchers to learn and understand causes of clefts. If you take part your donation may help discover new diagnostic tests for orofacial clefts or new treatments to prevent this disease.
Possible risks to the participant:
The risks of injury during blood draw are minimal and include slight bruising, bleeding or discomfort at the place where blood is drawn from your arm. We will minimize this risk by having your blood drawn by a trained medical professional.

Possible benefits to the participant:
There will not be any direct benefit to you for taking part in the study however the results of the study will help people in future.

Cost and payments to the participant:
For this study you need not pay anything. Participation is completely voluntary and no payment will be provided.

Confidentiality:
Information obtained in this study is strictly confidential. You and your son/daughter names will not be used in reporting of information in publications or conference presentations

Participant’s right to withdraw from the study:
If you no longer wish to continue you and your son / daughter may withdraw at any stage from the study. At the same time your refusal will not affect your future medical care in any way.

Voluntary consent by the participant:
Your participation is entirely voluntary. If you refuse to participate there will be no penalty or loss of benefits to which you are otherwise entitled. You may stop your participation at any time.
Appendix

Persons to contact:

You may ask any questions about the study at any time by contacting the research supervisor, Dr. L.V. K.S. Bhaskar, Assistant Professor, Department of Biomedical Sciences, Sri Ramachandra University, Chennai. Telephone: 091-9940524037; email: lvksbhaskar@gmail.com.

I understand the consequences involved in participation in this research study that are explained to me. I have had an opportunity to ask questions and I am satisfied with the answers I have been given.

In making my donations I understand that:

- The DNA (anything derived from my blood) will be stored indefinitely at Sri Ramachandra University and will be used for this and future genetic studies on craniofacial abnormalities.
- There will be no cost, nor any financial benefit to me for participating in the study. If my samples lead to the development of a commercial product in the future I will not receive payment for this.
- If at any time I decide that I no longer wish to participate in the study, my son/daughter samples will be discarded upon my written request to the Study Investigators. This will not affect my future medical treatment.
- The samples will remain in the custody of Sri Ramachandra University. They will be stored in good faith, but their suitability for future use cannot be guaranteed. Samples will not be used for purposes other than those agreed to in this consent form.
- All future studies using my samples will have to conform to the Scientific and Human Research Ethics Committees set out by Sri Ramachandra University, Chennai. I will not be notified about future use of my samples.
- I may be approached again to participate in future studies but I am under no compulsion to do so.
- All laboratory data is confidential and will not be released within legal limit.
• My signature below acknowledges my son/daughter voluntary participation in this test, but in no way releases the laboratory and staff from their professional and ethical responsibility to me.

I ______________________ (please print name) hereby voluntarily consent to allow myself or my son/daughter to participate in the genetic study on non-syndromic clefts as described above. Approximately 3-5 ml of blood sample being collected and used for genetic analysis. I wish to be contacted if findings are made that have implications for me or my family.

<table>
<thead>
<tr>
<th>Participating Mother’s Signature</th>
<th>Date</th>
<th>Witness' Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Name of child in the study
Consent for storage and future use of unused samples
If any of the (TYPE OF SAMPLE i.e, blood,tissue). I have provided for this research project is unused or leftover when the project is completed.

☐ I wish my blood sample to be destroyed immediately.
☐ I want my blood sample to be destroyed after .......... year.
☐ I give permission for my blood sample to be stored indefinitely.

AND

☐ I give permission for my blood sample to be stored and used in future research but only the same subject as the current research project
☐ I give permission for my blood sample to be stored and used in future research of any type which has been permission approved
☐ I give permission for my blood sample to be stored and used in future research except for research About

AND

☐ I want my identity to be removed from my blood sample
☐ I want my identity to be kept in my blood sample

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Name of participant:..........................................................

Signature of participant:..........................................................

Date:..........................................................
IF ILLITERATE

I have witnessed the accurate reading of the consent form to the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: ..........................................................  Thumb print of participant

Signature of witness: ..........................................................

Date: .................................................................

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant and to the best of my ability made sure that the participant understands that the following will be done:

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant

Print name of researcher/person taking consent ..........................................................

Signature of researcher/person taking the consent ..........................................................

Date: ..........................................................