Photography Consent Form

TITLE: Developing 3D Craniofacial Morphometry Data and Tools to Transform Dysmorphology

SPONSORS: National Institutes of Health, the University of Calgary, Alberta Heritage Fund for Medical Research

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This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your or your child’s participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

Ethics ID: REB14-0340
Developing 3D Craniofacial Morphometry Data and Tools to Transform Dysmorphology
PI: B. Hallgrimsson
Version 2, 12/01/2015
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**BACKGROUND**
You or your child are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

**WHAT IS THE PURPOSE OF THE STUDY?**
This is an international study aiming to better characterize genetic syndromes that include facial abnormalities and to eventually develop a system to help physicians diagnose these disorders. To accomplish this, we will collect medical information and take special three-dimensional (3D) facial photographs of people, and in some cases their relatives, with many different such syndromes and use these photos to precisely measure and define the specific facial abnormalities associated with each syndrome. We will then develop computerized methods to help physicians diagnose these syndromes. Furthermore, we will deposit the 3D photographs and corresponding medical data into the National Institutes of Health “FaceBase” database (https://www.facebase.org/) so they can also be used by other scientists to advance their research.

This study is designed to learn more about how some specific facial features of genetic syndromes and other conditions differ from normal and how these differ from other conditions. This study is not designed to treat any illness or to improve your or your child’s health.

**WHAT WOULD MY CHILD HAVE TO DO?**
If you or your child joins the study, you will sign this consent form. We will then collect some information about you or your child, in some instances we will review some of your or your child’s medical records, and we will take a 3D photograph of you or your child, which will provide computerized information about the shape of your or your child’s face. This study is for research only, and will not affect your or your child’s medical care. Total study participation will take about 10-15 minutes.

**ARE THERE ANY POSSIBLE BENEFITS OR HARMs?**
You or your child will not experience any discomforts or risk from the 3D photography. There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed. Your photo and information may be shared with other qualified scientists who are specifically reviewed and approved to see your data. While it’s unlikely, it is possible these researchers might recognize your or your child’s photograph.

**DOES MY CHILD HAVE TO PARTICIPATE?**
Participation in this study is entirely voluntary and you many withdraw yourself or your child from the study at any time without jeopardizing your or your child’s health care. If you wish to withdraw, you may contact any of the investigators listed in this document at any time. If the investigators determine that you or your child is not suitable for this study, they may withdraw you or your child at any time. If your child becomes of legal age during their participation in this study, their personal consent will be sought for them to continue.
WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?
You will not be asked to visit the clinic outside of visits included in your or your child’s care, and you will not have to pay for any additional parking. You will not be reimbursed for your or your child’s participation in this study.

WILL MY RECORDS BE KEPT PRIVATE?
If you or your child participates, the reports that relate to this research may be made available to the National Institutes of Health (USA) and the regulatory authorities including the University of Calgary Conjoint Health Research Ethics Board, the Health Protection Branch in Canada, and the Food and Drug Administration in the United States. These organizations will treat such information with strict confidentiality. We will, however, share the images of you or your child and the genetic data with other scientists for research purposes. Unless otherwise required by law, no records bearing your or your child’s name will be provided to anyone except the regulatory authorities, where necessary, and investigators involved in this study. All material and data obtained from this study may be stored for future analysis. Subject to the limitations you have indicated above, it may be used without obtaining further consent from you.

The investigator will deposit your or your child’s research data, genetic information, and facial scan in the FaceBase Hub Data Repository, a secure research database funded by the National Institute of Dental and Craniofacial Research (NIDCR). Importantly, no identifying information such as name, address, phone number, etc. will be stored in this database. The purpose of the FaceBase database is to make data available to other qualified researchers to advance knowledge of craniofacial biology and its disorders. Only qualified researchers may access the data, after review and approval by a special FaceBase “data access committee” constituted by NIDCR. These researchers’ use of the stored data is limited to their approved research projects, as authorized by NIDCR. The general public does not have access to this secure database. The same information will also be shared with authorized researchers who are working directly with the study investigators, with the same limitations and conditions stated above.

The use and disclosure of your or your child’s information has no time limit. You can cancel your permission to use and disclose your or your child’s information at any time by writing to the study’s Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your or your child’s information, your part in this study will end and no further information about you or your child will be collected. Your cancellation would not affect information already collected in this study. To revoke your consent, notify Dr. Benedikt Hallgrimsson in writing.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?
In the event that you or your child suffers injury as a result of participating in this research, no compensation will be provided to you or your child by NIH, the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

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SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your or your child’s participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your or your child’s health care. If you have further questions concerning this research, please contact: Dr. Benedikt Hallgrimsson at 403-220-3060 or 403-220-8411.

Participant’s parent/guardian name ____________________________ Signature and Date ____________________________

Investigator/Delegate’s Name ____________________________ Signature and Date ____________________________

Witness’ Name ____________________________ Signature and Date ____________________________

The University of Calgary Conjoint Health Research Ethics Board has approved this research study. If you have any questions concerning your rights as a possible participant in this research, please contact The Chair of the Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

A signed copy of this consent form has been given to you to keep for your records and reference.