

Title of Research Project:

Inducing Stem Cells from Skin to Model Human Disease

Investigator (s):

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Co-Investigators:

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Purpose of the Research:

Your child has a disorder for which the cause is not completely understood and difficult to diagnose by the usual methods. We will be collecting a small piece of skin during your child's diagnostic work up/surgical procedure. Understand that this will not be something additional, but rather it will be part of your clinically indicated treatment.

Once we obtain these samples, we will send them to the lab for isolation of fibroblast cells. Fibroblasts cells are the building blocks of the connective tissue found in our bodies and the biggest supply is our skin. Research has shown that these fibroblasts, with the proper treatment, can induce production of elementary stem cells. These stem cells can be modelled after any human disease.

With these new cells we can study the causes of a variety of diseases.

Description of the Research:

Your child is having an operation/procedure as part of the usual treatment plan. During this procedure, we would like to collect a sample of your child's skin to send to our research laboratories. The sample is collected as part of the scheduled procedure and will not require any additional procedures.

Once received in the lab the sample will be prepared for the isolation of fibroblasts cells. These fibroblasts cells will be treated to form stem cells known as Pluripotent cells. These induced pluripotent stem (iPS) cells can be modelled after any human disease. These iPS cells will be lead to new insights into the cellular responses during varying stages of difficult to diagnose human disease.

Potential Harms:

There are no known harms associated with participation in this study.

Potential Benefits:

There is no immediate potential benefit for your child in the donating of this sample. Research knowledge from studies of cells may benefit others or, in very unusual circumstances (very unusual because of the time involved in research), they may benefit your child in the future.

We will use these cells in Discovery Research. Discovery Research will lead to new information about certain conditions, causes and cell behaviour during varying stages of the disease. This type of research will be important in the advancement of our knowledge about human disease at a cellular level.

Confidentiality:

The cells are maintained with a unique number that does not reveal your child's identity. The cells will only be traceable to your child's hospital number by the SickKids investigators responsible for the management of this project. Information about your child's age, sex, diagnosis and treatment will be linked to the unique number. No other identifying information will be kept. The ability to link this data to the sample(s) will allow us to determine the importance of new research findings to patient care and results of treatment. This consent is for the collection of cells and their study in culture only. Any further studies will not be undertaken without approval of the REB.

We will respect your privacy. No information about who your child is will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers.

Sick Kids Clinical Research Monitors, employees of the funder or sponsor Canadian Institutes of Health Research, or the regulator of the study may see your health record to check on the study. By signing this consent form, you agree to let these people look at your child's records. We will put a copy of this research consent form in your patient health record and give you a copy as well.

Participation:

Being part of this study and donating your child's cells is your choice. If you choose not to participate, your family will still be able to come for care at SickKids. If you choose to participate and donate your child's cells, you can still withdraw at any time and you will continue to have access to quality care at SickKids. However, any cells that have already been processed to stem cells will continue to be used, but anything remaining, from the original donation will be destroyed.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this information and we will ask you if you still want to be part of the study.

During this study, we may create new tests, new medicines or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future, for being part of this study.

If your child becomes ill or are harmed because of study participation, we will treat your child for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

Reimbursement:

There is no payment for donation of your child's cells to the project.

Sponsorship:

The sponsors of this research are Canada Research Chair program and the Canadian Institutes of Health Research through the awarding of grants.

Conflict of Interest:

I, and the other research team members have no conflict of interest to declare

Consent:

By signing this form, I agree that:

- 1) You have explained this study to me. You have answered all my questions.
- 2) You have explained the possible harms and benefits (if any) of this study.
- 3) I know what I could do instead of having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time. My decision about my child taking part in the study will not affect my child's health care at Sick Kids.
- 4) I am free now, and in the future, to ask questions about the study.
- 5) I have been told that my child's medical records will be kept private except as described to me.
- 6) I understand that no information about my child will be given to anyone or be published without first asking my permission.
- 7) I agree, or consent, that my child _____ may take part in this study."

I have read and understood pages 1 to 4 of this consent form.

Printed Name of Parent/Legal Guardian

Parent/Legal Guardian's signature & date

Printed Name of person who obtained consent

Signature of Person who obtained consent & date

Printed Witness' name (if the parent/legal guardian
does not read English)

Witness' signature & date

If you have any questions about this study, please call Ben Alman at 416-813-7981.

If you have questions about your rights as a subject in a study or injuries during a study,
please call the Research Ethics Manager at 416-813-5718.”