

University of California, San Diego
Assent to Act as a Research Subject
(Ages 13-17 years)

Making neurons (brain cells) from skin cells to understand brain diseases

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?

Study Investigator and Sponsor
Dr. Joseph G. Gleeson

This is a research study. Research studies include only subjects who choose to take part. You are being asked to take part in this study because you or someone in your family may or may not have a brain disease. Please take your time to make your decision about whether you would like to be in this study. Talk to your family about it. Be sure to ask any questions that you might have.

We want to get about 100 people per year to donate skin samples for this research.

Why is this study being done?

By studying brain cells we want to understand what causes brain diseases. But it is impossible to get brain cells from people of course. Scientists recently figured out a way to get skin cells to turn into brain cells. So because you have a brain disease, we want to take a small sample of your skin, and turn the cells into brain cells. This will help us understand the causes of brain diseases in children.

What will happen to you in this study and which procedures are standard of care and which are experimental?

This is what will happen to you if you are in this study. Dr. Gleeson or someone that works with Dr. Gleeson will give you a shot of numbing medicine, and after it numbs your skin, he will cut a small piece of your skin and send it to the laboratory. The piece of skin will be about the size of a drop of water. Then Dr. Gleeson will cover it with a Band-Aid. If you notice any redness or pain, tell your mom or dad, who will call Dr. Gleeson to get it treated. There will be a checkup visit to make sure that the cut has healed. There will be a small scar at the site of the cut.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

Collecting the skin sample will only take about 15 minutes.

Once we have your skin sample in the lab, we will grow it and keep it in the freezer for many years. We will defrost the cells if we need to study them again. If you wish to withdraw from our study you can do so at any time and we will destroy your samples and medical information. However, it is possible that we will give the sample to some other doctors who also want to study cells from someone with your type of brain disease, and in this case, we might not be able to track down all of the cells you gave us.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

There will be a pinprick when we inject the numbing medicine. You should not feel the cut when we take the small piece of skin, but if it hurts, we can stop. The spot needs to be kept clean or it might get infected and then it would need some antibiotic

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?

You can decide that you do not want to be in this study. No one will get mad at you or make you feel bad.

What benefits can be reasonably expected?

You are agreeing to give your skin sample even though there will be no benefit to you for being in this study. We hope to learn more about brain diseases in children by studying your sample.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be requested to tell your parents or email the study team at contact@gleesonlab.org

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your assent?

You may be withdrawn from the study for the following reasons: If Dr. Gleeson is not able to use your skin sample for research then you will not be included in the study. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?

We are not paying people to be in this study. It is your choice if you want to be in this study.

What if you are injured as a direct result of being in this study?

If you are injured or become ill as a direct result of this research study, you will be provided with medical care.

What about your confidentiality?

We will keep your information in confidence. This means we will only tell those who have a need or right to know. Your information might be seen by the people at your doctor's office if

