Subject's Name:_____

Title of Research Protocol: **CIRM International Tissue Collection for Neurodevelopmental Disabilities**

Investigator's Name: Dr. Joseph Gleeson

Protocol Number and Expiration Date: **150765**

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

CIRM International Tissue Collection for Neurodevelopmental Disabilities

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?

Dr. Gleeson and his research team are conducting a research study to find out more about children with disabilities related to the brain or nerves. You have been asked to participate in this study because you 1) have a medical condition that affects your brain or nerves or 2) are healthy with normal growth and development. There will be approximately 275 participants.

Why is this study being done?

The purpose of this study is to better understand medical conditions in children by creating special cells called induced pluripotent stem cells (iPS), meaning that they are created from your skin cells using special chemicals or genes and can become many different types of cells. These cells can be stored for long periods of time and researchers can turn them into other tissues like nerves or heart cells and then study these cells to try to understand how they work, or why they don't work, and investigate treatments or test possible therapies.

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

If you agree to participate in this study, the following will happen to you:

1. We will ask you questions about how you are feeling and doing in school.
2. We will examine you just like in the doctor's office.
3. We will take a small sample of skin from behind the arm or other inconspicious place with a 2mm punch. There won't be any sutures needed.

All of these things will be done just for research purposes and are not part of your regular doctor's visit.

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

The questions and doctor's exam should take no more than one hour to complete. Taking the skin sample should take less than 15 minutes. The total time for this study will be 1 hour and 15 minutes or less.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. These include the following:

1. A small rash on your skin from the skin puncture
2. Some bleeding after the skin sample has been done
3. Some brief pain from the skin puncture
4. Feeling dizzy
5. Feeling lightheaded
6. Someone who is not a member of the study team could find out that you participated (loss of confidentiality).

Because this is a research study, there may be some unknown risks that are currently unforeseeable.

What are the alternatives to participating in this study?
The alternative to participation in this study is to not participate.

What benefits can be reasonably expected?
There will be no direct benefit to you from these procedures. Dr. Gleeson and his research team, however, may learn more about brain and nerve disabilities in children from the skin that you donate. You may benefit from the knowledge that your participation may further scientific research and help others in the future.

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 contact Dr. Gleeson and his research team and let them know.

You will be told if we learn any important new information 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: 1) if the study doctor considers it to be in your best interest or the Institutional Review Board requests that you be discontinued. 2) if the study doctor, the Institutional Review Board, or the sponsor ends the study. You may also be withdrawn from the study if you do not follow the instructions given you by the study team.

Will you be compensated for participating in this study?
There is no compensation offered for participating 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 receive medical care from the hospital or clinical where you are participating. The hospital or clinic will not provide any other form of compensation to you if you are injured.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. All of the information we collect during the course of this study will be kept locked and secured and it will be released to no one unless you ask us to do so. In the course of collection of the clinical information we may need to review your medical chart. This information as well, will be kept confidential and not shared with anyone outside this project. We will not release this information to insurance companies, family members, work places or any other institutions. Even though, the risk of losing confidentiality via medical records cannot be fully eradicated, we take all the precautions to protect this information.

Research records may be reviewed by the UCSD Institutional Review Board and Other regulatory agencies responsible for overseeing research, such as the federal Office for Human Research Protections and the California Institute for Regerative Medicine.

Who can you call if you have questions?
Joseph Gleeson, MD and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Joseph Gleeson, MD at 858-822-3786 or via e-mail at contact@gleesonlab.org.

You may call the Human Research Protections Program Office at (858) 657-5100 to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Assent

You agree to participate.

_____ _____
Subject Signature Date

_____ _____
Signature of person who explained this form Date