Joseph G. Gleeson, MD and his associates are conducting a research study to find out more about the causes of brain diseases in childhood (genetic abnormalities of brain development such as mental retardation).

You have been asked to participate because you have indicated your willingness to donate blastocysts for research uses. These blastocysts will be used by the Gleeson Lab to learn more about the kinds of mutations that can cause brain diseases, and when they first arise. There will be approximately 800 new participants joining this study every year. To date there have been over 2700 individuals participating in this project.

If you agree to be in this study, the following will happen to you:
1. One or more blastocysts that you have previously agreed to donate for research will be analyzed genetically. This means that the Gleeson Lab will extract and analyze the genetic material. These blastocysts will no longer be in storage, and will not be available for your use in the future.
2. You will not receive compensation for participating in this study.

Participation in this study may involve some added risks and discomforts. These include:
1. There is a chance that participation in this study could cause psychological distress, economic and social harm. Some people involved in genetic studies have felt anxious about the possibility of carrying an altered gene that places them at risk or that can be passed on to children. If these feelings arise at any time during the study, you may contact us and we will arrange for you to speak with a genetic counselor.
2. Social and economic harms associated with gathering of genetic information. We will do our best to keep all information confidential, but the testing may find a defective gene that puts you at risk for developing a genetic disease at some time in the future. This information, if disclosed to the wrong source, may adversely affect you economically and socially and adversely affect your insurability and employability and cause you to be stigmatized. We will not make this information available to anyone unless you ask us to do so. 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.
3. In the course of collection of the clinical information we may need to review your medical records, MRI scans, pathology reports, laboratory or progress reports, etc. This information as well, will be kept confidential and not shared with anyone outside this project. We will not release information to insurance companies, family members, work places or any other institutions. Even so, the risk of losing confidentiality via medical records cannot be fully eradicated, we take all the precautions to protect this information.
4. In order to help advance future genetic discoveries, we may be required to deposit genetic sequence, diagnosis, and de-identified pedigree into the NIH’s (National Institute of
Title of Research Protocol: The Genetics of Childhood Neurological Diseases

Investigator’s Name: Dr. Joseph Gleeson

Protocol Number and expiration date: 140028 At the completion of this study

Health) restricted-use database. Neither your personally identifiable information (PII), nor your genetic material would be shared in this database. Your PII will remain confidential. Only de-identified genetic data would be deposited into such database.

5. A sample of the genetic material from the blastocyst(s) will be kept with Dr. Gleeson for a period of at least 5 years and possibly indefinitely, and Dr. Gleeson, his associates or successors in these studies will be responsible for deciding how it will be used. In addition to Dr. Gleeson, your genetic material may also be studied by current or future researchers collaborating on this project to use. The sample will not include your name or any other identifying information.

The specimens collected from you and the DNA that they contain may also be used in additional research to be conducted by the University of California personnel collaborating in this research. These specimens, DNA, and their derivatives may have significant therapeutic or commercial value. You consent to such uses. If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Gleeson, who will use his best efforts to stop any additional studies. However, in some cases, it may be impossible to locate and stop such future research once the materials have been widely shared with other researchers at the University of California.

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program at (858) 246-4777 for more information about this, to inquire about your rights as a research subject, or to report research-related problems.

This study may be of no direct benefit to you or members of your family. If as a result of participation in this study we obtain information that could significantly affect your health or well being, we will attempt to inform you of the existence of this information. You may then decide if you wish to know what we have learned. Dr. Gleeson hopes to develop improved diagnostic procedures and possibly new methods of treatment. In addition, this information may also be used to further understanding of neurological disorders in individuals.

Instances are known in which a subject in a research study has been required to furnish genetic information as a precondition in applying for health insurance and/or a job. Participation in this study does not mean that you have had genetic testing. Genetic testing means having a test performed and the results provided to you and your doctor. If you are interested in having genetic testing performed, you should consult your doctor, as some commercial tests are available. Your doctor can provide you with the necessary information to determine if such a test would be appropriate for you.

Human Research Protections Program
UC San Diego
Approved
Current Approval: 06/25/2021
Do not use after 06/26/2022
Intended Parent 1 Name: _________________________________________________
Intended Parent 2 Name: ____________________________________________
Title of Research Protocol: The Genetics of Childhood Neurological Diseases
Investigator’s Name: Dr. Joseph Gleeson
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Dr. Gleeson and/or __________________________ on Dr. Gleeson’s behalf has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Gleeson at (858) 246-0547.

Your alternative option to participation in this study is not to participate. Your involvement in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this or any institution. Research records will be kept confidential to the extent provided by law. You have received a copy of this consent document and a copy of “Experimental Subject’s Bill of Rights” to keep.

You agree to participate.

______________________   ________________   ____________
Intended Parent 1 Signature  Witness  Date

______________________   ________________   ____________
Intended Parent 2 Signature  Witness  Date