

Intended Parent 1 Name: _____

Intended Parent 2 Name: _____

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

**University of California - San Diego
Blastocyst Research Consent Form**

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. Blastocysts are a rapidly dividing ball of cells. Three days after fertilization, a normally developing embryo will contain about six to 10 cells. By the fifth or sixth day, the fertilized egg is known as a blastocyst. The blastocyst(s) to be used in this research would normally be discarded because you have chosen to discard the material (e.g. frozen blastocysts which you no longer require for your treatment which will be referred to as normal blastocysts in excess of clinical need). 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 20 new participants joining this part of the study every year.

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. Following this process these blastocysts will no longer be in storage and will not be available for your use in the future.
2. These donated blastocysts will be used for genetic research and potential production of cell lines. This means the donated blastocysts may be grown in-vitro following the current ethical time limits in the United States. The blastocysts will be broken up into cells or cell clusters, where the Gleeson Lab will try to grow cultures of new cells that come from the blastocyst. Cells multiple by dividing in two and the genetic material is replicated each time a cell divides, therefore these cell lines would contain your DNA and have the potential to live indefinitely.
3. Donated blastocysts will be manipulated and destroyed during the research procedures. All blastocysts will be destroyed following current ethical time limits in the United States. Donated blastocysts will never be implanted for reproduction purposes or be used to carry out an *in vitro* fertilization procedure. Donated blastocysts will never be used to produce a pregnancy or a baby.
4. You will not receive compensation for participating in this study

What will happen to information and/or biospecimens collected from me?

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Participation in this study may involve some added risks and discomforts. These include:

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1. Your participation in this research will not require any extra time from you, other than the time it takes to sign this consent form.
2. 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.
3. Risks of Genetic Testing: Federal and State laws generally protect your genetic information in the following ways: a) Health insurance companies and group health plans may not request your genetic information from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

We will minimize the possibility of results from this research being linked to you, but there is always the remote possibility that information from the research may be disclosed. If your genetic risk for certain diseases is accidentally divulged to the wrong source, you might be discriminated against in obtaining life or health insurance, or employment.

4. 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, workplaces 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.
5. 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 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.

While the public database will not contain information traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic information in these databases back to you. For example, someone could compare information in a database with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic information to you.

While your privacy and confidentiality are very important to us and we will use safety measures to protect it, we cannot guarantee that your identity will never become known.

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6. The blastocysts you donate to this research project will not be available for future fertility uses. This means that if you later decide that you want to have a child through *in vitro* fertilization, you will have to undergo a completely new *in vitro* fertilization cycle.
7. 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 at any time and for whatever reason that you do not want the donated blastocysts collected from you to be used for research, you may tell this to Dr. Gleeson, who will use his best efforts to stop any additional studies. However, if you withdraw your consent after the blastocysts have left the fertility clinic, then the blastocysts will no longer be suitable for reproductive purposes and will have to be destroyed. Please be aware that, 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. Once the blastocysts are cultured or grown for research use, they can no longer be withdrawn. If stem cells are collected from your blastocysts, you will not be able to change your mind or request that any of the collected stem cells be removed from this research project.

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 Office of IRB Administration 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. Cell lines that are derived may not be available for your treatment in the future. 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

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available. Your doctor can provide you with the necessary information to determine if such a test would be appropriate for you.

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