John Paul II Medical Research Institute
Mercy Medical Plaza Suite 305
540 E. Jefferson St., Iowa City, IA 52245
319-887-2873 (office); 319-887-2870 (fax)

Cellular Engineering Technologies Inc.
2500 Crosspark Rd, E232
Coralville, IA 52241
319-665-3000 (office); 319-665-3003 (fax)

CONSENT FORM

Title: Extracting Target Tissue For Producing Induced Pluripotent Stem Cells

Principal Investigator: Alan Brent Moy, M.D.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research project is to develop induced pluripotent stem (IPS) cells. IPS cells are primitive stem cells derived by genetically reprogramming your adult cells. IPS cells are unique because they represent potential cell therapies to cure your disease. In addition, IPS cells represent cell tools that can be used to identify new drugs that can more effectively treat your disease in a more personalized manner than what currently exists in medicine. Unlike embryonic stem cells, IPS cells fall within the moral guidelines of the Catholic Church. Recently, scientists have produced germ cells (egg and sperm, and any cell in the lineage that produces these cells) from IPS cells in mice and produced offspring, other researchers are pursuing this line of research with humans. The John Paul II Medical Research Institute will not engage in germ cell research using your human IPS cells. This study proposes to extract a small sample of tissue from you to isolate cells that will go on to be genetically reprogrammed. Tissues will be obtained using a minimally invasive approach from a licensed physician skilled in the art. The intent of this study is to recruit patients specifically for research by obtaining tissue from those that either: (1) have a rare (orphan) genetic disease like Cystic Fibrosis or ALS; or (2) have a common non-genetic disease like Type II diabetes.

Tissue will be obtained by performing small biopsies or aspirations from any one of the following minimally invasive procedures:

1. Skin biopsy.
2. Fat biopsy or aspirate.
3. Blood sample from a venipuncture

This study has two broad intents: (1) to support the research operation of the John Paul II Medical Research Institute (JP2MRI) whose mission is to use these cells for finding cures. (2) to commercially sell these IPS cells to advance global biomedical research for specific diseases.

The primary goal of this study is to create a disease-specific stem cell repository that will be operated under the direction and management of JP2MRI for the purpose of using these disease-specific stem cells for developing therapies for a variety of diseases. These cells will be used for internal research and development conducted by JP2MRI and its collaborators. There are two parts to this stem cell repository. The first part involves creating IPS cell lines from patients with clinical diseases. The second part involves collecting prospective clinical information on the patient. The data would include relevant clinical information that defines a patient's IPS cells. The patient will be given a request to allow relevant medical information about their disease to be released from their physician to the Institute

in accordance with Federal laws. The Institute will enter the data on a computerized system or the patient can directly enter their clinical data through a secure web-based portal.

In the event that these cells are needed by third parties such as industry, government, or academia, the cells will be commercially sold by Cellular Engineering Technologies, Inc. (CET) under the terms of a license agreement. The specific research of those customers varies depending upon the specific research programs of those scientists who work in industry, government, or academia. Biomedical research is inhibited and slowed because scientists do not have access to these human cells. By providing commercial human IPS cells to other scientists, biomedical research aimed at finding cures can be significantly accelerated.

By signing this consent, you surrender all rights, including future financial rights, to the tissue or products created from that tissue. However, a good faith effort will be performed to provide your stem cells for future cell therapy if it is a prerequisite for you to enter into a clinical trial.

HOW IS YOUR PRIVACY PROTECTED?

The John Paul II Medical Research Institute will manage the privacy information of the clinical database. The Institute will create a random identification number for you so that your contact information and identity is protected. The Institute will not disclose your contact information or identity without your written permission to any third party, in accordance with Federal laws. However, de-identified clinical information may be made available to third parties or to JP2MRI scientists as part of their research.

WHAT PROCEDURES ARE PERFORMED ON SAMPLES?

Tissue samples will be transported to JP2MRI where cells will be purified. The isolated cells will be grown in Petri dishes. There are a wide variety of research applications that could be conducted on IPS cells that are dependent on the specific research interest of the end user in accordance with their research protocols, which are governed by local and federal laws. JP2MRI and CET do not regulate the research of their customers. Examples of such research could include a variety of DNA and protein analyses, duplication of DNA or cells, or the creation of cells or tissue cultures to evaluate potential drug targets and treatments for a number of diseases. The cells from this study are restricted for research purposes and will not be used for patient treatments or used for laboratory analyses that may negatively impact you, such as impacting your ability to acquire medical insurance.

HOW MANY PEOPLE WILL PARTICIPATE?

The study will be an ongoing research project at the John Paul II Medical Research Institute in conjunction with the practicing physicians. The study is open-ended.

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HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, it is generally anticipated that you will not be subjected to further tissue biopsy procedures. However, the Institute may approach you in the future for more updated medical information about your particular disease, which is an important part of better interpreting the

biological significance of your stem cells. Under that circumstance, we would ask for consent to allow medical information about your disease to be released from your personal physician to the Institute to update your medical records.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to donate a small sample of tissue by any one of the following procedures:
1. Skin biopsy.
2. Fat biopsy or aspirate.
3. Blood sample from a venipuncture.

It is the expectation that the procedure you sign up for will exclude you from having any of the remaining procedures performed.

1. Skin biopsy.
A physician will take a small sample of skin. A physician will provide a local anesthetic to your skin. Next, the physician will either perform a punch biopsy or he/she may excise a small piece of skin using a scalpel blade creating a wound the size of 3 grains of rice lined up in a row. The physician may be required to suture the ends of the wound back together. You will be required to return to the physician to have the wound inspected for signs of infection and to have the sutures removed.

2. A fat biopsy or aspirate.
A physician will anesthetize an area where there is underlying fat. Then through a small incision a small amount of fat will be harvested (1-2 cubic millimeters). Alternatively, by using a syringe and needle in the anesthetized area some liquid fat will be drawn out (~5-10 milliliters). If a small incision is used to harvest the fat, some fine sutures may be needed to close the wound and seven to ten days later the sutures will need to be removed. In the case of aspiration with a needle, a Band-Aid or other bandage would suffice. The physician will need to see the area of incision or aspiration seven to ten days later to insure it has healed properly.

3. Blood sample from a venipuncture.
This procedure requires drawing blood by routine venipuncture. Registered nurses (RN), phlebotomists, or medical assistants will perform the venipunctures. It is anticipated that a tube of blood (up to a maximum of 30 ml) would be obtained. The blood sample collection will take approximately 5-10 minutes. For a routine phlebotomy, the skin will first be cleaned with an antiseptic solution, and a tourniquet will be placed on the upper arm. A sterile needle will be inserted in a vein and blood will be drawn. Afterwards the needle will be removed and pressure will be applied to the site using a gauze pad.

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WHAT ARE THE RISKS OF THIS STUDY?

1. Skin biopsy.
You may experience some minor discomfort from the anesthetic and from the biopsy. There may be a bruise at the biopsy or incision site or some minor bleeding. Rarely subjects will become light-headed or faint, and very rarely there may be a minor infection resulting from the procedure.

2. Fat biopsy or aspirate.
You may experience some discomfort from the anesthetic and from the biopsy. There may be a bruise at the biopsy or incision site or some minor bleeding. Rarely subjects will become light-headed or faint, and very rarely there may be a minor infection resulting from the procedure.

3. Blood sample from a venipuncture.
Most people experience some discomfort when the needle is inserted. Occasionally there will be a bruise at the blood-drawing site, or some minor bleeding. Rarely subjects will become light-headed or faint, and very rarely there may be a minor infection resulting from the procedure.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not immediately benefit from this study. However, this study does have the potential to provide a personal IPS cell line that could be used to better understand your disease, as well as provide a cell line that may be used to discover possible treatments or a cure. Sometime in the future, there may also be a potential for developing replacement tissue that could cure your disease by regenerating a diseased organ. At the minimum, we anticipate the timeline to find cures for your disease will be shortened.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be compensated accordingly for being in this research study. If you undergo either a skin biopsy or a fat biopsy or aspirate you will be compensated $100. If you provide a blood sample from a venipuncture you will be compensated $25.

WHO IS FUNDING THIS STUDY?

The John Paul II Medical Research Institute will be funding the projects.

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WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other parties may become aware of your participation in this study. Federal government regulatory agencies, representatives of the National Institutes of Health, and the John Paul II Medical Research Institute Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified. There will be no links maintained between the sample collected and your identity.

FINANCIAL DISCLOSURE OF RESEARCHERS

Dr. Moy is President of Cellular Engineering Technologies, Inc. and has a financial interest, which is being disclosed. The study does not involve a treatment modality.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF PATIENTS HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact any of the principal investigators:

Name	Telephone number	e-mail
Alan Moy M.D.	319-688-7367	alan.moy@jp2mri.org
Sara Ternes	319-688-7367	sara.ternes@jp2mri.org
Megan Driscoll	319-688-7367	megan.driscoll@jp2mri.org

If patients have questions about the rights of research subjects or research related injury, please contact the John Paul II Medical Research Institute, Mercy Medical Plaza Suite 305, 540 E. Jefferson St., Iowa City, Iowa, 52245, 319-887-2873.

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Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)