

ADULT INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF PROJECT: IDENTIFICATION OF GENES AND RISK FACTORS FOR HYPEREMESIS GRAVIDARUM

PRINCIPAL INVESTIGATORS: T. MURPHY GOODWIN, M.D. AND MARLENA S. FEJZO, PH.D.

DEPARTMENTS: DEPARTMENT OF MATERNAL-FETAL MEDICINE, USC AND DEPARTMENT OF MEDICINE, UCLA

24-HOUR TELEPHONE NUMBER: (310) 210-0802

WHY IS THIS STUDY BEING DONE?

We invite you to take part in a research study conducted by Marlena S. Fejzo, Ph.D., Department of Maternal-Fetal Medicine, USC and Department of Medicine, UCLA and T. Murphy Goodwin, M.D., Department of Maternal-Fetal Medicine, USC. This study is about Hyperemesis Gravidarum (HG), a condition of severe nausea and vomiting during pregnancy. We hope to learn if there are any differences in genes between affected individuals and unaffected friend controls (a control is a study participant who did not have HG who will be compared to the study participant with HG). You are invited as a possible participant, because you had HG or because you are a friend of a study participant with HG and would like to participate as an unaffected control for the study. About 2,400 individuals will take part in this study.

If you are a relative of a participant in a large family with HG (3 or more affected individuals), we are inviting you to participate now in the collection of samples and information for a follow-up family study to confirm our findings in this study.

WHAT IS INVOLVED IN THE STUDY?

If you decide to take part, this is what will happen:

1. You will be asked to answer a questionnaire regarding your medical history, family history and other possible risk factors for HG. The survey will be completed online and contains sensitive questions such as "How many voluntary/therapeutic terminations?", "Is this child healthy and well-functioning (normal) at this time?", "How long did HG affect you emotionally? (number months, years, ongoing, describe)?" You do not have to answer any questions that cause you distress.

2. You will be asked to donate saliva samples (about 2 mls or 1/2 teaspoon of saliva). The sample collection will be self-administered (collected by you) via a kit we mail to you with directions on how to collect the sample and mail it back to the study site. If you have questions about any part of this process, you may contact us at any time to guide you through it or answer your questions.

3. If you had a diagnosis of HG, you will be asked to send your medical records confirming your diagnosis by a medical professional and the use of IV (intravenous – into the vein) therapy, IV nutrition, or other forms of tube feeding to treat HG. You are not required to send your medical records to participate, and we do not need your entire set of records relating to your pregnancy(s). We are asking you to send copies of the pages of your records confirming diagnosis and treatment (with IV therapy, IV nutrition, or other forms of tube feeding) in one pregnancy, if possible. Please review what you are sending to protect yourself against sending us medical information you do not wish to disclose. Only Dr. Fejzo will review medical records. All medical records confirming diagnosis and treatment will be kept in a locked file cabinet accessible only to Dr. Fejzo and any information in the records that does not relate to HG diagnosis and treatment will be shredded.

The genetic analyses that are done in this study are for research purposes only and you will not be provided with the results.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Saliva: There are no known risks associated with the saliva collection process used to collect approximately 2 mls (1/2 teaspoon) saliva.

Genetic Research: This study involves research in genetics that could be used to develop genetic testing in the future. At this time, any information obtained from this research cannot provide meaningful information about the future health of any study participant. If you decide to participate in this study, you will be involved in genetic **research** only. If you are asked by your insurance company, you can answer that you have **not** had genetic **testing**.

There have been concerns about the possibility of discrimination based on genetic findings. Despite this concern, to date, this has not been a significant problem, with only very rare reports. Federal and State legislation provide some protection against employment or health insurance discrimination based on genetic findings.

Questionnaire: Some of the questions may make you feel uneasy or embarrassed. You may choose to skip questions that make you uncomfortable.

This research may involve risks that are currently unforeseeable.

ANTICIPATED BENEFITS TO SUBJECTS

There is no benefit to you from taking part in this study. This study is not being done to improve your condition or health. You have the right to refuse to participate in this study.

ANTICIPATED BENEFITS TO SOCIETY

We hope the information learned from this study will benefit other patients with HG in the future.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to take part in this study.

WILL YOUR INFORMATION BE KEPT PRIVATE AND CONFIDENTIAL?

The investigator and the Institutional Review Board (IRB) will keep your records private as far as the law allows. The only people who will know that you are a research subject are members of the research team. No information about you , or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law.

We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name, so no information will be included that would reveal your identity. Only the people who work on the study will see your answers to the questionnaire provided in this study. The individual responses to survey data will not be printed and will be electronically deleted after analysis of the data. Your personal information, research data, related records, and saliva sample will be stored with your ID number only. The code linking your ID number to your name will be stored only on the locked password protected computer of Dr. Fejzo, to prevent access by unauthorized personnel.

Each tissue and fluid sample contains genetic information about your parents, and ancestors such as information contained in DNA, RNA, or protein. It may be helpful to study members of your family. Your relatives will not be contacted without your permission.

GENETIC INFORMATION IN YOUR SAMPLE: POSSIBLE LIMITS TO INDIVIDUAL CONFIDENTIALITY

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants, even if there is no name on the samples. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in the future.

We have learned from past research that we will not always be able to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

Sometimes genetic information suggesting different parentage is obtained during research. We do not plan to report such findings to participants.

We will store any genetic research results from this study at USC Department of Maternal-Fetal Medicine and UCLA Department of Medicine. We will not put the genetic information in your medical records. Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information. All information is stored under conditions that protect the privacy of study participants. For example, all electronic data is coded and password protected and all hard copies are stored in a locked file cabinet to prevent access by unauthorized personnel.

WHAT ARE THE COSTS?

Neither you nor your insurance plan will be billed for your taking part in this study. The saliva cell sampling and genetic research will be conducted at no cost to you or your health plan. If you had HG, you may volunteer to pay to have your medical records sent to Dr. Fejzo. You may have to pay to have your records sent; however, this is not a required part of the research. No other procedures are required.

If you are living outside the United States, you will be asked to cover the costs of the consent phone call to Los Angeles and the shipping of saliva sample kits for you and your friend control from Los Angeles, California to your residence and back to Los Angeles, CA for analysis.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You will not receive any payments for taking part in this study.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you get hurt or sick from taking part in the study, you must pay for the care. You will not receive any compensation if you get hurt or sick.

POSSIBLE COMMERCIAL PRODUCTS

The saliva specimens obtained for the purposes of this study will be collected by UCLA and provided to USC. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is VOLUNTARY. Your decision whether or not to take part will not affect your current or future care or your relationship with USC and UCLA or your right to health care or other services to which you are otherwise entitled. You are not waiving any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and withdraw your consent and discontinue participation at any time without prejudice to your future care at USC or UCLA.

NEW FINDINGS

During the course of this study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

You may contact Dr. Marlena S. Fejzo at 310-210-0802 with any questions or concerns about your participation in this study. If you feel you have been hurt by taking part in this study, please contact Dr. Marlena S. Fejzo at 310-210-0802. If you have any questions about your rights as a study subject, please contact the Institutional Review Board Office at LAC+USC Medical Center, IRD Building, 2020 Zonal Ave., Suite 425, Los Angeles, CA 90033 (Telephone number: 323-223-2340) and the University of California, Los Angeles, Office of Protection of Research Subjects, 11000 Kinross Avenue, Box 951694, Los Angeles, CA, 90095-1694 (Telephone number: 310- 825-8714). You will get a copy of this consent form.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions were answered to my satisfaction. I have decided to sign this form in order to take part in this study. This form with your signature, should be faxed or mailed to the Principal Investigator, Dr. Fejzo, who will then sign the form and mail a copy back to you.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Adult Subject	Signature	Date Signed
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SIGNATURE OF INVESTIGATOR:

I have explained the research to the subject and answered all of her questions. I believe that she understands the information described in this document and freely consents to participate.

Name of investigator	Signature	Date Signed
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Study ID: HS-06-00056 Valid From: 9/24/2010 To: 9/23/2011

Information About Fluid Samples Collected as Part of This Research:

Please mark how your saliva cell samples may be used by initialing "Yes" or "No." No matter what you decide to do, it will not affect your participation in this study.

a) My saliva cell samples may be kept for use in future research on HG.

Yes _____ No _____ Initials _____

b) Someone from USC or UCLA may contact me in the future to take part in more research.

Yes _____ No _____ Initials _____

CONSENT FORMS:

AFTER reviewing by phone with Marlena, if you are consenting to be part of the study, please sign and return to the following address by fax or mail:

Marlena S. Fejzo, Ph.D.
675 Charles E. Young Dr. South
5535 MRL Bldg., Slamon Lab
Los Angeles, CA 90095
Fax: (310)825-3761

For cases with HG only: please have your medical records confirming diagnosis and iv therapy, iv nutrition, or other forms of tube feeding mailed to the following address:

Marlena S. Fejzo, Ph.D.
675 Charles E. Young Dr. South
5535 MRL Bldg., Slamon Lab
Los Angeles, CA 90095

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