

Study Title: Identification of Genes and Risk Factors for Hyperemesis Gravidarum
Principal Investigators: T. Murphy Goodwin, M.D. and Marlena S. Fejzo, Ph.D.

EXPERIMENTAL SUBJECT’S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time _____

Signature: _____
(subject)

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.

DEPARTMENT: DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

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

WHY IS THIS STUDY BEING DONE?

We invite you to take part in a research study. 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 2,000 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.
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. Goodwin will review medical records. All medical records confirming diagnosis and treatment will be kept in a locked file cabinet accessible only to Dr. Goodwin and any information in the records that does not relate to HG diagnosis and treatment will be shredded.

Information About Tissue and/or 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) My saliva cell sample may be kept for use in any future medical research.

Yes _____ No _____ Initials _____

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

Yes _____ No _____ Initials _____

d) I agree to have my saliva cell sample shared with other researchers.

Yes _____ No _____ Initials _____

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.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

There is no benefit to you from taking part in this study. 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?

The investigator and the Institutional Review Board (IRB) will keep your records private as far as the law allows. Unless otherwise required by law, your records will be kept confidential. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name. Only the people who work on the study will see your answers to the questionnaire provided in this study.

Every tissue or fluid sample has information about a person's genes. By using genes, a person might be identified, even if there is no name on the samples. We will make every effort to keep your genetic information private as far as the law allows.

We will store any genetic research results from this study at USC Department of Obstetrics and Gynecology. We will not put the genetic information in your medical records. 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. Goodwin. 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.

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. 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 stop being in the study at any time.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

You may contact Dr. T. Murphy Goodwin at 323-226-3306 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. T. Murphy Goodwin at 323-226-3306. 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). 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. I have decided to sign this form in order to take part in this study.

Name of Adult Subject	Signature	Date Signed
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Form Valid For Enrollment
From
3/7/2008 To 12/17/2008
Institutional Review Board
HS-06-00056

CONSENT FORMS:

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

Melissa L. Wilson, Ph.D., M.P.H.
Norris Topping Tower #6419
1441 Eastlake Ave. , MC-9175
Los Angeles, CA 90033
Fax: 323.865.0473

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:

T. Murphy Goodwin MD
Women's and Children's Hospital
1240 North Mission Road
Los Angeles, CA, 90033
Room 5K-40