CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

Detection of miRNAs in HPA Axis Function in Healthy Subjects

1. WHO IS CONDUCTING THIS RESEARCH STUDY?

Principal Investigator: Anat Ben-Shlomo, MD, 310-423-7900

After hours contact: Anat Ben-Shlomo, MD, 310-423-7900

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are interested in collecting blood samples to examine the blood of healthy individuals after an injection of dexamethasone. Dexamethasone is a steroid that is very similar to cortisol, which is a hormone that is naturally released in response to stress. We have already tested the blood of mice and discovered specific genes that are related to the release of cortisol, and we would like to see if these genes can be found in humans too.

You are a "healthy subject" research participant. A "healthy subject" means that you do not have the condition or disease that is being studied.

Being asked to be part of a genetic study does not necessarily mean that you or other family members have a particular disorder or an inherited risk for a disorder.

3. HOW MANY PEOPLE WILL PARTICIPATE?

About 20 people will take part in this study at CSMC.

4. HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for up to two hours, of which one hour is the length of time to complete the procedures in this study. Please see the section "What Study Procedures Are Involved?" for additional information.

5. WHAT STUDY PROCEDURES ARE INVOLVED?

This section provides a summary of the procedures if you take part in this research study.

Access to a vein in your arm will be established prior to performing the test. The dexamethasone will be delivered into and blood will be drawn from this vein. Approximately 12 mL (2.5 teaspoons) of blood will be drawn before the dexamethasone is injected and then every 15 minutes over the course of 1 hour. A total of 60 mL (about 12.5 teaspoons) will be drawn during the study.

The samples taken from you will be collected solely for research purposes. This sample would otherwise not be taken if you did not participate in this research study.

6. WHAT WILL MY SAMPLE BE USED FOR?

DNA and RNA are the substances in our cells inherited from our parents. They contain "genes" which can predict physical traits (e.g., eye and hair color, height, etc.). They also direct the body to produce certain proteins and hormones used in normal functioning. We will isolate DNA and/or RNA from your sample and test it to see if we can find the gene(s) that are involved in the production of the hormone cortisol.

Genes can also have a role in a person's risk for certain illnesses or disorders. We are not analyzing your genes to detect any illness or disorder.

Specimens collected for this study may be valuable for scientific, research, teaching purposes, or developing a new medical product. By agreeing to participate in this research, you are donating the specimens to CSMC and authorizing CSMC and members of its staff to use your specimens for these purposes. After they are donated, CSMC or its designee will have exclusive rights to these specimens including any products, tests, discoveries, benefit or other interest coming from the specimens.

CSMC may keep these research samples indefinitely or until the samples are all gone. These samples are not available for clinical (diagnostic) purposes. Therefore, if you wish to have any diagnostic testing done in the future, as a result of this or other research, it must be performed using a new sample.

7. WILL I RECEIVE INFORMATION ABOUT MY SAMPLES?

The research tests done in this study are performed in a research only lab (not a certified clinical lab) where the results are intended for research purposes only. Therefore, we will not inform you of the test results obtained from this study or include them in your Cedars-Sinai medical record.

Unanticipated Incidental Findings

If, unexpectedly, we find that results of your research procedures could suggest important medical information and we determine there is something you or your doctors can do in response to this finding, we will contact you using the last contact information provided by you. If necessary, we may recommend additional clinical testing to confirm the research finding. The cost of any additional testing and any related treatment will be your responsibility.

8. WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

Risks of Dexamethasone may include the following, some may be serious

- Fatigue
- Nausea
- Vomiting
- Fever
- Abdominal pain
- Increased appetite
- Rash
- Dizziness
- Trouble breathing
- Mental/mood swings
- Unusual hair/skin growth
- Muscle pain/cramps
- Easy bruising/bleeding
- Insomnia
- Bone/joint pain
- Vision problems
- Higher blood pressure, retaining water, changes in salt or potassium levels in your body

- Allergic reactions, such as itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Intravenous (IV) lines:
You will receive the study drug and have blood drawn through an intravenous (IV) line. An IV line is a small tube that is attached to a catheter and inserted by needle into a vein usually in your hand or arm. Qualified medical professionals will place IV lines for use in this study.

IV lines are usually safe and well tolerated and complications are rare, but can include phlebitis (swelling of the vein) and infection. The IV may come out accidentally or blood may leak around the line. If the IV is not in the vein, medication or fluid can enter the surrounding soft tissues, and can be associated with swelling, discomfort, bruising and irritation. Rarely, a clot can develop in the IV line itself. If this happens, the staff may remove the old IV line and start a new IV line. There is also a small risk of feeling lightheaded and fainting.

Blood Draw
Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting.

Genetic Studies
Genetic studies have raised concern as to whether the studies would place research subjects at risk for discrimination based on genetics. The federal Genetic Information Nondiscrimination Act (GINA) was passed to address this concern. GINA makes it illegal for medical insurance companies and most employers to discriminate based on genetic information. The protections of GINA do not apply to life, disability, or long-term-care insurance. Although there are substantial protections against the risk of discrimination, you should be aware of this general concern.

We try to protect all research subjects from placing them in a position where sensitive information could be disclosed that could lead to discrimination or the misuse of their information. This consent describes how your identifiable information will be protected under "How Will My Private Information Be Kept Confidential?" In addition, information for this genetic research study is kept separate from the hospital medical records and will not be put in the official Cedars-Sinai medical record by research staff.

Reproductive and Lactation Risks

Taking part in this research study can affect an unborn baby. Therefore, you should not participate in this study if you believe you may be pregnant.

Women should not breastfeed a baby while on this study.

The following paragraph is required if the research involves women of child-bearing potential and the safety profile of the study drug or device, or study procedure, (such as, radiation, etc.) in pregnancy is unknown.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant during participation in this research, the study drug might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

Unknown Risks
In addition to the risks described above, there may be other discomforts or risks to you which are presently not foreseeable. Many side effects may go away shortly after the study medication or procedure is stopped. However, in some cases they can be serious or long-lasting.

9. WHY WOULD MY PARTICIPATION BE STOPPED?

The investigator may decide to take you off this research study, even if you would like to continue. Some common examples of why investigators might take research participants off research include the following: funding for the research is stopped; the whole study is stopped or modified at CSMC or at all sites for any reason; or the research participant is unable to comply with the protocol procedures.

You may decide to stop the procedures described in the section "What Study Procedures Are Involved?" at any time. You may also request that the researchers stop using your samples if all of the following conditions are met at the time of your request: (1) your samples haven't been used up; and (2) they can still be linked to you (e.g., the researchers haven't removed identifying information from the samples). Otherwise, you will not be able to withdraw your sample, since it will no longer be identifiable.

10. ARE THERE DIRECT BENEFITS IN TAKING PART IN THE STUDY?

You should not expect to benefit from taking part in this research study.

11. HOW CAN MY PARTICIPATION BENEFIT OTHERS?

While no benefit is ever guaranteed, we hope the information learned from this research study will benefit individuals in the future by helping us to learn which genes are associated with cortisol production.

12. ARE THERE ANY OTHER OPTIONS?

You may choose to not participate in this study. Your medical care will not be changed in any way as a result of this decision.

13. HOW WILL MY PRIVATE INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

You will be asked to sign a separate "Authorization Form" that outlines who your information may be shared with for the purposes of this research and under what circumstances.

14. WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and your insurance company will not be charged for your participation in this research study.

15. WILL I BE PAID?

You will receive a $25 gift card to Target for your participation.

16. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once, if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research related illness or injury?
A research-related injury or illness is a direct result of the Study Drug or a procedure performed only as a part of the study and is not part of your standard clinical medical treatment. Injury or illness related to or caused by non-research-related activities (such as treatment provided outside of this study) would not be considered research-related. If you are being treated for a research-related injury or illness, you will not pay for the costs of your appropriate medical care provided at CSMC or in any emergency room. Cedars-Sinai may, however, ask for reimbursement where allowed from parties such as your health plan. If you choose to obtain non-emergency care elsewhere, you or your health plan may be responsible for the costs of that care. CSMC has no plans to pay for losses such as lost wages or pain or suffering. You do not waive any of your legal rights by signing this form.

17. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions or concerns about this research, please contact the Principal Investigator or one of the co-investigators listed under "Who is conducting this research study?" on the first page of this consent form.

If you have questions regarding your rights, concerns, or complaints about taking part in this study, please contact:

CSMC Institutional Review Board (IRB)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The CSMC IRB has been established to review, approve, and monitor all human research at CSMC with the purpose of minimizing risks and protecting the rights and welfare of research participants.

18. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have carefully read and understood the information presented in this informed consent form;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) For research where you will receive treatment or diagnostic intervention, you agree that your right to access copies of health information created during your participation in your research will be suspended while the research study is in progress; your right to access this information will be restored upon completion of the entire study;
(7) You understand that by consenting to participate in the research, you are not giving up any of your legal rights; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

If you have any additional questions during the course of your involvement in the research, please contact the investigator(s) and/or the IRB Office at any time.

We will give you a copy of this signed and dated consent form and a signed copy of the Experimental Subject's Bill of Rights.

SIGNATURE BY THE SUBJECT:

Name of Subject (Print)	**Signature of Subject**	**Date of Signature**

SIGNATURE BY THE INVESTIGATOR:

I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge. The subject has been provided with the Experimental Subject's Bill of Rights.

Printed Name of Investigator

Signature of the Investigator Who Obtained Consent	**Date of Signature**

SIGNATURE BY THE INTERPRETER/WITNESS

(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Name of Witness (Print)	Signature	Date Signed

CEDARS-SINAI MEDICAL CENTER

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Signature of Experimental Subject **Date**

Distribution instruction for investigators:

The signed (i) Consent form, (ii) Authorization for Use and Disclosure of Identifiable Health Information and (iii) "Experimental Subject's Bill of Rights" (the latter required if the research study involves medical interventions)* should be distributed to:

1) Subject
2) Principal Investigator's research records (original)