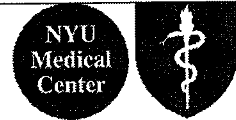
Institutional Review Board
NYU School of Medicine

Veteran's Administration Hospital
Physical Address: 423 East 23rd Street | 10th Floor, West Wing | NY, NY 10010
Mailing Address: 550 1st Avenue | #VET 10th Floor, West Wing | NY, NY 10016



Continuation/Annual Report: Approved

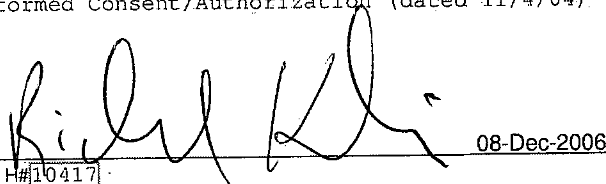
08-Dec-2006

Mapping Genes For Sex Determination

Principal Investigator	Dr. Ostrer, Harry	Review Type	Full () | Continuation/Annual Report
		Submitted	12-Oct-2006
Phone		Email	
IRB#	10417	Perf. Period	21-Nov-2006 - 20-Nov-2007
Location(s) Used	Bellevue Hospital		
Review Date	21-Nov-2006	Board/Meeting	Board B on 21-Nov-2006
Sponsor	NIH~	Subjects	50.00 (total) 50.00 (approved)

The New York University School of Medicine's Institutional Review Board (IRB) is in receipt of your latest submission for the above-referenced study. The submission was reviewed by the IRB on 21-Nov-2006 and the current IRB Status is: Approved.

Protocol (dated 6/9/03)
Informed Consent/Authorization (dated 11/4/04)



08-Dec-2006

RE: H#10417
Elan Czeisler
Director, Institutional Review Board (IRB)
OHRP #FWA00004952

Notes:

1. **You must submit all changes to this study (e.g., *protocol, recruitment materials, consent forms*, etc.) in writing to the IRB for review and approval prior to initiation of the change(s)**, except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. You must report all adverse and/or unanticipated event(s) that occur during the course of this study to IRB in writing in accordance with IRB Policy.
3. Use only IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. **Do not use expired consent forms.**
4. You must inform all research staff listed on this study of changes or adverse events which occur.
5. IRB's approval is valid until the end date of the performance period indicated above. A reminder for renewal should be e-mailed to you from the IRB 90, 60 and 30 days before this study's approval is scheduled to expire. However, you are responsible for submitting all renewal materials **at least eight weeks before expiration** regardless of whether or not you receive a reminder notice.
6. All IRB policy documents can be found on our website: http://www.med.nyu.edu/irb/
7. Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:
   - **NYU Hospital Center** (Tisch Hospital/Rusk Institute/Co-op Care) Irene Kreusher, VP, Tisch Hospital Administration. 212-263-2020
   - **Bellevue Hospital** Mr. Anand Veereraj, Research Administrator, Bellevue Hospital Research Committee. 212-562-4176; Ms. Setira Simmons, Research Administrator, Bellevue Hospital Research Committee. 212-562-7075
   - **GCRC** (General Clinical Research Center) Hal Rosenblatt, Research Grants Coordinator. 212-263-7900; 212-263-8040
   - **VA Medical Center** Administrator, R&D, Sub-committee for Human Studies. 212-686-7500 x7474
   - **HJD** (Hospital for Joint Diseases) Dr. Paul Gusmorino, Liaison Coordinator, Institutional Board of Research Associates. 212-598-6368

Office of Institutional Board of Research Associates
NYU School of Medicine
550 First Ave. Building #VET
10 West
NY, NY 10016
Phone: 212.263.4110
Fax: 212.263.4147

Principal Investigator: Harry Ostrer, M.D.

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH:

Mapping Genes for Sex Determination

A. PURPOSE OF THE STUDY:

You are being asked to volunteer in a research study. This consent/authorization form includes information about this study. The purpose of this study is to understand why some people are born with reproductive organs that do not develop as they should and may lose their normal function. These studies will help us to understand how our bodies control the development of our reproductive organs.

B. SUBJECT PARTICIPATION:

We estimate that the following number of subjects will enroll in this study:
At this site: 50 Total at all sites: 50

SUBJECT PARTICIPATION:
☒ Inpatient
☒ Outpatient
☐ other [healthy subjects, etc.] Please specify:

Your participation will involve 1 number of visits, which will take place over 1 day.

Each of these visits will take the following amount of time: 15 minutes

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This Consent Document is approved for use by the New York University's Institutional Review Board (IRB).
Only the IBRA-stamped approved form may be used.

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C. DESCRIPTION OF THE RESEARCH:

Procedures:
Review of your medical records.
Collection of tissue not required for diagnosis.
Blood Donation of approx. 7 cc. (equivalent to approx. 1 ½ tsp), Frequency of withdrawal: single.
Total Amount: approx. 1 ½ tsp

You are eligible to participate in this study because your reproductive organs (testes, ovaries) did not develop as expected. A blood sample will be taken. If you have an operation to biopsy or repair your reproductive organs, some tissue will be required for making the correct diagnosis, but, with your consent, the excess tissue could be used for research purposes. Information about your condition, including your age, family's place of origin, and history of relatives affected with reproductive conditions, will be obtained at the time that you enroll. Study staff will gather this information from review of your medical records and possibly one or more telephone calls to you.

The study will involve analysis of genetic markers (DNA, RNA, protein) from your blood and tissue that may have caused your condition. Your genetic makers and those from other people with reproductive conditions will be compared to the genetic markers from people unaffected by reproductive conditions. If a difference is found in your genetic markers, the results will be provided to your doctor.

D. COSTS/REIMBURSEMENTS:

All study-related costs associated with your being in this study will be paid by the sponsor, National Institutes of Health. You or your insurance company will not be charged or held responsible for the costs of your routine care (the care you would have received if you were not in this study).

If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

This study is being sponsored by a grant from the National Institutes of Health. Portions of the research team's salaries are being paid by this grant.

E. POTENTIAL RISKS AND DISCOMFORTS:

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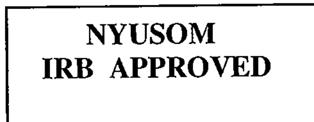

The following risks or discomforts may be occurring by being in this research study. Donating blood may occasionally include, pain, bruising, fainting or a small infection at the puncture site. If you are scheduled for surgery, the blood sample will be taken at the same time other blood samples are taken in preparation for your surgery. The risks associated with your operation will be discussed with you by your surgeon and are not affected by your participation in this study. Procedures to guarantee confidentiality are discussed below.
Among the risks that have been associated with genetic testing are learning about susceptibility to other diseases and possible unfair discrimination in employment and insurance.

F. POTENTIAL BENEFITS:

There is no direct benefit to you expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY

This is not a treatment protocol. You may choose not to participate in this study or to withdraw at any time without jeopardy to your care.

H. CONFIDENTIALITY:

If you consent to participate in this research, your personal information will be kept confidential and will not be reported to third parties without your consent. The sponsor of the study and NYUSM staff working under the direction of the IBRA may inspect records related this study, and will learn about your participation from this signed consent form. If you are having surgery, you will be asked to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of your treatment facility. The medical record is maintained by your treating physician or hospital, as applicable, and will be subject to New York State and federal laws and regulations concerning confidentiality of medical records.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive information about your participation during the course of this study. Except when required by law, study information shared with persons and organizations outside of New York University School of Medicine (NYUSM) will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

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When your study information will be disclosed outside of NYUSM as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. NYUSM will not disclose the code key, except as required by law.

Confidentiality of Your Medical Records
Your medical records will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. If your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The confidentiality of your medical record is also protected by federal privacy regulations, as described below.

Confidentiality of Your Study Information
Your study records include information that identifies you as a participant and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. If data from this study are to be published or presented, we will first take out the information that identifies you.

Retention of Your Study Information
The study results will be kept in your research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at NYU. Any research information in your medical record will be kept indefinitely.

Your HIPAA Authorization
A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, in most cases we must seek your written permission to use or disclose identifiable health information about you that we use or create [your "protected health information"] in connection with research involving your treatment or medical records. This permission is called an Authorization.

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not be in the research program, but refusing to sign will not affect your health care (or payment for your health care) outside the study.

 Subject's Initials: ______________ Date: ______________

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This Authorization will not expire unless you withdraw it in writing. You have the right to withdraw your authorization at any time, except to the extent that NYU has already relied upon it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K.

By signing this form you authorize the use and disclosure of the following information for this research:

- Your medical records
- Your research record
- Results of laboratory tests
- Clinical and research observations made during your participation in the research.

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research:

- Every health care provider who provides services to you in connection with this study
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- The following research sponsors and the people and companies they use to oversee, administer, or conduct the research: NIH
- The United States research regulatory agencies and other foreign regulatory agencies
- The members and staff of the hospital's affiliated Institutional Review Board
- The members and staff of the hospital's affiliated Privacy Board
- Principal Investigator: Harry Ostrer, M.D.
- Study Coordinator
- Members of the Research Team
- Members of the NYU/NYUMC Clinical Trials Office/Office of Research and Sponsored Programs
- Data Safety Monitoring Board/Clinical Events Committee

If any of the companies or institutions listed above merges or is sold during the course of this research, your Authorization will cover uses and disclosures of your protected health information to the new company or institution that assumes responsibility for the research.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:

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All forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study.

If you sustain any injury during the course of the research or experience any side effect to a study drug or procedure, please contact the Principal Investigator, Harry Ostrer, M.D., at the following telephone number 212 263-7596. If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. You do not give up any rights to seek payment for personal injury by signing this form.

J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:

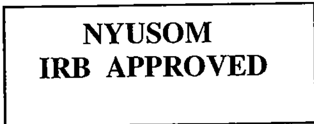
Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your Authorization for us to use or disclose your protected health information for the study. If you do decide to withdraw your consent, we ask that you contact Dr. Harry Ostrer in writing and let him know that you are withdrawing from the study. His mailing address is NYU School of Medicine, 550 First Avenue, MSB136, New York, NY 10016. If you wish to withdraw your Authorization as well as your consent to be in the study, you must contact Dr. Ostrer in writing. Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.



The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study.

The study doctor may also decide to withdraw you from the study for certain reasons. Some possible reasons for withdrawing a subject from the study would be inadequate tissue sample that precludes carrying out the analyses proposed.

It will not be possible for you to withdraw your tissue or DNA samples from this study, because it will no longer be possible to identify their being yours.

L. CONTACT PERSON(S):

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-263-4110.

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Harry Ostrer, M.D. at the following telephone number 212 263-7596.

AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

☐ I have read this consent form
or
☐ it was read to me by: ______________________.

Any questions I had were answered by: ______________________.

I ☐ am ☐ am not participating in another research project at this time.
(If yes, you should discuss this with your study doctor.)

I voluntarily agree to participate in this research program at:

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☐ NYUSM [Skirball Institute; Nelson Institute of Environmental Medicine; Post Graduate Medical School]

☐ The NYU Hospitals Center (Tisch Hospital; the Rusk Institute of Rehabilitation Medicine);

☐ Bellevue Hospital Center: this form and your study information will be available to Bellevue Hospital administration and their auditors.

☐ Hospital for Joint Diseases Orthopedic Institute;

☐ NYU College of Dentistry;

☐ The New York Campus of the Veteran's Affairs New York Harbor Healthcare System.

☐ Other, please specify:

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form.

☐ I agree to receive results of genetic testing information, OR

☐ I do NOT agree to receive results of genetic testing information.

By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures of my protected health information as described above.

WHEN THE SUBJECT IS AN ADULT:

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

 Subject's Initials: ______________ Date: ______________

* For subjects who may not be capable of providing informed consent, the signature of a legal representative is required. For a valid HIPAA authorization, the "personal representative" must have authority under state law to make health care decisions for the subject.

_______________________	_______________________/______
Print Name of Participant or Legal Representative*	Signature of Participant or Legal Representative* Date

_______________________	_______________________/______
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent Date

 Subject's Initials: ______________ Date: ______________

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