IRB Approval Number 2002-2608

University of California
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):
Mitochondrial Inborn Errors of Metabolism and ANT Defects in Mitochondrial Diseases; A Master Protocol
Sponsor/Funding Agency (if funded):
NIH

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information to the research team unless you give your permission. The research team includes the researchers and people hired by the University or the sponsor to do the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that the researcher, research team and research sponsor may use your health information for the research study. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing _____ *[insert UC campus or name of health care provider(s) releasing medical records]* to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

☐ Entire Medical Record	☐ Laboratory Reports	☐ Emergency Medicine Center Reports
☐ Health Care Billing Statements	☐ Dental Records	☐ History & Physical Exams
☐ Pathology Reports	☐ Operative Reports	☐ Diagnostic Imaging Reports
☐ EKG	☐ Radiology Reports	☐ Consultations
☐ Progress Notes	☐ Radiologic & MR Scans	☐ Outpatient Clinic Records
	☐ Discharge Summary	☐ Psychological Tests

☑ Other (describe)
NOT A UCI PATIENT-

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
____ I agree to the release of HIV/AIDS testing information.
____ I agree to the release of genetic testing information.
____ I agree to the release of information pertaining to mental health diagnosis or treatment as follows:
_____.

D. How will my Personal Health Information be used?

Your Personal Health Information may be released to these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC who are required by law to review the research;
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration, the research sponsor or the sponsor's representatives, or government agencies in other countries. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

E. How will my Personal Health Information be used in a research report?

If you agree to be in this study, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will **not** include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care, and a tracking code. The research report will also include information the research team collects for the study. The research team and the research sponsor may use the research report and share it with others in the following ways:

1. To perform more research;
2. Share it with researchers in the U.S. or other countries;
3. Place it into research databases;
4. Use it to improve the design of future studies;
5. Use it to publish articles or for presentations to other researchers;
6. Share it with business partners of the sponsor; or
7. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over. Research reports can be used forever.

G. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

H. Signatures

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)--*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative (where IRB approved)

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____

Parent or Legally Authorized Representative's Name (print) Relationship to the Subject

_____ _____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is read to the subject in English, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date

AUTHORIZATION TO OBTAIN HEALTH INFORMATION
From
Outside Health Care Providers

Patient Name: _____ **Medical Record Number** _____

Date of Birth: _____

I the undersigned hereby authorize:

_____
Name of physician or facility to release health information

_____
Physician or Facility Street address

_____
City, State **Zip Code**

_____
Telephone **Fax Number**

To be released to:

- ☐ UCI Family Health Center - Anaheim 300 W. Carl Karcher Way, Anaheim, CA 92801
- ☐ UCI Gottschalk Medical Plaza - UCI Irvine, Irvine, CA 92697
- ☐ UCI Manchester Pavilion - Orange 200 South Manchester Ave., Orange, CA 92868
- ☐ UCI Medical Pavilions - Orange 101 The City Drive South, Orange, CA 92868
- ☐ UCI Family Health Center - Santa Ana 800 N. Main Street, Santa Ana, CA 92701
- ☐ UCI Westminster Medical Center - 15355 Brookhurst St., Westminster, CA 92638
- ☑ UCI Mitomed

UCIMC Unit and /or Clinic requesting Health Information

Information to be RELEASED

☐ Discharge Summary	☐ Laboratory Reports	☐ Emergency Medicine Reports
☐ Billing Statements	☐ Dental Records	☐ History & Physical Exams
☐ Pathology Reports	☐ Operative Reports	☐ Diagnostic Imaging Reports
☐ EKG	☐ Radiology Reports	☐ Consultations
☐ Progress Notes		☐ Outpatient Clinic Records
☐ Vaccinations/Immunizations		
☐ Other _____		

SPECIFY THE DATE OR TIME PERIOD FOR INFORMATION SELECTED ABOVE

_____

SPECIFIC AUTHORIZATIONS

The following information will not be released unless you specifically authorize it by marking the relevant box (es) below:

- ☐ I specifically authorize the release of information pertaining to drug and alcohol abuse diagnosis or treatment (42 C.F.R. §§2.34 and 2.35).
- ☐ I specifically authorize the release of information pertaining to mental health diagnosis or treatment (Welfare and Institutions Code §§5328, *et seq.)*
- ☐ I specifically authorize the release of HIV/AIDS testing information (Health and Safety Code §120980(g)).
- ☐ I specifically authorize the release of genetic testing information (Health and safety Code §124980(j)).

83500 (Rev 09/04)

AUTHORIZATION TO OBTAIN HEALTH INFORMATION
From
Outside Health Care Providers

THE PURPOSE OF THIS RELEASE IS (check one or more)

- ☐ Continuity of care or discharge planning
- ☐ Billing and payment of bill
- ☐ At the request of the patient/patient representative
- ☐ Other (state reason) PARTICIPATION IN RESEARCH

NOTICE

UCIMC and many other organizations and individuals such as physicians, hospitals and health plans are required by law to keep your health information confidential. If you have authorized the disclosure of your health information to someone who is not legally required to keep it confidential, it may no longer be protected by state or federal confidentiality laws.

MY RIGHTS

- I understand this authorization is voluntary. Treatment, payment enrollment or eligibility for benefits may not be conditioned on signing this authorization except if the authorization is for: 1) conducting research-related treatment, 2) to obtain information in connection with eligibility or enrollment in a health plan of which, 3) to determine an entity's obligation to pay a claim, or 4) to create health information to provide to a third party. Under no circumstances, however, am I required to authorize the release of mental health records.

- I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization, I must do so in writing and present my written revocation to the Health Care provider listed above. I understand that the revocation will not apply to information that has already been released in response to this authorization.

- I am entitled to receive a copy of this Authorization.

SIGNATURE

_____ Date: _____

(Signature of Patient or Patient's Legal Representative)

_____ Time: _____ AM/PM

Printed Name

_____

(If signed by someone other than the patient, state your legal Relationship to the patient/authority

_____

Witness or Translator