Endocrinology Requisition Form

The University of Chicago Genetic Services Laboratories
5841 South Maryland Avenue, Room G701/MC0077, Chicago, IL 60637
Toll Free: 888.824.3637 | Local: 773.834.0555 | Fax: 773.702.9130
ucgslabs@genetics.uchicago.edu | dnatesting.uchicago.edu | CLIA#: 14D0917593 | CAP#: 18827-49

Patient and Sample Information

Name: *Last* _____ *First* _____ **Date of Birth (mm/dd/yyyy):** _____

Gender: ☐ Male ☐ Female **MRN:** _____

Ethnicity: ☐ Caucasian ☐ African-American ☐ Hispanic ☐ Asian ☐ Ashkenazi Jewish ☐ Other _____

Date Sample Drawn: _____ **Specimen Type:**

☐ Peripheral Blood (3-10 cc in EDTA (purple) top tube ☐ DNA (DNA samples are only accepted if the DNA extraction or isolation was performed at a CLIA-certified laboratory.)

Ordering Physician Information

REPORTING RESULTS: Reports will only be faxed out. Please check the boxes below for those who should receive by fax.

☐ **Referring Physician:** _____

Phone: _____ Fax: _____

Email: _____

☐ **Genetic Counselor:** _____

Phone: _____ Fax: _____

Email: _____

☐ **Referring Lab:** _____

Phone: _____ Fax: _____

Email: _____

Indication for Testing - REQUIRED

ICD-10: _____

☐ **Asymptomatic**

☐ **Symptomatic (please describe):** _____ Age of onset: _____

Clinical findings for patients with Diabetes (please check all that apply):

☐ Hyperglycemia ☐ On Insulin therapy Responsive to sulfonylureas? ☐ YES ☐ NO ☐ UNKNOWN

Clinical findings for patients with Hyperinsulinism (please check all that apply):

☐ Hypoglycemia ☐ Elevated plasma insulin concentration Diazoxide Responsive? ☐ YES ☐ NO ☐ UNKNOWN

Results of F-Dopa PET (if available):_____

☐ **Related family history (please specify):**_____ ☐ **No family history**

Parental Samples (Hyperinsulinism panels only)

Parental samples are highly recommended for interpretation of proband results. Send 3-10ccc in EDTA. Please label parental sample with full name and DOB. There is no charge if parental testing, if performed.

MOTHER **Date Sample Drawn:** _____ ☐ Not Available ☐ To be sent later

Name: *Last* _____ *First* _____ **Date of Birth:** _____ **MRN:** _____

☐ **Asymptomatic** ☐ **Symptomatic (hyperinsulinism) – please specify** _____ ☐ **Unknown**

FATHER **Date Sample Drawn:** _____ ☐ Not Available ☐ To be sent later

Name: *Last* _____ *First* _____ **Date of Birth:** _____ **MRN:** _____

☐ **Asymptomatic** ☐ **Symptomatic (hyperinsulinism) – please specify** _____ ☐ **Unknown**

Ordering Checklist

☐ Test Requisition Form *(required)*
☐ Completed Indication for Testing/ICD-10 study code *(required)*
☐ Completed Billing Information *(required)*
☐ Completed Research Consent Form *(recommended)*

Note: All samples should be shipped via overnight delivery at room temperature to the address at the top of this page. No weekend or holiday deliveries. Label each specimen with the patient's name, date of birth and date

For Office Use Only

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Congenital Hyperinsulinism testing

- ☐ Tier 1 Panel: Diazoxide Unresponsive Hyperinsulinism Panel (KCNJ11, ABCC8, GCK sequencing, ABCC8 deletion/duplication; turnaround time 7 days)
- ☐ Comprehensive Congenital Hyperinsulinism Panel
- ☐ Congenital Hyperinsulinism Sequencing Panel
- ☐ Congenital Hyperinsulinism Deletion/Duplication Panel

Comprehensive Monogenic Diabetes testing

- ☐ Neonatal Diabetes / MODY Sequencing Panel

Disorders of Sex Development (DSD) testing

- ☐ Abnormal/Ambiguous Genitalia Sequencing Panel
- ☐ Hypogonadotropic Hypogonadism Sequencing Panel
- ☐ Hypogonadotropic Hypogonadism Deletion/Duplication Panel
- ☐ Kallmann Syndrome Sequencing Panel
- ☐ Kallmann Syndrome Deletion/Duplication Panel
- ☐ Hypospadias Sequencing Panel
- ☐ 46,XX Disorder of Sex Development/Complete Gonadal Dysgenesis Sequencing Panel
- ☐ 46,XX Disorder of Sex Development/Complete Gonadal Dysgenesis Deletion/Duplication Panel
- ☐ 46,XY Disorder of Sex Development/Complete Gonadal Dysgenesis Sequencing Panel
- ☐ 46,XY Disorder of Sex Development/Complete Gonadal Dysgenesis Deletion/Duplication Panel

Dyslipidemia testing

- ☐ Dyslipidemia Sequencing Panel
- ☐ Dyslipidemia Deletion/Duplication Panel
- ☐ Hypercholesterolemia Sequencing Panel
- ☐ Hypercholesterolemia Deletion/Duplication Panel

Maturity-Onset Diabetes of the Young (MODY) testing

- ☐ MODY Panel
- ☐ Neonatal Diabetes / MODY Sequencing Panel
- ☐ Neonatal Diabetes / MODY Deletion/Duplication Panel
- ☐ *GCK* (MODY2) Sequencing ☐ *GCK* (MODY2) Del/Dup

Neonatal Diabetes testing

- ☐ Comprehensive Neonatal Diabetes Mutation Analysis
- ☐ 6q24 Methylation-Specific MLPA
- ☐ Neonatal Diabetes Sequencing Panel
- ☐ Neonatal Diabetes Deletion/Duplication Panel
- ☐ *KCNJ11* Sequencing
- ☐ UPD6 (requires sample from both parents also)

Lipodystrophy testing

- ☐ Comprehensive Lipodystrophy Sequencing Panel
- ☐ Comprehensive Lipodystrophy Deletion/Duplication Panel
- ☐ Congenital Generalized Lipodystrophy Sequencing Panel
- ☐ Congenital Generalized Lipodystrophy Deletion/Duplication Panel
- ☐ Partial Lipodystrophy Sequencing Panel
- ☐ Partial Lipodystrophy Deletion/Duplication Panel

MCT8 (Allan-Herndon-Dudley syndrome) testing

- ☐ Tier 1 (*SLC16A2 (MCT8)* Thyroid panel) followed by Tier 2 (*SLC16A2* (*MCT8)* sequencing) if Tier 1 abnormal.

**3-10cc blood in an EDTA tube and 3-10cc blood in a red top tube required.

Monogenic Obesity testing

- ☐ Monogenic Obesity Sequencing Panel
- ☐ Monogenic Obesity Deletion/Duplication Panel
- ☐ Non-Syndromic Monogenic Obesity Sequencing Panel
- ☐ Non-Syndromic Monogenic Obesity Deletion/Duplication Panel
- ☐ Bardet Biedl Sequencing Panel
- ☐ Bardet Biedl Deletion/Duplication Panel

Pancreatic Agenesis testing

- ☐ *PDX1* Sequencing ☐ *PDX1* Del/Dup
- ☐ *GATA6* Sequencing ☐ *GATA6* Del/Dup
- ☐ *PTF1A* Sequencing ☐ *PTF1A* Del/Dup

Premature Ovarian Failure testing

- ☐ Premature Ovarian Failure Sequencing Panel
- ☐ Premature Ovarian Failure Deletion/Duplication Panel

Rickets testing

- ☐ Hypophosphatemic Rickets Sequencing Panel
- ☐ Hypophosphatemic Rickets Deletion/Duplication Panel

Thyroid Disorders testing

- ☐ Congenital Hypothyroidism Sequencing Panel
- ☐ Congenital Hypothyroidism Deletion/Duplication Panel
- ☐ Hyperparathyroidism Sequencing Panel
- ☐ Hyperparathyroidism Deletion/Duplication Panel
- ☐ Hypoparathyroidism Sequencing panel
- ☐ Hypoparathyroidism Deletion/Duplication Panel

Other testing (Rare Syndromic Forms of Monogenic Diabetes)

Alström syndrome
☐ *ALMS1* Sequencing ☐ *ALMS1* Del/Dup

Fanconi-Bickel syndrome
☐ *SLC2A2* Sequencing ☐ *SLC2A2* Del/Dup

Hypoinsulinemic Hypoglycemia with Hemihypertrophy
☐ *AKT2* Sequencing ☐ *AKT2* Del/Dup

IPEX syndrome (Immune dysregulation, polyendocrinopathy, enteropathy, X-linked)
☐ *FOXP3* Sequencing ☐ *FOXP3* Del/Dup

Congenital malabsorptive diarrhea
☐ *NEUROG3* Sequencing ☐ *NEUROG3* Del/Dup

Mitchell-Riley syndrome
☐ *RFX6* Sequencing ☐ *RFX6* Del/Dup

Neonatal diabetes with Congenital Hypothyroidism
☐ *GLIS3* Sequencing ☐ *GLIS3* Del/Dup

Pigmented Hypertrichotic Dermatosis with Insulin-Dependent Diabetes Mellitus (PHID)
☐ *SLC29A3* Sequencing ☐ *SLC29A3* Del/Dup

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Thiamine Responsive Megaloblastic Anemia (TRMA)

☐ *SLC19A2* Sequencing ☐ *SLC19A2* Del/Dup

Type A Insulin Resistant Diabetes with Acanthosis Nigricans

☐ *INSR* Sequencing ☐ *INSR* Del/Dup

Wolcott-Rallison syndrome

☐ *EIF2AK3* Sequencing ☐ *EIF2AK3* Del/Dup

Wolfram syndrome

☐ Wolfram Syndrome Sequencing Panel

☐ Wolfram Syndrome Deletion/Duplication Panel

Woodhouse-Sakati syndrome

☐ *DCAF17* Sequencing ☐ *DCAF17* Del/Dup

Targeted Mutation Analysis

(Testing for a previously detected mutation or sequence change)

Requires prior approval by UCGS Lab Staff if this is a gene for which we do not offer full sequencing.

Gene: _____

Change: _____

Name of Proband / U of C lab number: _____

Relationship to proband: _____

Single Gene Sequence Analysis

Any gene included in one of our sequencing panels can also be ordered individually. Please contact UCGS Lab Staff for prior approval before ordering.

Gene Requested: _____

Single Gene Deletion/Duplication Analysis

Any gene included in one of our deletion/duplication panels can also be ordered individually. Please contact UCGS Lab Staff for prior approval before ordering.

Gene Requested: _____

The UNIVERSITY of CHICAGO
Genetic Services
www.dnatesting.uchicago.edu

BILLING OPTIONS

All samples received with incomplete billing information will delay processing time.
Test cancelled while "in progress" will be billed for the amount of work completed up to that point.
*Please forward all billing questions to: youtlaw@bsd.uchicago.edu or call (**773-834-8220**).*

Patient Name: *Last* _____ *First* _____ (MI): _____ Date of Birth: _____

1.) Institutional Billing *(Pre-payment is required for all samples referred from outside the US or Canada.)*

Billing Institution: _____ PO#: _____

Financial Contact: _____ Phone: _____ Fax: _____

Address: _____ City: _____ State: _____ Zip: _____

Email (required): _____

2.) Self-Pay

We accept all major credit cards. Please call our office (773-834-8220) for credit card processing.

Important notice: *We will not be responsible for refunding any "cost differential" that may occur as a result of a patient seeking any type of reimbursement.*

☐ Wire Transfer (Please include 'Genetics Services Laboratories' and invoice numbers to ensure proper receipt.)
Electronic funding information, as follows: The Northern Trust Bank **– (Physical Address)** 50 S. LaSalle Street, Chicago, IL 60675
ABA/Routing No.: 071000152, International SWIFT Code: CNORUS44, University of Chicago Wire Account No.: 28509

Amount $_____(USD) Date of Transfer: _____ Name of Institution: _____

☐ Check/Money Order **(Make check/money order payable to: *The University of Chicago Genetic Services*)** Amount Enclosed $_____
(Please note: All bank fees for returned checks will be added to the original charge of patient invoice)

3.) Insurance Billing – *please note this option is not available for all tests. Please see our website for more details. Prices listed on our website are not applicable for insurance billing, please contact us for insurance pricing information. We do NOT accept Illinois or any out-of-state Medicaid)* *A legible photocopy of the front and back of the insurance card and insurance authorization must be included.*

ICD-10 Diagnosis Code(s): _____ **(*Must be provided or insurance cannot be filed.*)**

Policyholder Name: _____ Date of Birth: ____/____/_____ Gender: ☐ Male ☐ Female

Policyholder Address: _____ City: _____ State: _____ Zip: _____

Relationship to the Patient: ☐ Self ☐ Spouse ☐ Dependent ☐ Other Preauthorization # (*if applicable*): _____

Name of Primary Insurance: _____ Policy No. _____ Group No.: _____

Insurance Address: _____ City: _____ State: _____ Zip: _____

PCP/Referring Physician Name: _____ NPI #: _____

Name of Secondary Insurance: _____ Policy No.: _____ Group No.: _____

Insurance Address: _____ City: _____ State: _____ Zip: _____

The policy holder's signature to the following statement: I hereby authorize any physician who treated or attended to me or my dependent(s) to furnish any medical information requested. In consideration of services rendered, I hereby transfer and assign to the University of Chicago Genetic Services Laboratories any benefits of insurance I may have. I assume responsibility for the balance of the cost of testing not paid by my insurance company. A photocopy of this authorization shall be considered as effective and valid as original.

Authorized Signature: _____ Date: ____/____/_____

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL FOR THE BETTER UNDERSTANDING OF THEIR GENETIC CONDITION

Protocol Number: 11-0151

Name of Subject :_____

Date of Birth: _____

STUDY TITLE: Molecular Genetic Studies of Rare Orphan Genetic Disease

Research Team: Soma Das, Ph.D.
5841 S. Maryland Ave. Room L-155 MC 0077, Chicago, IL 60637
773-834-0555

You are being asked to allow your child to participate in a research study that may help us learn more about the genetic condition for which you are being tested. This consent form describes the study, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to contact us with questions and feel comfortable making a decision whether to participate or not. If you decide to participate in this study, please sign this form**. Throughout this consent form, "you" will refer to you or your child, as appropriate.**

WHY IS THIS STUDY BEING DONE?

You have already consented to clinical genetic testing. We are asking you to also participate in further studies. The purpose of these studies is to learn more about the genetic cause of diseases tested for in our lab, gather more information about these disorders, and experiment with new methods that may be better for testing.

WHAT IS INVOLVED IN THE STUDY?

During this study, Dr. Das and her team will collect information about you for this research. We may contact your doctor to request additional Protected Health Information (PHI), which consists of any health information related to your diagnosis (such as date of birth, medical record number, primary diagnosis, clinical features, relevant and family history, outcome). The data collected will be used to develop a database of patients being tested for genetic diseases and will be kept for the duration of the database. This study will look at how often different genetic mutations happen and clinical information related to the mutation.

When our lab is researching new genes or testing methods that are related to your diagnosis, we may include your sample, with others from similar patients in a small study before offering this new test. This data will help in directing doctors about the likelihood of a positive or negative test result in their patient. We may also use your sample to set up new methods that will improve the clinical testing in our laboratory. Your clinical information and sample, without any identifiers, may also be shared with other researchers that are interested in this specific condition.

HOW LONG WILL I BE IN THE STUDY?

Once enrolled, you will likely remain in this study as long as your DNA sample remains in our laboratory. If you want your sample, to be removed from the study at any time, please contact us, and the sample will not be used for further studies. Existing results will remain in our database until the study ends.

WHAT ARE THE RISKS OF THE STUDY?

There are no known added risks of the research. No additional information will be obtained from you, as all of the information has already been collected as part of clinical genetic testing or evaluation by your doctor.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to your family. We may identify a cause for the genetic disease in your family. If a mutation is identified in your DNA, through our testing, your referring doctor will be notified and will receive a clinical report. Our study may also be helpful in finding the genetic causes of disease and will benefit doctors and patients as a group.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate.

WHAT ARE THE COSTS?

There will be no additional costs to you or your insurance company resulting from this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?

You and your child will not be paid to participate.

WHAT ABOUT PRIVACY?

Study records that identify you will be kept private. All of your personal information will be entered into a password-protected database to prevent access to non-authorized personnel. If your data is shared with other researchers, all patient identifiers will be removed. Data from this study may be used in medical journals or presentations. If results from this study or related studies are made public in a medical journal, individual patients will not be identified. If we wish to use a patient's identity in a medical journal, we will ask for your permission at that time.

As part of the study, Dr. Das and her team will report any positive results of further testing to your referring doctor and/or genetic counselor. Dr. Das may also share these results, without your name or date of birth, with other researchers.

People from the University of Chicago, including the Institutional Review Board (IRB), a committee that oversees research at the University of Chicago, may also view the records of the research. If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information. Dr. Das does not have to give you any results that are not are not important to your health or your family's health at that time.

This consent form will be kept by the research team for at least six years. The study results will be kept in your child's research record and be used by the research team indefinitely. When the study ends, your personal information will be removed from all results. Any information shared with your doctor may be included in your medical record and kept forever.

The Genetic Information Nondiscrimination Act (GINA) is a federal law that may help protect you from health insurance or employment discrimination based on genetic information. GINA is a federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is optional. You may choose not to participate at any time during the study. Choosing not to participate or leaving the study will not affect your child's testing at the University of Chicago.

If you choose to leave the study and you do not want any of your child's future health information to be used, you must inform Dr. Das in writing at the address on the first page. Dr. Das may still use your child's information that was collected before to your written notice. You will be given a signed copy of this form. This consent form does not have an expiration date.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have further questions about the study, please call 773-834-0555.

If you have any questions about your rights in this research study you may contact the IRB, which protects participants in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: University of Chicago, Institutional Review Board, 5841 S. Maryland Ave., MC7132, I-625, Chicago, IL 60637.

Consent

I have received information about this research project and the procedures. No guarantee has been given about possible results. I will receive a signed copy of this consent form for my records.

I give my permission to participate in the above research project.

Signature of Subject:_____

Date: _____

I give my permission for my child/relative/the person I represent to participate in the above research project.

Signature of Parent / Legal Guardian / Legally Authorized Representative:

_____

Date: _____