Emory University School of Medicine Research Subject HIPAA Authorization to Use or Disclose Health Information that Identifies You for a Research Study

Name of Study: Clinical Research in Genetics (CRIG)  Study Number: 1317-2004

Name of Principal Investigator: Stephen Warren, PhD; David H. Ledbetter, PhD

Subject Name: ____________________________

The privacy of your health information is important to us. In protecting your health information that identifies you, we will follow all requirements of the Health Insurance Portability and Accountability Act ("HIPAA" for short) that apply. This form will let you know how we will use any health information that you give us for this study that identifies you.

Please read this form carefully and if you agree with it, sign it at the end.

Research Study: You are being asked to participate in a research study at Emory University. The purpose of this research is to get a better understanding of the genetic causes of human diseases.

People That Will Use or Disclose Your Health Information that Identifies You and Purpose of Use/Disclosure:

The following people and groups will use and disclose your health information in connection with the study. In this form, all of these people and groups are called the "Information Users":

- The principal investigators, their research staff and people and organizations that they use to help them conduct the Research Study will use and disclose your health information to do this work.

- There are a number of University persons/units, government agencies and other individuals and organizations that may use and disclose your health information to make sure that the Research Study is being conducted correctly and safely, and to monitor and regulate the research or public health issues. These people and organizations include the following: the Emory University Institutional Review Board; the Emory University Clinical Trials Office; the Emory University Office of Research Compliance; research monitors and reviewers; data safety monitoring boards; any government agencies who regulate the research including the Office of Human Subjects Research Protections, and public health agencies.

By signing this document you agree to allow any of these Information Users to use or disclose your health information that identifies you in order to conduct the Research Study, or to monitor or regulate research. In addition, we will comply with any laws that require us to disclose your health information, such as laws that require us to report child
abuse or elder abuse. We also will comply with legal requests, or orders that that require
us to disclose your health information, such as subpoenas or court orders. Finally, we
may share your health information with a public health authority that the law authorizes
to collect or receive such information for the purpose of preventing or controlling disease,
injury or disability and/or conducting public health surveillance, investigations or
interventions.

Description of Health Information that Identifies You that Will be Used or Disclosed

The Information Users may use or disclose the following health information about you: A
copy of your entire genetics clinic medical record will be made and placed in your
research record for use in the study.

Revoking your Authorization:
You do not have to sign this Authorization. In addition, if you sign this Authorization,
later, you may change your mind at any time and revoke (take back) this Authorization. If
you want to revoke this Authorization you must write to: Drs. Stephen Warren and David
Ledbetter.

If you revoke your Authorization, the Researchers will not collect any more health
information that identifies you, but they may use or disclose identifiable information that
you already gave them in order to notify any of the other Information Users that you have
taken back your authorization; to maintain the integrity or reliability of the Research
Study; and to comply with any law that they are required to obey.

Other Items You Should Know:

HIPAA only applies to people or organizations that are health care providers, health care
payers or healthcare clearinghouses. HIPAA may not apply to all Information Users. If
HIPAA doesn’t apply to an Information User, then that User doesn’t have to follow
HIPAA requirements when it uses or discloses your health information.

You do not have to sign this authorization form, but if you do not, you may not
participate in the Research Study or receive research-related treatment. You may still

We will put a copy of your signed informed consent form for the Research Study and
your signed HIPAA Authorization form into any medical record that you may have with
Emory Healthcare facilities. Laboratory and medical procedure results received from
Emory Healthcare facilities may also be placed in any medical record that you have with
Emory Healthcare facilities.

If the Research Study involves medical treatment, then, in order to maintain the integrity
of the research study, you generally will not have access to your personal health
information related to this Research Study until the study is complete. When the study is
complete, then, at your request, you may generally have access to any of your personal
health information related to the research that makes up a part of the medical information
and/or other records that your health care providers use to make decisions about you. If
access to this information is needed before the end of the Research Study for your
treatment, then the information may be provided to your physician.

If your identifying information is removed from your health information, then the
information that remains will not be subject to this authorization or covered by HIPAA,
and it may be used or disclosed to other persons or organizations, and/or for other
purposes.

Expiration Date: The Researchers will add your PHI to a database that they are
compiling for research purposes. There is no date or event after which your authorization
will expire and your PHI will no longer be used for this purpose.

As a study participant, if you any questions regarding the study, you may call Drs.
Warren or Ledbetter, the study's Principal Investigator's at (404) 778-8500. If you have
any questions regarding your rights as a study subject, you may call Dr. Colleen DiLorio,
Chair of the Emory University Institutional Review Board at (404) 712-0720.

A copy of this authorization form will be given to you.

Signature of Study Subject OR Subject's Legal Authorized Representative

Date ___________  Time___________

Printed Name of Study Subject OR Subject's Legally Authorized Representative

If Representative, Relationship to Study Subject: ________________________________

Signature of Person Obtaining Authorization

Date ___________  Time___________