Participant Verbal Informed Consent Form
For Participants in the United States

Sponsor / Study Title:	**Amicus Therapeutics Inc. / "A GLOBAL PROSPECTIVE OBSERVATIONAL STUDY OF WOMEN WITH FABRY DISEASE AND THEIR INFANTS DURING PREGNANCY AND BREASTFEEDING"**
Protocol Number:	**AT1001-037**
Principal Investigator:	**Amy Miller, PharmD**
Telephone:	1-**888-239-0758 (toll free number) (24 hours)**
Address:	**Fabry Pregnancy Registry** **United BioSource Corporation** **200 Pinecrest Plaza** **Morgantown, WV 26505-8065**

INTRODUCTION

Amicus Therapeutics Inc., the study Sponsor, has set up this voluntary observational pregnancy study to collect valuable information on the pregnancies of women with Fabry Disease that were and were not exposed to Galafold during pregnancy, as well as the babies resulting from those pregnancies and any adverse events affecting breastfeeding. The study plans to enroll about 20 participants. Amicus Therapeutics Inc. has contracted and is working with United BioSource (UBC) / Pregnancy Coordinating Center (PCC) to conduct this research study.

You and your baby resulting from your pregnancy are being asked to participate in this research study because you have a diagnosis of Fabry Disease and may or may not have taken Galafold during your pregnancy or during breastfeeding. This form will explain the purpose of this research study and other important information. You need to provide only your verbal consent to enroll in the study; therefore, with your permission we would like to record our consent discussion for the study's files. At the end of the call we will ask if you would like to verbally consent to enroll in the study.

RISKS

This is an observational study. There is no additional medical intervention outside of your normal standard of care that you are receiving at your doctor or other licensed medical practitioner's office. All data that is collected as part of this study is taken from the information that your doctor has documented in your medical notes during your normal doctor's visits, as well as the results of any tests that were performed during these visits.

There are no additional medical risks for you or your baby when you participate in this observational pregnancy study. While every effort will be made to safeguard your personal information, there is a small risk that your and your baby's information may be unintentionally disclosed. For this reason, absolute confidentiality cannot be guaranteed.

BENEFITS

There is no direct benefit for you or your baby for volunteering to be in this study. However, your participation in this study will help Amicus Therapeutics Inc. to determine if there are any effects of Galafold on pregnant women or babies whose mothers were exposed to Galafold during pregnancy or while breastfeeding. The study data will be provided to regulatory agencies so that other women who become pregnant while being treated with Galafold can better understand the effects of Galafold on pregnant women and their babies.

PARTICIPATION

Your participation in this study is strictly voluntary. To participate in the study, you will be asked to do the following:

- Verbally state that you want to participate in the study (also known as verbal informed consent). You need to provide only your verbal consent to enroll in the study; therefore, with your permission we would like to record our consent discussion for the study's files. At the end of the call we will ask if would like to verbally consent to enroll in the study. We will be mailing a copy of this consent to you for your files, if you would like to sign and date it and send it to us you can do so.
- Once the Pregnancy Coordinating Center (PCC) has your verbal informed consent, they will send you a Medical Information Release (MIR) form to sign, date and return. By signing and dating the MIR form, you give permission to the PCC to contact your doctor or other licensed medical practitioner and your baby's doctor or other licensed medical practitioner for medical information.
- Provide information to the PCC at the time of enrollment (at time of verbal consent) and additional information once per trimester during your pregnancy and at the following timepoints:
    - Pre-natal follow up visit at 34 weeks (Obstetric health care provider will be contacted)
    - At the estimated date of delivery, and;
    - When your baby is 3, 6, 9, and 12 months of age.

INFORMATION

During enrollment, the PCC will ask you basic questions about your health and pregnancy, as well as your contact information, including your address and phone number. The PCC will also ask you to identify two secondary contacts. The secondary contacts must be someone outside of your household who are able to contact you in case the PCC is unable to reach you.

You will be contacted by the PCC one time during each trimester of your pregnancy, on the estimated date of delivery, and if you are breastfeeding, when your baby is 3, 6, 9 and 12 months of age. The PCC will collect the following information:

- Any changes in the contact information you provided at enrollment
- Any changes in the status of your pregnancy
- Any changes in Galafold treatment, if applicable, and changes in other medications
- Any pre-natal testing at the pre-natal follow up visit
- Any changes to your baby's health status when you are contacted when your baby is 3, 6, 9 and 12 months of age
- The breastfeeding status and information

In addition, your doctor or other licensed medical practitioner who is caring for you during pregnancy will be contacted at the initial pregnancy report, around 34 weeks of your pregnancy and, again, within 2 weeks of your estimated delivery date. The PCC will also contact your baby's doctor or other licensed medical practitioner when your baby is approximately 3, 6, 9 and 12 months old to determine if there are any changes in your baby's health status.

COMPENSATION AND STUDY-RELATED EXPENSES

This observational pregnancy study is being sponsored by Amicus Therapeutics Inc.; the PCC is being paid by Amicus Therapeutics Inc., to conduct the study. During your participation, you will not be paid for the study-required phone calls described in this informed consent form. There are no additional costs for your participation in this study. While you are in this study, the cost of your usual medical care, procedures, medications and doctor visits, will continue to be billed to you or your insurance.

POSTING OF RESEARCH STUDY ON WEB

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this study will also be available on the Food and Drug Administration (FDA) Women's Health Research web site.

PRIVACY

Information about your health collected while you are in this study will be kept in confidence and in accordance with privacy statutes and regulations (for example, Health Information Portability and Accountability Act, HIPAA). As is customary, the Sponsor of the study, Amicus Therapeutics Inc., may be required to provide certain safety information to the Institutional Review Board (IRB) and the FDA including personal medical information. There is a small risk that your and your baby's information may be inappropriately disclosed. This means absolute confidentiality cannot be guaranteed. In any presentation of the results of the study at meetings or in publications, your identity will remain anonymous and confidential.

This study will remain open for a minimum of 10 years. Your information will remain at the PCC until approximately 2 years after the end of the study.

WITHDRAWAL
Enrollment in the Galafold Observational Pregnancy Study is completely voluntary. You may leave the study for any reason at any time. If you decide to stop participating, the quality of your and your baby's medical care will not be affected, and you and your baby will not be penalized or lose any benefits that you and your baby may be entitled to. If you decide to leave the study before your participation has ended, Amicus Therapeutics Inc., will still use the information collected before your withdrawal. The request for withdrawal from the study must be made to the PCC by you or your health care provider.
The study investigator or the Sponsor can stop the study at any time without your consent.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

ALTERNATIVES TO PARTICIPATION
This pregnancy follow-up is for research purposes only. The only alternative is to not participate in this study.

WHOM TO CONTACT
If you have questions about the study, please contact the study staff listed on page 1 of this document.

An IRB is an independent committee established to help protect the rights of research participants. If you have any questions about your or your newborn's rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Participant Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00042753.

A copy of this Participant Informed Consent Form will be mailed to you for your records. The PCC will sign and date this form but your signature and date are optional. If you choose to sign and date this form and return to the PCC, please make a copy of it for your records before mailing.

We will also include the Medical Information Release Form (MIR) form that you will need to sign, date and return in the self-addressed and pre-stamped envelope.

PCC Associate reviewing Participant Informed Consent Form:

_____	_____
Printed name/Signature of PCC Associate	Date Signed
_____	_____
Printed name/Signature of Study Participant **(optional)**	Date Signed

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide for you and your newborn child to be in this study, the Study Investigator and research team will use and share health data about you and your newborn child to conduct the study. Health data may include:

- Name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your doctor visits, including test results.

Health data may come from your and your newborn child's study records or from existing records kept by your and your newborn child's doctor or other health care workers.

For this study, the research team may share health data about you and your newborn child with authorized users. Authorized users may include:

- Representatives of Amicus Therapeutics Inc.
- United BioSource (UBC) / Pregnancy Coordinating Center (PCC)
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and Sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

Your and your newborn child's health data will be used to conduct and oversee the research, including for instance:

- Describe and estimate the frequency of pregnancy complications in women with
  Fabry disease who were exposed to at least 1 dose of Galafold during pregnancy and fetal and infant outcomes in infants through 1 year of age.
- Describe and estimate the frequency of adverse events effecting lactation in women with Fabry disease and infants through 1 year of age who were exposed to at least 1 dose of Galafold during pregnancy and/or breastfeeding.

Once your and your newborn child's health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you and your newborn child will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you and your newborn child at any time by writing to the Study Investigator at the address listed on the first page of this form. If you do this, you and your newborn child will not be able to stay in this study. No new health data that identifies you or your newborn child will be gathered after your written request is received. However, health data about you and your newborn child that has already been gathered may still be used and given to others as described in this form.

Your right to access your and your newborn child's health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your/your newborn child's study health data.

If you decide not to provide your authorization, you and your newborn child will not be able to take part in the study.

I voluntarily agree to allow study staff to collect, use and share my and my newborn child's health data as specified in this form. I am not giving up any of my or my newborn child's legal rights by providing my authorization.

Galafold PCC Associate reviewing Authorization to Use and Disclose Protected Health Information:

_____ _____

Printed name/Signature of PCC Associate Date Signed

_____ _____

Printed name/Signature of Study Participant **(optional)** Date Signed