Informed Consent Form for Adult Participants, Parents/Legal Guardians, and Participants Reaching the Age of Majority (AOM)

Sponsor / Study Title:	**Bayer AG / "Observational Pregnancy Safety Study of Women Exposed to Nifurtimox During Pregnancy to Describe the Risk of Pregnancy and Maternal Complications and Other Events of Interest on the Developing Fetus, Neonate, and Infant"**
Protocol Number:	**21944**
Principal Investigator:	**Annette Stemhagen, DrPH, FISPE**
Telephone:	**(877) 899-1393 (24 Hours)** **Pregnancy Coordinating Center Hours 8AM-5PM EST**
Address:	**UBC** **933 Canyon Road** **Morgantown, WV 26508**

If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed. When "you" appears in this form, it refers to your child except where it says otherwise.

Dear Participant,

You are being invited to take part in an observational study. In an observational study you will not be asked to change your medical treatment or care for the study. Your treatment or care, including any prescription medicines, will be decided by you and your doctor based on standard medical practice and independently of the study.

What it would mean for you to participate:

Taking part in this study and giving consent is entirely voluntary. Your regular medical care will not change if you decide not to take part in the study or if you decide to leave the study, and there will not be any penalties or loss of benefits.

In this study it will be necessary to handle personal data about you. Personal data is any information that is related to you, including information about your health. This information is protected by data privacy law. United BioSource, LLC (UBC) as the research team of this study is responsible for the lawful, fair, and transparent handling of your personal data collected in the study.

If you agree to take part in the study, you will be asked to sign and date an informed consent form. You can withdraw your consent to process your personal data without giving a reason at any time with effect for the future. If you do so, no further data will be collected from you. Data that had been collected until your withdrawal will be used further as complete study documentation is needed for the scientific integrity (quality) of the study as well as to foster (support) high standards of quality and safety of medicinal products.

The Informed Consent Form tells you in detail about the study and what will happen if you take part. Please read this information carefully. Ask your Study Coordinating Center research team or your principal investigator if there is anything that is not clear or if you would like more information.

(1) What is this study about? Why am I invited to take part?

This pregnancy registry shall help us to learn more about the pregnancies of women with Chagas' disease (American Trypanosomiasis) that were exposed to nifurtimox® referred to as LAMPIT.

You have been asked to take part because you are/were pregnant while being diagnosed with Chagas' disease and treated with LAMPIT during your pregnancy.

You and your baby's health data will be used to conduct and oversee the research, including for instance:

- Selected fetal/neonatal/infant outcomes, small for gestational (development) age, and postnatal (after childbirth) growth and development at birth and through up to the first year of life of your baby
- Pregnancy outcomes of interest
- Complications in women

The study plans to enroll about 50 participants globally.

(2) Are there risks or benefits from taking part in this study?

It is important to know that there is **no additional physical risk to your health** from taking part in this observational study.

This is because in an observational study you will not be asked to change your medical treatment or care for the study. Your treatment or care, including any prescription medicines, will be decided by you and your doctor based on standard medical practice and independently of the study.

There may be risks that are unknown.

It is also important to understand that **you will not directly benefit** from taking part in this study.

However, if you take part in this study, you may help other patients in the future by improving their knowledge of diseases and medical care.

(3) What will happen in the study?

During the study, information about you, your treatment and health will be collected.

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

You will be asked to do the following:

- Provide written informed consent. We will be mailing a copy of this consent to you for your files, you will need to sign, date, and return a copy to us.
- Sign the Medical Information Release (MIR) form. Once the Pregnancy Study Coordinating Center (SCC) has your written 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 SCC 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 SCC at the time of enrolment (at time of informed consent) and additional information once per trimester during your pregnancy and at the following timepoints:
    - Pre-natal follow up visit at 34 weeks ± 2 weeks
    - At the estimated date of delivery
    - When your baby is 3, 6, 9, and 12 months of age

The SCC will collect the following information:

- Any changes in the contact information you provided at enrolment
- Any changes in the status of your pregnancy
- Any changes in LAMPIT 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

In addition, your doctor or other licensed medical practitioner who is caring for you during pregnancy will be contacted at the initial pregnancy report, 34 weeks ± 2 weeks of your pregnancy and, again, within 2 weeks of your estimated delivery

date. The SCC 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.

Your participation in this study will last until your baby turns 12 months at maximum, however the LAMPIT Pregnancy Registry will remain open for a minimum of 10 years.

(4) How will my personal data be handled?

If you take part in this study, it will be necessary to handle **personal data** about you and your baby. Personal data is any information that is related to you or your baby, including information about you and your baby's health. This information is **protected by data privacy law**. United BioSource, LLC (UBC) as the initiator of this study is responsible for the lawful, fair, and transparent handling of your personal data collected in the study.

As part of this Informed Consent Form, you will be asked for your **authorization** to process your personal data. This authorization is one legal basis for data processing. Furthermore, processing of your personal data will be necessary to fulfill the **scientific research purposes** of this study and to foster high standards of quality and safety of medicinal products.

You are not obliged (required) to give your authorization or provide your data, but it is necessary if you wish to take part in this study.

The following sections describe how your personal data will be handled and what data privacy rights you have.

4.1 What kind of data may be collected?

The following type of personal data may be collected in the study:

- Name
- Address
- Phone number
- Date of birth
- What treatments or care you have had and how you respond to them
- Information on your health and medical condition including your medical history

  Information on your pregnancy and the birth of your child

4.2 How will my identity be kept private?

Your identity is only known by your principal investigator and the SCC. Your identity will not be disclosed to Bayer. Your personal identifiable information (name, address, phone number) will not be shared with anyone outside of the LAMPIT SCC.

To ensure the confidentiality of your identity, your study related data will be ”de-identified”. Information about your or your baby’s health collected while you are in the LAMPIT Pregnancy Registry will be kept in confidence and in accordance with privacy statutes and regulations (for example, Health Insurance Portability and Accountability Act [HIPAA]) by using a unique number as participant identifier.

4.3 Who receives my de-identified data?

For this study, the research team may share de-identified health data about you and your baby with authorized users. Authorized users may include:

- Representatives of Bayer AG. Your de-identified data will be provided to the initiator of this study and possibly other companies of the Bayer group. As is customary, the Sponsor of the study, Bayer AG may be required to provide certain safety information to the Institutional Review Board (IRB) and the United States Food and Drug Association (FDA) including health information. In any presentation of the results of the study at meetings or in publications, your identity will remain completely anonymous and confidential.
- 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.
- Service providers for handling your de-identified data.
- To other regulatory bodies for regulatory purposes (for example, to competent authorities for reporting of safety relevant information). Regulatory bodies may use the data also to learn more about study related diseases and related health problems.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with researchers and sponsors need to access your information to conduct this study.

- Other research doctors and medical centers participating in this research.

Once your 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.

4.4 For what purposes will my health data be used?

The health data may be used for the following purposes:

- To determine the results and answer the scientific questions of the study.

4.5 How long will my information be kept?

UBC will retain your records for at least 25 years after the end of the study. The retention period may be prolonged if required by law. Your personal information may also be stored for longer than the legally required retention period if it is necessary to demonstrate the scientific integrity of the study or to foster high standards of quality and safety medicinal products.

(5) What are my privacy rights?

The personal data that are collected for study purposes are protected by data privacy law. It ensures that you have the following rights:

- You can **withdraw your authorization** to process your personal data without giving a reason at any time with effect for the future by writing to the principal investigator at the address listed on the first page of this form. If you do this, it will not be possible for you to continue taking part in this study. No further data will be collected from you. Data that had been collected until your withdrawal will be further used as complete study documentation is needed for the scientific integrity of the study as well as to foster high standards of quality and safety of medicinal products.
- Request information about the **handling of your data**.
- Request **correction of your data** if it is wrong or not complete. During the assessment of this request, you have the right to limit the handling of such data.
- Ask for the **transfer of your data** to you or someone else, in a format that is structured, commonly used and machine-readable.
- File a **complaint with a supervisory authority** using the contact information in the “Whom to Contact About This Study” section below.

- Along with your withdrawal, data protection law provides you with the right to **request the deletion** of your data. Please note that only data which is necessary for the study will be collected from you. To ensure the scientific integrity of the study, the completeness of the related documentation as well as high standards of quality and safety of medicinal products, it might not be possible to delete data once it has been collected for the study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The principal investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the principal investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:

  Study Subject Adviser

  Advarra IRB

  6100 Merriweather Dr., Suite 600

  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00062745.

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.

ALTERNATIVES

This study is for research purposes only. The only alternative is to not participate in this study.

COST AND COMPENSATION

There will be no charge to you, and there will be no payment, for your participation in this study.

CONFIDENTIALITY

The principal investigator, or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name.

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.

WITHDRAWAL

The principal investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

Consent and Authorization of the Participant

I confirm that:

- The LAMPIT Pregnancy Registry research team has explained the study to me, and I have had enough time to consider the study.
- I understand that taking part in this study and giving my consent is entirely voluntary. My regular medical care will not change if I decide not to take part in the study or if I decide to leave the study.
- I understand that my consent and authorization is required for the processing of my, and my baby's personal data in the manner and for the purposes described in the Informed consent Form. I understand that processing of my personal data will also be necessary to ensure the scientific integrity of the study.
- Information about my treatment may be collected also from other physicians involved in my care.
- I received a copy of the Informed Consent Form after I sign and date the form.
- I have read and understood the Informed Consent Form.

I agree to take part in the study and consent to the processing of my personal data in the manner and for the purposes described in the Informed Consent Form.

Participant

_____

Participant's full name (print)

_____ _____

Date Participant's signature

Parent/Legal Guardian of

_____

Child's full name (print)

_____

Parent/Legal Guardian's Full Name (Print)

_____ _____

Date Parent/Legal Guardian's Signature

I confirm that information in the Informed Consent Form and any other written information was accurately explained to, and apparently understood by, the participant and that consent was freely given by the participant.

_____

Person Obtaining Consent's Full name (print)

_____ _____

Date Person Obtaining Consent's signature

FOR CHILDREN WHO BECOME ADULTS

I have been told that my parents/legal guardian agreed for me to participate in this research study as a minor. I have ready and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant Reaching Age of Majority's full name (print)

_____ _____

Date Participant Reaching Age of Majority's signature