Participant Verbal Informed Consent Form
And
Authorization to Use and Disclose Protected Health Information
For Participants and Parents/Legal Guardian of Minor Participants in the United States

Sponsor / Study Title:	**GW Research Ltd. / "OBSERVATIONAL PREGNANCY SURVEILLANCE PROGRAM OF PATIENTS EXPOSED TO EPIDIOLEX® (EPIDYOLEX®) DURING PREGNANCY TO ASSESS THE RISK OF PREGNANCY AND MATERNAL COMPLICATIONS AND OTHER EVENTS OF INTEREST ON THE DEVELOPING FETUS, NEONATE, AND INFANT"**
Protocol Number:	**GWEP21095**
Principal Investigator:	**Amy Miller, RPh, PharmD**
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Address:	**United BioSource Corporation** **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.

INTRODUCTION

GW Research Ltd., the study Sponsor, has set up this observational pregnancy study to better describe the safety profile of Epidiolex when exposure occurs during pregnancy. This study will collect valuable information on the risks of Epidiolex exposure on pregnancy and on fetal, neonatal, and infant outcomes. In the US, Epidiolex is indicated for treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

You are being asked to participate in this study because you have taken at least 1 dose of Epidiolex during the 13 days prior to your last menstrual period (LMP) or during pregnancy. This study will also follow infants through 12 months of age who were exposed to at least 1 dose of Epidiolex in utero. Patients exposed to an non approved product containing cannabidiol (CBD) during pregnancy who do not also have exposure to Epidiolex during the 13 days prior to their LMP or during the pregnancy will not be eligible to participate. No mandatory visits, tests, or assessments are required for this study. Pregnant participants and infants will be treated according to the standard of care. This form will explain the purpose of this 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.

About 50 participants will be in this 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. 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, up to 12 months of age, 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 GW Research Ltd. to determine if there are any effects of EPIDIOLEX on pregnant women, or babies whose mothers were exposed to Epidiolex during pregnancy or within 13 days prior to your LMP. The study data will be provided to the U.S. Food and Drug Administration (FDA) and other regulatory agencies as appropriate so that other women who become pregnant while being treated with EPIDIOLEX can better understand the effects of Epidiolex 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 Study Coordinating Center (SCC) has your verbal informed consent, they will send you a Medical Information Release (MIR) form to sign, date and return. Signing and dating the MIR is optional; however, 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 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
    - At the estimated date of delivery, and;
    - When your baby is 3, 6, 9, and 12 months of age.

INFORMATION
During enrollment, the SCC will ask you basic questions about your health and pregnancy, as well as your contact information, such as address and phone number. The SCC will also ask you to identify a secondary contact. The secondary contact should be someone outside of your household who can provide your contact information in case the SCC is unable to reach you.

You will be contacted by the SCC one time during each trimester of your pregnancy, and additionally at your pre-natal follow up visit, on the estimated date of delivery, and 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 enrollment
- Any changes in the status of your pregnancy
- Any changes in Epidiolex 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, if you sign this consent the SCC will contact you and if you also sign the MIR your doctor or other licensed medical practitioner who is caring for you during pregnancy will be contacted at the initial pregnancy report, at each trimester of your pregnancy. The SCC will also contact your obstetric healthcare provider (HCP) for your pregnancy information at your prenatal follow-up and at the estimated date of delivery. The SCC will collect information from the infant's HCP at 3, 6, 9 and 12 months of age 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 GW Research Ltd.; the study investigator and SCC are being paid by GW Research Ltd., to conduct the study at this site. During your participation, you will not be paid for your participation in this study. 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 FDA Women's Health Research website.

PRIVACY
Information about your health collected while you are in the EPIDIOLEX Pregnancy study will be kept in confidence and in accordance with all applicable privacy statutes and regulations (for example, Health Insurance Portability and Accountability Act [HIPAA]). Participant names will be coded and not identifiable to the sponsor. As is customary, the Sponsor of the study, GW Research Ltd. may be required to provide certain safety information to the Institutional Review Board (IRB), the FDA, and other regulatory agencies as appropriate, including personal medical

information. 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 SCC until five years after the end of the study.

WITHDRAWAL
Enrollment in the EPIDIOLEX Observational Pregnancy study is completely voluntary. You may leave the study for any reason at any time. If you decide to refuse or 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, no further data will be collected but GW Research Ltd. will still use the information collected before your withdrawal unless otherwise specified. The study investigator or the sponsor can stop the study at any time without your consent if it is of clinical benefit to you.

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 observational pregnancy study is for research purposes only. You can choose not to participate in this study.

There is another pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antiepileptic drugs (AEDs), such as EPIDIOLEX, during pregnancy. You may also choose to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling the toll free number 1-888-233-2334 or visiting http://www.aedpregnancyregistry.org/.

It is possible to participate in both studies, or you may choose to participate in only one study. You may also choose to participate in no studies.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you have questions, concerns or complaints about the study such as:

- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;

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

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: Pro00074748.

A copy of this Participant Informed Consent Form will be mailed to you for your records. The EPIDIOLEX SCC will sign and date this form but your signature and date are optional. If a signed and dated copy is received by the SCC a copy will be sent to you for your records.

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

EPIDIOLEX SCC Associate reviewing Participant Informed Consent Form:

_____ _____

Printed name/Signature of PCC Associate Date Signed

_____ _____

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

STATEMENT OF PARENTAL / LEGAL GUARDIAN PERMISSION

I have read 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 for my child to participate in this study until I decide otherwise. I do not give up any of my or my child's legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____ _____

Printed name/Signature of Parent/Legal Guardian **(optional)** Date Signed

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the 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:

- GW Research, Ltd.
- 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.
- 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:

- Estimate the frequency of pregnancy and fetal/neonatal outcomes through 1 year of age in women who were exposed to at least 1 dose of EPIDIOLEX.

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 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 decided not to provide your authorization, your right to other medical treatment will not be affected. However, you 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.

EPIDIOLEX Study Coordinating Cener (SCC) 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

_____ _____

Printed name/Signature of Parent/Legal Guardian **(optional)** Date Signed