Informed Consent Form for Adult Participants and Parents/Legal Guardians of Minor Participants

Sponsor / Study Title:	**Ascendis Pharma / "A Global Pregnancy Safety Study To Assess Maternal, Fetal, And Infant Outcomes Following Exposure To YORVIPATH® (Palopegteriparatide) During Pregnancy And Breastfeeding"**
Protocol Number:	**ASND0043**
Principal Investigator:	**Amy Miller RPh, PharmD**
Telephone:	**877-229-2184 (24-Hour)**
Address:	**United BioSource Corporation** **933 Canyon Road** **Morgantown, WV 26508**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant, and the participant offered the ability to leave the study if desired.

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.

You should keep a copy of this form. If you have any questions or problems during the study, call the phone number(s) above.

Introduction:

You have been asked to take part in a non-interventional, observational research study of a marketed drug, YORVIPATH® (palopegteriparatide). This drug is approved for sale and use in patients with hypoparathyroidism. This study is being done to find out maternal, fetal and infant outcomes following exposure to YORVIPATH® (palopegteriparatide) during pregnancy and breastfeeding. The sponsor of this study is Ascendis Pharma Bone Diseases A/S (referred to as "Ascendis Pharma") who is the manufacturer of YORVIPATH® (palopegteriparatide). This form goes over the study and the study procedures. The Principal Investigator will answer any questions you may have about this form and the study.

Ascendis Pharma is paying the Principal Investigator and/or the study coordinating center to collect information about the outcomes of using this drug during pregnancy and breastfeeding.

Your Rights:

This form gives you information about the study, and this information will be discussed with you. You should ask questions about any part of the information that you do not understand. Once you understand the study, and if you agree to take part, you will be asked to sign this form. You do not give up any legal rights by signing this informed consent form. You will be given a copy of this form to keep.

Before you learn about the study, it is important that you know the following:

- Whether or not you take part in this study is entirely up to you.
- You may decide not to take part or, if you do take part, you may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are entitled.
- If the study is changed in any way, which could affect you, you will be told about the change. You may be asked to sign a new, revised informed consent form.

Your Responsibilities:

If you decide to participate in this study, you may have certain responsibilities that the Principal Investigator or study coordinating center staff will discuss with you.

Purpose Of The Study:

The purpose of this study is to collect information and find out maternal, fetal and infant outcomes following exposure to YORVIPATH® (palopegteriparatide), a marketed drug.

You will be one of about 50 participants in this study in the Unites States (U.S.). It is thought that the entire duration of the study will take 10 years to finish. Your participation in the study duration will last at most for 21 months, 9 months of pregnancy follow-up and 12 months of infant follow-up.

Study Treatments:

If you choose to participate in this study, you will continue your treatment with YORVIPATH® (palopegteriparatide) as part of your standard of care. Ascendis Pharma will not be providing any drug.

Procedures:

After you sign this form the following information will be collected to find out if you are able to take part in this study.

- Whether you have been exposed to at least one or more doses of YORVIPATH® at any time within 15 days prior to conception and/or during pregnancy.

If you are able to take part, you will be given an ID number, and the information below will then be collected at enrollment:

- Contact information
- Information about your pregnancy/status
- Birth date, race, ethnicity, height weight and level of education
- Information on past pregnancies
- Maternal medical history

The following information will be collected during your pregnancy:

- Information about your pregnancy and estimated delivery date
- Pregnancy examinations
- Pregnancy complications
- Medications taken during your pregnancy
- Intake of Alcohol, smoking and drugs

The following information will be collected when you have given birth:

- Information about your delivery and possible complications
- Information about the newborn(s) (e.g. gender, birth weight and birth weight)
- Information about complication and breastfeeding

The following information will be collected about your child until 12 months of age:

- Illnesses
- Growth and development
- Breast feeding status

Pregnant participants and infants will be treated according to your doctors' standard of care. No mandatory visits, tests, or assessments are required in this study. In case of something unexpected that might be related to YORVIPATH® (palopegteriparatide), the Principal Investigator will stay in contact with you until you get better.

Risks, Discomforts, Or Inconveniences:

YORVIPATH® (palopegteriparatide) is a marketed drug which you will be taking as part of your routine care. You will not be at any increased risks other than those risks outlined in the YORVIPATH® (palopegteriparatide) prescribing information. Please refer to YORVIPATH® (palopegteriparatide) prescribing information.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

There may be other risks that are unknown. This research study is for research purposes only. The only alternative is to not participate in this study.

Reasonably Expected Benefits:

YORVIPATH® (palopegteriparatide) is a marketed drug that you are already receiving as treatment of hypoparathyroidism. There is no direct benefit to you or your newborn from your participation in the study. This study may give information to other people in the future that may lead to a better understanding on the maternal, fetal and infant outcomes following exposure to YORVIPATH®.

New Findings:

If the study is changed in any way or new important information is discovered which could affect your willingness to continue participation in the study, you will be told about the change, and you may be asked to sign a new revised consent form.

Reasons For Ending Your Participation In The Study:

You may withdraw from the study at any time during the study without reason and without losing any rights. Withdrawal from the study will not affect your medical care or access to YORVIPATH® (palopegteriparatide). The Principal Investigator, according to his or her judgment, may withdraw you from the study at any time. Reasons for withdrawing you from the study may include:

- Your failure to follow study directions or requirements of the study plan
- Termination of the study by:
    - The Principal Investigator for your site
    - The sponsor Ascendis Pharma
    - A regulatory authority (e.g., the Food and Drug Administration [FDA])
    - Advarra institutional review board (IRB)

An IRB reviews research involving human participants to ensure it is ethical and safe.

If you withdraw from the study we will stop collecting any further data from you; however, we will also keep the information about you that we have already obtained and such information will be used as documentation for the study results and as required for compliance with legal and regulatory obligations in connection with the study.

Arrangement After Study Termination

If the study is stopped before the planned end date, the Principal Investigator will inform you. This will not impact the treatment options that you are entitled to. The Principal Investigator will make arrangements for your care to be continued.

Compensation And Study-Related Expenses

Enrolled participants that successfully attend and complete the data collection requirements at the specified timepoints, as described in the "Procedures" section of this document may be eligible for compensation of up to $100.00 at each timepoint for a maximum of $500.00. Your information will be collected through the study coordinating center during enrollment and throughout the study.

You will be contacted by the study coordinating center staff during enrollment, estimated time of delivery, and when your baby is 6, 9 and 12 months of age. You will receive payments from a contracted vendor, and you will be issued a credit card that your funds will be loaded on to and can be used at your discretion. You will receive a $100 pre-paid gift card following the collection of this information at each of the following timepoints shortly after the information is collected:

- Enrollment - $100
- Birth - $100
- 6 Month - $100
- 9 Month - $100
- 12 Month - $100

This observational research study is being sponsored Ascendis Pharma; the study coordinating center is being paid by Ascendis Pharma to conduct the 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.

Will This Study Be Published?

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.

Use Of Your Personal Data

If you would like to take part in the study, certain personal data will need to be collected from you and from your medical records for the purpose of the study.

Ascendis Pharma is responsible for your personal data collected for the study. The Principal Investigator will collect the data and is professionally obligated to protect your data and keep it confidential. He/she will encode your data by replacing your name with a study unique participant ID number for use in this study. This will minimize the amount of personal data that identifies you.

As Ascendis Pharma is based in the European Union (EU), it has the legal obligation to comply with the EU privacy law known as the General Data Protection Regulation (GDPR), in addition to any local requirements in your home country. For this reason, Ascendis Pharma needs to inform you of its purposes and legal basis for using your personal data:

1) Reliability and Safety: It is necessary for Ascendis Pharma to use your personal data to comply with legal obligations applicable to studies and to ensure high standards of quality and safety of health care and medicinal products (see the legal basis for such use in GDPR articles 6.1(c) and 9.2(i)); and

2) Scientific Research: It is necessary for Ascendis Pharma to use your personal data to pursue its legitimate interest in developing and marketing a medicinal product and for scientific research purposes.

What Kind Of Personal Data Is Collected

The personal data collected and used for the study includes data about your health and medical condition, your medical history and background information such as your age, sex and ethnic origin.

Who Will Have Access To Your Personal Data

The Principal Investigator/United BioSource (UBC) Study Coordinating Center (central site) designee will enter the uncoded personal data collected about you for the purpose of the study into your personal medical records. Such data as well as your original medical records may be reviewed at United BioSource (UBC) Study Coordinating Center (central site), by people that are not part of the site staff, e.g., by Ascendis Pharma/representatives of Ascendis Pharma for monitoring purposes, health authorities, institutional review boards for safety and quality oversight or health or data protection authorities to ensure compliance with applicable laws.

The coded personal data collected about you for this study will be shared with relevant external parties outside the research site or study coordinating center including Ascendis Pharma and its group companies, institutional review boards, health authorities and people or organizations providing study services to Ascendis Pharma (e.g., clinical research organizations, and Information Technology providers).

Only in very limited situations may your uncoded personal data be shared with parties outside the research site/study coordinating center, and if so, only when needed for specific reasons, e.g.,

for logistics or reimbursement purposes where a vendor hired by Ascendis Pharma needs information such as your name, address or account number to carry out their tasks. Ascendis Pharma will not know your identity during this process.

Your coded data may also be shared with health authorities as well as vendors and collaboration partners for legal and regulatory purposes.

Transfer Of Your Personal Data

For the purpose of the study and the above-mentioned activities, it will be necessary for Ascendis Pharma to make cross-border transfers of your personal data, including to locations outside your home country. As Ascendis Pharma is based in the EU, cross-border transfers of your personal data will be done in accordance with GDPR.

This means that Ascendis Pharma, when transferring personal data out of the EU/European Economic Area (EEA), will either rely on the EU Commission's decision that the receiving country offers an adequate level of data protection or base the transfer on a standard agreement made by the EU Commission known as Standard Contractual Clauses (a copy of which can be obtained by contacting the Principal Investigator who will reach out to Ascendis Pharma).

Transfers to national authorities outside the EU/EEA (such as the FDA in the US) will take place for important reasons of public interest such as for legal and regulatory purposes in different countries.

How Long Will Your Personal Data Be Stored

Your personal data will be stored by Ascendis Pharma or their representatives for at least 25 years after the study has ended in accordance with applicable European laws and regulations or longer if required by local laws. Your medical records kept by the Principal Investigator will be stored for as long as required by local requirements, which is currently 7 years.

Your Rights

You have certain rights over your personal data. These rights include the right to access and review your personal data, change and/or delete personal data if it is incorrect and restrict or object to the personal data being processed. However, please note that Ascendis Pharma needs to manage your personal data in specific ways for the research to be reliable and accurate which may affect these rights.

If you have any questions or concerns about the processing of your personal data you should contact the Principal Investigator, who will pass it on to Ascendis Pharma as appropriate. If your concerns cannot be resolved to your satisfaction, you have the right to file a complaint with your home country's data protection supervisory authority or any EU data protection authority which can be found by following this link: https://edpb.europa.eu/about-edpb/about-edpb/members_en#member-dk.

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 Principal Investigator's or study site's decision to withdraw you from participation;

Please contact the Principal 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: Pro00091794.

Statement Of Understanding And Informed Consent:

1. I have been given a copy of all previous pages of this form. I have read it, or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I understand that I have not waived any of my legal rights.
2. I understand the study procedures described above.
3. I consent to take part in this study on the date I sign this form.
4. I understand that my participation is voluntary and that I may withdraw my consent to take part in this study at any time without prejudice to my future medical treatment.
5. I am aware that representatives of Ascendis Pharma (including the clinical research organization working with Ascendis Pharma, monitors and auditors) or representatives of institutional review boards, health authorities and data protection authorities may review my medical records, but will treat them with strict confidentiality. I authorize these individuals to have access to my records.
6. I will receive a copy of this signed and dated consent form.

_____
Adult Participant's Name Printed

_____ _____
Signature of Adult Participant Date *DD/MMM/YYYY*

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date *DD/MMM/YYYY*

_____
Authority of Legally Authorized Representative to act on behalf of Participant

_____
Parent/Legal Guardian's Name Printed

_____ _____
Signature of Parent/Legal Guardian Date *DD/MMM/YYY*

Person Obtaining Consent's Declaration

I have carefully explained the nature and purpose of this study to the participant in language he/she understood. The person signing this consent form has been given adequate time to read this information and the opportunity to ask questions regarding the nature, risks and benefits of participation in this observational safety study.

_____

Printed Name of Person Explaining Consent
or Conducting the Consent Process

_____ _____

Signature of Person Explaining Consent or Conducting the Consent Process Date *DD/MMM/YYYY*