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Oct 09, 2019

Consent/Parental Permission and HIPAA authorization to Participate in a Study

Title: Establishing a Cost-effective Return of Results to Parents of Boys in VISION-DMD Clinical Trials

Protocol No.: VBP15-ROR
WIRB® Protocol #20192458

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Sponsor: ReveraGen BioPharma

Study is funded by: National Institutes of Neurological Diseases and Stroke (National Institutes of Health)

Study-Related Phone Number(s): 240-672-0295
646-283-1074 (24 Hours)

You are being asked to be in a research study.

Introduction

Return of data to parents/caregivers of participants in clinical trials demonstrates respect for participants' ownership of their health data. However, disclosure of an individual's research results raises many ethical and logistical challenges. There are many questions regarding the perceived and real usefulness of the information, how the data is communicated, the impact of return of results on the well-being of parents and participants, feelings toward the research experience, and subsequent research participation. In a clinical trial with many recruitment sites and patients, the burden on physicians/coordinators may be a concern, and there are challenges regarding re-identification of data, and the need to reconsent if consent for sharing was not part of original consent. Challenges associated with randomized trials include the timing and approach to sharing individual level data. There are

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additional regulatory and legal challenges associated with return of research results across international boundaries. To inform this project, we have held discussions with leaders of DMD foundations; all strongly endorsed the value of providing a DMD child's clinical trial data to their parents/guardians

This form is designed to tell you things you need to think about before you decide if you want to participate in this study. **It is entirely your choice. If you decide to participate in the study, you may change your mind at any time.** The decision to participate in this study will not affect any aspect of your son's participation in vamorolone clinical trials. The decision to participate will not cause you to lose any medical benefits you have. If you decide not to take part in this study, your doctor will continue to take care of your son.

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

Feel free to take your time thinking about whether you would like your son to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. You are free to refuse to join this research or join now and decide to withdraw later. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. By signing this form you will not give up any legal rights.

What is the purpose of this study?

The purpose of this study is to evaluate the process of informing patients about re-consent for returning results to the families of trial participants. We will get feedback from stakeholders (parents/guardians, physicians, advocates/foundations), and this information will help to improve the process and design the most ethical and efficient system possible. This system is designed to protect the privacy of trial participants and maintain the integrity of the clinical trial.

As part of the study, the sponsor (ReveraGen BioPharma) will return individual and aggregate research results to the parents/guardians of clinical trial participants.

What will I be asked to do?

You will be asked to complete a survey pre-data return. This will be an anonymous survey—your identity and your child's identity will not be linked to your responses. Responses will be compiled and analyzed together with other people's responses.

Next you will be mailed an encrypted USB drive with your child's data and a summary of the data from all who participated in the trial. You will also be provided with the password to access this drive via email. If you would prefer a paper copy, please let the study coordinator know. After you receive your child's data and a summary of data from all who participated in the trial, you will receive another survey. Again, your identity and your child's identity will not be linked to your responses. Responses will be compiled and analyzed together with other people's responses.

Your physician (the clinical trial investigator at your site) will be notified when you enroll in the study, and he/she will be asked to complete a survey after the data has been returned to you. This will provide information from the perspective of the physician.

You will be asked to directly contact the coordinator at ReveraGen by phone or email if you have questions. This is to maintain confidentiality.

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If you have questions about the data and how it relates to your child's health, please discuss with your physician.

What are the possible risks of participating in the study?

Risk of loss of confidentiality:
Your son will only be identified by a study site and date of birth, to protect his confidentiality. At ReveraGen, only a single coordinator will know your identity and communicate with you directly.

Although many precautions are being taken (only identifying your data by your child's birthdate/study site), use of a dedicated coordinator who will be the only one at ReveraGen who knows your identity, there is a risk of loss of confidentiality.

There is a risk of the USB drive being lost. The information on it will be encrypted, and only date of birth/study site will be on the drive with the data (no other identifying information).

Receiving your child's data could lead to distress or confusion. It could raise additional questions. Some questions may be answered by our coordinator. Questions about how this information may or may not impact your child's health. We encourage you to discuss these questions with your physicians.

What are the potential benefits of participating in this study?

A potential benefit of participating in this study is the receipt of your child's data and a summary of compiled results from others in the trial. This research may also help guide our approach to providing data to future subjects in clinical trials.

Will I be compensated for my time and effort?

You will not be offered compensation for participating in this study.

The are no costs associated with participating in the study.

What are my other options?

You have the option not to participate in this study.

How will my confidentiality be maintained?

- A single coordinator at our company will be the only one to know your identity. She will be contacted by you, and will store your child's name, date of birth, address, your email address, and study site (as provided by you) in a password-protected file stored on a cloud-based server.
- The coordinator will request your child's data using only the site location and date of birth as identifiers.

The following entities may review the study records and medical records (including your son's identifying information in rare cases) to make sure that the study is carried out correctly and that we are following the law and protecting the children in the study: US Food and Drug Administration, the study's Coordinating Centers, the study sponsor ReveraGen BioPharma and its representatives, the National Institutes of Health (NIH), and the Institutional Review Board or ethics board overseeing the study activities at Western IRB.

Data obtained from this study may be presented, or published or shared with other investigators interested in DMD. However, nothing shared will contain information that can identify your son.

Hoffman E, *et al. BMJ Open* 2024; 14:e080097. doi: 10.1136/bmjopen-2023-080097

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Contact Information

Contact Suzanne Gaglianone at 609-206-0939 or suzanne.gaglianone@reveragen.com

- if you have any questions about the study

Contact Laurie Conklin at 240-672-0295, 646-283-1074 (24 Hours) or laurie.conklin@reveragen.com

- if you have questions/concerns/complaints about the conduct of the study or if you feel you or your son have been harmed by participating in this research.

Contact the Western IRB at (800) 562-4789

- if you have questions about your son's rights as a treatment recipient.
- if you have questions, concerns or complaints
- If you would like to provide feedback

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Participation in this research requires us to access your son's medical record.

What information may be used and given to others?

The study doctor will get your son's personal and medical information. For example:

- Past and present medical records
- Research records

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

What if I decide not to give permission to use and give out my son's health information?

Then you and your son will not be able to be in this research study.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your son's health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

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When you withdraw your permission, no new health information identifying your son will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

VOLUNTARY CONSENT:
The above information has been explained to me and all of my current questions have been answered.

I understand that I am encouraged to ask questions at any time, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

_____
Child's Name (Print)

_____
Parent or Guardian's Name (Print)

_____
Relationship to Subject (Child)

_____ _____
Parent or Guardian's Signature Date

CERTIFICATION OF INFORMED CONSENT:
I certify that I have explained the nature and purpose of this screening to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____
Printed Name of Person Obtaining Consent

_____
Role in Research Study

_____
Signature of Person Obtaining Consent

_____
Date