IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Mar 23, 2023

RESEARCH SUBJECT CONSENT FORM

TITLE:	A MULTI-CENTER STUDY TO COLLECT DATA FOR BASIC PHYSIOLOGICAL RESEARCH IN NEONATAL ABSTINENCE SYNDROME (NAS) AND EVALUATE THE AUTOMATED FINNEGAN/ESC DATA COLLECTION PROCESS
PROTOCOL NO.:	NAS-002 WCG IRB Protocol #20231030
SPONSOR:	Rekovar, Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

In this consent form "you" generally refers to the research subject. If you are being asked as the parent or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.

- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to collect data to develop an AI (artificial intelligence) algorithm that will predict NAS symptoms and provide suggested treatment.

About 150-200 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last one week or longer depending on circumstances.

What happens to me if I agree to take part in this research?

The research will be done at the hospital where the subject in located.

A Rekovar Monitoring Kit will be provided to the subject by the institution. A wristband will be attached to the subject's wrist to monitor vitals and other biometrics. That data is processed and visualized on the tablet's monitoring portal.

A camera will be in place to monitor behavior of the subject. The footage is stored and viewable on the tablet's monitoring portal. The patient's face is blurred out to keep confidentiality. The footage will solely be used to develop predictive analytics in the future.

Nurses will input symptoms observed into the monitoring portal to track throughout the day. All data is stored in a secure network and is anonymized/encrypted to ensure confidentiality of the subject. Nurses will come throughout the day to swap and clean wristbands as well as proceeding with their normal procedures. All procedures are repeated until the end of the study.

The Rekovar Monitoring Kit is investigational, which means that it is not approved by the Food and Drug Administration (FDA). The data collected will be used for submission of clearance for FDA approval.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to understand the warning and cautions of using the device:

- This device kit is not intended to replace appropriate medical supervision and safe practices.
- Do not use the wristband during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.
- Do not use the wristband if it is damaged, leaking or appears to be tampered with.
- Do not submerge the wristband in water.
- Healthcare providers should advise patients to seek medical attention if a severe adverse event or allergic reaction occurs or persists for more than 2-3 days.

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

Could being in this research hurt me?

[START]Although there are minimal risks to being involved in this research, possible risks include discomfort or irritation from the wristband which goes away after the procedure is stopped. It is unlikely for the wristband to cause discomfort or irritation due to its biocompatible (USP Class VI, ISO10993) material. In the rare occurrence that a wristband malfunctions it may cause harm to the subject. However, there are fail safes built in to prevent this from happening. There may also be a loss of confidentiality.
[END]

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include faster diagnosis and treatment due to the continuous monitoring of NAS symptoms from the device. Possible benefits to others include standardizing the diagnosis and treatment for NAS, allowing the process to be easier and more accurate for physicians and nurses. Standardized diagnosis and treatment will reduce the stay for newborns as they will get proper treatment from using this system.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor.
- People who work with the research sponsor.
- Government agencies, such as the Food and Drug Administration (FDA).
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy, however all data is encrypted and protected on a secure network server.

<name of research site and investigator> has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about you collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings. However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

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.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Costs and Payment

There will be no cost to you for participating in this study. You will not be paid for being in this study.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest.
- You have a side effect that requires stopping the research.
- You need a treatment not allowed in this research.
- The research is canceled by the FDA or the sponsor.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

There are no adverse consequences or risks to a subject who withdraws.

Statement of Consent:

- Assent of children is not required.

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date
Printed name of subject (not required if subject personally provided consent)	Date
Signature of person obtaining consent	Date

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

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

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

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
- Institutional Review Board (IRB)

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.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your 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.

When you withdraw your permission, no new health information identifying you 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.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Date

Signature of child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care