

Quadrant Biosciences

TITLE: Virtual Care Registry

PROTOCOL NO.: None
WCG IRB Protocol #20226755

SPONSOR: Quadrant Biosciences

INVESTIGATOR: Andrew Brindle, BS
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**STUDY RELATED
PHONE NUMBER(S):** (315) 314-5854 (24 hours)

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.

Consent / Authorization Form

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.

In this consent form, “you” always refers to the subject. If you are a parent or guardian, please remember that “you” refers to the study subject.

Background/Purpose:

Research studies include only those individuals who choose to take part. Please take your time to make your decision. Please ask the study staff to explain any words or information that you do not understand. You may also want to discuss it with family members, friends or other health care providers. Approximately 1,000,000 participants between the ages of 16 months with no upper age limit are expected to participate in this registry.

We are asking for your permission to allow us to place your name and patient identification into a research registry.

It is anticipated that the research registry will assist our investigators in two important ways. First, it will allow researchers to review and study the medical records of many individuals to answer future research questions. Second, it will help researchers identify and recruit patients who are eligible for participation in future research studies.

All patients who are being evaluated through the As You Are platform are being asked to participate in this Research Registry.

Procedures:

If you decide to take part, you will be asked to complete this consent form. Your name and patient identification will be placed into the research registry. This will permit research studies to be conducted on the information contained within the electronic medical record and recorded videos of your appointments. You are being asked to allow us to contact you if one of our researchers determines, through review of your information, that you are eligible for participation in future research studies. Please note that if you qualify for any future research studies, you will be asked to sign a separate consent form that outlines in detail the nature of this research study, including its potential risks and benefits.

We will continue to place your information into the Research Registry until you withdraw your consent for participation in the research registry.

Risks/Discomforts:

There is minimal risk associated with this research study. The risk involved with participating in this study is:

Privacy: There is a potential risk to your privacy and/or identity as information about you will be used; however, we feel this is a very minimal risk as the data will be stored on a HIPAA-Compliant secure server.

Benefits:

There is no direct benefit to you for participating in this research study; however, the information learned may help others in the future.

Voluntary Participation:

Your participation is entirely voluntary and you may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Alternatives:

Your alternative is to not participate.

Costs/Payments:

There are no costs to you associated with this registry. All costs for the research related items noted above are being paid for by Quadrant Biosciences. You will not receive compensation for your participation.

Questions:

If you have any questions, concerns, or complaints about the research, or in the event of a research related injury, please contact Andrew Brindle at research@asyouare.com or (315) 314-5854 (24 hours). If you have any questions, concerns, or complaints about the research or questions about you or your child's rights as a research subject, please contact WCG IRB at 855-818-2289 or clientcare@wcgclinical.com.

In Case Of Injury:

There are no risks of physical injury associated with your participation in the research registry.

Confidentiality of Records and Authorization to Use/Share Protected Health Information for Research:

If you agree to participate in this research, identifiable health information about you or your child will be used and shared with others involved in this research. To be in this research we need your permission to collect and share this information. Federal law protects your right to privacy concerning this information.

When you sign this consent form at the end, it means that you have read this section and authorize the use and/or sharing of the protected health information as explained below.

Individually identifiable health information under the federal privacy law is considered to be any information from your medical record, or obtained from this study, that can be associated with you and relates to your past, present, or future physical or mental health or condition. This is referred to as protected health information.

Your protected health information will be kept confidential. Your identity will not be revealed in any publication or presentation of the results of this research.

Why is it necessary to use/share your protected health information with others?

The main reason to use and share health information is to conduct the research as described in this consent form. This information may also be shared with people and organizations that make sure the research is being done correctly, and to report unexpected or bad side effects you may have.

In addition, we may be required by law to release protected health information about you or your child; for example, if a judge requires such release in a lawsuit or if you tell us you intend to harm yourself or others.

What protected health information about you will be used or shared with others as part of this research?

We may use and share the results of tests and questionnaires. We may also use and share information from your medical and research records. We will only collect information that is needed for the research.

Who will be authorized to use and/or share your protected health information?

The researchers and staff at Quadrant Biosciences participating in the research will use your or your child's protected health information for this research study. In addition, WCG IRB who is responsible for protecting the rights of research subjects may have access to you or your child's protected health information.

The researchers and their staff will determine if your protected health information will be used or shared with others outside of Quadrant Biosciences for purposes directly related to the conduct of the research.

With whom would the protected health information be shared?

The protected health information may be shared with:

- Federal agencies that supervise the way the research is conducted, such as the Department of Health and Human Services' Office for Human Research Protections, U.S. Food and Drug Administration (FDA), or other governmental offices as required by law.

All reasonable efforts will be used to protect the confidentiality of your or your child's protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Therefore, once you or your child's protected health information is disclosed (leaves Quadrant Biosciences), the Federal privacy law may not protect it and it could be disclosed without your permission.

For how long will your protected health information be used or shared with others?

There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

However, video recordings of your appointments will only be retained for 12 months after your last appointment.

Can you withdraw your authorization to collect/use/share your protected health information?

You have the right to withdraw your permission (revoke authorization) for us to use and share your health information, by putting your request in writing to the investigator in charge of the study. This means that no further private health information will be collected. Once authorization is revoked, you or your child may no longer participate in this research

activity. Revoking your authorization only affects uses and sharing of information obtained after your written request has been received, but not information obtained prior to that time. You do not have to authorize the sharing of your protected health information, but if you do not, you cannot participate in this research.

Even after you withdraw your permission, Quadrant Biosciences may continue to use and share information needed for the integrity of the study; for example, information about an unexpected or bad side effect you experienced related to the study.

Can you have access to your health information?

At the end of the study, you have the right to see and copy health information; however, your access may be limited while the study is in progress. The results of the salivary analyses and eye tracking test are for research purposes only and will not be released to you.

Consent to Participate In Research & Authorization to Use and Share Personal Health Information:

All children are required to assent, unless the parent determines that the capability of the child is so limited that the child cannot reasonably be consulted. Documentation of assent is not required.

[Check Box] By checking the checkbox, I agree and it is my intent to electronically sign and electronically submit this form. I understand that by checking the checkbox, I will be applying my electronic signature to this application and that I will be bound with the same force and effect as if I had signed this application on paper by hand. The nature and the purpose of the Research Study have been explained to me (and my child if applicable); I agree to participate (or have my child participate) in the research study. I also agree that the participant's personal health information can be collected, used and shared by the researchers and staff for the research study described in this form.

[Check Box] By checking the checkbox, I agree and it is my intent to electronically sign and electronically submit this form. I understand that by checking the checkbox, I will be applying my electronic signature to this application and that I will be bound with the same force and effect as if I had signed this application on paper by hand. I agree to be re-contacted about future research opportunities.

[I Agree Button]