HCHS/SOL-RHYTHM
SOL-RHYTHM Screening and Consent – ZSB QxQ

10/30/2024

Introduction

The SOL-RHYTHM Screening and Consent form is designed to capture information about screening, eligibility, and informed consent for all participants approached for the SOL-RHYTHM ancillary study.

Q0a-8 captures information about the screening process and verifies participant eligibility. Use the *SOL-RHYTHM In-Person Recruitment Script, SOL-RHYTHM In-Person Proxy Recruitment Script, SOL-RHYTHM Phone Recruitment Script*, or the *SOL-RHYTHM Phone Proxy Recruitment Script*, in the participant's or proxy's preferred language.

Q9-13a captures information about informed consent. Refer to the *SOL-RHYTHM MOP* for information about consent procedures.

Question by Question Instructions

For each question, enter or select the appropriate response.

ADMINISTRATIVE INFORMATION

Q0a. Enter the date of the most recent contact attempt for screening. Update with each new contact attempt. The date listed should ultimately reflect the screening date.

Q0b. Enter the Staff ID of the person who completed the most recent contact attempt or screening.

SCREENING STATUS

Q1. Select whether screening information was collected in-person or over the phone.

Q2. Select screening status. If participant was screened but requires a re-screen (**Q6=1** or **Q7=1**), screening status is **1** "Participant contacted and screened". Set **Q2=2** "Participant contacted but screening not completed" only if participant did not complete all screening questions.

Q2a-2a1. If participant refuses screening, sites may optionally ask why the participant refused, or the participant may volunteer a reason without being asked. Do not read out the answer choices for the participant; let the participant respond freely. Select the option from the dropdown menu that best fits the reason the participant gave for refusal. If none of the answers in the dropdown menu fit, set **Q2=9** "Other" and specify the reason in **Q2a1**.

If the participant does not give a reason for refusal, set **Q2=0** "Participant did not give reason".

ELIGIBILITY CRITERIA

Q3-Q7. Read each question aloud to the participant in their preferred language and record the answer.

For questions Q3-Q5, if the answer is "Yes", the participant is ineligible for the study.

As of October 2024, question 6, "Do you plan to travel by plane in the next 14 days", no longer affects participant eligibility. Participants may enroll in the study even if they plan to travel. However, FC staff should point out the instructions in the participant handout reminding participants to notify TSA

that they are wearing a medical device, and to request a pat-down at the airport instead of going through the x-ray machine. There are no safety concerns related to going through the x-ray machine while wearing the Zio device, but the x-rays may interfere with device function.

ELIGIBLITY STATUS

Q8. In CDART click “Save and Reload”, or click the manual refresh field wheel to autofill this field with the participant’s eligibility status. The field is editable.

If the answer to all of **Q3, Q4, Q5,** and **Q7** are **0** “No”, this field will display **1**, meaning the participant is eligible for SOL-RHYTHM. Schedule a time for application either in-clinic or over the phone according to the participant’s preference and continue to the consent process.

If the answer to any of **Q3, Q4,** or **Q5** is **1** “Yes”, this field will display **0**, meaning the participant is ineligible. Save and end form. Do not continue with the consent process.

If the answers to **Q3, Q4,** and **Q5** are all **0** “No,” but **Q7** is **1** “Yes,” participant is eligible. However, they cannot participate until after their scan. **Q8** will display **2**. Schedule a time with the participant after their return to conduct a rescreening.

CONSENT

Q9-9a. Record the date the consent process was conducted and the Staff ID of the Field Center Staff member conducting the consent process.

Q10. Record whether consent procedure was conducted in the clinic or over the phone.

Q11. Record the consent status.

If the participant withdraws their consent after initially agreeing to participate, set **Q11=3** “Withdrew consent after initially agreeing” and update **Q13** and **Q13a.** This only applies to situations in which the participant explicitly states they no longer want to participate in SOL-RHYTHM and would not like to receive any further contacts about the study.

A “soft withdrawal” does not require this field to be updated. This would include any situation in which the participant does not notify the study that they would like to withdraw, even if:

- The participant does not apply device after initially consenting to the study
- The participant cannot be reached through reminder calls or texts
- The participant removes the device prior to the end of the 14-day period
- Participant does not send the device back to iRhythm
- Participant agrees to wear a replacement device, but ultimately does not apply the replacement device or does not send the replacement device back to iRhythm

Q12a-12b. Record whether participant consents to receive their results by mail (**Q12a**) and/or by email (**Q12b**). Note that if participant did not give consent to receive results by mail nor by email (both **Q12a and Q12b** are marked **0** “No”, participant will not receive their study results.

Q13-13a. These fields are enabled only if **Q11=3** “Withdrew consent after initially agreeing.” Record the date the participant withdrew consent and the ID of the Field Center Staff member recording.