



SOL MRI Screening and Consent Tracking Form

MSE – QxQ

7/16/2019

General information

The **MSE** form is designed to capture information from screening, eligibility and informed consent for all contacted participants. Complete **Section A** at time of phone contact and **Section B** at time of MRI visit. If site staff does not have access to a computer at time of MRI visit, complete **MSE** paper form, and key it into **CDART** within 48 hrs. Remember to mark the form COMPLETE in the CDART form screen once screening is fully complete and the MRI scan is obtained.

Hard Refusal in V2 ICT

If you find an ID that is a “Hard Refusal”, properly recorded in the V2 ICT, complete MSE data entry as follows:

MSE1 – Enter the date the “Hard Refusal” status was discovered

MSE2 – Enter the Staff ID of the person who is entering the MSE form

MSE3 – Set to answer option 3 (Refused, screening not done [End])

Enter a Notelog is MSE3 stating: Participant made a hard refusal prior to MRI call

Question by Question Instructions:

Section A: Phone Contact information/results

Q1. Contact Date (mm/dd/yyyy) is the date of phone call

Date of phone call; continue to update as needed. This date should reflect the date of the final code entered in **Q3**.

For participants reported as deceased or moved out of area, record the date (**Q1**) when the entry was made and the staff ID number (**Q2**) of the person who made the entry. **NOTE:** This information can be obtained from a recruitment effort outside the INCA-MRI call (e.g. AFU or another AS). Do the data entry the same way for these cases (**Q1** & **Q2** should reflect date of entry and staff who made the entry).

Q2. Staff ID: Enter/update Staff ID as needed. The staff ID should reflect the person that made the final code in **Q3**.

Q3. Call Screening information?

0= Unable to contact for screening or enrollment [**End form, call back**]

1= Yes, contacted participant and screened

2= Callback, participant was contacted but screen not completed [**End form, call back**]

3= Refused, screening not done [**End**]

4= Moved out of area/country [**End**]

5= Reported deceased [**End**]

Update Q3	as needed, to reflect correct code as follows:
=0	Not able to contact the participant, continue calling participant until they are contacted and screened.
=1	When participant contacted and screen.
=2	If participant did not have time to talk and/or was not willing to provide details. Try to schedule a call back. Update the call screening information as needed.
=3	If participant refuses to participate prior to the screening process, i.e. the subject refuses participation immediately at time of call contact. Thank them for their time and end the call.
=4	When the participant has moved too far away to come to the center or if they have moved out of the country. Thank the informant for their time. This variable identifies those participants who are ineligible because they cannot physically come to the site for the MRI scan. If the participant is willing to travel to the site to participate even when they are presently living out of the area, then Q3=1 .

Update Q3	as needed, to reflect correct code as follows:
=5	<p>If they are reported deceased at time of call. Thank the informant for their time.</p> <p>If the participant is reported deceased for the first time on the MRI phone call, please inform the AFU team about this finding and have them complete the GHE1=5.</p> <p>For participants reported deceased or moved out of area during an AFU interview or any other recruitment effort, record the date (Q1) when the entry was made and the staff ID number (Q2) of the person who made the entry</p>

A1. Call Pre MRI Screening

Follow protocol instructions to screen the participant. To ensure that the MRI visit is not cancelled, complete the Pre-Screen at time of phone contact. Do not schedule an MRI appointment until the phone contact pre-screen is completed and participant is deemed eligible.

Q4. Pre-Screen completed? 0= No 1= Yes [GO TO 5]

If pre-screen is completed, continue to **Q5** to provide details on screening findings. If screening is not completed, please provide information in **Q4a**. Schedule a call back to complete the screening.

Q4a. If No, reason 1= Need of proxy [Call back/reschedule visit, End]

2= Medical information incomplete [Call back/reschedule visit, End]

1= Need of Proxy: select this option if participant does not understand the information provided and there is a suspicion of need of proxy. Follow **SIB** administration protocol to evaluate need of proxy at time of phone contact. Schedule a call back with proxy if needed.

2= Medical information incomplete: select this option if participant believes they have a contraindication to receiving an MRI but they need to gather more information; schedule a call back to complete screening.

Q5. Absolute contraindications found in prescreening? 0= No 1= Yes [Set Q7=1, End]

If the participant has an absolute contraindication (e.g. pacemaker. See protocol for additional information), thank the participant for their time, let them know how important they are to the study, and end the call.

SET Q5=1 and Q7 =1 (ineligible).

Note on Permanent Makeup and Face Tattoos

FCs need to confirm with their MRI technician how the MRI center deals with face tattoos or permanent makeup. Before undergoing an MRI procedure, the patient should be asked how old their tattoo is. If the tattoo was applied within four weeks of the scheduled scan, the participant will need to be rescheduled. Scanning a new tattoo (<4 weeks old) could cause morphing of the tattoo.

The FDA's Office of Cosmetics and Color assures that tattoo burns from MRI machines seem to occur only rarely and without lasting effects. There have been no reported issues relating to the tattoo's country of origin and/or whether it was applied in a professional setting, however, the MRI technician will make the final call. Every Field Center should adhere to their Imaging Center's protocols regarding facial tattoos and permanent makeup. Try to get as much information as possible about where they got the tattoo and when. Consult with the technician to see if the participant would be eligible for the MRI based on the information the participant has provided; if the technician indicates that this is an absolute contraindication, record this in **Q5** and enter a Notelog in this question as follows:

Tattoo Description	Notelog Code, Q5
Face Tattoo outside the US	TF
Face Tattoo in US questionable location	TFQ
Permanent Makeup outside US	PM
Permanent Makeup in US questionable location	PMQ

Every participant with a facial tattoo/permanent makeup should be closely monitored using visual and auditory means throughout the scan. The participant should be made aware that there is a small possibility that the tattoo may cause a tingling or burning sensation. The participant should be advised to immediately inform the MRI tech regarding any unusual sensation at the site of the tattoo, and the scan should be stopped immediately. Beforehand, a cold compress (a wet towel) can be placed over the tattoo site as a precautionary measure.

NOTE: If site MRI center has a contraindication not listed in the study protocol, (e.g. they do not scan participants with face tattoos), then make **Q5=1** and note reason in the Notelog for future reference.

Q6. Possible contraindications found in prescreening? 0= No

1= Yes [Follow protocol, confirm eligibility].

If the participant has a potential contraindication (e.g. subject had a hip replacement), inform the participant that you have to confirm eligibility with the MRI technician. Schedule a call back to provide a final determination. If technician clears the possible contraindication, proceed with scan. This question does not need to be updated when contraindication is cleared.

Note that contraindications can be site specific. For this reason, we cannot provide a full list of standardized possible contraindications. Use caution in your judgement, consult with the MRI technician if there is a concern about a specific health condition or implant. This question is mainly to assist sites in recording possible contraindications that would need further evaluation before study participation.

Possible contraindication cleared by Site MRI Center Tech:

If the technician (site MRI center) clears the possible contraindication reported at time of screening, please proceed to code the form as follows:

- Code **Q6=1** (possible contraindication reported)
- Code **Q7=3** (eligible and agreed to participate) or =2 (eligible but refused to participate), according to the participant's decision to participate in the study.

Note: At time of visit, the participant should be personally screened by the MRI technician before the scan. Complete section **B2. MRI Technician Review** accordingly.

A2. Call Pre-Screening Result

Q7. Enrollment Status in Ancillary Study

1= Ineligible [End],

2= Eligible but refused to participate [End]

3= Eligible and agreed to participate

After the phone contact pre-screen is finalized, record enrollment status. If they are eligible and agree to participate, proceed to schedule an MRI visit date in **Q8**. If ineligible or refused, thank the participant and end the call.

Q8. MRI Schedule Date

Record the agreed MRI visit scheduled date, update when MRI visit is rescheduled for any reason. (e.g. no-show, scan interruption with reschedule, or the MRI center reschedules, etc.) Field Center can add a Notelog to clarify, for future reference, the reason why the scan was rescheduled.

Section B: MRI Visit Information

Complete this section when the participant comes to the MRI visit. **DO NOT** complete this section for no-shows.

If participant fails to show up for the scheduled visit and the site would like to have a reference for the reason, proceed to enter a Notelog in **Q8**. Place this participant in the call-back list to reschedule the scan.

B1. Informed Consent Tracking**Q9. Consented by: 1= Proxy 2= Participant**

Identify who consented for the MRI, the participant or proxy. Follow protocol to determine need of proxy.

Q10. Staff ID: Enter Staff ID of the person who administered the IC at time of MRI visit.

Q11. Consent date: Enter the date the IC was signed.

Q12. Consent/assent Status 0= Refused to participate [End] 1= Agreed to participate

Enter final consent agreement status.

B2. MRI Technician Review

The MRI exam cannot be performed until the technician has screened the participant according to the FC MRI center protocol and they have reviewed any contraindications found at time of pre-screen.

This section is to record the final review from field center MRI technician. Complete this section for all participants when the technician review has been completed.

Q13. MRI Technician screened participant? 0= No [Go To 15] 1= Yes

If the technician proceeds to scan the participant, set Q13=1 & Q14=1

Q13 will also serve as a final review for any possible contraindications assessed at the call pre-screen. Follow protocol information related to safety. If the technician proceeds to scan the participant, set **Q13=1**.

Set to 0= No [Go To 15]: If the FC MRI technician, for any reason, fails to screen the participant and/or fails to review any contraindications found at pre-screen, the MRI cannot be done. Set **Q15=0** (not performed), and provide information in **Q15a** on why it was not performed.

Set to 1= Yes: After the technician screens the participant according to FC MRI center protocol and they review any pre-screen contraindications (if any). If there aren't any contraindications set to **Yes** once the technician has completed the FC MRI center form. Continue with **Q14**.

Q14. MRI eligibility approved by Technician? 0= No 1= Yes

Set to 0= No: If technician does not approve eligibility, thank the participant for their time and inform them that they are not eligible for the study. Let them know that participant safety is our primary concern. Continue by setting **Q15=0** (not performed), and provide information in **Q15a** on why the scan was not performed.

Set to 1= Yes: For all participants that were approved to complete the scan.

B3. MRI Status

Q15. MRI exam was... 0= Not performed [END] 1= Performed

Set **Q15=1**, if the MRI scan obtains an image that can be transferred to the MRI reading center at UCDavis. If an image was not obtained, for any reason, the scan will be considered as not performed, set **Q15=0**. See below for data entry details.

Q15a. If not performed, specify

Indicate the reason why the MRI was not performed after approved and consented.

Incomplete/Partial MRI

In the event that an MRI was interrupted but a partial image was obtained, proceed to code as follows:

1. Set **Q15=1** (Performed)
2. Enter a Notelog in **Q15** = Partial. Entering this one word in the Notelog is the best way to allow us to identify partial scans most effectively. Proceed to enter the reason in **Q16**, see below.
3. In order to report the reason why a scan was not completed, please enter a Notelog in **Q16** describing the reason why the image was partial. This is the most effective method of helping us to identify reasons why a scan is incomplete/partial.

If MRI Scan was interrupted and no image was obtained:

Set **Q15=0** (Not performed)

Any comments on interrupted (no-image) scans should be entered in a Notelog in **Q15**.

Q16. MRI exam Date: Enter date of MRI was completed.

REMEMBER to mark the form as **COMPLETE**,
in the CDART form screen once screening is fully complete and the MRI scan is obtained.