MRI Screening Questionnaire – QxQ

General Information

The MRI Screening Questionnaire is used to determine eligibility for the SOL Liver and Heart Study. The questionnaire is administered once the participant has been approached and received a brief description of the study, typically by telephone (Telephone Script). Much of the questionnaire can be completed initially by telephone, but certain questions require in-person assessment. The questionnaire can be administered to screen out ineligible participants by telephone. If the participant remains eligible after telephone-based questioning, the participant can next have the informed consent reviewed over the phone. If based on this preliminary informed consent, the participant remains interested, s(he) can be scheduled for a face-to-face visit after administration of the covid-19 screener determines eligibility for in-person participation.

Question by Question Instructions

Initial study eligibility

1. Check whether participant is (YES) or is not (NO) interested in MRI.

2. If answer to question 1 is NO, please indicate the reason (free text field).

General study eligibility.

Introduction. Questions on certain health conditions such as hepatitis C virus (HCV), human immunodeficiency virus (HIV) or alcohol use may be sensitive, but are essential for appropriately focused study of non-alcoholic fatty liver disease and heart disease. It is important to be mindful of such sensitivities in posing these questions. It is key that the participants understand that these conditions are being asked about to permit attainment of the prespecified goals of this research study. There is no prejudice or judgment on participants with regard to the conditions asked about.

Please use the script provided to present the rationale for potentially sensitive questions as part of screening for the research study: "There are certain medical conditions that we want to get information about. These conditions are important to Hispanic/Latino health, but they are not the focus of this research study on non-alcoholic fatty liver disease and heart disease. It is essential for us to ask you about these conditions to determine whether you are eligible to participate in the research study. We recognize that some of these questions may be sensitive. We appreciate your cooperation, as your answers to these questions will allow us to appropriately study non-alcoholic fatty liver disease and heart disease."

2a. For women, ask if they have had a double mastectomy (bilateral breast removal surgery). Document if such a history is present with a YES response, or a NO response

otherwise. *If the response is YES, the person is not eligible to participate in the study, and the interview can conclude.*

2a1. Ask the participant if (s)he has ever tested positive for HCV, or received treatment for HCV? HCV has been the most common cause of chronic hepatitis (inflammation of the liver), and the leading cause of end-stage liver disease, but advent of direct acting antiviral medications has now made infection with HCV largely curable. If the participant responds YES to these questions, this should be indicated. If the participant is uncertain about having had this infection, then mark the response as NO. *An answer of YES makes the person ineligible to participate in the study, and the interview can conclude.* For participants who indicate that they are HCV positive, if they have not sought or received treatment, they should be referred for evaluation by a health care provider.

2b, 2c. Inquire if the participant has a history of chronic liver disease. Here, the focus is on chronic conditions other than non-alcoholic fatty liver disease (NAFLD) that cause liver damage. These conditions include autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, Wilson's disease, hemochromatosis or cirrhosis from previous heavy alcohol use. Also included is a history of liver cancer, liver radiation therapy or liver surgery. If the participant states that history of any such conditions or interventions is present, indicate YES as the response. If the participant does not know the name of his/her liver condition, but indicates that s(he) has been told by a health provider that they have such disease, and it is not related primarily to fat build-up in the liver, also mark YES. If the participant says there is no such history, and does not report a liver condition other than NAFLD that requires chronic medical care, mark the response as NO. *An answer of YES to this question makes the person ineligible to participate in the study, and the interview can conclude.* For participants with chronic liver disease who are not receiving medical care, these can be referred for local medical evaluation.

2d. Inquire if the participant has ever received an organ transplant, such as liver, kidney, pancreas, heart, lung, bone marrow, etc. If such a history is present, please enter YES as a response. Otherwise, enter NO. *An answer of YES to this question makes the person ineligible to participate in the study, and the interview can conclude.*

2e. Ask if the participant is currently receiving dialysis (hemodialysis or peritoneal dialysis) for end-stage kidney disease. If currently receiving dialysis, please enter YES. Enter NO otherwise. *An answer of YES to this question makes the person ineligible to participate in the study, and the interview can conclude.*

2f. Ask the participant how many alcoholic drinks on average s(he) consumes per week. A standard alcoholic beverage is one glass of wine or can of beer or a shot of whiskey or other spirits. This may be prepopulated from central Visit 3 data, but otherwise, document the specific number of drinks. If alcohol intake is >21 drinks/week (men) or >14 drinks/week (women), mark the answer in 2f1 as YES, and NO otherwise. *If YES, the person is not eligible to participate in the study, and the interview can conclude.*

2g. Inquire if the participant has tested positive for human immunodeficiency virus (HIV) or is currently receiving treatment for HIV. If the answer is affirmative, mark the response a YES, and NO otherwise. *A response of YES makes the person ineligible to participate in the study, and the interview can conclude.* If the participant is positive but not treated, we recommend evaluation for treatment with available effective medications for this condition.

2h. Interviewer is asked to document if any of the questions in section A were answered "yes," in which case the participant is ineligible to participate in the study. If so, enter YES, and proceed to question 24. Otherwise, enter NO.

MRI eligibility screening

3. Ask the participant if s(he) has a pacemaker, implanted cardioverter defibrillator, nerve or bone stimulator or any implanted electronic or metallic device inside his/her body that could make MRI unsafe. Ask the question broadly, probing for any and all implants. Consideration of whether a metallic implant or device is safe can be narrowed down using the following guidelines.

- Electronic devices such as pacemakers, defibrillators, stimulators or pumps are *unsafe*.
- Implants in the head (e.g., cranial plates) are *unsafe* for MRI, as are most breast expanders and metallic penile prostheses.
- By contrast, orthopedic implants in joints or bones of the extremities or spine are *safe* (e.g., hip replacements, knee replacements, and orthopedic rods, screws or pins).
- Also safe are hernia repairs using a mesh, lens implants such as those for cataracts, tissue markers, and breast implants.

If an unsafe device or implant is present, the answer is YES. If the implant is safe, the answer is NO. Please note that we will not be obtaining medical records or following up with participants' health providers to determine the type of implant and its safety for MRI. Unless the implant is known to be safe (based on the type of implant, e.g., hip replacement, or because the participant has had an MRI safely after its insertion), and the field center clinician approves proceeding, the answer should be YES. If the participant is uncertain, consultation of the clinician may likewise be made at staff discretion. But if it cannot be determined with confidence that the metallic implant is safe, an answer of YES should be recorded. If the metallic implant is removable, for instance, external piercings or rings, the answer will be a NO so long as the participant is willing and able to remove these. If these will not or cannot be removed, the answer will be YES. As with all implants, it will ultimately be the judgment of local MRI facility staff as to whether a participant's implant is safe for MRI, and local facility MRI staff can be consulted if there is uncertainty. *A response of YES is a contraindication to MRI, and the interview can conclude.*

4. Inquire if the participant has ever had brain surgery for a cerebral aneurysm that would (potentially) make MRI unsafe. (Note that the focus of the question to the participant is on the history; a determination of whether it would be unsafe is up to the field center's medical or MRI team in accordance with the local MR safety policies.) Such surgery is associated with presence of metallic clips in brain arteries. Some types of clips, such as titanium and nitinol clips, are MRI safe or conditional, but others are not. If medical documentation can be obtained for review by MRI facility staff, and a confident determination is made that the clips are safe, the participant remains eligible for MRI. If the clip is determined conditional, as long as the conditions are met, the participant also remains eligible for MRI. In the absence of such documentation, a history of brain surgery for cerebral aneurysm is a contraindication to MRI. Enter YES in the presence of a history of brain aneurysm surgery that would make MRI unsafe. Enter NO in the absence of such a history or if the surgery is well documented to have been done with clips that are MRI safe or conditional, as determined by MRI facility staff. *A response of YES is a contraindication to MRI, and the interview can conclude.*

5. Ask the participant if s(he) is claustrophobic or feels particularly anxious in closed, confined spaces. If the participant indicates that the anxiety is at a level where s(he) would not, or probably would not, be able to remain in the MRI scanner for approximately 1 hour, mark the answer as YES. Otherwise mark the answer as NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

6 and 6a. Ask participant for his/her weight. This can be confirmed by weighing the participant on a scale at the time of the initial visit at staff and field center investigators' discretion. If self-reported weight is greater than 350 lbs (greater than 159 kg), answer the question as YES, and NO otherwise. *A response of YES is a contraindication to MRI, and the interview can conclude.*

6b and 6c. Ask the participant for his height. Use the link: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm to calculate body mass index (BMI) by entering participant's height and weight. Height and weight can be entered in standard units (feet and inches, lbs) or metric units (centimeters and kilograms). Alternatively, if information on BMI is available from Visit 3, this can be used instead.

7. In 7a, the interviewer documents that the site location is Chicago or San Diego by entering YES if that is the case, and NO otherwise. If NO, interviewer proceeds to Q8. If YES, proceed to 7b. Based on the answer to 6c, if BMI$\geq$40 kg/m^2 in men or BMI$\geq$35 kg/m^2 in women enter YES in 7b. Otherwise, enter NO, and proceed to Q8. If the answer to 7b is YES, the participant must have measurement of sagittal abdominal diameter at an initial visit before MRI is scheduled to make sure that participant's vertical dimension when supine will allow him/her to fit in the scanner. (Of note, we are modifying sagittal abdominal diameter here to apply to the largest vertical height of the *abdomen or chest* when lying on his/her back. If the greatest vertical dimension is not at the level of the abdomen but of the chest, then this effectively becomes the sagittal thoracic diameter.) Once a measurement is made, if the highest vertical dimension of

the abdomen or chest is ≥32 cm, please answer 7c as YES. Otherwise enter a NO. *A response of YES is a contraindication to MRI.*

8. For women, inquire if the participant is pregnant or has a history of being pregnant in the past 3 months (90 days). This should be asked of all women 60 or younger. If the participant is uncertain about her status, a urine pregnancy test will be necessary. If the participant knows that she is pregnant or has been pregnant in the last 90 days, enter an answer of YES. Otherwise, enter NO. If the participant is pregnant or recently completed her pregnancy, she would be eligible for participation in MRI ≥90 days after delivery; however, if she is breastfeeding, she would not be eligible for IV contrast at that time. *A response of YES is a contraindication to MRI, and the interview can conclude.*

9. Ask if the participant has ever been shot with bullets, BBs or shrapnel that would make MRI unsafe. (Note that the focus of the question to the participant is on the history; a determination of whether it would be unsafe is up to the field center's medical or MRI team in accordance with the local MR safety policies.) Indicate if YES or NO. In the participant gives such a history or is unsure about the history, and there is no documentation to support a determination that an MRI would be safe, enter a YES. If, on the other hand, medical documentation can be obtained that such metallic objects have been entirely removed and/or the participant has safely completed MRI previously, with review by MRI facility staff determining that MRI would be safe, enter NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

10. Inquire if the participant has ever been a machinist, welder or metal worker, or if s(he) has ever had metal removed from his/her eyes, such that an MRI would be unsafe. (Note that the focus of the question to the participant is on the history; a determination of whether it would be unsafe is up to the field center's medical or MRI team in accordance with the local MR safety policies.) If the participant gives a positive history or is unsure about the history, and there is no documentation to support a determination that MRI would be safe, enter YES. Otherwise enter NO. If, despite the participant's prior occupation as a machinist, welder or metal worker or previous removal of metal from the eyes, subsequent orbital X-rays document no metal, and review by MRI facility staff determines that MRI would be safe, enter NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

11. Ask if the participant uses hearing aids or has ever had a cochlear (inner ear) implant that would make MRI unsafe. (Note that the focus of the question to the participant is on the history; a determination of whether it would be unsafe is up to the field center's medical or MRI team in accordance with the local MR safety policies.) If the participant gives an affirmative response or is uncertain about the history, and there is no documentation to support a determination that MRI would be safe, enter YES. Otherwise enter NO. If circumstances exist, such as removal of a prior implant that can be medically documented, which upon review by MRI facility staff make MRI safe, enter NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

12. Determine if the participant has had heart surgery for replacement of a valve with a prosthesis. Because such prostheses can interfere with imaging of the heart, such participants will be excluded. Enter a response of YES or NO. *A response of YES excludes the participant from MRI, and the interview can conclude.*

13. Ask if participant is able to have an MRI by being inside a scanner for about 60 minutes. Enter a response of YES or NO. *A response of NO excludes the participant from MRI, and the interview can conclude.*

If any of Q3-Q5, Q6a, Q7c, Q8-Q12 = Yes OR if Q13 = No, person is ineligible for study participation [Go to Q24]

13a. Interviewer is asked to document if participant is eligible based on MRI screening questions. If so, enter YES, and if NO proceed to question 24.

IV contrast eligibility screening based on participant interview:

14. Inquire if participant has had an MRI with gadolinium contrast (injected dye used in MRI studies) in the past 6 months. Because we want to allow a 6-month interval before repeat administration of gadolinium contrast, the participant will not be eligible for MRI with contrast if gadolinium was administered within this period. Note that other kinds of contrast, such as for computed tomography (CT), are not relevant to administration of gadolinium and do not count. Answer with a YES or a NO. *If YES, the participant cannot have an MRI with contrast until the 6-month interval is met.* The preference is to recontact the participant at a later date to schedule the contrast MRI once the requisite time period has elapsed. An alternative is to enroll the participant for non-contrast MRI now if s(he) is eligible.

15. Ask if the participant has a history of allergic reaction to MRI gadolinium contrast. Again, note that gadolinium is different than the contrast administered for computed tomography (CT). A mild or moderate allergic reaction to CT contrast is not a contraindication to MRI with contrast, but will need to be detailed in the Asthma and Allergy Screening Questionnaire. Indicate a response of YES or NO. *If YES, participant is ineligible for contrast MRI.*

16. This question has been removed.

17. For women, ask if they are currently breast feeding. Enter YES or NO. *If YES, participant is ineligible for contrast MRI.*

If any of Q14-Q17 = Yes, person is ineligible for IV contrast.

17a. Interviewer is asked to document if participant is eligible for contrast based on screening questions. If so, enter YES and proceed to next section. If NO proceed to question 20.

If participant eligible for IV contrast, proceed to Asthma and Allergy screening.

18. Ask if participant has a history of asthma. If YES, proceed to Asthma and Allergy Screening Questionnaire. Otherwise enter a response of NO and proceed to Q19. If there is a history of asthma, indicate in Q18a after completing Asthma questionnaire if contrast is contraindicated by entering a response of YES. If Asthma questionnaire indicates that participant is eligible for contrast, enter a response of NO. *If YES is marked, participant is ineligible for contrast MRI.*

19. Ask if participant has a history of allergies to food, drugs or insect stings. If YES, proceed to Asthma and Allergy Screening Questionnaire. Otherwise enter a response of NO and proceed to Q20. If there is a history of such allergies, indicate in Q19a after completing Allergy questionnaire if contrast is contraindicated by entering a response of YES. If Allergy questionnaire indicates that participant is eligible for contrast, enter a response of NO. *If YES is marked, participant is ineligible for contrast MRI.*

Study participation

20. If participant is eligible for MRI (with or without contrast) based on responses to questions 2a through 13, proceed with obtaining preliminary phone consent. Once written informed consent is given, enter a response of YES. If written informed consent is declined by participant, enter NO. If only preliminary consent has been obtained over the phone, leave blank. If YES, proceed to in-person laboratory testing.

MRI or IV contrast eligibility based on laboratory testing: *To be completed after participant consented.*

21a and b. Enter value of estimated glomerular filtration rate (eGFR) based on creatinine testing from either point-of-care StatSensor test or Core Laboratory testing. The eGFR is determined by using the CKD EPI 2009 calculator provided in the following link: https://www.mdcalc.com/ckd-epi-equations-glomerular-filtration-rate-gfr Enter participant sex, age and creatinine value. Record the lower value of the eGFR range reported by the calculator. If it is <45 ml/min/1.73 m^2, enter a response of YES to Q 21b. Otherwise enter a response of NO. *If YES is marked, participant is ineligible for contrast MRI.*

22. For women age 60 or younger, answer YES. For all others, answer NO. If NO, may skip to Q24.

22a. For women age 60 or younger, ask if they have had prior surgery to remove the uterus and/or both ovaries and enter the response. Removal of the uterus or both ovaries would make them incapable of conceiving a child. If there is a prior history of surgery to remove the uterus, the right and left ovaries, or both, please enter YES. If there is no such history, enter NO. If YES, as per site procedures, may skip to Q24.

However, if status is less than fully certain, enter UNSURE. If uncertain or if the site protocol calls for it, may proceed to Q22b for added check.

22b. For female participants age 60 or younger, ask the date of the last menstrual period and enter it in 22b.
22b1.If this is up to and including 12 months from the date of questioning, enter YES. If its longer than 12 months, enter NO. If participant is uncertain about the date, enter UNSURE. If longer than 12 months, the participant can be considered post-menopausal. If NO, and consistent with site procedures, may skip to Q24. Otherwise, proceed to Q23.

23. Field centers and staff will use their discretion on whom to do a urine pregnancy test on. But field centers may consider giving a urine pregnancy test to all women age 55 or younger. It is encouraged that this be done at the time of the initial visit, but irrespective of whether it is performed at this visit, urine pregnancy testing should be conducted in all women of childbearing potential on the day of MRI prior to being cleared to have the scan. For women of childbearing potential, indicate in Q23 whether the required urine pregnancy test has been performed. This test must be performed before such women have an MRI. Mark the response as YES once performed, or as NO otherwise.

23a. If the answer to question 23 is YES, indicate if urine pregnancy test is positive by entering a response of YES. If the answer is YES, please provide participant with a letter notifying her of this result, and advising her to follow-up with a physician for evaluation. If the urine pregnancy test is negative, enter a response of NO. If urine pregnancy test is not performed at this time or is not necessary, leave blank.

24. Indicate if participant is eligible for MRI based on the interview and any laboratory testing performed as of the date of form completion. This is based on the responses to Q2a-13, Q20, or Q22-23a. If later testing, namely, a positive urine pregnancy test (Q23a), makes the participant ineligible for MRI subsequently, this can be entered on the same form template in CDART at a later date. Enter a response of YES or NO as appropriate. *If NO, participant is ineligible to take part in MRI.*

25. Indicate if participant is eligible for IV contrast MRI based on interview and any laboratory testing performed as of the date of form completion. This is based on responses to Q14-Q17, Q18a, Q19a or Q21b. If later testing, namely, an eGFR<45 ml/min/1.73 m^2, makes the participant ineligible for IV contrast subsequently, this can be entered on the same form template in CDART at a later date. Enter a response of YES or NO as appropriate. *If NO, participant is ineligible to have a contrast MRI.*

26. Enter initials of staff reviewing consent form and Questions 2a-23, Asthma and Allergy Screening forms and laboratory test results, and determining that participant consented to (preliminarily or fully) and is eligible for MRI and/or IV contrast.

If participant is consented (preliminarily or fully), that is, Q20 is left blank or is a YES, and is eligible (Q24 is a YES), the participant may be scheduled for MRI. An MRI with contrast may only be scheduled if the answer to Q25 is a YES. Note that if only a preliminary consent has been obtained and a creatinine value has not been measured (no calculated eGFR), these will need to be done on the day of the in-person visit for MRI prior to being eligible to undergo the procedure or receive contrast.

If the participant is eligible, proceed to administration of informed consent, to be completed in person at the time of the initial visit. Prior to scheduling the initial visit please confirm that the Covid-19 Screener responses indicate that the participant is eligible to come in for an in-person visit.