HCHS/SOL INCA MRI Ancillary Study (AS#2016.02)
QxQs

NIA grant: Ancillary to HCHS/SOL: MRI Measures of Cerebrovascular Injury and AD Atrophy in a Study of Latinos (RF1 AG054548, C DeCarli & H Gonzalez)

English
MMA - Minor Adverse Event Form QxQ
MSE - Screening Enrollment Form QxQ
PMS - MRI Screening Form English QxQ
UPM - Unanticipated Problem Form QxQ

HCHS/SOL V2-Minor Adverse Event Form
MMA- QxQ Updated on 6/21/2018

General Instructions

An adverse event (AE) is an adverse change in health or unfavorable medical occurrence that occurs in a person who participates in HCHS/SOL, which may or may not be caused by participation in the study. Adverse events include both physical and psychological harms temporally associated with the individual's participation in the research, whether or not considered related to the subject's participation in the research. Serious adverse events (SAEs) and unanticipated problems that are not foreseen in the study protocol or referred to in the informed consent must be reported to the local Institutional Review Board (IRB), and then to the study sponsor (NHLBI), according to the schedule set out below.

This form should be completed within 7 days of a minor adverse event. An event is minor if it DOES NOT affect a pregnant study participant, a fetus or a newborn, or if it DOES NOT result in any of the following outcomes: Death, A threat to life, Requires (inpatient) hospitalization, Likely causes persistent or significant disability or incapacity, Likely associated with a congenital anomaly or birth defect, Requires treatment to prevent one of the outcomes listed above, other than for pre-existing conditions detected as a result of participation in HCHS/SOL, its tests and examination protocol. **For SOL INCA MRI: Minor adverse events (MMAs) are anticipated and expected to occur as stated risks in the study protocol, whether study related or otherwise.**

OHRP considers unanticipated problems to include any incident, experience, or outcome that meets all of the following criteria:

a. Unexpected;

b. Related or possibly related to participation in the research; and

c. Suggesting that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All serious adverse events (SAEs) are considered to be unanticipated and unexpected, whether they are study-related, possibly study-related, or not study-related. Minor adverse events (MMAs) may be study-related, possibly study-related, or not study-related. Refer to MOP-2 for more details on Adverse Events.

HCHS/SOL V2-Minor Adverse Event Form
MMA- QxQ Updated on 6/21/2018

Table 5. Unanticipated Problems and Adverse Events - Actions by the HCHS/SOL Study Agencies and Timing						
Type of Event	**HCHS/SOL Field Center**			**Coordinating Center**	**HCHS/SOL Ops and Measmts. Cmte.**	**Steering Committee**
Serious Adverse Event (SAE)/ **Serious Unanticipated Problem** (UP)	Address any ppt. safety issues; inform medical director and PI	Record SAE in the HCHS/SOL DMS (CDART)	Report AE to IRB	Notify NHLBI	Review study procedures; propose revisions if warranted	Review report of AE and study procedures; modify protocol if required
Time / Schedule	Immediate	48 hrs.	72 hrs.	Within 7 calendar days	Within 14 calendar days	Within 30 calendar days
Non-serious Unanticipated Problem (UP)/ Non-serious or Minor AE	Address any ppt. safety / comfort issues	Record AE in the HCHS/SOL DMS (CDART)	Report AE to IRB	Notify NHLBI,	Review study procedures with experts; propose revisions if required	Review report of AE and study procedures; modify protocol if required
Time / Schedule	Immediate	48 hrs.	Within 7 calendar days	Quarterly	Within 30 calendar days	Quarterly
Anticipated Problem or AE (not deemed serious)	Address any ppt. safety / comfort issues	Record AE in the HCHS/SOL DMS	No	No	N.A.	Review report
Time / Schedule	Immediate	48 hrs.	N.A.	N.A.	N.A.	Quarterly

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	If they are reported deceased at time of call. Thank the informant for their time. 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**. 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

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.

SOL INCA MRI Pre-Screening Guidelines
PMS– QxQ
6/7/2018

General Instructions

The PMS is a paper form ONLY (will not be entered in CDART) that should be kept in the participant's record at the site.

The Pre-MRI screening form is a questionnaire that helps the research personnel determine if the MRI procedure is safe for a study participant. **The presence of certain metallic, electronic, magnetic or mechanical implants, devices or objects over or inside the body have been deemed hazardous in the magnetic resonance environment.** Participants with these implants or devices in their bodies are contraindicated for the MRI procedure.

The MRI pre-screening form is administered by the research personnel to all eligible study participants over the phone; if no contraindication to the procedure is found then the MRI is scheduled. Besides participant safety, it is important to avoid cancelled scan slots due to incomplete pre-screening at time of phone contact. On the day of the appointment, prior to taking the participant to the MRI scan room, the MRI technologist will review the MRI screening form provided by the site staff, and will complete the required screening form for the local MRI center with the study participant. The field center staff will request a copy of the MRI center screening form to keep in the participant's field center record.

The MRI Pre-screening form has English and Spanish versions, select the form in the participant's language of preference.

Absolute contradictions (exclusions) for MRI include:

1) Pacemaker or implantable defibrillator
2) Aneurysm Clips
3) Metallic Foreign body in the eye
4) "Triggerfish" contact lens
5) Gastric Reflux device
6) Insulin pumps

If the participant has an absolute contraindication to MRI, inform them that they are not qualified for the study and thank them for their time.

QxQ Instructions

Q1. Have you ever had surgery or similar invasive procedure in which medical devices may have been implanted?

0= No Participant does not report a surgically implanted device

1= Yes Record the implant information and proceed to obtain approval. Document the type of surgery, the facility where it took place and the date. If the participant is unable to recall the exact date make attempts to determine an approximate date by asking questions like:

"Do you remember if the surgery was done in summer or fall of that year?"

"Was it around a holiday like Thanksgiving, Christmas or mother's day?"

Try to document at least the year and month to facilitate the medical records investigation to obtain the operative report. Find out if the participant has medical records of that procedure and/or the implant card. The information obtained must be reviewed with the MRI safety officer before scheduling the participant for the MRI and the MRI Implant Required information form IRI needs to be completed.

Q2. Have you ever had any previous MRI imaging studies?

0= No Participant does not report previous imaging studies

1= Yes Complete MRI corresponding information. List the following information for each of the imaging studies in the space provided: Part of the body that was imaged, date and facility.

For the dates: If the participant is unable to recall the exact date, try to document at least the year and month make attempts to determine an approximate date by asking questions like:

"Do you remember if the surgery was done in summer or fall of that year?"

"Was it around a holiday like Thanksgiving, Christmas or mother's day?"

Q3. Have you ever worked with metal (such as grinding, fabricating etc.) or ever had an injury to the eye involving a metallic object (such as metallic slivers, shavings, shrapnel, foreign body)?

0= No Participant does not report working with metal or eye injury by a metallic object.

1= Yes If they might have a piece of metal in the eye, you should not scan them until you confirm this information. If they DO have a metallic foreign body in their eye (this is an absolute contraindication for MRI) STOP and inform them that they are not qualified for the study and thank them for their time.

If the participant reports having working with metal on the situations described and they do not believe they have a piece of metal in their eye, review the information with the MRI technician before scheduling the participant.

Female Participants ONLY (Q4-Q7)

The purpose of this set of questions is to exclude pregnant and/or breastfeeding participants from the MRI examination. Review the participant's age, at the top of the form to determine which questions to ask the participant.

Female participants Younger than 55 years of age

State to the participant:

"I apologize for asking the next 5 questions if it makes you feel uncomfortable, but this information is important for your safety." Record the answers.

Female participants Older than 55 years of age

Complete ONLY Q6. Skip questions 4, 5 and 7.

Q4. Are you pregnant, or is there a possibility that you are pregnant?

0= No Continue with screening. If participant is UNSURE please consult the sites MRI technician or the UCDavis PI

1= Yes This is a contraindication, STOP and inform them that they are not qualified for the study and thank them for their time.

Q5. Are you breastfeeding?

0= No Continue with screening.

1= Yes This is a contraindication, STOP and inform them that they are not qualified for the study and thank them for their time.

Q6. Date of last menstrual period: Record the date for **All** females, including those older than 55 years of age.

Note: If the participant is unable to recall the exact date, try to document at least the year and month. Make attempts to determine an approximate date by asking questions like:

"Do you remember if the surgery was done in summer or fall of that year?"
"Was it around a holiday like Thanksgiving, Christmas or mother's day?"

Q7. Are you taking any type of fertility medication or having fertility treatments?

0= No Continue with screening

1= Yes Please report this information to MRI technician.

Q8. Are you taking oral contraceptives or receiving hormone treatment?

0= No Continue with screening

1= Yes Please report this information to MRI technician.

All Participants

Q9. Do you have a history of seizure disorder or epilepsy?

Ask this question to all participants.

0= No Continue with screening

1= Yes This is NOT a contraindication. This question is for MRI technician information Only. Please report this information to MRI technician.

PAGE 2- IMPLANT LOCATION INFORMATION

Read the whole list to the participant, this will help them remember all the implants they might have in their body. If you are not sure if an implant might be a contraindication for the MRI, consult the site MRI technician or UCDavis PI to confirm.

For additional implant information, refer to the **Implant Exception List** included in the protocol (MOP, and study website).

Let the participant know that some implants will have to be removed before the MRI is performed. The screening form lists those implants that are to be removed. If you have questions about these implants, consult the site MRI technician for additional information.

Items to Remove before MRI as identified in the PMS form

- Transdermal Patch Delivery System (e.g. Nicotine)
- Body piercing(s) (Remove all metallic objects)
- Hearing aid
- Dentures

Tell the participant:

"This is a long list of possible implants, so if any apply to you, just say 'yes.' If not, let me read through each of them".

Read each implant location listed in the form, mark the answer for each of the choices provided.

If yes, annotate in the drawing accordingly. Draw a line from the type of implant towards the area on the body where that implant is located. This will allow identification of the location of each implant in the diagram.

For example, if you have a participant with an artificial left knee, specify in the space provided next to "Joint replacement," left knee implant. Then draw a line from this statement to the left knee in the image.

If no, mark no and continue to read from the list.

SIGNATURE AREA

First Signature Line:

Provide printed name, and signature of the research staff who administered the screening over the phone and the screening date.

Completed by:

Participant, Relative line:

Record the name of the person providing the information [participant or relative (proxy)]. Please note that the Relative is the same as a proxy. If the relative/proxy is providing the information, document the relation with the participant.

Physician or other line:

The last line is used to document the name for the MRI technician reviewing the form. The date of the MRI will be recorded in the CDART MSE form. If your site would like to have the date of the MRI in this form you can note it next to the name.

SOL INCA MRI Unanticipated Problems
UPM– QxQ
5/30/2018

Introduction

The UPM form is completed within 48 hours of an event or occurrence that qualifies as an unanticipated problem (UP) ostensibly related to participation in the SOL-INCA-MRI. A UP is defined as any experience or outcome that is unexpected, and related (or possibly related) to participation in SOL-INCA-MRI, and is suggestive that the research places the study participant or others at greater risk of physical, psychological, economic, or social harm then was previously known. UPs are reported to the local IRB, to the study PI, and to NHLBI (via the SOL-INCA-MRI coordinating center). Completing the UPR form will accomplish this latter notification requirement.

A. Event information.

Item 1-5; this section is pre-formatted to record the information on the HCHS/SOL field center contract, the principal investigator and field center, the date the UP occurred, and whether it was reported to the principal investigator and to the field center IRB, as well as the respective dates of these reports.

Item 6; indicates whether the UP was associated with a main component of the MRI visit examination, or whether it is associated with other elements of an individual's participation in this study. If so, specify under Item 6.

Item 7; provides a text field to describe the event, succinctly but in sufficient detail to determine its nature and potential severity. The circumstances surrounding the UP or leading to its occurrence should be mentioned.

Item 8; indicates whether at the time of reporting the UP is ongoing or resolved.

Item 9; presents a text field to briefly summarize the action taken in response to the UP.

B. Actions Taken.

Section B is to be completed at the SOL-INCA-MRI coordinating center.