



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

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

CAC - Capacity Assessment Checklist

IRI - MRI Implant Required Information Form

MMA - Minor Adverse Event Form

MSE - Screening Enrollment Form

PMS - MRI Screening Form English

SAE - Serious Adverse Event Form

UPM - Unanticipated Problems Form

Spanish

PMS - MRI Screening Form Spanish



HCHS/SOL INCA MRI Capacity Assessment Checklist

CAC ver. 11/28/2017

ADMINISTRATIVE INFORMATION

Date of Consent: / /
(mm/dd/yyyy)

Time: : am / pm Staff ID:

Place PARTICIPANT information label here
Containing full name, HCHS ParticipantID

Instructions: This paper form is to be administered to the participant in person after reading the IC, at the time of MRI visit. If participant is not able to consent, the alternate respondent (proxy) must complete Surrogate Maker form to complete Informed Consent for the participant.

A. Consent Dialogue Name of alternate respondent (proxy): _____

1. Was protocol presented to/discussed with participant? No 1=Yes Other: _____
2. Was protocol presented to/discussed with participant's alternate respondent (proxy)?
No Yes Other: _____

B. CONSENT ABILITIES

3. Did participant *make a choice* to participate in SOL INCA MRI study? No Yes Marginal
 Choice: Participate Not Participate Defer Decision Decision Unclear Other
 Briefly explain _____

4. Did participant show *understanding* of the research protocol and its elements, including risks/benefits of participation?
 No Yes Marginal Briefly explain _____

5. Did participant *show reasoning/provide rational reasons* for participation/non-participation in the research protocol? No Yes Marginal Briefly explain _____

6. Did participant show an *appreciation of the personal risks/benefits* of participation/non-participation in the research protocol? No Yes Marginal Briefly explain _____

C. CAPACITY /INFORMED CONSENT/ASSENT

7. Was participant competent to consent to participation/non-participation in research protocol?
 No Yes Other Briefly explain: _____

8. Was informed consent for research participation obtained from the participant?
 No Yes Other Briefly explain: _____

9. If participant unable to consent, was informed consent for research participation obtained from *alternate respondent (proxy)*? No Yes Other Briefly explain: _____

10. If participant unable to consent and *alternate respondent (proxy)* approved participation, did participant show **assent** to participation? No Yes N/A Unclear Other _____
 Briefly explain: _____

Completed by: _____ Date: / / (mm/dd/yyyy)
 [Signature]



HCHS/SOL INCA MRI Implant Required Information Form

IRI ver. 1/19/2018

ADMINISTRATIVE INFORMATION

Date: / /
(mm/dd/yyyy)

Staff ID:

Place PARTICIPANT information label here
Containing full name, HCHS ParticipantID
Site PI

Instructions: Participants with implants must be approved by the MRI safety officer before a MRI scan may be performed without exception. Provide required information on implants in this form

Participant Information Required for MRI Safety Clearance

	Implant 1	Implant 2	Implant 3
1. Type of Implant:			
2. Location of Implant:			
3. Date of implantation:	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4. Manufacturer:			

_____/_____
Signature/Printed name of Person Completing Form

Date: / /
Month Day Year



HCHS/SOL INCA MRI Minor Adverse Event Form

ID NUMBER:	<input type="text"/>	FORM CODE: MMA	Contact Occasion:	<input type="text"/>	0	1	SEQ #	<input type="text"/>
	<input type="text"/>	VERSION: 1, 6/21/2018		<input type="text"/>				<input type="text"/>

Administrative Information

0a. Completion Date: / / (m m / d d / y y y y)

0b. Staff ID:

Instructions: 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. Minor adverse events (MAEs) are anticipated and expected to occur as stated risks in the study protocol, whether study related or otherwise.

A. EVENT INFORMATION – Completed at the HCHS/SOL Field Center

1. Contract No.:
HHSN

2. Principal Investigator:

3. Field Center:

4. Date MMA occurred: (m m / d d / y y y y)

5. Reported to:

Principal Investigator	No	0	<input type="checkbox"/>	Yes	1	<input type="checkbox"/>	date reported: <input type="text"/>
Field Center IRB	No	0	<input type="checkbox"/>	Yes	1	<input type="checkbox"/>	date reported: <input type="text"/>

6. Source of the event:

- Interview with study participant 1
- Blood draw 2
- Glucose load 3
- Echocardiography scan 4
- MRI Scan 5
- Other physical examination or tests 6
- Other 7

Specify: _____

7. Describe the event (Enter in a notelog on DMS.)

ID NUMBER:

FORM CODE: MMA
VERSION: 1, 6/21/2018

Contact Occasion: 0 1 SEQ #

8. Indicate whether the event is: Ongoing 1 Resolved 2

9. Describe what action was taken (Enter in a notelog on DMS.)

10. Is this type of event foreseen in the Informed Consent or study MOP?

No 0 Yes 1 (Go to End) Don't know 9

11. Likelihood of relationship to participation in HCHS/SOL:

- Unrelated (clearly not related) 1
- Unlikely (doubtful related) 2
- Possible (may be related) 3
- Probable (likely related) 4
- Definite (clearly related) 5

B. ACTIONS TAKEN BY INVESTIGATORS - Completed by the HCHS/SOL Coordinating Center

12. Reported to: NHLBI / / OSMB / /

13. Was a change to the protocol made because of this MMA?

No 0

Yes 1 If Yes, date changed: / /

14. Were any other actions taken by the investigators in response to this MMA?

No 0

Yes 1 If Yes, date action taken: / /

15. If yes to either of the above questions, please specify: _____

16. Completion Date: / / CSCC Staff ID:



HCHS\SOL INCA MRI Screening and Enrollment Form MSE

ID NUMBER:

FORM CODE: MSE
VERSION: A 3/27/2019

Contact Occasion

0 1

SEQ #

0 1

Instructions: Complete this form for all contacted participants. Complete section A at time of phone contact, and section B at time of MRI visit. Refer to QxQ for additional information.

A. PHONE CONTACT

1. Contact Date (mm/dd/yyyy): / /

2. Staff ID:

3. Phone 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]

A1. Call Pre-MRI – Screening

4. Pre-Screen completed? 0= No 1= Yes [Go To 5]

4a. If No, reason 1= Need proxy [Schedule Call back, End]

2= Medical information incomplete [Schedule Call back, End]

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

6. Possible contraindication found in prescreening? 0= No 1= Yes [Follow protocol, confirm eligibility]

A2. Call Pre Screen Result

7. Enrollment Status in Ancillary Study 1= Ineligible [End]

2= Eligible but refused to participate [End]

3= Eligible and agreed to participate

8. MRI schedule Date / / (mm/dd/yyyy)

B. MRI Visit

B1. Informed Consent Tracking

9. Consented by: 1= Proxy 2= Participant

10. Consenting Staff ID:

11. Consent date: / / (mm/dd/yyyy)

12. Consent/assent Status 0= Refused to participate [End]

1= Agreed to participate

B2. MRI Technician Review

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

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

B3. MRI Status

15. MRI exam was... 0= Not performed 1= Performed [Go To 16]

15a. If not performed, Specify: _____ [END]

16. MRI exam Date / / (mm/dd/yyyy)



HCHS/SOL INCA MRI Pre-MRI Screening Form

PMS ver. 5/9/2018 English

ADMINISTRATIVE INFORMATION

Date: / /
(mm/dd/yyyy)

DOB: / / Staff ID:

Height: _____ Weight: _____

Place PARTICIPANT information label here
Containing full name, HCHS ParticipantID
Site PI

Instructions: Participants with implants must be approved by the MRI safety officer before a MRI scan may be performed without exception.

1. Have you ever had surgery or similar invasive procedure in which medical devices may have been implanted? No Yes

If yes, please list:

Type of surgery

Date (mm/dd/yyyy)

/ /

/ /

2. Have you had any previous MRI imaging studies? No Yes

If yes, please list:

Body Part

Date (mm/dd/yyyy)

Facility Location

_____ / /

_____ / /

_____ / /

3. Have you ever worked with metal (grinding, fabricating, etc.) or ever had an injury to the eye involving a metallic object (e.g., metallic slivers, shavings, shrapnel, foreign body)? No Yes

If yes, please describe: _____

For female participants only:

4. Are you pregnant, or is there a possibility that you are pregnant? (if unsure, please notify MRI operator or Principal Investigator) No Yes

5. Are you breastfeeding? No Yes

6. Date of last menstrual period: / / (mm/dd/yyyy)

7. Are you taking any type of fertility medication or having fertility treatments? No Yes

8. Are you taking oral contraceptives or receiving hormone treatment? No Yes

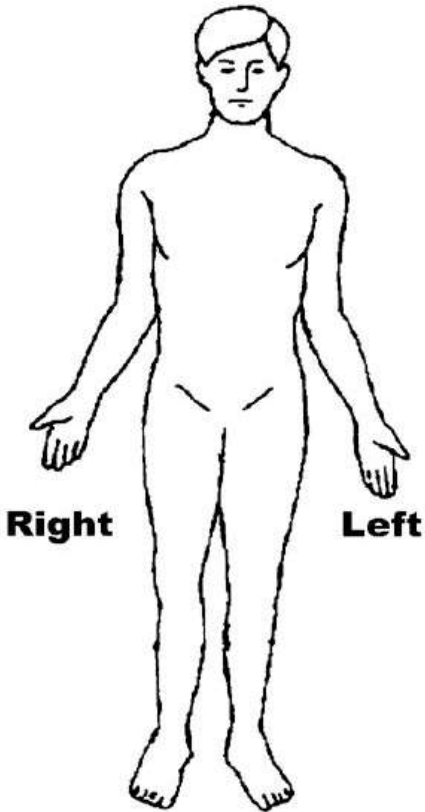
9. Do you have a history of seizure disorder or epilepsy? No Yes

**PARTICIPANTS WITH IMPLANTS MUST BE APPROVED BY THE MRI SAFETY OFFICER
BEFORE A MRI SCAN MAY BE PERFORMED WITHOUT EXCEPTION.**

**Some of the following items may be hazardous to your safety and some can interfere with the MRI examination.
Please check the correct answer for each of the following. Do you have any of the following:**

Yes	No	Implant Location
<input type="checkbox"/>	<input type="checkbox"/>	Dental Hardware (e.g. metal crowns, braces, retainers)
<input type="checkbox"/>	<input type="checkbox"/>	Cardiac pacemaker
<input type="checkbox"/>	<input type="checkbox"/>	Implanted cardiac defibrillator
<input type="checkbox"/>	<input type="checkbox"/>	Aneurysm clip(s)
<input type="checkbox"/>	<input type="checkbox"/>	Carotid artery vascular clamp
<input type="checkbox"/>	<input type="checkbox"/>	Neurostimulator
<input type="checkbox"/>	<input type="checkbox"/>	Insulin or infusion pump
<input type="checkbox"/>	<input type="checkbox"/>	Implanted drug infusion device
<input type="checkbox"/>	<input type="checkbox"/>	Bone growth/fusion stimulator
<input type="checkbox"/>	<input type="checkbox"/>	Cochlear, otologic, or implant
<input type="checkbox"/>	<input type="checkbox"/>	Any type of prosthesis (eye, penile, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Heart valve prosthesis
<input type="checkbox"/>	<input type="checkbox"/>	Artificial limb or joint
<input type="checkbox"/>	<input type="checkbox"/>	Electrodes (on body, head, or brain)
<input type="checkbox"/>	<input type="checkbox"/>	Intravascular stents, filters, or coils
<input type="checkbox"/>	<input type="checkbox"/>	Shunt (spinal or intraventricular)
<input type="checkbox"/>	<input type="checkbox"/>	Vascular access port and/or catheter
<input type="checkbox"/>	<input type="checkbox"/>	Swan-Ganz catheter
<input type="checkbox"/>	<input type="checkbox"/>	Any implant held in place by a magnet
<input type="checkbox"/>	<input type="checkbox"/>	Transdermal Patch Delivery System (e.g. Nicotine.) (Remove before MRI)
<input type="checkbox"/>	<input type="checkbox"/>	IUD or diaphragm
<input type="checkbox"/>	<input type="checkbox"/>	Tattooed makeup (eyeliner, lips, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Body piercing(s) (Remove before MRI)
<input type="checkbox"/>	<input type="checkbox"/>	Any metal fragments (including bullets, shrapnel)
<input type="checkbox"/>	<input type="checkbox"/>	Internal pacing wires
<input type="checkbox"/>	<input type="checkbox"/>	Aortic clip
<input type="checkbox"/>	<input type="checkbox"/>	Metal or wire mesh implants
<input type="checkbox"/>	<input type="checkbox"/>	Wire sutures or surgical staples
<input type="checkbox"/>	<input type="checkbox"/>	Harrington rods (spine)
<input type="checkbox"/>	<input type="checkbox"/>	Metal rods in bones
<input type="checkbox"/>	<input type="checkbox"/>	Joint replacement: _____
<input type="checkbox"/>	<input type="checkbox"/>	Bone/joint in, screw, nail, wire, plate
<input type="checkbox"/>	<input type="checkbox"/>	Hearing aid (Remove before MRI)
<input type="checkbox"/>	<input type="checkbox"/>	Dentures (Remove before MRI)
<input type="checkbox"/>	<input type="checkbox"/>	Breathing disorder
<input type="checkbox"/>	<input type="checkbox"/>	Movement disorder
<input type="checkbox"/>	<input type="checkbox"/>	Claustrophobia
<input type="checkbox"/>	<input type="checkbox"/>	Anxiety
<input type="checkbox"/>	<input type="checkbox"/>	Other: _____

Please mark on the figure below, the location of any implant or metal inside of or on your body.



Before your MRI, please **remove all metallic objects** including keys, hairpins, barrettes, jewelry, watch, safety pins, paperclips, money clip, credit cards, coins, pens, belt, metal buttons, pocketknife, & clothing with metal in the material.

NOTE: YOU ARE REQUIRED TO WEAR EARPLUGS OR EARPHONES DURING THE MRI EXAMINATION.

Signature/Printed name of Person Completing Form

Date: / /
Month Day Year

Form completed by: Participant Relative: _____
Name & relationship to participant

Physician or other: _____
Name & relationship to participant

ID NUMBER:									
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FORM CODE: SAE
VERSION: 1, 6/1/2018

Contact Occasion:

0	1
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SEQ #	0	0
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8. Describe the event (Enter in a notelog on DMS.)

9. Indicate whether the event is: 1 Ongoing 2 Resolved

10. Describe what action was taken (Enter in a notelog on DMS.)

11. Likelihood of relationship to participation in HCHS/SOL:

- Unrelated (clearly not related) 1
- Unlikely (doubtful related) 2
- Possible (may be related) 3
- Probable (likely related) 4
- Definite (clearly related) 5

B. ACTIONS TAKEN BY INVESTIGATORS - Completed by the HCHS/SOL Coordinating Center

12. Reported to: NHLBI / OSMB /

13. Was a change to the protocol made because of this SAE?

- No 0
- Yes 1 If Yes, date changed: /

14. Were any other actions taken by the investigators in response to this SAE?

- No 0
- Yes 1 If Yes, date action taken: /

15. If yes to either of the above questions, please specify: _____

16. Completion Date: / CSCC Staff ID:

ID NUMBER:

FORM CODE: UPR
VERSION: 1, 5/30/2018

Contact Occasion:

0 1

SEQ #

Indicate whether the event is: Ongoing 1

Resolved 2

8. Describe what action was taken (limit to 250 words or less)

B. ACTIONS TAKEN - Completed by the HCHS/SOL Coordinating Center

9. Reported to: NHLBI / / OSMB / /

10. Was a change to the protocol made because of this UP?

No 0

Yes 1 If Yes, date changed: / /

11. Were any other actions taken by the investigators in response to this UP?

No 0

Yes 1 If Yes, date action taken: / /

12. If yes to either of the above questions, please specify: _____

13. Completion Date: / / CSCC Staff ID:



HCHS/SOL INCA MRI Pre-MRI Screening Form-Spanish

PMS ver. 5/15/2018 Spanish

ADMINISTRATIVE INFORMATION

Fecha: / /
(mm/dd/yyyy)

DOB: / / Staff ID:

Estatura: _____ Peso: _____

Place PARTICIPANT information label here
Containing full name, HCHS ParticipantID
Site PI

Instructions: Participants with implants must be approved by the MRI safety officer before a MRI scan may be performed without exception.

1. ¿Ha tenido usted, alguna vez, alguna cirugía o algún procedimiento invasivo similar, en el cual le hayan implantado algún aparato médico? No Sí

Si, sí por favor descríballo:

Tipo de cirugía:

Fecha (mm/dd/yyyy)

/ /

/ /

2. ¿Ha tenido usted anteriormente algún estudio de imágenes de MRI? No Sí

Si sí, en que parte del cuerpo?

Parte del cuerpo

Fecha (mm/dd/yyyy)

Lugar donde Ocurrió

 / /

 / /

 / /

3. ¿Ha trabajado usted, alguna vez, con metal (moliendo, fabricando, etc.) o ha recibido alguna vez alguna herida en los ojos con un objeto metálico (ej. astilla metálica, raedura, esquirola, Shrapnel, o algún cuerpo extraño)? No Sí

Si sí, por favor descríballo: _____

Solamente para participantes de género femenino:

4. ¿Está usted embarazada o existe la posibilidad de que esté embarazada? No Sí
(if unsure, please notify MRI operator or Principal Investigator)

5. ¿Está usted amamantando (lactando)? No Sí

6. ¿Fecha de su último ciclo menstrual?: / / (mm/dd/yyyy)

7. ¿Está usted tomando algún tipo de medicamento de fertilidad o recibiendo tratamiento para fertilidad? No Sí

8. ¿Está usted tomando contraceptivos oralmente o recibiendo tratamiento hormonal? No Sí

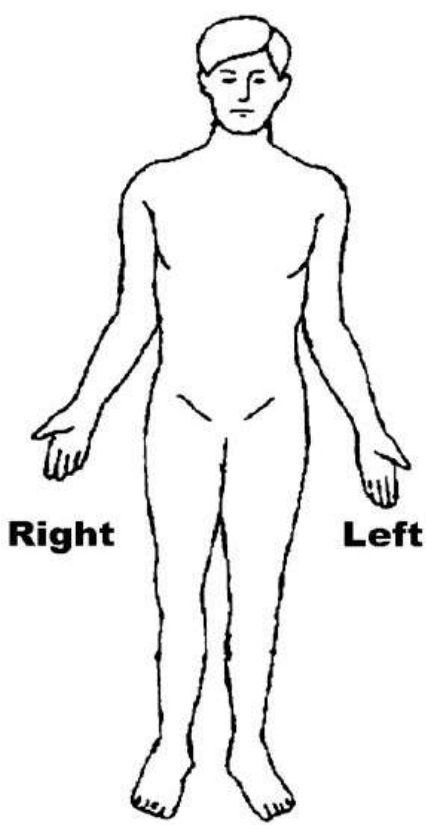
9. ¿Tiene usted historia de ataques epilépticos o epilepsia? No Sí

PARTICIPANTS WITH IMPLANTS MUST BE APPROVED BY THE MRI SAFETY OFFICER BEFORE A MRI SCAN MAY BE PERFORMED WITHOUT EXCEPTION.

Algunos de los siguientes artículos pueden ser peligrosos para su seguridad y pueden interferir con el examen de MRI (Siglas en Inglés). Por favor señale la respuesta adecuada para cada una de los siguientes. Tiene usted alguno de los siguientes:

Sí	No	Ubicación del implante
<input type="checkbox"/>	<input type="checkbox"/>	Hardware Dental (e.g. corona de metal, brackets/braces, retenedor)
<input type="checkbox"/>	<input type="checkbox"/>	Marcapasos cardíaco
<input type="checkbox"/>	<input type="checkbox"/>	Implante cardíaco/ desfibrilador
<input type="checkbox"/>	<input type="checkbox"/>	Pinza(s) de aneurisma
<input type="checkbox"/>	<input type="checkbox"/>	Pinza vascular de la arteria carótida
<input type="checkbox"/>	<input type="checkbox"/>	Estimulante neural
<input type="checkbox"/>	<input type="checkbox"/>	Insulina o bomba de infusión
<input type="checkbox"/>	<input type="checkbox"/>	Implante de un aparato para la infusión de droga
<input type="checkbox"/>	<input type="checkbox"/>	Crecimiento óseo/ estimulante de fusión
<input type="checkbox"/>	<input type="checkbox"/>	Implante en la cóclea, otológica
<input type="checkbox"/>	<input type="checkbox"/>	Cualquier tipo de prótesis (ojo, del pene, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Prótesis valvular cardíaca
<input type="checkbox"/>	<input type="checkbox"/>	Extremidad o coyuntura (articulación) artificial
<input type="checkbox"/>	<input type="checkbox"/>	Electrodo (en el cuerpo, cabeza o cerebro)
<input type="checkbox"/>	<input type="checkbox"/>	Conducto, cánula (Stent), filtros o espirales intravasculares
<input type="checkbox"/>	<input type="checkbox"/>	Desviador (espinal o intraventricular)
<input type="checkbox"/>	<input type="checkbox"/>	Puerto de acceso vascular y/o catéter
<input type="checkbox"/>	<input type="checkbox"/>	Catéter Swan – Ganz
<input type="checkbox"/>	<input type="checkbox"/>	Algún implante sostenido en su lugar por un magneto (imán)
<input type="checkbox"/>	<input type="checkbox"/>	Sistema de entrega por medio de parche transdérmico (ej. Nicotina) (Quíteselo antes del MRI)
<input type="checkbox"/>	<input type="checkbox"/>	DIU dispositivo intrauterino o diafragma
<input type="checkbox"/>	<input type="checkbox"/>	Maquillaje permanente (delineador de ojos, labios, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Perforaciones en el cuerpo, Piercing (Quíteselos antes del MRI)
<input type="checkbox"/>	<input type="checkbox"/>	Algún fragmento metálico (incluyendo balas, esquirlas, sharpnel)
<input type="checkbox"/>	<input type="checkbox"/>	Alambres de estimulación interna
<input type="checkbox"/>	<input type="checkbox"/>	Clip aórtico
<input type="checkbox"/>	<input type="checkbox"/>	Implantes metálicos o de malla de alambre
<input type="checkbox"/>	<input type="checkbox"/>	Suturas metálicas o grapas quirúrgicas
<input type="checkbox"/>	<input type="checkbox"/>	Barras de Harrington (espinal, columna)
<input type="checkbox"/>	<input type="checkbox"/>	Barras de metal en los huesos
<input type="checkbox"/>	<input type="checkbox"/>	Reemplazo de coyunturas (articulación artificial): _____
<input type="checkbox"/>	<input type="checkbox"/>	Tornillos, clavos, alambres o placas en los huesos/coyunturas
<input type="checkbox"/>	<input type="checkbox"/>	Audífono (Quíteselo antes del MRI)
<input type="checkbox"/>	<input type="checkbox"/>	Dentadura postiza (Quítesela antes del MRI)
<input type="checkbox"/>	<input type="checkbox"/>	Desorden respiratorio
<input type="checkbox"/>	<input type="checkbox"/>	Desorden de movimiento
<input type="checkbox"/>	<input type="checkbox"/>	Claustrofobia
<input type="checkbox"/>	<input type="checkbox"/>	Ansiedad
<input type="checkbox"/>	<input type="checkbox"/>	Other: _____

Por favor señale en la figura abajo, el lugar donde tiene el implante o metal en



Right **Left**

Antes del MRI, por favor **quítese todos los objetos metálicos** incluyendo llaves, pinzas de pelo, clip de papel, clip de billetes, monedas, bolígrafos, cinturón, botones metálicos, navajas y ropa que contiene metal en la tela.

NOTA: SE REQUIERE QUE USTED USE TAPONES DE OIDOS O AUDÍFONOS DURANTE EL EXAMEN DE MRI.

Fecha: / /
Month Day Year

Signature/Printed name of Person Completing Form _____

Form completed by: Participant Relative: _____
Name & relationship to participant

Physician or other: _____
Name & relationship to participant