



HCHS/SOL - Unanticipated Problem (UPR)

ID NUMBER:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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FORM CODE: UPR
VERSION: 2, 8/22/2019

Contact Occasion:	<input type="text"/>	<input type="text"/>
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SEQ #	<input type="text"/>	<input type="text"/>
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ADMINISTRATIVE INFORMATION

0a. Completion Date (mm/dd/yyyy):

0b. Staff ID:

Instructions: This form should be completed within 48 hours of an Unanticipated Problem (UP). UPs include any experience or outcome that is unexpected, and related or possibly related to participation in HCHS/SOL, and suggestive that the research places subjects or others at a greater physical, psychological, economic, or social risk or harm than was previously known.

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

1. Contract No.:

HHSN

2. Principal Investigator:

3. Exam Site/ Field Center:

4. Date UP occurred: [MM/DD/YYYY]

5. Reported to:

- | | | | |
|---------------------------|-----|------------------------|---|
| a. Principal Investigator | No | 0 <input type="text"/> | |
| | Yes | 1 <input type="text"/> | a1. date reported: <input type="text"/> |
| b. Field Center IRB | No | 0 <input type="text"/> | |
| | Yes | 1 <input type="text"/> | b1. date reported: <input type="text"/> |

6. Source of the event:

- | | |
|-------------------------------------|------------------------|
| Interview with study participant | 1 <input type="text"/> |
| Blood draw | 2 <input type="text"/> |
| Glucose load | 3 <input type="text"/> |
| Dexa scan | 4 <input type="text"/> |
| MRI scan | 5 <input type="text"/> |
| CT scan | 6 <input type="text"/> |
| Other physical examination or tests | 7 <input type="text"/> |
| Other source | 8 <input type="text"/> |

ID NUMBER:									
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SEQ #

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a. If Other source, specify: _____

7. Describe the event (Enter a note in CDART):

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

9. Describe what action was taken (Enter in a note in CDART):

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

No 0 ☐ Yes 1 ☐ **[END FORM]** Don't Know 9 ☐

11. Likelihood of relationship to participation in HCHS/SOL **[Answered by site Principal Investigator only]:**

- 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 Coordinating Center

12. Reported to: a. NHLBI b. OSMB

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

No 0 ☐

Yes 1 ☐

14. If Yes, date changed: Were any other actions taken by the investigators in response to this UP?

No 0 ☐

Yes 1 ☐

a. If Yes, date action taken:

15. If Yes to either Question 13 or 14, please specify: _____

16. a. Completion Date: b. CSCC Staff ID: