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