STOP II TRIAL
HEAD MRI SCAN

AFFIX PATIENT LABEL

HERE

SECTION A TO BE COMPLETED BY STOP II NEURORADIOLOGIST

A1. Person completing form (Name): _____ (Initials): | | | |

A2. Date of MRI procedure (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Was the patient's MRI data copied to a STOP II optical disk? ☐ **1. NO** ☐ **2. YES**

↓

A3.a What is the file name of the patient's MR study on the STOP II Optical Disk?

_____

A4. Was DWI performed (<u>required</u> only for suspected neurological events)? ☐ **1. NO** ☐ **2. YES** ☐ **-1 N/A**

A5. Is the MRI study adequate for interpretation? ☐ **1. NO** ☐ **2. YES**

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A5.a. Reason
- ☐ 1. Incomplete Study
- ☐ 2. Motion Artifact
- ☐ 3. Other

↓

A5.b Specify:_____

_____

RESCHEDULE STUDY WITHIN 2 WEEKS

A6. Is there evidence for any of the following?

A6.a. Aneurysm ☐ 1. NO ☐ 2. YES

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A6.a1. Location: _____

A6.b. Arteriovenous malformation ☐ 1. NO ☐ 2. YES

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A6.b1. Location: _____

A6.c. Tumor ☐ 1. NO ☐ 2. YES

↓

A6.c1. Location: _____

****IF THE ANSWER TO ANY OF QUESTIONS A6.a. – A6.c. IS YES, PLEASE CONTACT CENTER INVESTIGATOR ****

☐ ML ☐ DE

SECTION B TO BE COMPLETED BY STUDY COORDINATOR

B1. Reason for MRI procedure:

☐ 1. Pre-Randomization Study ☐ 2. Routine Follow-up Study

☐ 3. Exit from Study ☐ 4. TCD Endpoint or 3 inadequate TCD exams by at least 2 examiners

☐ 5. New Neurological Event

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B1.a. Date of event (Month/Day Year) ___ ___/___ ___/___ ___ ___ ___

B1.b. Type of event:

☐ 1. TIA

☐ 2. Cerebral Infarction

☐ 3. Intracranial Hemorrhage →B1.b1. Type ☐ 1. Intraparenchymal ☐ 2. Subarachnoid ☐ 3. Intraventricular

☐ 4. Other: → B1.b2. Specify: _____

☐ 6. Post-meningitis event → B1.c. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.d. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

☐ 7. Post-head injury event → B1.e. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.f. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B2. Date optical disk with MRI study sent to the STOP II Data Coordinating Center (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

SECTION C TO BE COMPLETED BY DCC DATA MANAGER

C1. Is this MRI scan being compared to a previous scan? ☐ 1. NO ☐ 2. YES

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Which Scan(s)?
C.1.a. Pre-randomization scan dated ___ ___/___ ___/___ ___ ___ ___
C.1.b. Previous scan dated ___ ___/___ ___/___ ___ ___ ___

C2. Are event CT scans enclosed? ☐ 1. NO ☐ 2. YES

↓

C2.a. Date of CT scan (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___
C2.b. Date of neurological event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

C3. Type of neurological event:

☐ 1. TIA
☐ 2. Cerebral Infarction
☐ 3. Intracranial Hemorrhage → C3.a. Type
  ☐ 1. Intraparenchymal
  ☐ 2. Subarachnoid
  ☐ 3. Intraventricular
☐ 4. Other: → C3.b Specify: _____

C4. Reason event CT scan enclosed for review (CHECK ALL APPLICABLE):

☐ 1. MRI was not performed
☐ 2. Patient had an intracranial hemorrhage
☐ 3. Other: → C4.a Specify: _____

SECTIONS D - J TO BE COMPLETED BY READERS

D1. Readers: a. (Name): _____ (Initials): | | | |

b. (Name): _____ (Initials): | | | |

D2 Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

D3. Study acceptable for interpretation? ☐ 1. NO ☐ 2. YES

↓

D3.a. Reason: _____

_____

D4. **SCAN QUALITY (CHECK ONE):**

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

D5. **DWI**

D5.a Are DWI films available for review for this study? ☐ **1. NO**

☐ **2. YES**

E1. ATROPHY (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

Type of atrophy:

E2. GENERAL: ☐ 1. NO ☐ 2. YES

- a. Sulcal ☐ 1. NO ☐ 2. YES
- b. Ventricular ☐ 1. NO ☐ 2. YES
- c. Level of severity ☐ 1. MILD ☐ 2. MODERATE ☐ 3. SEVERE

E3. FOCAL: ☐ 1. NO ☐ 2. YES

- a. Sulcal ☐ 1. NO ☐ 2. YES
- b. Ventricular ☐ 1. NO ☐ 2. YES
- c. Specify Area(s): c1. _____

USE THE FOLLOWING CODES FOR QUESTIONS E4 AND E5

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

	a. Pre-randomization Study	**b. Previous Study**
E4. Status of *Generalized* atrophy compared to: **(Enter Code)**	☐	☐
E5. Status of *Focal* atrophy compared to: **(Enter Code)**	☐	☐

If NEW, specify new area(s):

a1. _____ b1. _____

a2. _____ b2. _____

a3. _____ b3. _____

F. DISCRETE FINDINGS (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Improved B = Same (no progression) C = NEW lesion D = Worse (progression) E = Cannot determine F = N/A

	a.	b.	c.	d.	e.	f.	g.	h.	i.
				LOCATION(S)				STATUS COMPARED TO	
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	Pre-rand. Study	Previous Study
1.									
2.									
3.									
4.									
5.									
6.									
7.									

G. VASCULATURE (COMPLETE THE TABLE USING THE FOLLOWING CODES):

DESCRIPTION CODES:
0 = NOT SEEN (Technically)
1 = VISUALIZED - PATENT
2 = OCCLUDED

	a. RIGHT	b. LEFT
G1. Internal carotid: cavernous		
G2. Internal carotid: supraclinoid		
G3. MCA		
G4. ACA		
G5. PCA		
G6. Basilar		

G7. Collateral Blood Vessels **(CHECK ONE):** ☐ 1. RIGHT ☐ 2. LEFT ☐ 3. BOTH ☐ 4. NOT PRESENT

USE THE CODES TO THE RIGHT FOR QUESTION G8

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

	a. Pre-rand. Study	b. Previous Study
G8. Status of vasculature compared to: **(Enter Code)**		

H1. BONY CHANGES (CHECK ONE):

☐ 1. Normal ☐ 2. Diffuse thickening ☐ 3. Focal abnormality

↓

H1.a. Specify: _____

_____

_____

USE THE CODES TO THE RIGHT FOR QUESTION H2

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

		a. Pre-rand. Study	b. Previous Study
H2. Status of bony changes compared to:	**(Enter Code)**		

I. COMMENTS:

J. EVENT CT SCANS

J1. Were CT films reviewed? ☐ 1. NO → **FORM COMPLETE** ☐ 2. YES → **CONTINUE TO J2**

J2. ATROPHY ON CT SCAN (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

Type of atrophy:

a1. GENERAL: ☐ 1. NO ☐ 2. YES

a. Sulcal	☐ 1. NO	☐ 2. YES	
b. Ventricular	☐ 1. NO	☐ 2. YES	
c. Level of severity	☐ 1. MILD	☐ 2. MODERATE	☐ 3. SEVERE

a2. FOCAL: ☐ 1. NO ☐ 2. YES

a. Sulcal	☐ 1. NO	☐ 2. YES
b. Ventricular	☐ 1. NO	☐ 2. YES

c. Specify Area(s): c1. _____

J3. Does the CT scan show evidence of intracranial hemorrhage? ☐ 1. NO ☐ 2. YES

Type:	**1. NO**	**2. YES**
a. Subarachnoid	☐	☐
b. Intraventricular	☐	☐
c. Subdural	☐	☐
d. Epidural	☐	☐
e. Intraparenchymal	☐	☐

J4. DISCRETE FINDINGS ON CT SCAN (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (Punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Acute B = Subacute C = Chronic

	a.	b.	c.	d.	e.	f.	g.	h.
				LOCATION(S)				
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	STATUS
1.								
2.								
3.								
4.								
5.								
6.								
7.								