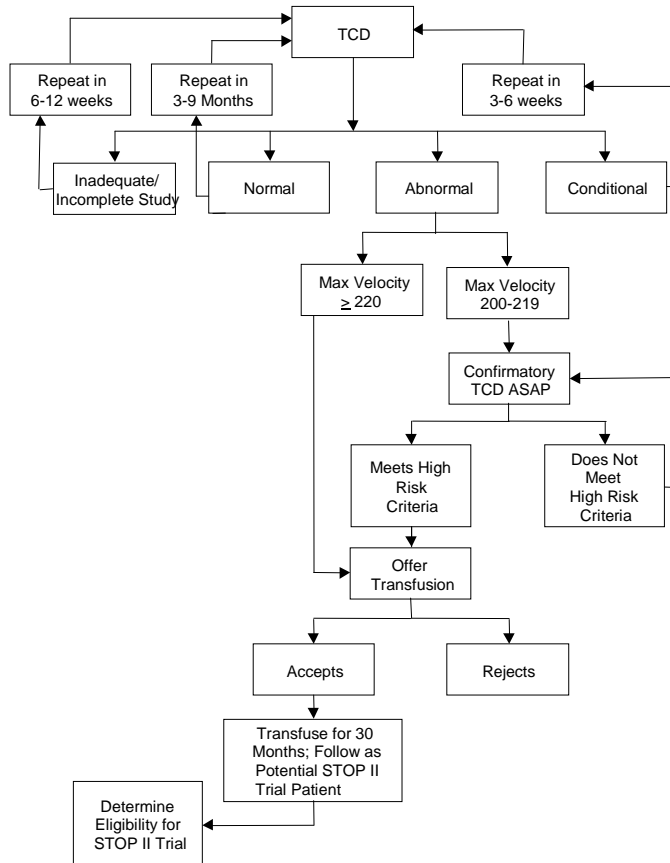


# SCHEDULE OF MEASUREMENTS

## A1. TCD Exam Schedule for Screening Patients

STOP II TCD SCREENING FLOWCHART



## A2. STOP II Form Completion Schedule for Screening Patients

Form # & Name	When Completed			
	Each TCD Exam Visit *	Notification of Eligibility for Clinical Transfusions	Annual Follow-up **	Suspected Neuro Event
01A Eligibility Questionnaire for TCD Screening Exam	X			
02 Transcranial Doppler (TCD) Examination Form	X			
03 Treatment Decision by Parent-Guardian of Newly Identified Child With Two Abnormal TCDs or One Abnormal TCD With TAMM Velocity ≥ 220 CM/SEC		X		
Q30 Quasi-Adjudication Neurological Event Form				X

\* See A1 for detailed TCD exam follow-up schedule

\*\* Discontinued June 2003

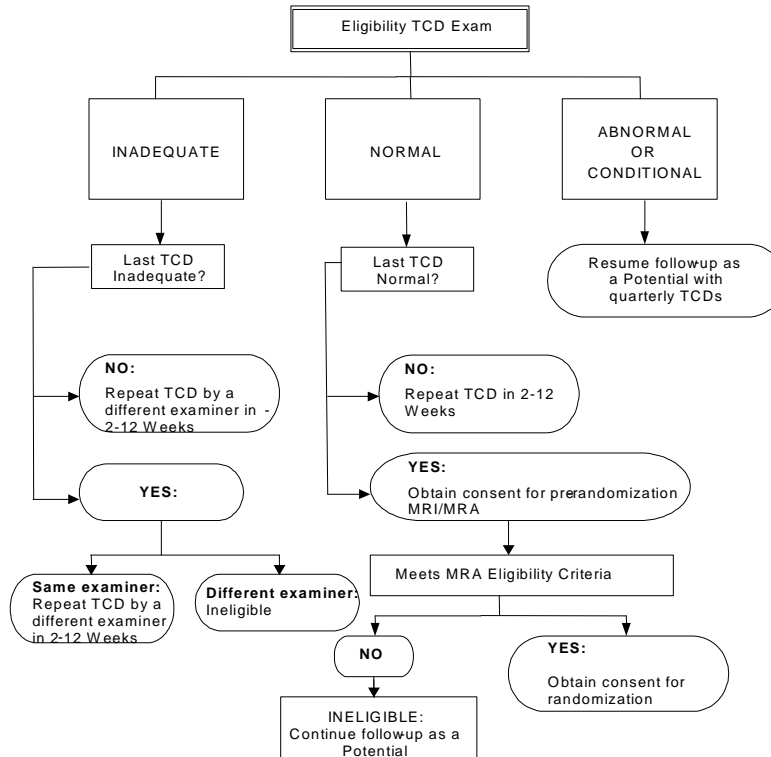
## B1. Schedule of Measurements for Potential (observation) Patients

	When Completed			
	Entry	Quarterly	Neurological Event	Transfusion
Vital Statistics/History	X	X	X	
CBC (local)	X	X		X
Quantitative Hb Analysis (local)	X	X		X
Ferritin (local)	X	X		
Liver Profile (ALT, GGT, LDH, bilirubin) (local)	X	X		
TCD	X	X *	X	
Neurology Consult Report			X	
MRI/MRA Reports			X	
Progress Reports		X		
Transfusion Information	X			X

\* Schedule determined by time on transfusion and previous results; see B2

## B2. TCD Exam Schedule for Potential Patients

TCD EXAM FLOWCHART FOR PATIENTS WHO MEET TRANSFUSION ELIGIBILITY CRITERIA\* FOR RANDOMIZATION



\* Adequate participation in a transfusion program was defined as at least 24 transfusions in the 30-month evaluation period with a maximum average interval of 5.4 weeks between transfusions, pre-transfusion Hb S  $\leq$  40% in at least two-thirds of the measurements obtained during the 30-month evaluation period, and no interruption in transfusion that exceeded 6 consecutive months.

### B3. STOP II Form Completion Schedule for Potential Patients

Form # and Name	When Completed			
	"Entry" Visit	Quarterly Visit	Transfusion	Suspected Neuro Event
01B Eligibility Questionnaire for Patients on Transfusion For Primary Stroke Prevention for < 30 Months	X			
01C Pre-Randomization Eligibility Questionnaire (for patients on transfusion for > 30 months)	X			
02 Transcranial Doppler (TCD) Examination Form	X	X <sup>2</sup>		
11 Intake History Form	X			
12 Physical Examination	X	X		
13B Local Laboratory Form for Non-Randomized Patients Receiving Transfusions	X	X	X	
15 Head MRI Scan		X <sup>3</sup>		
16B Quarterly Progress Report for Non-Randomized Patients Receiving Transfusions		X		
16R Quarterly Medical Record Review		X		
19 MRA Scan		X <sup>3</sup>		
22 Transfusion History Log	X <sup>1</sup>			
Q30 Quasi-Adjudication Neurological Event Form				X

<sup>1</sup> Not required for STOP randomized patients if DCC had information for all transfusions prior to "entry" visit

<sup>2</sup> See B2

<sup>3</sup> Part of pre-randomization evaluation; scheduled once patient met pre-randomization TCD and transfusion eligibility criteria for randomization

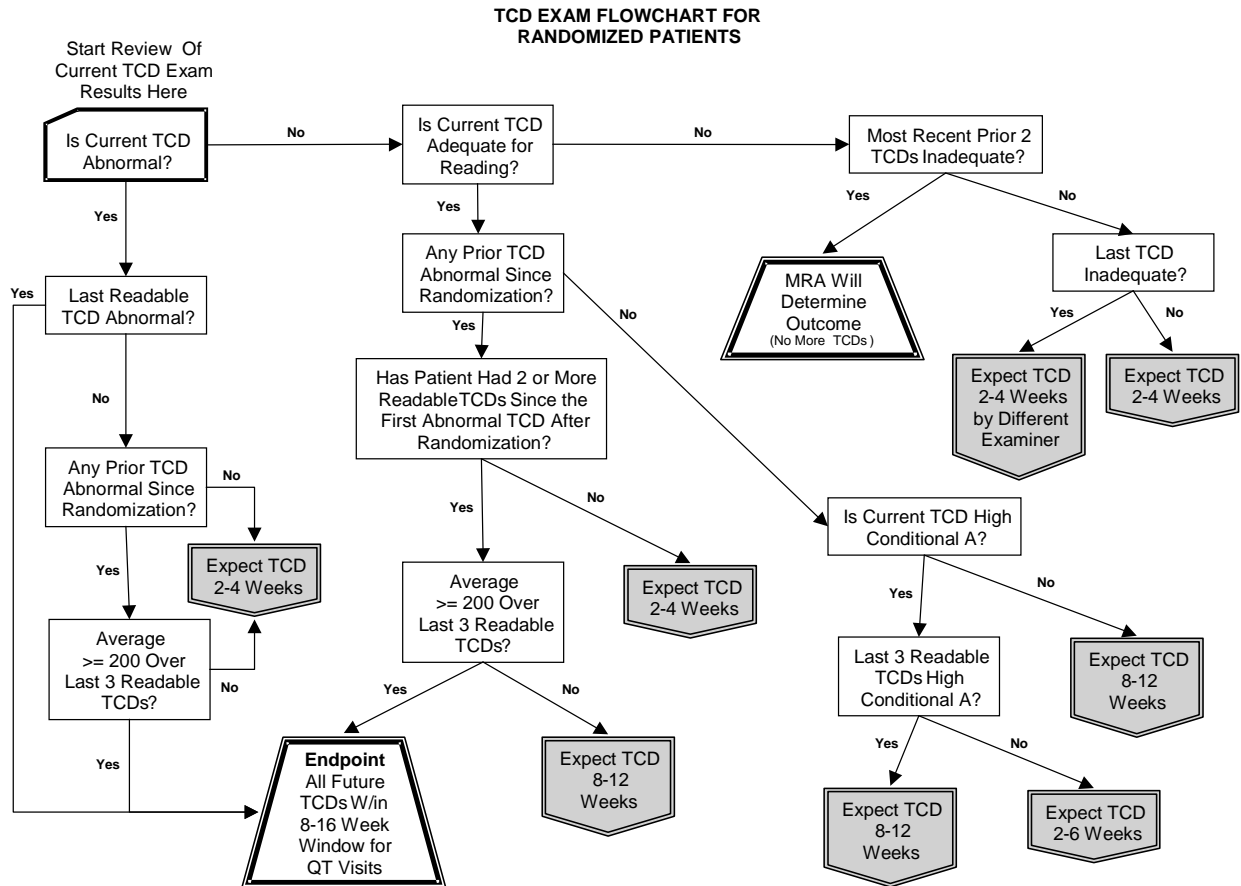
## C1. Schedule of Measurements for Randomized Patients

	When Completed					
	Entry	Quarterly	Every TX	Annual	Neurological Event	Study Exit
Vital Stats/History	X	X	X	X	X	X
CBC w/diff, retics, platelets	X	X	X	X	X	X
Serum Bank Sample	X	X		X	X	X
DNA Bank Sample	X					
Quantitative Hb Analysis	X	X	X	X	X	X
Ferritin	X	X		X		X
Liver Profile (ALT,GGT, LDH, bilirubin)	X			X		X
Hepatitis B & C Antibody Tests	X					X <sup>1</sup>
TCD		X <sup>2</sup>		X <sup>2</sup>	X	X <sup>2</sup>
MRI/MRA		<sup>2</sup>		X	X	X
DWI					X	
Neurological Exam	X			X	X	
Progress Report		X		X	X	X

<sup>1</sup> Only hepatitis C tested, and only if previous test was negative.

<sup>2</sup> See C2 for detailed schedule for TCD monitoring.

## C2. TCD Exam Schedule for Randomized Patients



### C3. STOP II Form Completion Schedule for Randomized Patients

Form # and Name	When Completed								
	Trial Entry Visit	Quarterly Visit	Annual Visit	Endpoint/Exit Visit	Transfusion	Suspected Neuro Event	Non-Neuro Event	Delayed Transfusion Reaction	Death
02 Transcranial Doppler (TCD) Examination Form		X <sup>1</sup>	X	X		X			
10 Trial Randomization Form	X								
12 Physical Examination	X	X	X	X					
13 Core Laboratory Form	X	X	X	X	X <sup>4</sup>	X			
14 Neurological Consultant Report	X		X	X		X			
15 Head MRI Scan		<sup>2</sup>	X <sup>3</sup>	X		X			
15A Event CT Scan						X (if done)			
16 Quarterly Progress Report for Randomized Patients	X	X	X	X					
16R Quarterly Medical Record Review	X	X	X	X					
19 MRA Scan		<sup>2</sup>	X <sup>3</sup>	X		X			
20 Transfusion Form					X				
21 Blood Unit Form					X				
30 Neurological Event Form						X			
31 Non-Neurological Event Form							X		
32 Delayed Transfusion Reaction Form								X	
33 Outcome of Hospitalization for Stroke, Meningitis, or Head Injury						X	X <sup>5</sup>		
40 Cause of Death Form									X

(1) See C2 for detailed monitoring schedule

(2) required following three inadequate TCD exams by at least two examiners

(3) required every 6 months if patient has history of repeated inadequate exams without moderate to severe arterial disease on MRA

(4) required only if randomized to continuation of transfusion arm

(5) required if event is meningitis or head injury