

Subject ID: _	
Date:	

## Screening Visit

## **Inclusion/Exclusion Criteria**

Inclusion Criteria:		
Patient/legally authorized representative has signed the informed consent	☐ Yes	□No
form.		
Age ≥18 years	☐ Yes	□ No
AIS symptom onset within 4.5 to 24 hours	□ Yes	□No
<ul> <li>Stroke onset is defined as the time the patient was last known to be at</li> </ul>		
their neurologic baseline (wake-up strokes are eligible if they present		
within the 4.5 to 24-hour time limits)		
<ul> <li>Note: All study-related treatment needs to be initiated within 24 hours</li> </ul>		
Signs and symptoms consistent with the diagnosis of an acute anterior	☐ Yes	□ No
circulation ischemic stroke involving occlusion of the ICA, M1, or M2 vessels		
Functionally independent (mRS 0-2) prior to stroke onset	☐ Yes	□ No
Baseline NIHSS ≥ 5 and that remains ≥ 5 immediately prior to randomization	☐ Yes	□No
Neuroimaging: ICA or M1, M2 occlusion (carotid occlusions can be cervical or	☐ Yes	□No
intracranial, with or without tandem MCA lesions) by MRA or CTA <b>AND</b> target		
mismatch profile on CT perfusion or MRI (ischemic core volume <70 mL,		
mismatch ratio is ≥ 1.8 and mismatch volume is ≥to 15 mL)		
The mismatch volume is determined by RAPID software based on		
the difference between the ischemic core lesion volume and the		
Tmax>6s lesion volume. If both a CTP and multimodal MRI are		
performed prior to enrollment, the latter of the 2 scans is assessed to determine eligibility. For patients screened with MRA, only an		
intracranial MRA is required (cervical MRA is not required). Cervical		
and intracranial CTA are typically obtained simultaneously in patients		
screened with CTA, but only the intracranial CTA is required for		
enrollment.		
ALTERNATIVE NEUROIMAGING		
If CTA (or MRA) is technically inadequate: Tmax >6s perfusion deficit		
consistent with an ICA or M1, M2 occlusion AND target mismatch		
profile (ischemic core volume <70 mL, mismatch ratio ≥1.8 and		
mismatch volume ≥15 mL as determined by RAPID software)		
If MR perfusion (MRP) is technically inadequate: ICA or M1, M2		
occlusion by MRA <b>AND</b> diffusion-weighted imaging (DWI) lesion		
volume < or equal to 25 mL for an M1 or ICA occlusion and < or equal		
to 15 mL for an M2 occlusion. If MRA is technically inadequate, a CTA		
can be used if performed within 60 minutes prior to the MRI. Carotid occlusions can		
be cervical or intracranial; with or without tandem MCA lesions.		
If CTP is technically inadequate: patient can be screened with MRI		
and randomized if neuroimaging criteria are met.		
and randomized it neuromagnig effects are free.		



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Ι	Date:			
Subject	ID:	 	 	

Ability to comply with the study protocol, in the investigator's judgment	☐ Yes	□ No
Exclusion Criteria		
Current participation in another investigational drug or device study	☐ Yes	□No
Active internal bleeding	☐ Yes	□No
Known hypersensitivity or allergy to any ingredients of tenecteplase	☐ Yes	□No
Known hereditary or acquired hemorrhagic diathesis, coagulation factor	☐ Yes	□No
deficiency; recent oral anticoagulant therapy with INR 1.7		
Use of one of the new oral anticoagulants within the last 48 hours	☐ Yes	□ No
(dabigatran, rivaroxaban, apixaban, edoxaban)		
Pregnant	☐ Yes	□ No
Intracranial neoplasm (except small meningioma), arteriovenous	☐ Yes	□ No
malformation, or aneurysm		
Seizures at stroke onset if it precludes obtaining an accurate baseline NIHSS	☐ Yes	□ No
Severe, uncontrolled hypertension (systolic blood pressure >180 mmHg or	☐ Yes	□ No
diastolic blood pressure >110 mmHg)		
Baseline platelet count <100,000/ $\square$ (results must be available prior to	☐ Yes	□ No
treatment)		
Baseline blood glucose >400 mg/dL (22.20 mmol/L)	☐ Yes	□ No
Baseline blood glucose <50 mg/dL needs to be normalized prior to	☐ Yes	□ No
randomization		
Clot retrieval attempted using a neurothrombectomy device prior to	☐ Yes	□ No
randomization		
Intracranial or intraspinal surgery or trauma within 2 months	☐ Yes	□ No
Treatment with a thrombolytic within the last 3 months prior to	☐ Yes	□ No
randomization		
Other serious, advanced, or terminal illness (investigator judgment) or life	☐ Yes	□ No
expectancy is less than 6 months		
History of acute ischemic stroke in the last 90 days	☐ Yes	□ No
History of hemorrhagic stroke	☐ Yes	□ No
Presumed septic embolus; suspicion of bacterial endocarditis	☐ Yes	□No
Any other condition that, in the opinion of the investigator, precludes an	☐ Yes	□ No
endovascular procedure or poses a significant hazard to the patient if an		
endovascular procedure was to be performed		
Imaging specific exclusions		
Unable to undergo a contrast brain perfusion scan with either MRI or CT	☐ Yes	□No
Extensive early ischemic change (hypodensity) on non-contrast CT estimated	☐ Yes	□No
to be >1/3 MCA territory, or significant hypodensity outside the Tmax_6s		



TIMELESS A Study of Imaging-eligible stroke treatment	A PHASE III, PROSPECTIVE, DOUBLE-BLINO, RANDOMIZED, LACEGO-CONTROLLED TRIAL OF THROMBOLYSIS IN IMMIGRIC ELIGIBLE, LATE-WINDOW PATIENTS TO ASSESS THE EFFICACY AND SAFETY OF TENECTEPLASE (TIMELESS)	Subject ID Dat	e:		_
perfusion lesion that inv	validates mismatch criteri	a (if patient is enrolled based			_
on CT perfusion criteria	)				
Significant mass effect			☐ Yes	□ No	
Acute symptomatic arte	erial occlusions in more th	an one vascular territory	□Yes	□ No	
confirmed on CTA/MRA	(e.g., bilateral MCA occlu	usions, or an MCA and a			
basilar artery occlusion)					
Evidence of intracranial	tumor (except small mer	ningioma) acute intracranial	☐ Yes	□No	
hemorrhage, neoplasm,	, or arteriovenous malfor	mation			
Did the subject meet t	he eligibility criteria fo	r the study?	☐ Yes	□ No	
Signature of Investigator (	Confirming Eligibility		Date (dd-mo	on-yyyy)	



Subject ID: _	 	
Date:		

#### **Informed Consent**

Visit Date (dd-mon-yyyy):		
Protocol Version # Subject was Consented:		
Date Informed Consent Signed (dd-mon-yyyy):		
ICF Signed by:	□ Subject	□ LAR
Method of Consent:	☐ In Person	
	☐ FAX	
	☐ Email	
	☐ Combination re	emote/in person

Signature of Study Staff Member Collecting Data:



Subject ID:		
_		
Date:		

## Demographics

Sex:	□ Male	☐ Female		
Date of birth:				
Age at Informed Consent:				
Ethnicity:	☐ Hispanic or Latino			
	☐ Not Hispanic or Latino			
	☐ Not reported			
	□ Unknown			
Race:	☐ American Indian or Alaska Native			
	☐ Asian			
	☐ Black or African American			
	☐ Native Hawaiian or Other Pacific Islander			
	□ White			
	□ Other			
Race Other, Specify:				
Veteran Status	□Yes			
	□ No			



A study of imaging-eligible stroke treatment TO ASSES:	THE FFICACY AND SAFETY OF LASE (TIMELESS)	Date:
Baseline CT		
Date of imaging:		
Start time of imaging:		
Side of lesion:		
	Left	
	Right	
Type of occlusion:		
	ICA	
	MCA-M1	
	MCA-M2	
	Other, specify:	
From the RAPID software, please pro Lesion volume.	vide ischemic core volume, mismatch rat	io, absolute mismatch volume, and Tmax >6s
Ischemic Core Volume:	mL	
Mismatch Ratio:		
Absolute Mismatch Volume:	mL	
Tmax >6s Lesion Volume:	mL	
Is scan sufficient quality to de	termine an ASPECTS score:	
	Yes	
	No	
If yes, complete below:		
a. Caudate head		
	Abnormal	
	Normal	
b. Lentiform nucleus		
	Abnormal	
a Incular ribban	Normal	
c. Insular ribbon	Abnormal	
	Normal	
d. Internal capsule	INOTHIA	
	Abnormal	

Subject ID: \_\_\_\_\_

Normal



Subject ID:		
Date:		

e.	Anterior MCA con	tex (IVII)
		Abnormal
		Normal
f.	MCA cortex latera	al to insular ribbon (M2)
		Abnormal
		Normal
g.	Posterior MCA co	rtex (M3)
		Abnormal
		Normal
h.	Anterior superior	to M1, rostral to basal ganglia (M4)
		Abnormal
		Normal
i.	Lateral superior to	M2, rostral to basal ganglia (M5)
		Abnormal
		Normal
j.	Posterior superior	to M3, rostral to basal ganglia (M6)
		Abnormal
		Normal
Intracrania	I hemorrhage:	
intracrama	i nemormage.	
		HI-1
		HI-2
		PH-1
		PH-2
		IVH
		Subdural
		Epidural
		SAH
		None
CTP infarct	volume:	mL



Subject ID: _		
Data		
Date:		

## **Mechanical Thrombectomy**

Mas mochanical through set	ou norformed?
Was mechanical thrombecton	ny periormea?
	Yes
	No
If no, please provide reason:	
	Subject has had partial recanalization
	Subject has had complete recanalization
	Unable to access clot Other, specify:
<del>-</del>	
Did the nationt receive genera	al anesthesia for the procedure?
— —	
	Yes No
Was there successful groin acc	Cess?
	Yes
	No
Baseline modified TICI score:	
□ 0- No	
	netration, but no distal branch filling artial reperfusion with incomplete (<50%) or slow distal branch filling
	artial reperfusion with incomplete (50-99%) or slow distal branch filling
☐ 3- Ful	l reperfusion
Date of mechanical thrombed	tomy:
Start time of arterial puncture	:
Able to access the clot?	
	Yes
	No
Start date of first contact with	clot:
Start time of first contact with	clot:
Final modified TICI score:	
□ 0- No	flow
☐ 1- Per	netration, but no distal branch filling

Signature of Study Staff Member Collecting Data:



TIMELESS & RANDOMIZED, PLACEBO-CONTROLLED TRIAL OF THROMBOLY/SIS IN IMAGING-GLIGIBLE, LATE-WINDOW PATIENTS	Subject ID:
A study of imaging-eligible stroke treatment  TO ASSESS THE EFFICACY AND SAFETY OF TENECTEPLASE (TIMELESS)	Date:
•	with incomplete (<50%) or slow distal branch filling with incomplete (50-99%) or slow distal branch filling
Number of passes to reach final mTICI 2b/3:	
End date of procedure:	
End time of procedure:	
Was recanalization achieved?	
☐ Yes ☐ No	
Date of reperfusion:	
Time of reperfusion:	
Select all vessels that were occluded at comple	tion of procedure:
<ul><li>□ Proximal ICA (cervical of MCA- M1</li><li>□ MCA- M2</li><li>□ Other, specify:</li></ul>	cavernous)
Was intra-arterial thromboytics used:	
☐ Yes	



Subject ID: _	
v	
Date:	

## **Vital Signs**

_		
Were vital signs collected?	□ Yes	□ No
Time of Vital Signs (24-hour clock):		
Date of Vital Signs:		
Weight:		□ kg
		□lb
Systolic Blood Pressure (mmHg):		
Diastolic Blood Pressure (mmHg):		
Measurement location-side of body	□ Right	□ Left
Pulse (beats/min):		
Temperature (Celsius):		☐ Oral
		☐ Rectal
		☐ Aural/Tympanic
		☐ Axillary
Respirations (breath/min):		

Signature of Study Staff Member Collecting Data:



Subject ID:	
Date:	

#### **Hematology Local Labs**

inclinationogy Local Labo	
Date collected (dd-mon-yyyy):	
Time collected (24-hour clock):	
WBC:	
RBC:	
Hemoglobin:	
Hematocrit:	
Platelets:	
Coagulation Local Labs	
Date collected (dd-mon-yyyy):	
Time collected (24-hour clock):	
INR:	
PT:	
aPTT:	
Chemistry Local Labs	
Date collected (dd-mon-yyyy):	
Time collected (24-hour clock):	
Glucose:	
Sodium:	
Potassium:	



Subject ID:	
Date:	

### **Study Drug Administration**

Was study drug admini	
was study drug admini	stereu:
	Yes
	No
lf no, reason not administ	rered:
	Adverse event
	Other, specify:
Date administered:	
Time administered:	
·····c adbered.	<del></del>
Kit ID administered:	
Dose administered:	mg
Total volume administe	ered: mL

Signature of Study Staff Member Collecting Data:



Subject ID:	
Date:	

#### **Medical History**

#### Targeted Medical History (list below if applicable):

Myocardial infarction, hypertension, atrial fibrillation, hypercholesterolemia, diabetes, prior stroke (excluding the qualifying stroke)

Myocardial infarction	☐ Yes	□ No
Hypertension	☐ Yes	□ No
Atrial Fibrillation	☐ Yes	□ No
Hypercholesterolemia	☐ Yes	□ No
Diabetes	☐ Yes	□ No
Prior stroke	☐ Yes	□ No

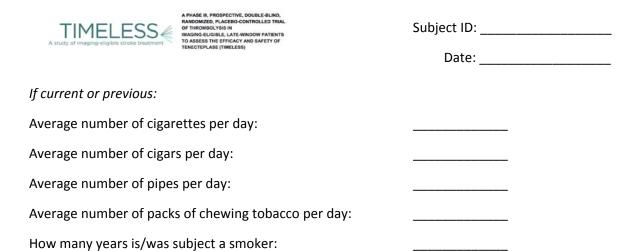
Medical Condition	Ongoing at	Ongoing at baseline?	
	□ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	
	☐ Yes	□ No	



Subject ID:	
Date:	
ast use:	

Social History	
Alcohol Use History	
	Never Current Previous
If <i>previous</i> was indicate	d, what was the month and year of last use:
If current or previous:	
How many year	rs did the subject consume alcohol:
Average numbe	er of drinks per week:
Substance abuse hist	
Current substance use?	
	Yes No
If yes:	
	Cannabinoids Amphetamines Opiates Caffeine Benzodiazepines Barbiturates Cocaine
Tobacco use history	
	Never Current Previous

If previous was indicated, what was the month and year of last use:





TIMELESS  OF THROMOLOUSIS IN  MAGING-ELIGIBLE, LATE-WAY AND SAFETY OF  A Study of imaging-pictuble strate treatment  TO ASSESS THE EFFICACY AND SAFETY OF	Subject ID:
A study of imaging-eligible stroke treatment TENECTEPLASE (TIMELESS)	Date:
Hospital arrival	
Date of qualifying stroke:	
Time of qualifying stroke (defined as time LKN):	
Did stroke symptoms start during hospitalization:	
□ Yes □ No	
Randomization hospital:	
□ ECC (HUP) □ nECC (PPMC, PAH)	
Was subject transferred from nECC hospital:	
□ Yes □ No	
Date of arrival at nECC hospital:	
Time of arrival at nECC hospital:	
Date of arrival at ECC hospital:	
Time of arrival at ECC hospital:	
Is mechanical thrombectomy planned:   Yes  No	
If no, please provide reason:	
☐ Subject has M2 occlu☐ Other, specify:	usion



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	1	1	

Interval: [] Baseline [] 2 hours post treatment [] 3 months [] Other	[] 24 hours post onset of symptoms ±20 minutes	[] 7-10 days
Time:: []am []pm		
Person Administering Scale		

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

Instructions Scale Definition Score Level of Consciousness: The investigator must choose a Alert; keenly responsive. response if a full evaluation is prevented by such obstacles as an 1 = **Not alert**; but arousable by minor stimulation to obey, endotracheal tube, language barrier, orotracheal trauma/bandages. A answer, or respond. 3 is scored only if the patient makes no movement (other than reflexive 2 = Not alert; requires repeated stimulation to attend, or is posturing) in response to noxious stimulation. obtunded and requires strong or painful stimulation to make movements (not stereotyped). 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and areflexic. 0 = **Answers** both questions correctly. **1b.** LOC Questions: The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions **Answers** one question correctly. will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, Answers neither question correctly. language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. 1c. LOC Commands: The patient is asked to open and close the 0 = **Performs** both tasks correctly. eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is 1 = **Performs** one task correctly. given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task 2 = Performs neither task correctly. should be demonstrated to him or her (pantomime), and the result scored (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored. 2. Best Gaze: Only horizontal eye movements will be tested. 0 = Normal.Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done. If the patient has a conjugate 1 = Partial gaze palsy; gaze is abnormal in one or both eyes, deviation of the eyes that can be overcome by voluntary or reflexive but forced deviation or total gaze paresis is not present. activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), score a 1. Gaze is testable in all 2 = Forced deviation, or total gaze paresis not overcome by the aphasic patients. Patients with ocular trauma, bandages, pre-existing oculocephalic maneuver. blindness, or other disorder of visual acuity or fields should be tested with reflexive movements, and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	1	1	

ours post onset of symptoms ±20 minutes [] 7-10 days	
<ul> <li>0 = No visual loss.</li> <li>1 = Partial hemianopia.</li> <li>2 = Complete hemianopia.</li> <li>3 = Bilateral hemianopia (blind including cortical blindness).</li> </ul>	
<ul> <li>0 = Normal symmetrical movements.</li> <li>1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).</li> <li>2 = Partial paralysis (total or near-total paralysis of lower face).</li> <li>3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).</li> </ul>	
<ul> <li>0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.</li> <li>1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.</li> <li>2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.</li> <li>3 = No effort against gravity; limb falls.</li> <li>4 = No movement.</li> <li>UN = Amputation or joint fusion, explain:</li> <li>5a. Left Arm</li> <li>5b. Right Arm</li> </ul>	
<ul> <li>0 = No drift; leg holds 30-degree position for full 5 seconds.</li> <li>1 = Drift; leg falls by the end of the 5-second period but does not hit bed.</li> <li>2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.</li> <li>3 = No effort against gravity; leg falls to bed immediately.</li> <li>4 = No movement.</li> <li>UN = Amputation or joint fusion, explain:</li> <li>6a. Left Leg</li> </ul>	
	0 = No visual loss.  1 = Partial hemianopia.  2 = Complete hemianopia.  3 = Bilateral hemianopia (blind including cortical blindness).  0 = Normal symmetrical movements.  1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).  2 = Partial paralysis (total or near-total paralysis of lower face).  3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).  0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.  1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.  2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.  3 = No effort against gravity; limb falls.  4 = No movement.  UN = Amputation or joint fusion, explain:  5a. Left Arm  5b. Right Arm  0 = No drift; leg falls by the end of the 5-second period but does not hit bed.  2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.  3 = No effort against gravity; leg falls to bed immediately.  4 = No movement.  UN = Amputation or joint fusion, explain:



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	/	1	

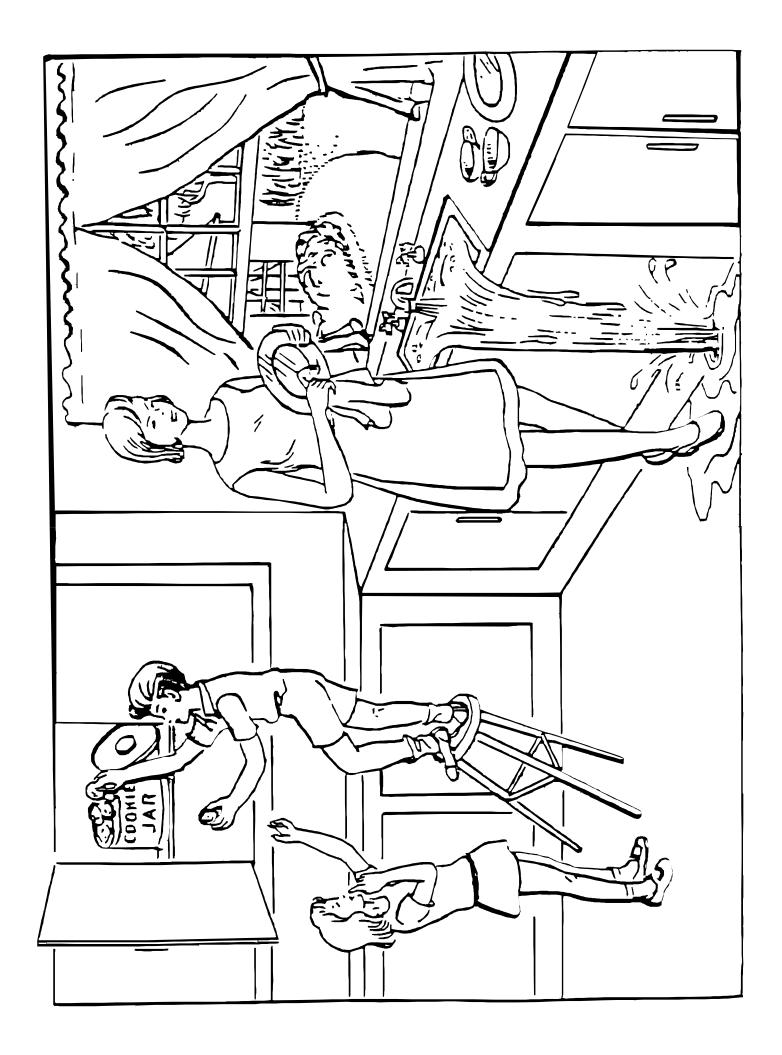
	Hospital(	
SCALE	Date of Exam /	
Interval: [] Baseline [] 2 hours post treatment [] 24 hours post treatment [] 25 hours post treatment [] 26 hours post treatment [] 27 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 29 hours post treatment [] 20 hours post post post post post post post pos		7
7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, ensure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice. In case of blindness, test by having the patient touch nose from extended arm position.	0 = Absent.  1 = Present in one limb.  2 = Present in two limbs.  UN = Amputation or joint fusion, explain:	
8. Sensory: Sensation or grimace to pinprick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas (arms [not hands], legs, trunk, face) as needed to accurately check for hemisensory loss. A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will, therefore, probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in a coma (item 1a=3) are automatically given a 2 on this item.	<ul> <li>0 = Normal; no sensory loss.</li> <li>1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched.</li> <li>2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg.</li> </ul>	
9. Best Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. For this scale item, the patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet and to read from the attached list of sentences. Comprehension is judged from responses here, as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in a coma (item 1a=3) will automatically score 3 on this item. The examiner must choose a score for the patient with stupor or limited cooperation, but a score of 3 should be used only if the patient is mute and follows no one-step commands.	0 = No aphasia; normal.  1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.  2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response.  3 = Mute, global aphasia; no usable speech or auditory comprehension.	
10. Dysarthria: If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN), and clearly write an explanation for this choice. Do not tell the patient why he or she is being tested.	0 = Normal.  1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty.  2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric.  UN = Intubated or other physical barrier, explain:	



NIH	Patient Identification		_
STROKE	Pt. Date of Birth/	/	_
	Hospital((		_)
SCALE	Date of Exam /	/	_
Interval: [] Baseline [] 2 hours post treatment [] 24 ho [] 3 months [] Other			7
11. Extinction and Inattention (formerly Neglect): Sufficient information to identify neglect may be obtained during the prior	0 = No abnormality.		
testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of	1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.		

11. Extinction and Inattention (formerly Neglect):	Sufficient
information to identify neglect may be obtained during	the prior
testing. If the patient has a severe visual loss preventi	ng visual
double simultaneous stimulation, and the cutaneous st	imuli are
normal, the score is normal. If the patient has aphasia	but does
appear to attend to both sides, the score is normal. The pro-	esence of
visual spatial neglect or anosagnosia may also be taken as	evidence
of abnormality. Since the abnormality is scored only if pre	esent, the
item is never untestable.	

one modality; does not recognize own hand or orients to only one side of space.



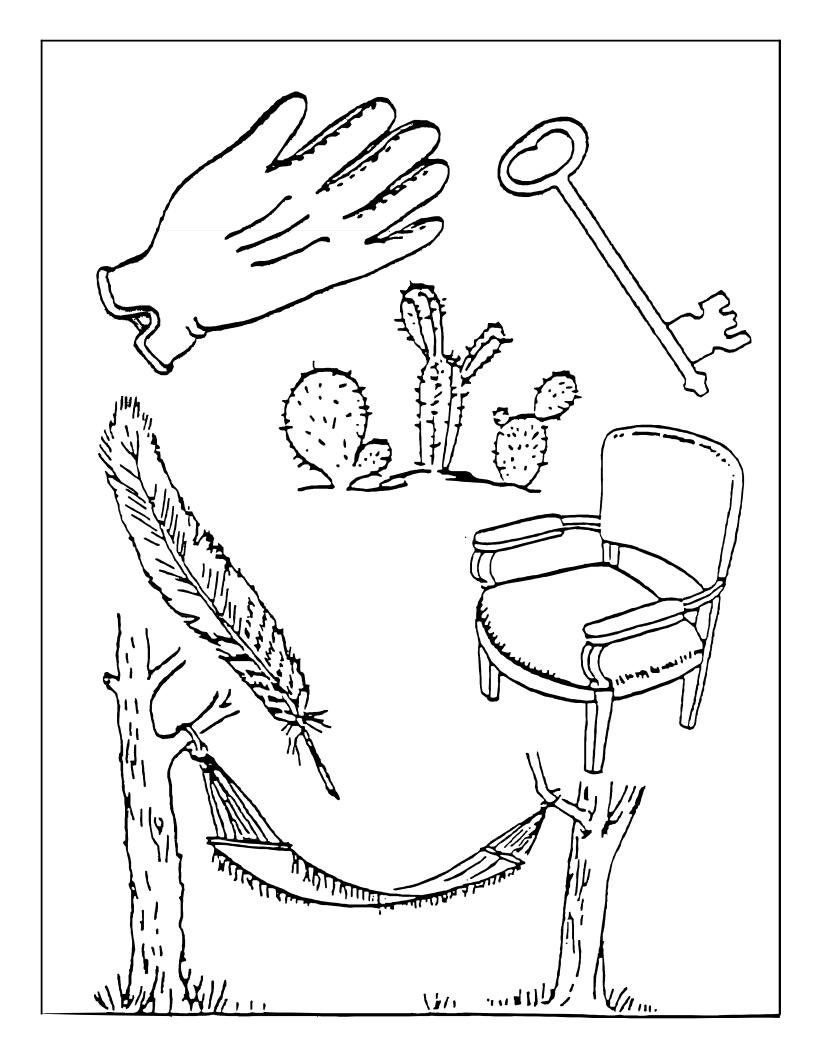
You know how.

Down to earth.

I got home from work.

Near the table in the dining room.

They heard him speak on the radio last night.



# **MAMA**

TIP - TOP

FIFTY - FIFTY

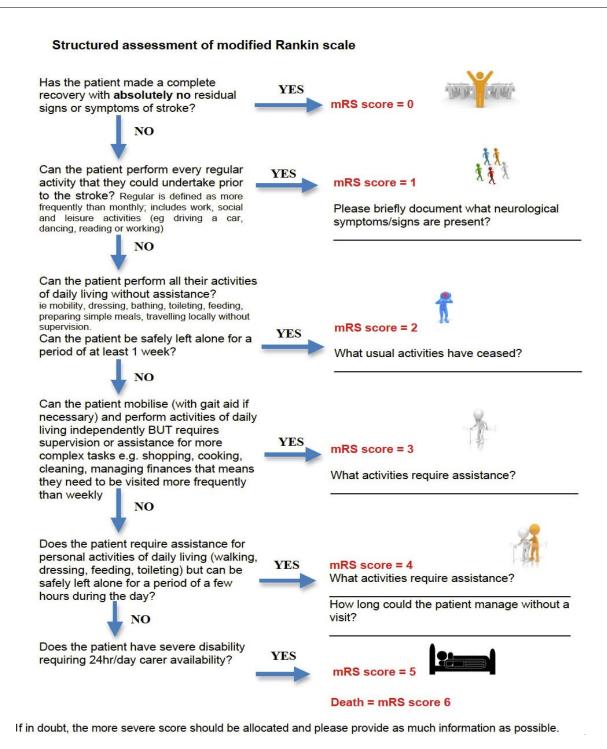
**THANKS** 

**HUCKLEBERRY** 

**BASEBALL PLAYER** 

				Site #
Page 1 of 2		Date Name of Assessor:		
Q01			duties and activities  O (2) Slight disability; unable to look after own affairs withou  O (3) Moderate disability require assistance  O (4) Moderately severe disabile unable to attend to own bodi	ing some help, but able to walk without lity; unable to walk without assistance and
Q02	First/Given name (50 character max			
Q03	Last/Family name (50 character max	of mRS assessor		
Q04	lf visit is 'Day 30' or 'Day 90'	Was the assessor blinded to treatment received?	O No	O Yes
Genera	al Comments:			

Subject #



General Comments:



TIMELESS	RANDOMIZEO, PLACEBO-CONTROLLEO TRIAL OF THROMBOLYSIS IN IMAGING-ELIGIBLE, LATE-WINDOW PATIENTS	Subject ID:	
A study of imaging-eligible stroke treatment	TO ASSESS THE EFFICACY AND SAFETY OF TENECTEPLASE (TIMELESS)	Date:	<u>.</u>
Follow up CT			
Date of imaging:			
Start time of imaging:			
Side of lesion:			
	□ Left □ Right		
Type of occlusion:			
	☐ ICA ☐ MCA-M1 ☐ MCA-M2 ☐ Other, specify:		
From the RAPID software, plea Lesion volume.	ase provide ischemic core volume, mismatch ro	atio, absolute mismatch vo	olume, and Tmax >6s
Ischemic Core Volume:	mL		
Mismatch Ratio:			
Absolute Mismatch Volum	me:mL		
Tmax >6s Lesion Volume:	:mL		
Intracranial hemorrhage:	:		
	<ul> <li>□ HI-1</li> <li>□ HI-2</li> <li>□ PH-1</li> <li>□ PH-2</li> <li>□ IVH</li> </ul>		□ Subdural □ Epidural □ SAH □ None
Degree of recanalization:			
	<ul><li>□ No recanalization</li><li>□ Partial recanalization</li><li>□ Complete recanalization</li><li>□ Not applicable</li></ul>		
If response is not applical	ble, choose one:		
Γ	☐ Image not obtained		

Date (dd-mon-yyyy)

☐ Image of insufficient quality

☐ Lesion not present or rated at baseline



FLAIR:

TIMELESS A study of imaging-eligible stroke treatment	OF THROMBI IMAGING-ELI TO ASSESS 1	PROSPECTIVE, DOUBLE-BLIND, D, PLACEBO-CONTROLLED TRIAL DLYSIS IN GIGBLE, LATE-WINDOW PATIENTS THE EFFICACY AND SAFETY OF SEE (TIMELESS)			
Follow up MRI					
Date of imaging:				_	
Start time of imaging:				_	
Side of lesion:					
		Left Right			
Type of occlusion:					
		ICA MCA-M1 MCA-M2 Other, specify	y:		
From the RAPID software, plea Lesion volume.	se prov	vide ischemic core	e volume, mismatch i	ratio, absolute misi	match volume, and Tmax >6s
Ischemic Core Volume:			mL		
Mismatch Ratio:			-		
Absolute Mismatch Volui	me:		_mL		
Tmax >6s Lesion Volume	:		_mL		
Intracranial hemorrhage:					
		HI-1 HI-2 PH-1 PH-2 IVH Subdural Epidural SAH None			
DWI lesion volume:		mL			

☐ Unknown

☐ Yes □ No



Subject ID:	
Date:	

		Date:
lf yes, were abnormalities identi	fied:	
	Yes	
	No	
GRE:		
	Yes	
	No	
	Unknown	
lf yes, were abnormalities identi	fied:	
	Yes	
	No	
Degree of recanalization:		
	No recanalization	
□ F	Partial recanalization	
	Complete recanalization	
	Not applicable	
lf response is not applicable, o	choose one:	
	mage not obtained	
	mage of insufficient quality	
□ L	esion not present or rated at baseline	



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	1	1	

Interval: [] Baseline [] 2 hours post treatment [] 3 months [] Other	[] 24 hours post onset of symptoms ±20 minutes	[] 7-10 days
Time:: []am []pm		
Person Administering Scale		

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

Instructions Scale Definition Score Level of Consciousness: The investigator must choose a Alert; keenly responsive. response if a full evaluation is prevented by such obstacles as an 1 = **Not alert**; but arousable by minor stimulation to obey, endotracheal tube, language barrier, orotracheal trauma/bandages. A answer, or respond. 3 is scored only if the patient makes no movement (other than reflexive 2 = Not alert; requires repeated stimulation to attend, or is posturing) in response to noxious stimulation. obtunded and requires strong or painful stimulation to make movements (not stereotyped). 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and areflexic. 0 = **Answers** both questions correctly. **1b.** LOC Questions: The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions **Answers** one question correctly. will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, Answers neither question correctly. language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. 1c. LOC Commands: The patient is asked to open and close the 0 = **Performs** both tasks correctly. eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is 1 = **Performs** one task correctly. given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task 2 = Performs neither task correctly. should be demonstrated to him or her (pantomime), and the result scored (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored. 2. Best Gaze: Only horizontal eye movements will be tested. 0 = Normal.Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done. If the patient has a conjugate 1 = Partial gaze palsy; gaze is abnormal in one or both eyes, deviation of the eyes that can be overcome by voluntary or reflexive but forced deviation or total gaze paresis is not present. activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), score a 1. Gaze is testable in all 2 = Forced deviation, or total gaze paresis not overcome by the aphasic patients. Patients with ocular trauma, bandages, pre-existing oculocephalic maneuver. blindness, or other disorder of visual acuity or fields should be tested with reflexive movements, and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	1	1	

ours post onset of symptoms ±20 minutes [] 7-10 days	
<ul> <li>0 = No visual loss.</li> <li>1 = Partial hemianopia.</li> <li>2 = Complete hemianopia.</li> <li>3 = Bilateral hemianopia (blind including cortical blindness).</li> </ul>	
<ul> <li>0 = Normal symmetrical movements.</li> <li>1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).</li> <li>2 = Partial paralysis (total or near-total paralysis of lower face).</li> <li>3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).</li> </ul>	
<ul> <li>0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.</li> <li>1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.</li> <li>2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.</li> <li>3 = No effort against gravity; limb falls.</li> <li>4 = No movement.</li> <li>UN = Amputation or joint fusion, explain:</li> <li>5a. Left Arm</li> <li>5b. Right Arm</li> </ul>	
<ul> <li>0 = No drift; leg holds 30-degree position for full 5 seconds.</li> <li>1 = Drift; leg falls by the end of the 5-second period but does not hit bed.</li> <li>2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.</li> <li>3 = No effort against gravity; leg falls to bed immediately.</li> <li>4 = No movement.</li> <li>UN = Amputation or joint fusion, explain:</li> <li>6a. Left Leg</li> </ul>	
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Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	/	1	

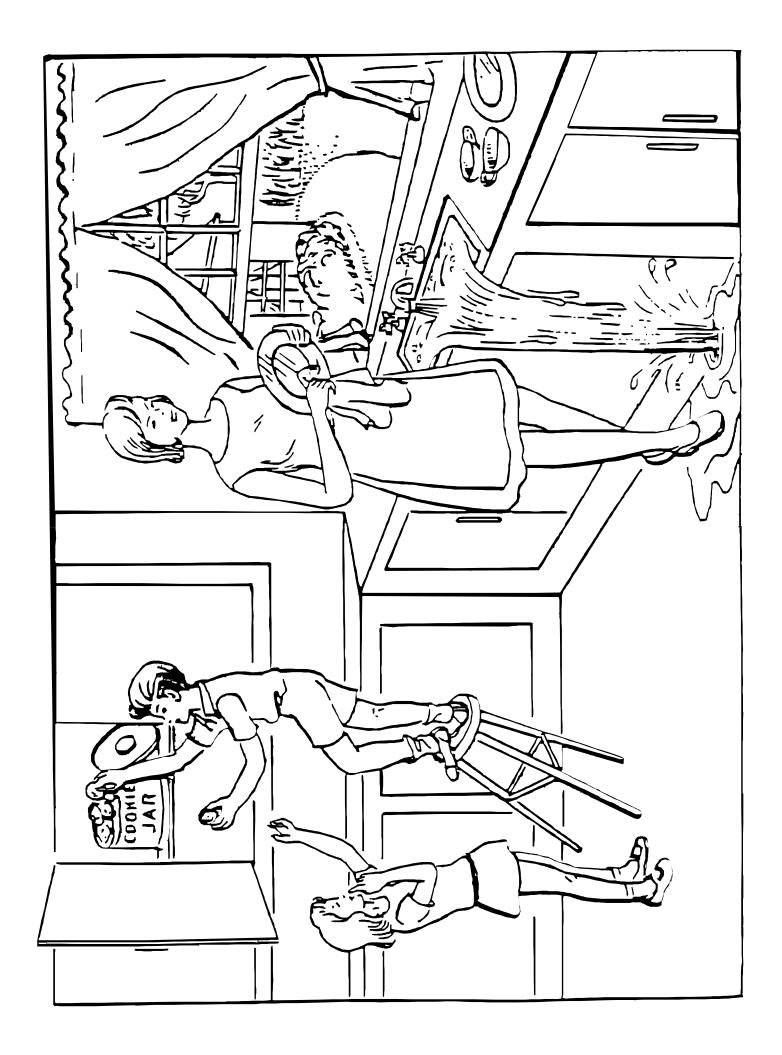
	Hospital(	
SCALE	Date of Exam /	
Interval: [] Baseline [] 2 hours post treatment [] 24 hours post treatment [] 25 hours post treatment [] 26 hours post treatment [] 27 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 29 hours post treatment [] 20 hours post post post post post post post pos		7
7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, ensure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice. In case of blindness, test by having the patient touch nose from extended arm position.	0 = Absent.  1 = Present in one limb.  2 = Present in two limbs.  UN = Amputation or joint fusion, explain:	
8. Sensory: Sensation or grimace to pinprick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas (arms [not hands], legs, trunk, face) as needed to accurately check for hemisensory loss. A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will, therefore, probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in a coma (item 1a=3) are automatically given a 2 on this item.	<ul> <li>0 = Normal; no sensory loss.</li> <li>1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched.</li> <li>2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg.</li> </ul>	
9. Best Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. For this scale item, the patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet and to read from the attached list of sentences. Comprehension is judged from responses here, as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in a coma (item 1a=3) will automatically score 3 on this item. The examiner must choose a score for the patient with stupor or limited cooperation, but a score of 3 should be used only if the patient is mute and follows no one-step commands.	0 = No aphasia; normal.  1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.  2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response.  3 = Mute, global aphasia; no usable speech or auditory comprehension.	
10. Dysarthria: If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN), and clearly write an explanation for this choice. Do not tell the patient why he or she is being tested.	0 = Normal.  1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty.  2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric.  UN = Intubated or other physical barrier, explain:	



NIH	Patient Identification		_
STROKE	Pt. Date of Birth/	/	_
	Hospital((		_)
SCALE	Date of Exam /	/	_
Interval: [] Baseline [] 2 hours post treatment [] 24 ho [] 3 months [] Other			7
11. Extinction and Inattention (formerly Neglect): Sufficient information to identify neglect may be obtained during the prior	0 = No abnormality.		
testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of	1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.		

11. Extinction and Inattention (formerly Neglect):	Sufficient
information to identify neglect may be obtained during	the prior
testing. If the patient has a severe visual loss preventi	ng visual
double simultaneous stimulation, and the cutaneous st	imuli are
normal, the score is normal. If the patient has aphasia	but does
appear to attend to both sides, the score is normal. The pro-	esence of
visual spatial neglect or anosagnosia may also be taken as	evidence
of abnormality. Since the abnormality is scored only if pre	esent, the
item is never untestable.	

one modality; does not recognize own hand or orients to only one side of space.



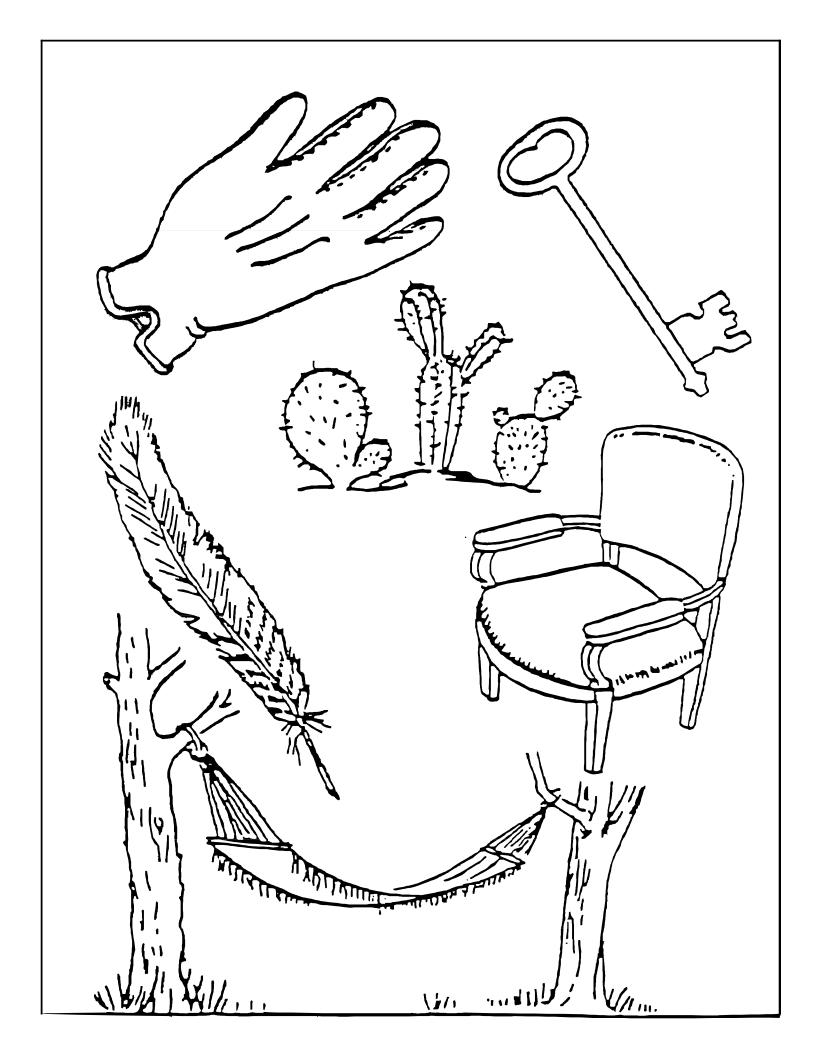
You know how.

Down to earth.

I got home from work.

Near the table in the dining room.

They heard him speak on the radio last night.



## **MAMA**

TIP - TOP

FIFTY - FIFTY

**THANKS** 

**HUCKLEBERRY** 

**BASEBALL PLAYER** 



PHASE II. PROSPECTIVE, DOUBLE-BLIND, AMDOMIZED, PLACEBIC-CONTROLLED TRIAL IT THROMBICLYSIS IN AGAING-BLIGHER, LLATE-WINDOW PATIENTS O ASSESS THE EFFICACY AND SAFETY OF ENECTEPLASE (TIMELESS)			
	  Left		
	Right		
	Yes No		

Intracranial hemorrhage:

Follow up CT

Date of imaging:

Side of lesion:

Was an ICH seen?

Start time of imaging:

HI-1	Subdural
HI-2	Epidural
PH-1	SAH
PH-2	None
IVH	

Signature of Study Staff Member Collecting Data:

Date (dd-mon-yyyy)



<b>TIMELESS</b>	OF THROME IMAGING-EL	D, PLACEBO-CONTROLLED TRIAL IOLYSIS IN IGIBLE, LATE-WINDOW PATIENTS THE EFFICACY AND SAFETY OF		Subject ID	):
A study of imaging-eligible stroke treatment	TENECTEPL	ASE (TIMELESS)		Date	:
Follow up MRI					
Date of imaging:					
Start time of imaging:					
Side of lesion:					
		Left Right			
Type of occlusion:					
		ICA MCA-M1 MCA-M2 Other, specif	fy:		
From the RAPID software, plea	ase pro	vide ischemic coi	re volume, mismatch ro	atio, absolute m	ismatch volume, and Tmax >6s
Ischemic Core Volume:			_ mL		
Mismatch Ratio:			_		
Absolute Mismatch Volu	me:		_ mL		
Tmax >6s Lesion Volume	::		_ mL		
Intracranial hemorrhage	:				
		HI-1 HI-2 PH-1 PH-2 IVH Subdural Epidural SAH None			
DWI lesion volume:		mL	-		
FLAIR:					

☐ Yes □ No

☐ Unknown



Subject ID: _	 	
Date: _		

TENECIE	ruae (Imerica)	Date:
f yes, were abnormalities identif	fied:	
	Yes	
	No	
GRE:		
	Yes	
	No	
	Unknown	
f yes, were abnormalities identif	ied:	
	Yes	
	No	
Degree of recanalization:		
	lo recanalization	
□ P	artial recanalization	
□ C	omplete recanalization	
	lot applicable	
f response is not applicable, c	choose one:	
□ Ir	mage not obtained	
□ Ir	mage of insufficient quality	
	esion not present or rated at baseline	

Signature of Study Staff Member Collecting Data:

Date (dd-mon-yyyy)



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam			

Interval: [] Baseline [] 2 hours post treatment [] 3 months [] Other	[] 24 hours post onset of symptoms ±20 minutes	[] 7-10 days
Time:: []am []pm		
Person Administering Scale		

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

Instructions Scale Definition Score Level of Consciousness: The investigator must choose a Alert; keenly responsive. response if a full evaluation is prevented by such obstacles as an 1 = **Not alert**; but arousable by minor stimulation to obey, endotracheal tube, language barrier, orotracheal trauma/bandages. A answer, or respond. 3 is scored only if the patient makes no movement (other than reflexive 2 = Not alert; requires repeated stimulation to attend, or is posturing) in response to noxious stimulation. obtunded and requires strong or painful stimulation to make movements (not stereotyped). 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and areflexic. 0 = **Answers** both questions correctly. **1b.** LOC Questions: The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions Answers one question correctly. will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, Answers neither question correctly. language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. 1c. LOC Commands: The patient is asked to open and close the 0 = **Performs** both tasks correctly. eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is 1 = **Performs** one task correctly. given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task 2 = Performs neither task correctly. should be demonstrated to him or her (pantomime), and the result scored (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored. 2. Best Gaze: Only horizontal eye movements will be tested. 0 = Normal.Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done. If the patient has a conjugate 1 = Partial gaze palsy; gaze is abnormal in one or both eyes, deviation of the eyes that can be overcome by voluntary or reflexive but forced deviation or total gaze paresis is not present. activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), score a 1. Gaze is testable in all 2 = Forced deviation, or total gaze paresis not overcome by the aphasic patients. Patients with ocular trauma, bandages, pre-existing oculocephalic maneuver. blindness, or other disorder of visual acuity or fields should be tested with reflexive movements, and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.



Patient Ide	ntification	· — — ·		
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	/	/_	

SCALE	Date of Exam /	/
Interval: []Baseline []2 hours post treatment []24 ho		
3. Visual: Visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat, as appropriate. Patients may be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrantanopia, is found. If patient is blind from any cause, score 3. Double simultaneous stimulation is performed at this point. If there is extinction, patient receives a 1, and the results are used to respond to item 11.	0 = No visual loss.  1 = Partial hemianopia.  2 = Complete hemianopia.  3 = Bilateral hemianopia (blind including cortical blindness).	
<b>4. Facial Palsy:</b> Ask – or use pantomime to encourage – the patient to show teeth or raise eyebrows and close eyes. Score symmetry of grimace in response to noxious stimuli in the poorly responsive or non-comprehending patient. If facial trauma/bandages, orotracheal tube, tape or other physical barriers obscure the face, these should be removed to the extent possible.	<ul> <li>0 = Normal symmetrical movements.</li> <li>1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).</li> <li>2 = Partial paralysis (total or near-total paralysis of lower face).</li> <li>3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).</li> </ul>	
5. Motor Arm: The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine). Drift is scored if the arm falls before 10 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime, but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. Only in the case of amputation or joint fusion at the shoulder, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice.	0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.  1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.  2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.  3 = No effort against gravity; limb falls.  4 = No movement.  UN = Amputation or joint fusion, explain:  5a. Left Arm  5b. Right Arm	
<b>6. Motor Leg:</b> The limb is placed in the appropriate position: hold the leg at 30 degrees (always tested supine). Drift is scored if the leg falls before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime, but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic leg. Only in the case of amputation or joint fusion at the hip, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice.	0 = No drift; leg holds 30-degree position for full 5 seconds.  1 = Drift; leg falls by the end of the 5-second period but does not hit bed.  2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.  3 = No effort against gravity; leg falls to bed immediately.  4 = No movement.  UN = Amputation or joint fusion, explain:  6a. Left Leg	
	6b. Right Leg	



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	/	1	

	Hospital(	
SCALE	Date of Exam /	
Interval: [] Baseline [] 2 hours post treatment [] 24 hours post treatment [] 25 hours post treatment [] 26 hours post treatment [] 27 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 29 hours post treatment [] 20 hours post post post post post post post pos		7
7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, ensure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice. In case of blindness, test by having the patient touch nose from extended arm position.	0 = Absent.  1 = Present in one limb.  2 = Present in two limbs.  UN = Amputation or joint fusion, explain:	
8. Sensory: Sensation or grimace to pinprick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas (arms [not hands], legs, trunk, face) as needed to accurately check for hemisensory loss. A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will, therefore, probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in a coma (item 1a=3) are automatically given a 2 on this item.	<ul> <li>0 = Normal; no sensory loss.</li> <li>1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched.</li> <li>2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg.</li> </ul>	
9. Best Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. For this scale item, the patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet and to read from the attached list of sentences. Comprehension is judged from responses here, as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in a coma (item 1a=3) will automatically score 3 on this item. The examiner must choose a score for the patient with stupor or limited cooperation, but a score of 3 should be used only if the patient is mute and follows no one-step commands.	0 = No aphasia; normal.  1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.  2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response.  3 = Mute, global aphasia; no usable speech or auditory comprehension.	
10. Dysarthria: If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN), and clearly write an explanation for this choice. Do not tell the patient why he or she is being tested.	0 = Normal.  1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty.  2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric.  UN = Intubated or other physical barrier, explain:	

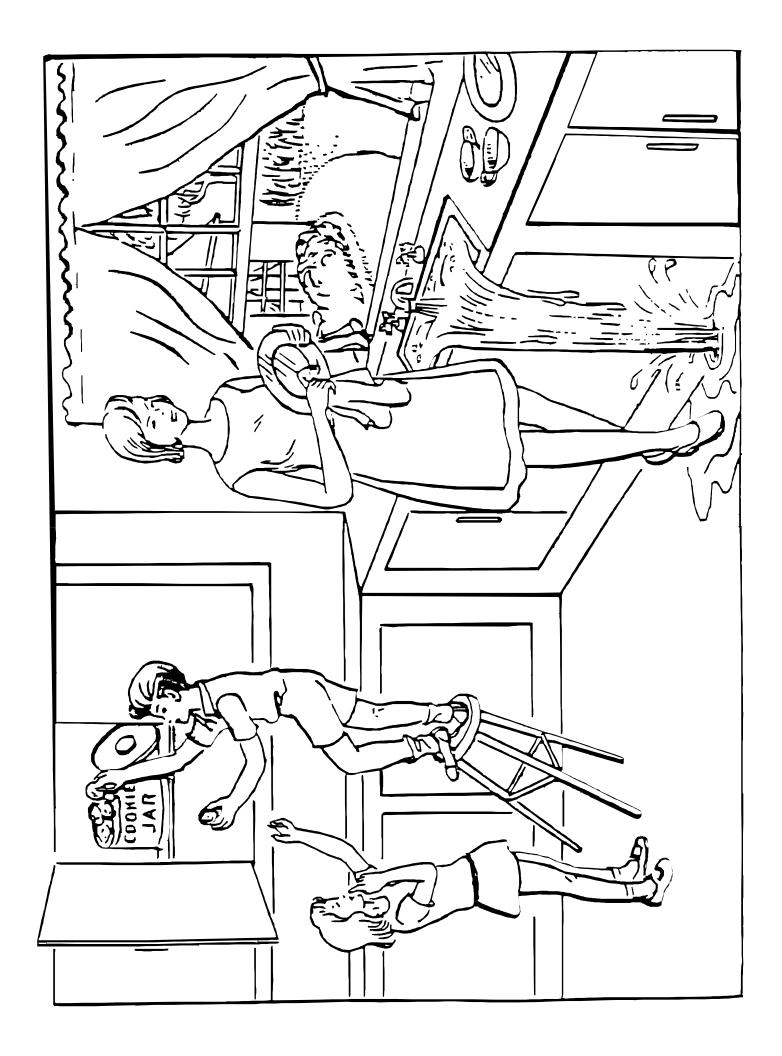


NIH	Patient Identification			
STROKE	Pt. Date of Birth//			
SCALE	Hospital((	) /	_)	
Interval: [] Baseline [] 2 hours post treatment [] 24 ho [] 3 months [] Other				
11. Extinction and Inattention (formerly Neglect): Sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of	<ul> <li>0 = No abnormality.</li> <li>1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.</li> </ul>			

2 = Profound hemi-inattention or extinction to more than one modality; does not recognize own hand or orients

to only one side of space.

Extinction and Inattention (formerly Neglect): Sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosagnosia may also be taken as evidence of abnormality. Since the abnormality is scored only if present, the item is never untestable.



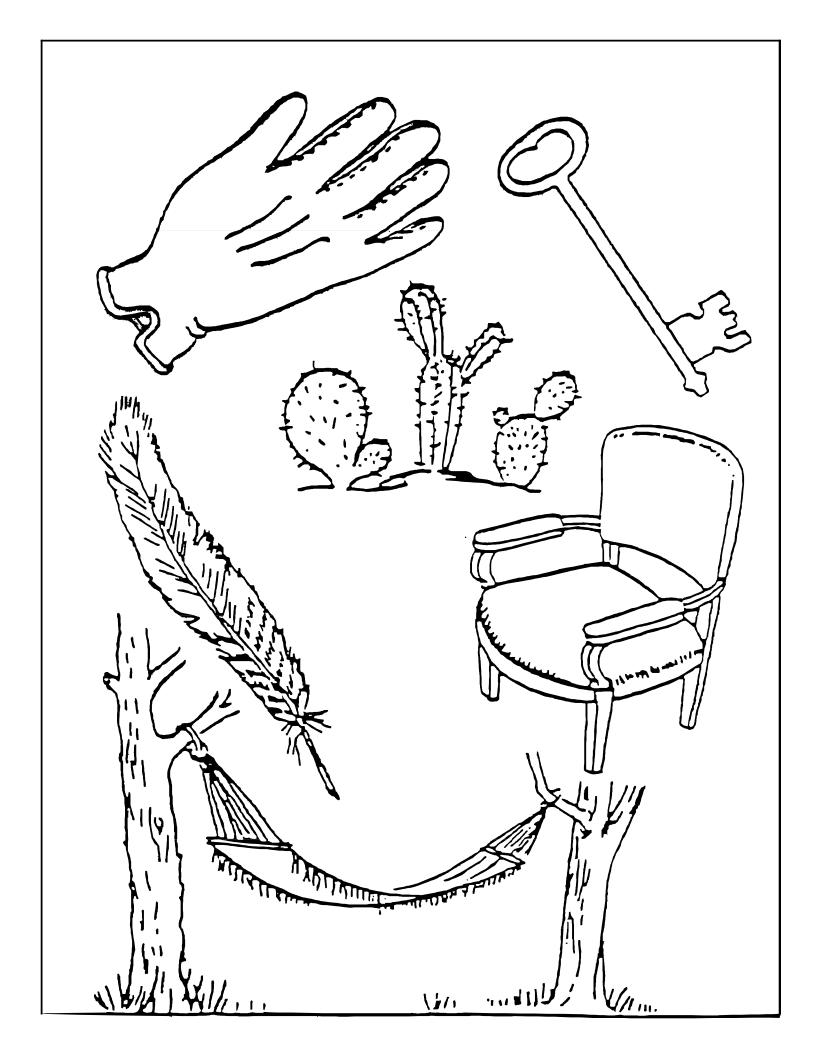
You know how.

Down to earth.

I got home from work.

Near the table in the dining room.

They heard him speak on the radio last night.



## **MAMA**

TIP - TOP

FIFTY - FIFTY

**THANKS** 

**HUCKLEBERRY** 

**BASEBALL PLAYER** 



Rater's name:

TIMELESS  A study of imaging-eligible stroke treatment	RANDOMIZED, OF THROMBOI IMAGING-ELIG	PLACEBO-CONTROLLED TRIAL LYSIS IN IBLE, LATE-WINDOW PATIENTS	Subject ID:
A study of imaging-eligible stroke treatment	TO ASSESS THE TENECTEPLAS	HE EFFICACY AND SAFETY OF SE (TIMELESS)	Date:
Hospital Discharge			
Date of discharge:			
Time of discharge:			
Discharge destination:			
		Home Acute rehab Skilled nursing Death Other, specify	facility
Stroke etiology:			
			m
mRS Assessment			
Was the assessment con	npleted	!?	
		Yes No	
Date of Assessment:			
Assessment score:			
Rater's name:			
NIHSS Assessment			
Was the assessment con	npleted	!?	
		Yes No	
Date of Assessment:			
Assessment score:			



TIMELESS  A study of Imaging-eligible stroke treatment	OF THROMBOLYSIS IN IMAGING-ELIGIBLE, LATE-WINDOW PATIENTS TO ASSESS THE EFFICACY AND SAFETY OF TENECTEPLASE (TIMELESS)	Subject ID:
Glasgow Outcome Score	Assessment	
Was the assessment com	pleted?	
	☐ Yes ☐ No	
Date of Assessment:		<del></del>
Assessment score:		

Signature of Study Staff Member Collecting Data:

Date (dd-mon-yyyy



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	1	1	

Interval: [] Baseline [] 2 hours post treatment [] 3 months [] Other	[] 24 hours post onset of symptoms ±20 minutes	[] 7-10 days
Time:: []am []pm		
Person Administering Scale		

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

Instructions Scale Definition Score Level of Consciousness: The investigator must choose a Alert; keenly responsive. response if a full evaluation is prevented by such obstacles as an 1 = **Not alert**; but arousable by minor stimulation to obey, endotracheal tube, language barrier, orotracheal trauma/bandages. A answer, or respond. 3 is scored only if the patient makes no movement (other than reflexive 2 = Not alert; requires repeated stimulation to attend, or is posturing) in response to noxious stimulation. obtunded and requires strong or painful stimulation to make movements (not stereotyped). 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and areflexic. 0 = **Answers** both questions correctly. **1b.** LOC Questions: The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions Answers one question correctly. will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, Answers neither question correctly. language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. 1c. LOC Commands: The patient is asked to open and close the 0 = **Performs** both tasks correctly. eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is 1 = **Performs** one task correctly. given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task 2 = Performs neither task correctly. should be demonstrated to him or her (pantomime), and the result scored (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored. 2. Best Gaze: Only horizontal eye movements will be tested. 0 = Normal.Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done. If the patient has a conjugate 1 = Partial gaze palsy; gaze is abnormal in one or both eyes, deviation of the eyes that can be overcome by voluntary or reflexive but forced deviation or total gaze paresis is not present. activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), score a 1. Gaze is testable in all 2 = Forced deviation, or total gaze paresis not overcome by the aphasic patients. Patients with ocular trauma, bandages, pre-existing oculocephalic maneuver. blindness, or other disorder of visual acuity or fields should be tested with reflexive movements, and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	1	1	

ours post onset of symptoms ±20 minutes [] 7-10 days	
<ul> <li>0 = No visual loss.</li> <li>1 = Partial hemianopia.</li> <li>2 = Complete hemianopia.</li> <li>3 = Bilateral hemianopia (blind including cortical blindness).</li> </ul>	
<ul> <li>0 = Normal symmetrical movements.</li> <li>1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).</li> <li>2 = Partial paralysis (total or near-total paralysis of lower face).</li> <li>3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).</li> </ul>	
<ul> <li>0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.</li> <li>1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.</li> <li>2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.</li> <li>3 = No effort against gravity; limb falls.</li> <li>4 = No movement.</li> <li>UN = Amputation or joint fusion, explain:</li> <li>5a. Left Arm</li> <li>5b. Right Arm</li> </ul>	
<ul> <li>0 = No drift; leg holds 30-degree position for full 5 seconds.</li> <li>1 = Drift; leg falls by the end of the 5-second period but does not hit bed.</li> <li>2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.</li> <li>3 = No effort against gravity; leg falls to bed immediately.</li> <li>4 = No movement.</li> <li>UN = Amputation or joint fusion, explain:</li> <li>6a. Left Leg</li> </ul>	
	0 = No visual loss.  1 = Partial hemianopia.  2 = Complete hemianopia.  3 = Bilateral hemianopia (blind including cortical blindness).  0 = Normal symmetrical movements.  1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).  2 = Partial paralysis (total or near-total paralysis of lower face).  3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).  0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.  1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support.  2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.  3 = No effort against gravity; limb falls.  4 = No movement.  UN = Amputation or joint fusion, explain:  5a. Left Arm  5b. Right Arm  0 = No drift; leg falls by the end of the 5-second period but does not hit bed.  2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.  3 = No effort against gravity; leg falls to bed immediately.  4 = No movement.  UN = Amputation or joint fusion, explain:



Patient Ide	ntification			
	Pt. Date of Birth	/	/	
Hospital		(		)
	Date of Exam	/	1	

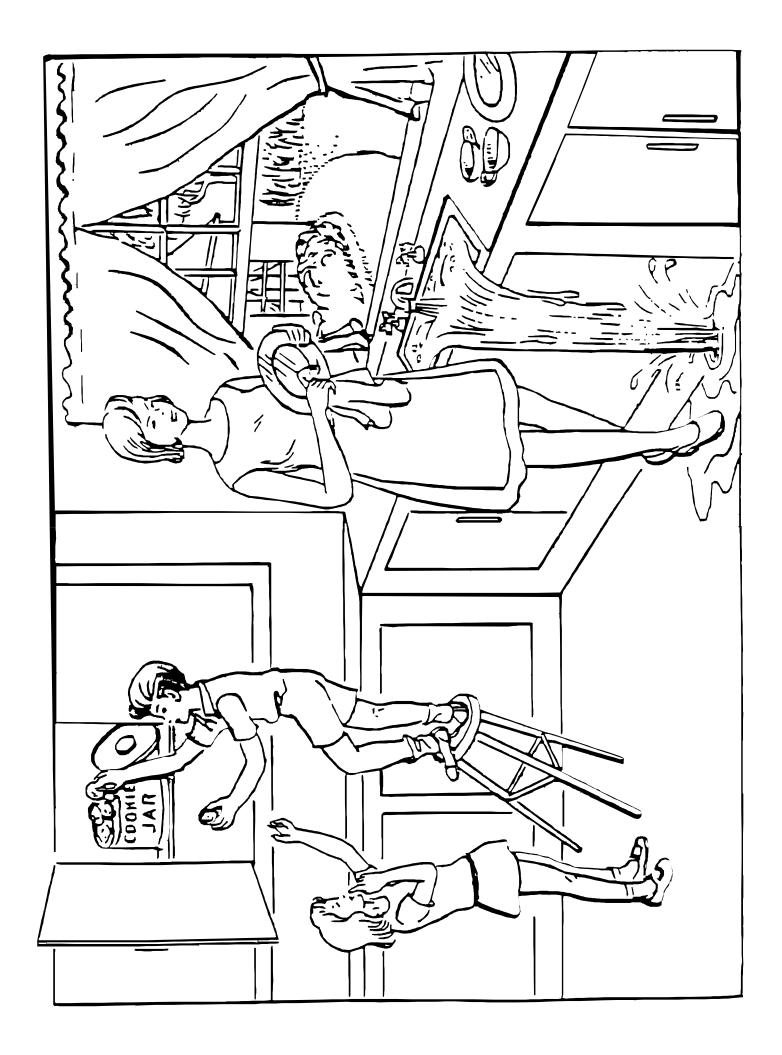
	Hospital(	
SCALE	Date of Exam /	
Interval: [] Baseline [] 2 hours post treatment [] 24 hours post treatment [] 25 hours post treatment [] 26 hours post treatment [] 27 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 28 hours post treatment [] 29 hours post treatment [] 20 hours post post post post post post post pos		7
7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, ensure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice. In case of blindness, test by having the patient touch nose from extended arm position.	0 = Absent.  1 = Present in one limb.  2 = Present in two limbs.  UN = Amputation or joint fusion, explain:	
8. Sensory: Sensation or grimace to pinprick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas (arms [not hands], legs, trunk, face) as needed to accurately check for hemisensory loss. A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will, therefore, probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in a coma (item 1a=3) are automatically given a 2 on this item.	<ul> <li>0 = Normal; no sensory loss.</li> <li>1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched.</li> <li>2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg.</li> </ul>	
9. Best Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. For this scale item, the patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet and to read from the attached list of sentences. Comprehension is judged from responses here, as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in a coma (item 1a=3) will automatically score 3 on this item. The examiner must choose a score for the patient with stupor or limited cooperation, but a score of 3 should be used only if the patient is mute and follows no one-step commands.	0 = No aphasia; normal.  1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.  2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response.  3 = Mute, global aphasia; no usable speech or auditory comprehension.	
10. Dysarthria: If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN), and clearly write an explanation for this choice. Do not tell the patient why he or she is being tested.	0 = Normal.  1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty.  2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric.  UN = Intubated or other physical barrier, explain:	



NIH	Patient Identification		_
STROKE	Pt. Date of Birth/	/	_
	Hospital((		_)
SCALE	Date of Exam /	/	_
Interval: [] Baseline [] 2 hours post treatment [] 24 ho [] 3 months [] Other			7
11. Extinction and Inattention (formerly Neglect): Sufficient information to identify neglect may be obtained during the prior	0 = No abnormality.		
testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of	1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.		

11. Extinction and Inattention (formerly Neglect):	Sufficient
information to identify neglect may be obtained during	the prior
testing. If the patient has a severe visual loss preventi	ng visual
double simultaneous stimulation, and the cutaneous st	imuli are
normal, the score is normal. If the patient has aphasia	but does
appear to attend to both sides, the score is normal. The pro-	esence of
visual spatial neglect or anosagnosia may also be taken as	evidence
of abnormality. Since the abnormality is scored only if pre	esent, the
item is never untestable.	

one modality; does not recognize own hand or orients to only one side of space.



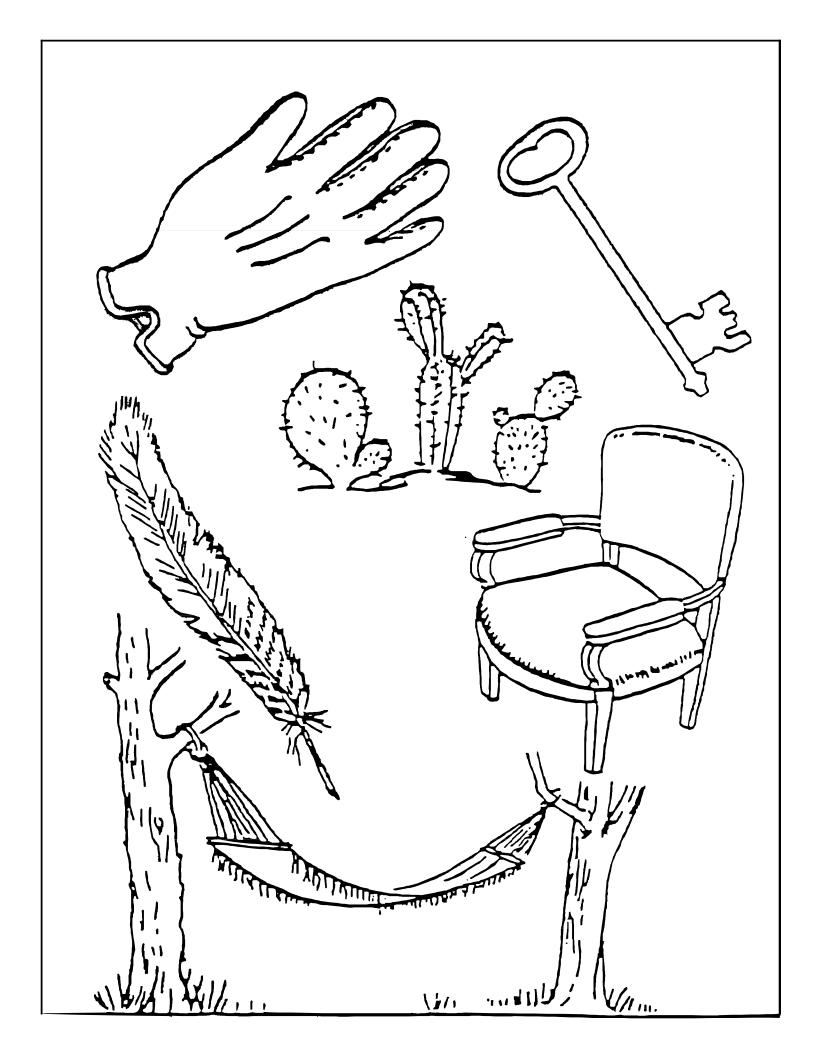
You know how.

Down to earth.

I got home from work.

Near the table in the dining room.

They heard him speak on the radio last night.



## **MAMA**

TIP - TOP

FIFTY - FIFTY

**THANKS** 

**HUCKLEBERRY** 

**BASEBALL PLAYER** 

<b>GLASGOW</b>	
<b>OUTCOME</b>	
<b>SCALE</b>	

Site #:	
Subject #:	
Date:	
Name	of Assessor:

*Note*: The scale presented here is based on the original article by Jennett and Bond. It has become common practice in clinical trial administration, however, to use a modified version that places the scores in reverse order (i.e., "good recovery" = 1, "moderate disability" =2, etc.).

Score	Description
1	DEATH
2	PERSISTENT VEGETATIVE STATE Patient exhibits no <i>obvious cortical</i> function.
3	SEVERE DISABILITY (Conscious but disabled). Patient depends upon others for daily support due to mental or physical disability or both.
4	MODERATE DISABILITY (Disabled but independent). Patient is independent as far as daily life is concerned. The disabilities found include varying degrees of dysphasia, hemiparesis, or ataxia, as well as intellectual and memory deficits and personality changes.
5	GOOD RECOVERY Resumption of normal activities even though there may be minor neurological or psychological deficits.
ΓΟΤΑL (1–	5):

### References

Jennett B, Bond M. "Assessment of outcome after severe brain damage." Lancet 1975 Mar 1;1(7905):480-4

# THE **BARTHEL**

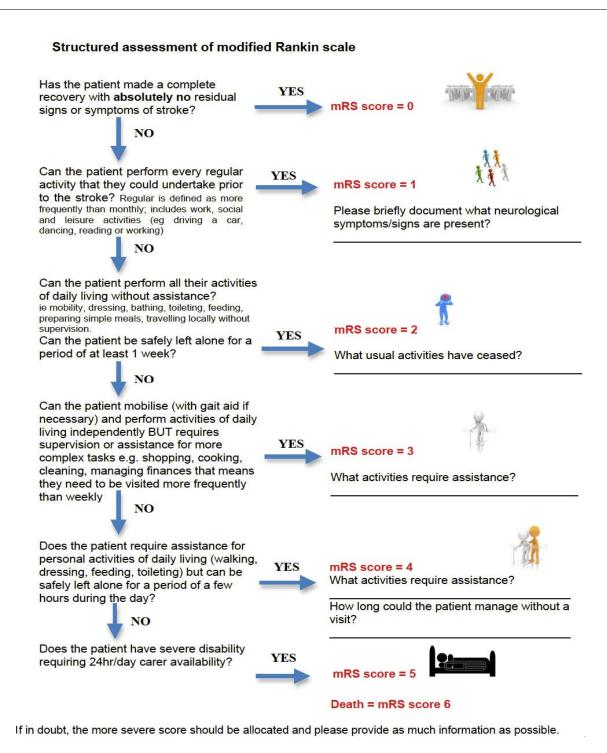
Site #:	
Subject #:	
Date:	

INDEX Name of Asso	essor:
Activity	Score
FEEDING  0 = unable 5 = needs help cutting, spreading butter, etc., or requires modified 10 = independent	diet
BATHING 0 = dependent 5 = independent (or in shower)	
GROOMING  0 = needs to help with personal care 5 = independent face/hair/teeth/shaving (implements provided)	
DRESSING  0 = dependent 5 = needs help but can do about half unaided 10 = independent (including buttons, zips, laces, etc.)	
BOWELS  0 = incontinent (or needs to be given enemas)  5 = occasional accident  10 = continent	
BLADDER  0 = incontinent, or catheterized and unable to manage alone 5 = occasional accident 10 = continent	
TOILET USE  0 = dependent 5 = needs some help, but can do something alone 10 = independent (on and off, dressing, wiping)	
TRANSFERS (BED TO CHAIR AND BACK)  0 = unable, no sitting balance  5 = major help (one or two people, physical), can sit  10 = minor help (verbal or physical)  15 = independent	
MOBILITY (ON LEVEL SURFACES)  0 = immobile or < 50 yards  5 = wheelchair independent, including corners, > 50 yards  10 = walks with help of one person (verbal or physical) > 50 yards  15 = independent (but may use any aid; for example, stick) > 50 yards	
STAIRS  0 = unable 5 = needs help (verbal, physical, carrying aid) 10 = independent	
Mahoney FI, Barthel D. "Functional evaluation: the Barthel Index."	TOTAL (0–100):

Maryland State Med Journal 1965;14:56-61. Used with permission.

			Site #	
Page 1 of 2			Date Name of Assessor:	
Q01			O (0) No symptoms at all O (1) No significant disability despite symptoms; able to carry out all usual duties and activities O (2) Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance O (3) Moderate disability requiring some help, but able to walk without assistance O (4) Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance O (5) Severe disability; bedridden, incontinent, and requiring constant nursing care and attention	
Q02	First/Given name of mRS assessor (50 character max)			
Q03	Last/Family name of mRS assessor (50 character max)			
Q04	lf visit is 'Day 30' or 'Day 90'	Was the assessor blinded to treatment received?	О No	O Yes
Genera	al Comments:			

Subject #



General Comments: