A HIPAA-compliant strategy for recruiting patients for research[1]

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INTRODUCTION

Progress in cognitive rehabilitation research demands adequate access to relevant patients for recruitment as study volunteers. This type of research generally selects for a particular impairment (e.g. hemispatial neglect) or neuroanatomical lesion (e.g., left prefrontal). Suitable candidates are sparsely represented in any single treatment facility; and many who are appropriate leave the system and cannot be tracked. Lack of access to relevant patients is a key problem for cognitive rehabilitation researchers and an impediment to those in related areas who would otherwise choose to enter this field.[1,2]

Recruitment is also impacted by mandates regarding privacy. Even before the federal "Health Insurance Portability and Accountability Act" (HIPAA), privacy protections at most institutions prohibited direct contact by researchers who were not known to the patient or were not involved in the patient's care. Although there is often provision for a pre-consent review of clinical charts, many institutions require that a treating clinician initiate the follow-up contact on behalf of the researcher. Direct recruitment is routinely barred for outside researchers and frequently for researchers who are employees, as well. However, with clinicians stretched thin by downsizing and increased productivity standards, this solution is often impractical and unworkable.

This report describes the advantages and limitations of a consent-based Patient Registry that was created for the expressed purpose of facilitating access to patients for cognitive rehabilitation research. Its development and management is supported by grants from the National Institutes of Health's National Center for Medical Rehabilitation Research to the Moss Rehabilitation Research Institute (MRRI). In the first five-years of its existence, the Patient registry recruited inpatients from three sites: Magee Rehabilitation Hospital, Bryn Mawr Rehab Hospital, and MossRehab, which is a part of the Albert Einstein Healthcare Network (AEHN). Beginning October 2005, the recruitment effort has shifted to MossRehab and multiple outpatient programs within and outside of AEHN. The Patient Registry is a component of the Neuro-Cognitive Rehabilitation Research Network (NCRRN), serving its mandate to enhance the quality, efficiency and level of cognitive rehabilitation research nationally.

[1] This is an updated summary of a published paper:
Schwartz M, Brecher A, Whyte J, Klein M. A Patient Registry for Cognitive Rehabilitation Research: A Strategy for Balancing Patients' Privacy Rights with Researchers' Need for access.
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THE REGISTRY AS A RESEARCH PROJECT

Under the HIPAA privacy rule, a covered entity's use or disclosure of "protected health information" (PHI) to create a patient registry, and the use or disclosure of PHI from a patient registry for future research purposes, are considered research activities.[3] Therefore, in order to maintain HIPAA compliance, the Patient Registry is treated as a research study and written informed consent/authorization is obtained from patients prior to placing their PHI into the Registry. In designing the study protocol, the authors participated in multiple discussions with AEHN's legal counsel and privacy officer regarding the consent/authorization process for the Registry. A key factor is that as researchers on an IRB-approved project, the Registry recruiters are considered part of AEHN's covered entity, that is, employees who require access to PHI in order to carry out their duties. This afforded them the right and responsibility to review patient charts on a "need to know" basis, i.e., for all and only the information relevant to Registry inclusion/exclusion criteria. Patients were advised that medical records review by approved researchers was routine practice when they received each institution's "Notice of Privacy Practices" upon hospital admission. It was the judgment of our IRB that authorization of direct recruitment privileges to a small staff of recruiters serving multiple research projects represents an acceptable compromise between patient's privacy rights and researcher's need for access. Our aim in this report is to share our experience with this recruitment model, in the hope that other researchers and other IRBs will draw useful lessons for their own institutions.

INCLUSION CRITERIA

Inclusion criteria for the Registry are informed by the needs of the participating studies and the general requirements of cognitive rehabilitation research in our network. For example, because this type research inevitably starts with a biased sample (those who have the condition or lesion in question) we do not strive for enrollment that is representative of the population undergoing rehabilitation.

In general, we cast a wide net for recruits to the Registry, leaving it to investigators of participating research studies to impose more stringent, study-specific criteria later. The sole inclusion criterion is presence of stroke or traumatic brain injury (TBI). These diagnoses were chosen based on the type of studies that we engage in. Facilities interested in other types of research (e.g. Alzheimer's, Multiple Sclerosis etc.) would choose different criteria. Exclusion criteria are: age less than or equal to 16; pre-morbid diagnosis of major psychiatric illness; indications of pre-existing developmental disorder or neurodegenerative disorder; significant vision or hearing impairment; and medical history of a dual diagnosis (non-concurrent stroke and TBI). Patients are excluded if a permanent move far outside the geographic area is planned, or if, upon consultation with the physician, their medical condition is deemed too fragile for participation or travel (e.g., end stage renal disease, cancer, or significant cardiac disease). doing

INFRASTRUCTURE AND MECHANICS

Site recruiters screen charts of all new admissions with a stroke or TBI diagnosis in accordance with the aforementioned exclusion and inclusion criteria. They then carefully investigate the decision-making capacity of each patient prior to initiating the consent process. For all who ultimately enroll, the recruiters collect a set of data variables, enter these into a

secure *Access* database [a], and are responsible for follow-up calls to patients to alert them to studies for which they qualify.

The Registry Coordinator trains and supervises the recruitment staff, and centralizes all follow-up contact with the patient. If a researcher asks to have a patient contacted who is currently participating in another project, the Coordinator facilitates a schedule of contact among competing studies. The Coordinator also insures that researchers report the outcome of follow-up contacts via an online log, submit relevant medical and demographic updates, and provide scores for designated neuropsychological and cognitive tests, deemed to have wide applicability in cognitive rehabilitative research. Additionally, the Coordinator formulates policies and procedures, processes statistics and maintains the Registry records.

PRIVACY PROTECTIONS INHERENT WITH THE RESEARCH REGISTRY

The consent process includes verbal and written assurances of confidentiality. Patients and family members are advised of the following:

- Only relevant health and research data are stored. Information regarding HIV status; history of substance abuse; and psychiatric history, which are considered "sensitive" in our hospital network, are not be recorded in the database. (Researchers whose study criteria impose exclusions for these conditions are instructed to query patients directly for such information as part of their screening protocol.)
- Specified demographic, medical and research information are recorded and linked with a case number to assure anonymity.
- Permission to review even the de-identified case records in the Patient Registry is limited to the staff of research projects that have been cleared by our institution's IRB and a special Registry oversight committee. This later board considers, among other things, the study's relevance to the NCRRN mission, and whether its recruitment goals are realistic in light of the supply and demand for patient resources.
- Personal identifiers (e.g. name, address) are available only to key staff of the Registry (recruiters, the database coordinator, database programmer and the P.I.s) until such time that the patient gives verbal permission to be contacted about a specific research study, at which point their contact information can be released to a team member from that study.
- Participating studies ask subjects to sign a disclosure form, authorizing release of the following back to the Registry: research participation dates, so that the patient is not called twice for the same study; demographic or medical updates, to insure the integrity of the recorded data; and clinical observations (including test scores), to maintain accurate, complete files.
- Subjects are free to withdraw from the Registry at any time, in which case all of their information will be deleted.
- Patients called for studies are asked with each contact whether or not they wish to continue their enrollment, and *all* patients are given that chance annually via a birthday letter. While some registries enroll all eligible patients who do not actively "opt out"[4], we prefer to have patients "opt in" and offer them annual invitations to withdraw.
- Patients whose birthday letters are returned without a forwarding address are investigated to determine current whereabouts, but if this effort proves unsuccessful, the patient is withdrawn and his or her records are deleted.

BENEFITS TO PARTICIPANTS

Benefits of participation for the patients and their families include the following:

- Families value the opportunity to be kept abreast of new advances by being informed about research studies: Results after nearly 6 years of *inpatient* recruitment (February 2001 recruitment start) show that only 25% (of 3,493 patients) decline to participate. 62% consent to be enrolled (the rest were "maybe-call in 4 to 6 months", or still considering upon discharge). After six months of starting *outpatient* recruitment, 73% (of 100 outpatients) enrolled. Following the transition from inpatient to outpatient status, earlier anxiety about transportation issues and finding time to participate, may dissipate. Of particular significance, we report that 90% of those enrolled, who are later called for research participation, agree to be contacted to hear about a study.
- Since informational contacts for all studies are funneled through one office, patients feel they have a personal agent, who works on their behalf to keep them aware of research opportunities, and minimizes the "hassle" factor of multiple uncoordinated calls.
- The data sharing capability of the Registry limits redundant background testing across studies, so that participation is streamlined for the patient
- The comprehensive automatic querying process insures that more patients efficiently hear of studies with potential benefits. In the case of some treatment studies, qualified patients may gain access to interventions not widely available, at a time when their insurance benefits have been exhausted. Non-treatment studies also offer a continued avenue of stimulation and both allow for close monitoring of health.

BENEFITS TO RESEARCHERS

Researchers also realize benefits with an centralized approach to patient recruitment and data management:

- *Access to Patients:* The results of an earlier survey indicated 100% of respondents felt the Registry was a useful source of recruitment. 38% of (13) participating researchers felt the registry afforded contact with a larger segment of the target population than would be available to them otherwise. (However, at the time of this survey, many studies drawing from the Registry still maintained separate recruitment sources.)
- *First-pass screening for inclusion/exclusion criteria:* By storing relevant medical, neuropsychological and behavioral test records, the process for screening for inclusion is simplified, reducing the need for extensive background testing.
- *Potential Cost savings to individual research grants:* 46% of our study respondents saved time and money from their own grants that otherwise would have gone to recruiting and screening costs. It coordinates the approach to potential research subjects by study teams that otherwise would be competing for these scarce resources and incurring separate enrollment costs.

REQUIREMENTS FOR SUCCESS

The success of this model is dependent on the strength of relationships between researchers and the rest of the hospital community.

- Recruiters operate with maximum efficiency when allowed authorization to directly screen charts, approach and consent patients, and collect medical information, as part of the Institution's covered entity.

- Lines of communication should remain open with members of the IRB and legal team in case modifications of the language of the consent and authorization forms are needed. It is essential to combine the essence of the law with clear and simplified language so that patients and their families don't lose out through misconception.
- The recruitment staff should possess strong interpersonal skills and a willingness to adopt a flexible work schedule. It is often necessary to be available at times outside of the normal nine-to-five workday in order to successfully contact family members by phone or in person.
- Recruiters should undergo extensive training that includes multiple observations of the informed consent process before approaching patients. Creating a guided script and educational brochure are helpful for this purpose. The cognitive impairments that frequently accompany stroke and TBI necessitate special steps to ensure that the approach and consent process conform to ethical standards.[5,6] Many problems will be prevented with a sensitive, well-informed staff.
- Key to the success of the project within a multi-program hospital is an in-depth study of each department's preference for method of communicating. Busy clinicians are still a promising entrée to the patients and a source of information not captured on often-sparse chart notes. Although you may need to develop the skills of an ambassador to navigate the culture of your facility; in the long run, good relationships foster an atmosphere wherein the recruitment staff is seen an asset to the treatment team.
- In keeping with the above, it is helpful to establish an efficient and reliable mechanism for clinician-mediated approach for those cases that are problematic.
- Access to a large inpatient and/or outpatient pool, within geographical constraints is essential to the success of this model.

LIMITATIONS

The implementation of this model presents a number of limitations as well:

- The Registry records can not be relied on to have complete or accurate data on factors relevant to study inclusion.
  - Studies that define the target sample narrowly (e.g., agrammatic aphasia; left dorsolateral prefrontal lesion) obtain small yields when they search the database for those specific classifiers.
  - It is not uncommon to call back patients who had a significant disability upon discharge only to find that they have recovered to near normal levels several months later. (However, such patients actually have proved useful for other research projects and can be triaged accordingly.)
  - Other inaccuracies in the Registry record are mostly due to gaps and errors in the hospital and rehabilitation charts from which the Registry records are created. As Registry participants are called to enroll in research studies, the updating feedback from those studies helps fill in the gaps and correct the inaccuracies.

- A survey of patients who enrolled in the Registry in its first year of operation indicated a reluctance to travel to participate in research studies, particularly when the commute was from city to suburbs, or the reverse. A few of the participating studies made arrangements to test patients at more than one site. However, the majority of studies either did not have the resources to do this or required specialized facilities that could not be duplicated. These studies benefited little from the Registry's listing of patients from a

second or third site. Indeed, this was one of the motivations for reallocating registry resources to outpatient facilities near the Research Institute.

- Our participating researchers generally find that they need to supplement recruitment with their own referral streams---typically, referrals from clinicians from other outpatient programs. This need will arise particularly for those studies that require high volume of patient enrollees, due to stringent inclusion criteria or large group size.
- The costs of running this Patient Registry are high, having to do with the numerous personnel hours involved. When other hospital sites were involved, we found it essential to have an on-site director who was familiar with the facility's policies and procedures (e.g., in relation to hiring practices; patient privacy safeguards) and who carried the authority to intervene if necessary. In its present form we have a fulltime Coordinator and two fulltime recruiters.

CONCLUSIONS

Subject recruitment is costly regardless of the method. We anticipate that continuing the Registry will require ongoing funding for its infrastructure or the allocation of proportional shares of the Registry's costs to individual grants that make use of it. The registry model is most appropriate for facilities that conduct multiple studies that recruit from the same patient populations and require high volumes of potential enrollees on account of narrow inclusion criteria or large group size. The frequency of direct patient contact required, and the feasibility of transporting or duplicating needed equipment, set additional constraints on the number and location of participating sites. For further information please access our website at www.NCRRN.org.

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Supplier:

a. Microsoft Corp., One Microsoft Way, Redmond, WA 98052

Recruitment Duties

- **TRAINING:** New recruiters will receive the updated packet of forms and protocols and have a two-week period of observation and training in all aspects of the recruiting and data collection process. They must become familiar with how to interact with brain injury and aphasic patients, and meet with each study team to understand all aspects of the current studies.

- Obtain copies of daily admission forms on the K-drive (MossRehab Admissions).

- Identify all patients that have either a CVA or TBI diagnoses.

- Review charts for all CVA & TBI inpatient admissions (Elkins Park & Tabor Road), all outpatient admissions at Elkins Park (SCOR, TOPS, Stroke-OP programs), Tabor Road, Moss Plaza (once weekly), and other pathways (weekly meeting with Ann Hammond, weekly check-in with the Physiatry appointments).

- Add potential subjects to CVA and TBI screening/tracking logs on PC **daily**. The screening logs are tracking devices to organize patient contacts, communicate status at any time to all others on the project, and to calculate statistics at month's end. When you enroll a patient enter their **ID code**, likewise if a patient has refused enter **Declined**. As dispositions are resolved, enter either: **Maybe** (this means the patient wants to be called 4-6 months after discharge), **Pass-no resolution** (this means that you tried to contact the patient's family and/or attempted to find the patient in the hospital on at least 3 occasions without success), **Pass-No contact** (this means no contact was attempted even though the patient was in the hospital at least 8 days), **ER DC** (this means the patient was discharged on or before 8 days in the hospital. In the note field further specify whether the patient was just an early discharge, discharged emergently to the ER, or discharged AMA-against medical advise). Update these logs with new information daily.

CVA REGISTRY SCREENING LOG: MossRehab Patients

CODE	Last Name	First Name	AdmDate	Mo. Scr	site	Age	Diag.	ETN	Gen	RR	If refuser, Missed, or Other, why?	Why failed to meet criteria
FAIL			4/3/2001	4	EP	67	CVA	2	M	MG		language barrier
MR0001			4/5/2001	4	TR	55	CVA	3	F	MR		
Pass-no Resolution			4/8/2001	4	TR	76	CVA	1	F	MR	tried on multiple occasions-never in room	
Declined			4/9/2001	4	EP	67	CVA	3	F	MG	too depressed-doesn't want to enroll	
Maybe			4/9/2001	4	EP	42	CVA	2	F	MG	call in 6-8 months	
Pass-no Contact			4/10/2001	4	TR	66	CVA	2	M	MR	pt dc'd after 8 days- without recruitment attempt	
ER DC			4/12/2001	4	EP	55	CVA	3	F	MG	pt dc'd ON or BEFORE 8 days- without recruitment attempt	

- Meet eligible patients, introduce self and registry project briefly, e.g. "We've identified you as someone who is qualified to hear about research projects that may interest you after your discharge. I'd like to leave some information for you and your family to review (brochure), and will be back to talk with you about it and answer any questions you may have before you are discharged". Leave brochure and follow-up within a week, or sooner, if the patient is scheduled as a short stay.

- Access person's cognition/orientation skills and make decision whether patient is able to consent for him/herself if interested. If patient is not oriented come back when family member is present. Ask the decisionally-capable patient if you can contact a family member to notify them of his/her intent to enroll.

- If patient says YES, contact family member via telephone to notify them that their family member (patient) wishes to enroll. If patient's family is difficult to get in touch with, try to call at many various times, but only leave up to 2 messages. You can also check with social services for when a family meeting is scheduled. Patients with cognitive issues MUST have a family member involved.

- Meet with all interested family members to explain the registry-<u>at their convenience.</u>

- Go through the informed consent process with the patient and family (if necessary). Once a patient is consented, make photocopies of the consent form. Give a copy to the patient and place a copy in the chart.

- ❖ Put the physician notification letter on chart and write note in the progress note section.

- ❖ Review the patient's rehab chart and transferred acute care records and obtain information to complete the data packet. Have patient sign a medical records release if the transferred chart has poor records. Send for medical records if necessary.

- ❖ Once all paperwork is complete assign the patient an ID code. Input patient's ID code onto the CVA & TBI screening/tracking logs.

- ❖ Input all of the patient's data into the database.

- ❖ Add patient to the FIM (Functional Independence Measure) waiting list and check *e-rehab* for completed info until final FIMs are logged. Update FIM list, deleting any patients whose information is 100% complete, and enter FIM values into the Registry.

- ❖ Place all Patient data forms in shredder bin after entry.

Medical Records Requests

- ❖ If patient information is missing from rehab and/or acute care chart, send for acute care medical records. Remember to check which acute care hospitals have their own forms and which ones will accept our form.
- ❖ Track date medical release was sent and returned in black binder and follow-up.

"Maybe" patients

- ❖ If patient says **Maybe** to consenting, place initial intake sheet in black binder and record and follow-up in 4-6 months.

Controls

- ❖ Ask family member/friends if they would be interested in hearing about research projects for individuals who have not had a CVA or TBI.

- ❖ Proceed with the consent process using the separate control consent form, if they want to enroll. Collect demographics information.

- ❖ Assign the control an ID code, and place all of their demographic information into the database.

- ❖ Add NIH information (gender and ethnicity) onto tracking log.

- ❖ For telephone contacts from controls responding to the ad placed in *Premier Years*, send control consent form and packet for them to sign and send back. Log in black book and follow-up. NOTE: approx. twice/year we get an influx of calls from this ad.

Studies-contacting patients

- ❖ After Adelyn has run a project's query, make phone calls to all of the eligible subjects or controls.

- ❖ Place all call updates in subject's individual file in the Registry and also on the project's tracking log.

- ❖ Keep consent dates, project completion dates, and reasons for refusal updated in each patient's individual file in the registry.

- ❖ Inform study team RAs of any new names added to their tracking log by email.

- ❖ Send out emails requesting that study team RAs make updates on their individual tracking log and that they provide us with update "sheets" for demographic changes, new neurological test data (MRI, CT scan info) and behavioral testing done in the course of the study- before you remove any completed patients' names from the logs.

- ❖ Train new study team RAs on the purpose of the registry and on how to complete the tracking forms.

- ❖ Run the Edit table report monthly to reconcile the numbers and catch inputting errors for each project.

B-Day Letters

- Print all birthday letters and labels for upcoming month using the query system built into *Access*.

- Prepare birthday letters for mailing and mail out no later then the 1st of the month.

- If birthday letters are returned, try to contact the subject and/or caregiver to receive updated address and or phone numbers. Check in the hospital "Last Word" system to see if there is any new information for them from recent doctor's appointments.

- If person is deceased or wants to withdraw, make the change in database- and, notify Adelyn, as the main NIH log has to be updated as well.

- Track all birthday letter returns and updates in black binder.

Miscellaneous

- Attend Einstein Neurosensory Unit Discharge Rounds (inpatients on the neurology service) once weekly.

- Assist with statistics as needed e.g. reconcile the usage stats by running the report and returning to the log to correct inaccurately entered numbers.

- Attend Stroke Club gatherings to further recruitment efforts.

- Set up and run the recruitment booth 4 sessions per week in the hospital lobby (this mainly attracts healthy control subjects).

CHART REVIEW FACE SHEET

LOCATION: EP_____ Tabor_____ Einstein_____ Other_____ Rm:_____ Dr._____

PATIENT: (Last name, first name)_____ GENDER: (circle) M F

Contact Person: _____ Relationship:_____Phone Nos._____

Contact Person: _____ Relationship:_____Phone Nos._____

Event Date:_____ Admission Date: _____ Diagnosis: (circle one) CVA TBI

****

☐ **PASS- family notification only** ☐ **PASS, but needs family as primary signature**

☐ **PASS, needs translator: language_____**

☐ **FAIL, if YES to *any* of the following:**

_____ Age (<16 years or > 80 years) Birthdate:_____ Current Age:_____

_____Dementia (Alzheimer's type)

_____Major psychosis (e.g. schizophrenia-DO NOT exclude if symptoms first occurred after a CVA or TBI.
DO NOT exclude for most cases of depression unless the condition has required >1 hospitalization.)
_____Blindness (BOTH eyes- blind in one eye is okay)

_____Deafness (profound- not correctable by hearing aids)
_____Developmental Disability (e.g. Mental Retardation)
_____Degenerative CNS disease (e.g. Parkinson's, Multiple Sclerosis, brain tumors or brain cancer)
_____Prior or other CNS insult or condition (e.g. prior CVA if TBI patient, or prior TBI if CVA patient, meningitis, anoxic, viral or metabolic encephalapathy, Epilepsy, Cerebral Palsy)
_____Non-English speaking & translator for this language is unavailable at this site.

_____Patient is moving permanently out of the area and CAN NOT return to participate
_____Patient is deemed medically fragile (e.g. on dialysis, and can't participate in an outpatient research project.)

☐ **PATIENT DECLINED why?_____**

☐ **PATIENT SAID "MAYBE", CALL IN 4-6 months**

☐ **MET FAMILY AND PATIENT, BUT NO RESOLUTION PRIOR TO DISCHARGE**

☐ **MULTI-ATTEMPTS AT CONTACT WERE UNSUCCESSFUL**

☐ **PATIENT DISCHARGED EMERGENTLY (within 8 days of admission)**

☐ **PATIENT DISCHARGED WITHOUT CONTACT MADE (>8 days after admission)**

TBI SCREEN: (check all that apply) LOC____ PTA_____ GCS_____ +NEURO FINDINGS_____

Pertinent Medical History- for metal screening (surgeries, fractures, shunts, filters etc.) _____

INFORMED CONSENT PROCESS FOR INPATIENTS

DETERMINING DECISIONAL IMPAIRMENT

Site recruiters should use at least three measures to determine a patient's decision-making capacity to comprehend the informed consent process prior to introducing the Research Registry: (1) chart documentation; (2) interviews with staff members; and, (3) multiple, if necessary, informational interactions with the patient. If the patient is clearly not capable to make decisions (i.e. disoriented, unable to attend, remember or comprehend simple sentences due to cognitive impairment), the procedure is terminated until a family member or surrogate decision -maker is available, preferably in person, but acceptably by phone.

PATIENT IS CLEARLY DECISIONALLY-IMPAIRED

- We do not approach the patient for consent except in the presence of a family member.
- If a patient is deemed *decisionally-impaired* and we are unable to make contact with a family member, the patient CAN NOT be enrolled in the patient registry.

ATTAINING ASSENT

- We do, however, try to solicit "assent" from patients if they are adults who are deemed incapable of making the primary decision; or, if they are under 18 years of age, and a parent or guardian is making the primary decision. If a child under 18 is incapable of responding to the "assent" form at the time of research registry enrollment, continue the consent process with the parent or guardian. Then, at a later date, the child will have the opportunity to register assent prior to participating in a study, when more cognitively aware.

PATIENT IS CLEARLY DECISIONALLY-CAPABLE

- If the chart review results in a judgement that the patient is capable to make decisions, we proceed as follows:
    a. The consent form is discussed with the patient, querying him/her for the level of understanding of the main points (e.g. "What did you understand from what I just read to you?"). If the patient has a speech output deficit (e.g., aphasia),

questions may be structured to maximize responses (e.g. yes/no questions). With respect to the requirements of being able to recall the research protocol over time, the expectation is that minimally, the patient should be able to recall this **information for the duration of the informed consent interview, so that they recall why they are signing the consent form. Patients with specific memory deficits are not expected to recall this information over longer time periods.**

b. Inform the patient that it is standard procedure to 'involve' a family member in the *inpatient consent process* as a courtesy to let them know that you have been in to see the patient. (This is the case with all activities at MossRehab. The culture in our institution is very family-oriented.) Ask the patient if this is okay with him/her. If the patient agrees, contact the family member by phone to describe the Registry and notify them of the patient's desire to participate and obtain a verbal "assent". (NOTE: This is not "co-consent" or proxy consent. In this case, we are notifying the family that the patient wants to participate, NOT asking the family if it is okay.) However, family members may want to have more information, or a chance to discuss this with the patient and be actively involved in the decision. In some cases they may argue against participation for the patient, due to prior bias about research in general, or simply because they feel they can't get involved in the transport. It is always best to anticipate this and pre-empt any concerns. If the *decisionally-capable* patient is reluctant or *unwilling* to have a family member involved for any reason, we have the patient sign the waiver on the consent form and continue with the process of enrollment. We also, in this case, ask the patient's physician to concur that the patient is *decisionally-capable*, and make a note of that in the patient's medical record.

c. Written consent is obtained from the patient in the presence of a witness. The *decisionally-capable* patient may be enrolled in a the Research Registry as soon as he/she has signed the consent form.

Informed Consent Process for Outpatients

PATIENT IS CLEARLY DECISIONALLY-IMPAIRED: Same procedure as with inpatients

ATTAINING ASSENT: Same procedure as with inpatients

PATIENT IS CLEARLY DECISIONALLY-CAPABLE: Same procedure as with inpatients-with the exception that if an outpatient does NOT want to involve a family member, we do not have to ask his or her physician to concur with decisional-capability. The outpatient can be enrolled at any point after signing in the presence of a witness.

TITLE OF PROJECT: Rehabilitation-Research Registry for Stroke and TBI
NAME OF THE PRINCIPAL INVESTIGATOR:
PRINCIPAL INVESTIGATOR'S PHONE:
CO-INVESTIGATOR:
RECRUITING COORDINATOR:
RECRUITING STAFF:
DATABASE PROGRAMMER:
FUNDING SOURCE: NIH/National Center for Medical Rehabilitation Research
GRANT TITLE: Cognitive Rehabilitation Research Network

CONSENT FOR PARTICIPATION IN A RESEARCH INVESTIGATION

INTRODUCTION

The research project titled "Rehabilitation Research Registry for Stroke and TBI" was approved by the Albert Einstein Healthcare Network Institutional Review Board on February 17, 2000.

PURPOSE OF THE STUDY

The purpose of this project is to identify persons with stroke or traumatic brain injury (TBI) who are interested in volunteering for rehabilitation research studies. You will be entered into a registry so that you can be notified about future studies that you may be eligible for. When contacted, you are free to choose whether or not you wish~~es~~ to participate in a specific research study. These studies look at how stroke and TBI affect things like speech, attention, memory and action, what treatment approaches work best, and what changes in brain function go along with recovery.

PROCEDURES

- *What is the registry?* The registry is a set of case records organized in a computer database.

- *What information will be put into the Registry?* For each participant, the information in the Registry will include:
  1. Contact information: name, address, telephone number, caregiver information, medical history.
  2. Findings from tests used to diagnose the stroke or brain injury, including brain scans and results from neurological exams or neuropsychological tests.
  3. A list of the research studies he/she volunteered for and the dates of his/her participation.
  4. Findings from neuropsychological tests given during research, which further clarify the original diagnoses.

  Note: Information considered "sensitive", such as HIV status, history of substance abuse and history of mental illness will not be recorded in the Registry.

- *How will your privacy be protected?* The registry will identify people by number, not by name. The names will be known only to the Project Staff listed at the top of this form.

- *Who has access to the registry?* Only researchers who have received approval to conduct a research study within the Cognitive Rehabilitation Research Network can access the Registry. At the present time, the Network includes researchers from Philadelphia-area institutions, including MossRehab, Magee, Bryn Mawr Rehab, Temple University, and University of Pennsylvania. The mission of the Cognitive Rehabilitation Research Network is to expand rehabilitation research throughout the Northeast region of the United States. Therefore, in the future, access to the registry may expand to include some researchers who conduct research outside the Philadelphia region.

- *How will I be notified about research studies for which I might be qualified?* Researchers will select possible participants from the Registry by code and will ask the Recruiting Coordinator, who has access to names and phone numbers, to contact them. If you are identified as a possible research volunteer, a Registry recruiter will contact you by telephone. At this point, you can decide if you want to meet with the research team to learn more about the study or not. If you agree, your name and phone number will be given to a member of the research team, who will call you to set up an interview. The Registry recruiter will keep a record of when you were called and whether or not you agreed to have your name and phone number released to the research team.

- *What if you want to have your information removed from the Registry?* Each time you are notified about an upcoming study, you will be asked whether you wish to remain in the Registry. If you say no, your case record will be deleted from the Registry and destroyed, and you will not be contacted again about research conducted within the Cognitive Rehabilitation Research Network. You can also tell the Registry Coordinator or the Principal Investigator that you want to withdraw at any time by calling (insert phone number). Your record will be immediately deleted and destroyed.

RISKS/DISCOMFORTS

You may receive phone calls informing you about upcoming research projects when you qualify. The number of phone call you receive about research has been minimized by centralizing the follow-up contacts through the Recruiting Coordinator's office and limiting the number of individuals who can access you name, address, or telephone number through the Registry. At most, you will be called four times per year. Some enrollees are never called.

BENEFITS

By participating in the Registry project, you may be notified about future research studies for which you might choose to volunteer. As a research volunteer, you may help improve the quality of rehabilitation services for people who experience stroke or TBI in the future. There may also be direct benefits to you. For example, you might volunteer for an experimental treatment study that proves effective in reducing your disability.

RIGHTS

Your participation in this project is voluntary. You can withdraw your consent and stop participation at any time without affecting your relationship with your doctors or the Jefferson Health System.

New information developed during the course of this project that might affect the understandings in this consent will be brought to your attention.

Your participation in this study may be ended by the Principal Investigator or the sponsor if they feel it is in your best interests.

No guarantees have been made as to the results of your participation in the study. Even if you agree to participate in the Registry, there is no guarantee that you will be called about a future research study. If you are called, you do not have to agree to participate.

CONFIDENTIALITY AND HIPAA AUTHORIZATION

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health and research information about you. You must give permission for the Patient Research Registry to create, collect, use or share health and research information about you for the purposes of the study. This permission is called an Authorization.

- *What personal health and research information is created, collected and used by the Patient Research Registry?*

By signing this form, you authorize the use and sharing of the following information by the Patient Research Registry:

1. Your contact information and the contact information of your caregiver
2. Personal demographic information (e.g. your birthdate, occupational status)
3. Your medical records and information we collect from you about your medical history
4. Results of brain scans
5. Names of studies that you participated in and dates of your participation.
6. Clinical tests and research observations made during your participation in research projects.

- *Why is your personal information being created, collected and used?*

Your personal contact information is important to the registry staff, so that they can get in touch with you to alert you to a study for which you qualify. Your personal health and demographic information, medical records, and the results of any brain scans you had are the factors that are used to match you to a future study. The follow-up information assures that you are not called for the same study twice, and helps researchers decide if you qualify for another study before calling you needlessly.

NOTE: Any health information that is used under this Authorization will **NOT** include any special health information related to genetic testing, treatment for AIDS/HIV, psychiatric care and treatment, or treatment for drug and alcohol abuse unless specified above.

- *Who may use or share your personal health and research information?*

By signing this form, you authorize the following persons and organizations to receive your protected health information for purposes related to the Research Registry:

1. Patient Registry Staff listed at the top of page one.
2. Members of a Patient Registry-approved research study, ONLY when you have given permission for that study to contact you.
3. In addition, appropriate offices of the NIH/National Center for Medical Rehabilitation Research, or Albert Einstein Healthcare Network and its Institutional Review Board, which is the committee responsible for ensuring your welfare and rights as a research

participant**.** These offices may review and/or photocopy study records which may, if they feel it necessary, identify you as a subject.

If information obtained in the study is published, it will not be identifiable as your results unless you give specific permission.

The Albert Einstein Healthcare Network complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. A copy of the Notice will be provided to you.

The information collected during your participation in this study will be kept indefinitely. Your Authorization for this study will not expire unless you cancel it. You can cancel this Authorization at any time by writing to the study investigator. If you cancel your Authorization, you will not be able to continue to participate in this research. The principal investigator and the research team may continue to use information about you that was collected before you cancelled the Authorization. However, no new information will be collected about you after you cancel the Authorization.

You have a right to refuse to sign this form. If you do not sign the form, you may not be in the research study, but refusing to sign will not affect your health care outside the study.

COMPENSATION

In the event of any injury resulting from your participation in this project, you will be provided with clinically appropriate medical care for that injury within the capabilities of the Network. The Albert Einstein Healthcare Network will determine the extent, if any, to which it will assume financial responsibility.

If you have questions about this study or if an injury occurs, Dr. Myrna Schwartz or her designate can be reached at (insert phone number) to answer any questions you may have. For questions about your rights as a research subject, you may contact (insert name), Chair of the Institutional Review Board, Albert Einstein Healthcare Network, Paley Bldg., First Floor, (insert phone number).

UNDERSTANDING OF PARTICIPATION

I have read all 5 pages of this form and understand and agree to the material contained therein. By signing this document, I am agreeing to participate in this Research Registry project. I will receive a copy of this form.

_____ Date _____

(name and relationship, if kin or guardian signs for subject)

Witness: _____ Date: _____

Investigator (PI or designee): _____ Date: _____

Recruiter: _____ Date: _____

LIST OF INDIVIDUALS AUTHORIZED TO OBTAIN CONSENT AS RECRUITERS:

(Include names of all permissible recruiters)

If I do not speak or understand English, the above material has been explained to me in _____ a language I do understand by _____

(translator / relationship to subject)

Signature: _____ Date: _____

****

FAMILY NOTIFICATION

1. The research team has advised that a responsible family member or friend should be notified about my participation in this project. By signing below I indicate my desire not to notify any other person about my decision.

Signature: _____ Date _____

OR

2. Notification of the following family member or friend (name of co-consenter and relationship to subject) _____ , was completed on (date) _____ by telephone.

Signature (of Investigator to whom consent was communicated):

_____

OR

3. The Patient Research Registry has been explained to me and I have been notified that (patient)_____wants to participate.

Signature: _____

Relationship to subject: _____ Date: _____

Date IRB Approval of Consent Form: _____

VARIABLES TO BE ENTERED
PATIENT DATABASE-DEMOGRAPHICS INFORMATION-SECTION 1

RECRUITER ID

DEFINITION: Person entering data into the database for this patient, NOT the person who recruited the patient for the database.

PATIENT ID

DEFINITION: 6-digit code number unique for each patient.
Moss patient codes begin with MR####

PATIENT LAST NAME, PATIENT FIRST NAME

DEFINITION: Patient's full name. Do not leave blanks. Do not just note a first initial. This entry becomes a mail label for the birthday letter project.

PATIENT ADDRESS

DEFINITION: Patient's full address. Do not leave blanks.

PATIENT HOME PHONE

DEFINITION: Patient's home phone. Do not leave blanks.
Include area code in the format ###-###-####. If no phone number is available at discharge code 009-009-9999 for unknown

PATIENT SOCIAL SECURITY NUMBER

DEFINITION: Patient's 9-digit social security number from the hospital chart. You can enter it in this format if only available this way: XXX-XX-1906

GENDER

DEFINITION: Enter M or F to indicate patient's gender.

PATIENT BIRTHDATE

DEFINITION: Only patients >16 or older at the time of injury are to be entered into the database.
Enter date in the format "mm/dd/yyyy"

EDUCATIONAL LEVEL

DEFINITION: Highest grade in school completed at the time of the STROKE or head injury

1= < =8th	6= 2 year degree	77=other
2= 9-11	7= 4 year degree	99=unknown
3= HS grad/GED	8= 4+ some grad school	
4=trade/RN	9= MS/MA	
5= HS plus college	10= PhD/MD	

HANDEDNESS

Code as R= right, L= left, and Ambiextrous
DEFINITION:

- Right-handed patients use the right hand for writing and other manual operations more easily and readily than the left.

- Left-handed patients use the left hand for writing and other manual operations more readily than the right.
- Ambidextrous patients use both hands equally well for writing and other manual operations.

BIRTHPLACE

DEFINITION: City and state (If born in the United States) or city and country (if born outside the United States) where patient was born. Country is NOT a required field. So, the cursor doesn't automatically advance to it. You must purposely place the cursor in that field. Only input if the country is OTHER than the United States.

ENGLISH LANGUAGE HISTORY

DESCRIPTION: "Is English the only language the patient speaks?" This is NOT meant to capture languages taken in high school, but people who are truly bilingual. If yes, skip to " Does patient speak English with a dialectal or regional accent?" If English is not the only language the patient speaks, determine and list the other languages (up to 3) the patient speaks. Determine if the patient learned English along with any of the additional languages from birth, or if patient learned English after the additional language(s) were established (use age 12 years as a guide). If patient learned English after the additional languages were established, code approximate number of years patient has spoken English. Language studies use this information to determine a patient's eligibility. They wouldn't want to take a patient who might have word finding difficulty because they don't know English vs. due to a brain lesion.

REGIONAL ACCENT

DEFINITION: Patient speaks English, but exhibits a distinct accent. (e.g. U.S. regional such as Southern or outside of the U.S. such as Eastern European). Do not code dialectal differences in this category i.e. Black English Dialect. (This data will be important for some studies of phonology.)

IDENTIFIED ETHNIC GROUP- NIH GROUPINGS

1=Asian	5=Hispanic-White	9=other or >one race
2=Black	6= Hispanic-unreported	10 =unknown or unreported
3=White	7=American Indian/Alaskan Native	
4=Hispanic-black	8=Native Hawaiian/Pacific Islander	

MARITAL STATUS

1=Single	4=separated	7=other
2=Married/Cohab>=7years	5=widowed	9=unknown
3=divorced		

CAREGIVER INFORMATION

DEFINITION: This is either the person(s) who will have *primary responsibility* for patient's care upon discharge, or someone else who can serve as a *contact person* for this patient. (Do not include

other patients or other residents who will have no responsibility for this patient.) Try to determine if this individual would like to participate as a control patient in the future.

EMPLOYMENT STATUS

DEFINITION: Code the employment status at the time of the STROKE or brain injury. Code up to two, if applicable. If more than two, list the two consuming the most time per week.

primary ___ secondary____

1=unemployed/not in school	6=fulltime employed	11=disabled
2=part time student	7=homemaker	77=other
3=fulltime student	8=special employed	88=no secondary employment
4=special education/other non-regular ed	9=retired (age)	99=unknown
5=part time employed	10=volunteer	

PATIENT DATABASE MEDICAL HISTORY: SECTION 2

LIST: HEALTH PROBLEMS

DEFINITION: Patients are NOT to be entered into the database if they have the following diagnoses in their medical history:

- Bipolar disorder, schizophrenia or other major psychosis *unrelated* to a prior STROKE or brain injury.
- Confirmed blindness in both eyes or profound deafness, such that the patient would not be able to hear the examiner state the task instructions. (Sensory deficits of lesser degrees will be Evaluated by each researcher at the time of screening for a particular project.)
- Degenerative CNS disease: e.g. patients with Parkinson's Disease, Multiple Sclerosis, Dementia of the Alzheimer's type, Epilepsy (pre-existing seizure disorder), encephalapathy
- Developmental Disorders i.e. Mental Retardation.

HEALTH PROBLEMS: For patients who fit the criteria, enter as complete a listing of premorbid health problems as you can. List *DOES NOT* include the current stroke or brain injury. List *DOES* include <u>past</u> stroke or brain injury. List *DOES* include illnesses, injuries, and medical conditions, including vision, hearing and mobility difficulties that were present prior to the current illness or injury. (DO NOT include any reference to psychiatric or psychological health problems i.e. patient had been treated for clinical depression; alcohol or other dug use and/or abuse; or information regarding HIV status. If patients are entered into the database and then subsequent record review reveals conditions that would have excluded them initially, enter the word "flagged" onto one of the medical history lines with no other commentary. Patients have been promised that sensitive information re: their health histories will not be entered.)

ONSET: Best estimate of when (how many years ago) the medical condition was diagnosed. Use information from chart and/or family interview. Write in the number of years patient has had the medical problem. This is not a requirement. Many people have no recollection or were just told that they had a condition which could have been present for years.

HEALTH PROBLEM NOTES: Comments that add clarification or more information to medical diagnosis. E.g. If patient has TKR (total knee replacement), enter which "side" of the body into notes.

FAMILY HISTORY OF SERIOUS ILLNESS & NEUROLOGICAL DISEASE

DEFINITION:
List serious illness and/or neurological disease, including the following: cancer (note type), hypertension, heart disease, diabetes, strokes, glaucoma, epilepsy, degenerative neurological disease, such as Parkinson's, Alzheimer's, multiple sclerosis, but *not limited* to the above. Include other significant illnesses as noted by the family.

FAMILY MEMBER: Lists the parent, grandparent, sibling or child who has/had the noted illness and/or neurological disease.

HISTORY OF LEARNING PROBLEMS

DESCRIPTION: Did the patient with a stroke or brain injury have any of the following prior to his/her injury:

1) Was officially classified as a special education student
2) Dropped out of school before high school graduation
3) Failed to advance to the next grade (held back)

HISTORY OF ADHD

DESCRIPTION: Did the patient with stroke or brain injury have a diagnosis of Attention Deficit Hyperactivity Disorder prior to his/her illness or injury. Many older adults will not know this, but may have a sense that they had attention problems in school.

FAMILY'S OPINION RE: PATIENT'S ATTENTION ABILITY

DESCRIPTION: Do family members who have been in contact with patient feel the patient has an attention problem now? If family was not contacted, code as "don't know".

LEARNING DISABILITY, ADHD & ATTENTION NOTES

DESCRIPTION: Comments that add clarification or more information to above.

UNRELATED SPEECH THERAPY HISTORY

DESCRIPTION: List of speech therapy services that patient had unrelated to this current stroke or head injury. Include services that patient received as a child for articulation, language, voice or stuttering. Include speech therapy services that patient received for *prior* strokes or brain injuries, if never enrolled in this registry.

UNRELATED PHYSICAL THERAPY HISTORY

DESCRIPTION: List of physical therapy services that patient had unrelated to this current stroke or brain injury. Include services that patient received as a child. Include physical therapy services that patient received for *prior* strokes or brain injuries, if never enrolled in this registry.

UNRELATED OCCUPATIONAL THERAPY HISTORY

DESCRIPTION: List of occupational therapy services that patient had unrelated to this current stroke or head injury. Include services that patient received as a child. Include occupational therapy services that patient received for *prior* strokes or brain injuries, if never enrolled in this registry

INVOLVEMENT IN RESEARCH PROJECTS OUTSIDE OF THIS REGISTRY

DESCRIPTION: Has the patient ever been involved in research at any other institution prior to this event? E.g. U. of Pa

This does NOT include Moss Rehabilitation Research Institute projects. They will get included in PATIENT STUDY section.

NOTE: You will be asked to supply start and end dates for the therapies and research participations. This is often difficult for patients to remember. If patient is still participating in any of outside project or therapy, fill in 01/01/1111 for the end date

Medical History scale for <1 year increments on disorders:

1 month+ .08 (.1)	**7 months= .58 (.6)**
2 months= .16 (.2)	**8 months= .66 (.7)**
3 months= .25 (.25)	**9 months= .75 (.75)**
4 months= .33 (.3)	**10 months= .83 (.8)**
5 months= .41 (.4)	**11 months= .91 (.9)**
6 months= .5 (.5)	**12 months= 1 (1)**

PATIENT DATABASE-CLINICAL INFORMATION (ACUTE CARE) –SECTION 3

Note: re DATES- If you have only the year e.g. 1996, insert 06 /30/ 1996.
If you have only the month and the year e.g. 12/1996, insert 12 /15/ 1996
If no dates are given for event, enter the admission to acute care date as the event date. If no admission or discharge date to hospital are given, enter 09 /09/ 9999.
(Explain all of these variations on the note line)
We will always try to follow-up to determine the real date, but something must be inserted in order to be able to continue to enter data for the patient.

EVENT ONSET DATE

DEFINITION: Date patient had a stroke or sustained a brain injury

HINT:

- date of injury/event (DOI) is often found on the trauma rescue sheet (yellow carbon). Take special note of the time of injury if E/R admission is close to midnight because the actual date of injury may be the day before. For example, the

patient is brought to the ER at 1 a.m. on Saturday, but he was injured at 11:30 p.m. on Friday.

EVENT DIAGNOSIS

DEFINITION: Only patients who have sustained a **stroke** or **brain injury** are to be enrolled in the database. Enroll patients who appear to have a combined diagnosis of STROKE and TBI, where the precipitating event is unclear, and where it looks like they happened simultaneously. (e.g. patient had a stroke subsequent to hitting head.) We do not admit patients who for e.g. have had a stroke and then 6 months later fell and sustained a brain injury while going down the stairs, or who have had a brain injury for 7 years and then suddenly have a stroke.

ETIOLOGY OF TBI

DEFINITION: Primary cause of the traumatic brain injury

1=non-penetrating TBI (includes depressed skull fracture)
e.g. motor vehicle accident, fall, blow to the head with a baseball bat or flying object

2=penetrating TBI e.g. gunshot or knife wound
7=other
8=not applicable
9=unknown

ETIOLOGY OF STROKE

DEFINITION: Primary cause of the Cerebral Vascular Accident (stroke) (see CT or MRI)

1=STROKE-hemorrhage
2=STROKE-infarct
3=STROKE-aneurysm
4=STROKE-TIA
7=other
8=not applicable
9=unknown

PRIMARY PERSON LIVING WITH

DEFINITION: Who was the primary person that the patient lived with?
•At the time just prior to the event of a stroke or brain injury

NOTE: If the patient will be living with more than one person, list the person most involved in the patient's life and care.

CODE: 1 Alone
2 Spouse (including common-law partners of 7 or more years
3 Parent(s)
4 Sibling(s)
5 Child/children (<21 years of age
6 Other Relative(s) or Adult child(ren) >=21 years of age
7 Roommate(s)/friend(s)
8 Significant other (not married)
9 Other patients (in hospital or nursing home)
10 Other residents (group living situation)
11 Personal Care attendant
77 Other (includes correctional facility inmates)
*88 Not Applicable –patient expired
99 Unknown

NAME OF ACUTE CARE FACILITY

DEFINITION: Name of Acute Care facility where patient received treatment.
Choose from the list or add a hospital if the facility is not listed.

NOTE: Be careful to enter correct facility e.g. We have listings for Bryn Mawr Rehab/ Bryn Mawr hospital (Acute)/ Bryn Mawr Terrace (assisted living- long term care)

- If patient was admitted directly to a Rehabilitation hospital, or
  If there are no records available from patient's acute care stay SKIP to PART C-REHABILITATION INFORMATION

ACUTE CARE ACCOUNT NUMBER

DEFINITION: The account number located on transferred records from the acute care facility that identifies the patient's stay with that facility.

NOTE: Write this number onto the line, regardless of how many characters it contains. It will be potentially used later to retrieve information that is unable to be located on the current record. Write UNKNOWN if there it is unavailable for any reason.

ACUTE CARE ADMIT DATE

DEFINITION: Date when patient was admitted to the acute care facility. This date may differ from the actual event date. Patients may delay coming to the hospital after an event or may have their event after their hospital admission for another condition.

ACUTE CARE DISCHARGE DATE

DEFINITION: Date when patient was discharged from the acute care facility.

- D/C date is often listed on the Diagnostic sheet or the typed Discharge summary

Acute care discharge and Rehab admit are usually the same date, but double check the rehab chart. If no dates are available, enter 09/09/9999.

MODE OF INJURY/ACCIDENT

DEFINITION: Describe conditions surrounding the onset of the brain injury.
Example of entries: Describe the mode of injury/accident: e.g. Motor Vehicle Accident, whether patient had been admitted to another facility first and then quickly transferred.

LENGTH OF UNCONSCIOUSNESS

DEFINITION: Date when an unconscious patient regained consciousness is determined by:

1) attainment of a documented Glasgow Coma Scale score > 8, or
2) documentation of a patient's ability to follow commands by a qualified clinician (e.g. speech-language pathologist, physician, neuropsychologist).

The length of unconsciousness can also be determined by

3) chart review.

The following procedure can be used to determine length of unconsciousness when patient is a) unconscious immediately at the scene, b) when patient is conscious at the scene, but subsequently loses consciousness, and c) when patient, if ever, emerges from periods of unconsciousness.

1. Obtain all available physician, nursing and therapy notes from the acute care hospitalization.
2. Review all notes to determine the first date on which *all* notes referencing ability to follow commands indicate that the patient was able to do so.

This is the date patient regained consciousness. If no dates are available, enter 09/09/9999.

HINT: Follow simple motor commands

- Using ER sheet and critical care flow sheet and look for 2 consecutive scores of "6" in the Best Motor Response. (Note: LOC – loss of consciousness)

If patient hasn't reached "6" by the time he/she leaves ICU then go to the progress notes. Look under neurology or trauma notes for MAE (moving all extremities) purposefully. If it says "MAE 0 purposeful" it means pt is not responding. MAE purposefully doesn't mean the patient is following commands, however if they aren't MAE with purpose then you know they still aren't able to follow commands. If always able to respond to motor commands then code the 3rd section:

"Was patient fully conscious throughout?" as: YES

Always enter the method used to determine this finding :
1=serial assessment- total GCS>8
2=documentation of subject's response to commands
(by physician or therapist formal Evaluation)
3=chart note that subject "was conscious"

POST TRAUMATIC AMNESIA

Date of Emergence

DEFINITION: Date of emergence from Post Traumatic Amnesia (PTA). PTA emergence can be defined as 1) the first date of the first of two GOAT scores of 76 or greater within a period of 24-72 hours, or 2) in the judgment of a qualified clinician (i.e. speech-pathologist, physician, neuropsychologist), the person has cleared PTA, but administration of the GOAT is not possible due to language functioning.

Date of emergence from PTA can also be determined by chart review. The following procedure can be used to determine the length of PTA based on hospital records.

1.) Obtain all available physician, nursing and therapy notes from the acute care hospitalization.
2.) Review all notes to determine the first date on which all notes referencing orientation indicate that the patient is fully oriented, that is oriented X3. This is orientation day 1.
3.) Review notes from the next calendar day to determine that all relevant notes indicate that the person is fully oriented.
4.) If orientation day 2 falls within three calendar days of orientation day 1, and if no notes from intervening days indicate less than full orientation, record orientation day 1 as the resolution date of PTA.
5.) If any note from calendar days intervening between orientation days 1 and 2 indicate less than full orientation, use day 2 as the new starting point (i.e. new day 1) and repeat procedure from step 3 above.
6.) If there is no orientation day 2 (i.e., if the patient is never fully oriented on more than one day; or if more than 3 days elapse after orientation day 1 with no further notation about orientation); code date of resolution as unknown. An exception would be if on the day before or the day of transfer to rehabilitation, the patient is specifically noted to be oriented. If the patient then produces a GOAT score >75 on the first two examinations after rehabilitation admission, code the date of PTA resolution in the usual manner.

Enter date patient emerged from PTA as "mm/dd/yyyy"
enter 09/09/9999 for unknown date

Always enter the method used to determine emergence from PTA:
1=serial testing (i.e. 2 GOAT scores of=>76)
2=judgement by qualified clinician
(Evaluation by physician/therapist)
3= chart review for documented orientation X3

GLASGOW COMA SCALE (WITHIN FIRST 24 HOURS)

DEFINITION: 1) For the first 24 hour period following patient's illness or injury, is there a valid way to determine the best and worst GCS scores. (i.e. is there a flowchart with serial assessments available).
2) If so, what are the highest scores reported in the first 24 hours.
3) and, what are the lowest scores reported in the first 24 hours.

Glasgow Coma Scale

- Eye Opening: 7 = Chemical Coma/ Paralysis, 9 = Unknown (ie. eyes swollen shut)
- Verbal: 7 = Chemical Paralysis, 8 = Intubated (tube in throat)
- Motor: 7 = Chemical Paralysis

If intubated only and not under chemical paralysis then use the highest and lowest Eye Opening and Motor but code Verbal as intubated and the total score as "88" for given column.

(if Glasgow Coma Scale flowchart is available, or there is a notation re: scores in the ER. etc.) then complete the following with whatever info is available:

Highest and/or lowest scores for:
eye opening, verbal, motor and then the *totals*

NEURORADIOLOGICAL STUDY WITHIN 8 HRS. OF THE EVENT

DESCRIPTION: Did patient have a neuroradiological study such as a CT or MRI within 8 hours of the stroke or brain injury. (Obtain photocopies of CT and MRI reports.)

HINTS:

- Intracranial hemorrhage may be referred to as a hemorrhage or hematoma or contusion
- Subdural – between dura & brain
- Epidural – between skull & dura
- Subarachnoid – bleeding in thin layer that covers brain and ventricles
- Intraparenchymal – blood in brain tissue; inside brain tissue
- Other – "little dots of blood" (petechial hemorrhage)

NOTES: If test findings were abnormal, try to fit findings to the below listed categories. But, don't labor over this. The simplest thing to do is enter the summary word for word in the neurological test section. The line space appears small, but you can enter paragraph length information

Lesion Cause	Lesion Site	Lesion Side
Subarachnoid hemorrhage	**Middle Cerebral Artery**	**Left**
Atrophy	**Posterior Cerebral Artery**	**Right**
Contusion	**Anterior Cerebral Artery**	**Bilateral**
Encephalomacea	**Basilar**	**Unspecified**
Subdural hematoma	**Posterior Communicating Artery**	
Hemorrhage	**Anterior Communicating Artery**	
Multi-infarcts	**Basal Ganglia**	
Petechial hemorrhage	**Brainstem**	
Ischemic stroke	**Frontal**	
Unspecified	**Parietal**	
	Temporal	
	Occipital	
	Frontal-Parietal	
	Frontal-Temporal	
	Temporal-Parietal	
	Parietal-Occipital	
	Temporal-Occipital	
	Frontal-Temporal-Parietal-Occipital	
	Frontal-Temporal-Parietal	
	Temporal-Parietal-Occipital	
	Corpus Callosum	
	Cerebellum	
	Deep White Matter	
	Cortex	
	Thalamus	
	Insular Cortex	
	Unspecified	

NEURORADIOLOGICAL STUDY FROM 8 hrs. up to and including 24 hrs. of THE EVENT

DESCRIPTION: Did patient have a neuroradiological study such as a CT or MRI between 8 –24 hours of the stroke or brain injury.

NEURORADIOLOGICAL STUDY after 24 HRS. OF THE EVENT, OR AT AN UNKNOWN TIME.

DESCRIPTION: Did patient have a subsequent neuroradiological study such as a CT or MRI after 24 hours of the stroke or brain injury.

For all of the above,
Enter type of test: CT, MRI, OTHER, UNKNOWN
IF test was normal Yes No Don't know
Within lesion specification columns, check if results indicated an old lesion. (NEW is the default setting)

METAL SCREENING (for capability to undergo MRI):

Metal Screening Completed? Default=No
Yes-no metal issues
Yes-investigated
Item found
manufacturer
model number
composition
Miscellaneous notes

CURRENT NEURO STATUS CODE:
(Since our initial programming for neurological test information has proved complicated for the query process, this summary number aids in being able to quickly query for appropriate patients.)

1= one lesion; only left
2= one lesion; only right
3= greater than one lesion; all on left
4= greater than one lesion; all on right
5= bilateral cortical lesions
6= one lesion on left, plus a small subcortical or silent lesion on right
7= one lesion on right, plus a small subcortical or silent lesion on left
8= unknown
9= brainstem only
10= brainstem plus other cortical
11= cerebellar only
12= cerebellar plus cortical
13= cerebellar plus brainstem
14= cortical plus cerebellar plus brainstem

PATIENT DATABASE-CLINICAL INFORMATION (REHAB CARE) -SECTION 4

NAME OF REHABILITATION FACILITY
DEFINITION: Name of Rehabilitation facility where patient is receiving/received treatment

REHABILITATION ACCOUNT NUMBER
DEFINITION: The account number located on patient's chart.
NOTE: Write this number onto the line, regardless of how many characters it contains. It will be potentially used later to retrieve information that is unable to be located on the current record.

REHABILITATION ADMIT DATE
DEFINITION: Date when patient was admitted to the rehabilitation facility. Usually, but not always, coincides with acute care discharge. If date is unknown, enter 09/09/9999.

REHABILITATION DISCHARGE DATE
DEFINITION: Date when patient was discharged from the rehabilitation facility. If date is unknown, enter 09/09/9999.

COORDINATOR'S NOTES:

Note about status for research participation

1=moderate aphasia- will participate at all sites

2=high level patient-will participate at all sites

3=severe patient- extremes-either nonverbal or Wernicke's jargon- will participate at all sites

4=will only go to Elkin's Park

5=will only go to Tabor Road

6=home visits only

7=possibly not available to participate

8=probably not available to participate

PRIMARY PERSON LIVING WITH

DEFINITION: Who is the primary person that the patient is living with at discharge from Rehab

NOTE: If the patient will be living with more than one person, list the person most involved in the patient's life and care.

CODE: 1 Alone
2 Spouse (including common-law partners of 7 or more years
3 Parent(s)
4 Sibling(s)
5 Child/children (<21 years of age
6 Other Relative(s) or Adult child(ren) >=21 years of age
7 Roommate(s)/friend(s)
8 Significant other (not married)
9 Other patients (in hospital or nursing home)
10 Other residents (group living situation)
11 Personal Care attendant
77 Other (includes correctional facility inmates)
*88 Not Applicable –patient expired
99 Unknown

PATIENT RESIDENCE AT REHAB DISCHARGE

DEFINITION: Where is the person with a stroke or brain injury going to live

when he or she is discharged from Rehabilitation

CODE:

1 Private Residence (includes house, apartment, mobile home, foster home, condominium, dormitory (school, church, college), military barracks, boarding school, boarding home, bunk-house, boy ranch, fraternity/sorority house, commune, shelter, migrant farmworker's camp)
2 Nursing Home (includes medi-center, residential institutions licensed as hospitals but providing essentially long-term, custodial, chronic disease care.)
3 Adult Home (includes adult foster care, independent living center, transitional living facility, assisted living, supported living, group home)
4 Correctional Institution (includes prison, jail, penitentiary, correctional center, labor camp, halfway house)
5 Hotel/Motel (includes YWCA, YMCA, guest ranch, inn)
6 Homeless
7 Hospital- Acute Care
8 Hospital- Rehabilitation
9 Hospital- Other (includes mental hospital)
10 Subacute care (includes subacute hospital bed, skilled nursing facility)
77 Other (includes correctional facility inmates) *88 Not Applicable –expired 99 Unknown

FIM-INITIAL & DISCHARGE (All patients at all facilities)

DEFINITION: The Functional Independence measure is completed after rehab admission and before rehab discharge. Enter numbers 1-7 for each variable. DO NOT tally the scores to get a total for physical, total for cognitive and combined total. Scores are available through the e-rehab system online.

FIM SKILLS ASSESSED:

Eating
Grooming
Bathing
Dressing- Upper body
Dressing- Lower Body
Toileting
Bladder Management- level of assistance
Bladder Management- frequency of accidents
Bowel Management- level of assistance
Bowel Management- frequency of accidents
Transfers: bed, chair, wheelchair
Transfers: toilet
Transfers: tub or shower
Locomotion: walk/wheelchair
Locomotion: stairs
Comprehension
Expression
Social Interaction
Problem Solving
Memory

CODES:

7 Complete Independence (Timely, safely)
6 Modified Independence (extra time, device)
5 Supervision
4 Minimal Assist (subject >75% of task)
3 Moderate Assist (50-74% of task)
2 Maximal Assist (25-49% of task)
1 Total Assist (subject <25% of task)
NA=Not applicable
8 Unknown

Item 14: Primary mode of locomotion on discharge
W Walking
C Wheelchair
9 Unknown

Primary mode of comprehension
a Auditory comprehension > 50%
v Visual comprehension > 50%
b Both used equally
10 Unknown

Item 18: Primary mode of expression
v Verbal expression > 50%
n Non-verbal expression > 50%
b Both used equally
9 Unknown

DISABILITY RATING SCALE (TBI patients only- at MossRehab)

DEFINITION: Disability Rating scale scores should be recorded within 72 hours of rehab admission and within 72 hours before rehab discharge. There are seldom listed scores for discharge, therefore, try to capture admission scores for the TBI patients.

Total score	Cognitive Feeding
Eye opening	Cognitive Toileting
Best Verbal	Cognitive Grooming
Motor sub-score	Level of functioning
	Employability

REHABILITATION HOSPITALIZATION THERAPIES

DEFINITION: What therapies the patient received during the Rehab stay:

Physical TX ___ 1=Eval only 2= Eval &Treatment 3=no Eval or treatment 4=Unknown
Occup. TX ___ 1=Eval only 2= Eval &Treatment 3=no Eval or treatment 4=Unknown
Speech TX: swallowing ___1=Eval only 2= Eval &Treatment 3=no Eval or treatment 4=Unknown
Speech TX:speech&lang___1=Eval only 2= Eval &Treatment 3=no Eval or treatment 4=Unknown

CLINICAL VARIABLES DURING THE REHABILITATION ADMISSION:

All variables should be assessed from completed evaluations or discharge summaries of physical, occupational, speech therapies and/or neuropsychological reports, whenever possible. However, clarify conflicting reports by conferencing with clinicians or attending patient care meetings.

Only assess the patient one time during the rehab stay, but be sure to assess all variables in the same time frame e.g. use all initial evaluations or all discharge evaluations. Record the date that assessment was completed for each variable.

Note the method used to assess each variable:
1=clinical Evaluation-initial
2-clinicial Evaluation-discharge
3=chart review
4=conference with treating physician, therapist, or case manager

This section provides us a “snapshot” of the patient at a point in time. It will be updated as the patient participates in studies in the future. Variables to be assessed are:

Arousability: Is patient arousable? Yes No Don't Know
Note level of arousability: e.g. 50% of time

Attention: Does patient have attention problems? Yes No Don't Know

Orientation: Does patient have orientation problems? Yes No Don't Know
if YES, further specify…
Does patient have orientation problems to TIME? Yes No Don't Know
to PERSON? Yes No Don't Know
To PLACE? Yes No Don't Know

Memory: Does patient have Memory Problems? Yes No Don't Know
Describe if possible: short term, long term, remote, visual memory?

Hemiparesis: Left side: Yes No Don't Know
Right side: Yes No Don't Know

Visual Field Defect: Does the patient exhibit a visual field defect? Yes No Don't Know
L-Left hemionopsia: Yes No Don't Know or R-hemionopsia Yes No Don't Know

Neglect: Does the patient exhibit Neglect?: Yes No Don't Know
Left side Yes No Don't Know
Right side Yes No Don't Know

Limb Apraxia:
Does the patient exhibit limb apraxia? Yes No Don't Know
if available, response to 3-item apraxia screen:
(OTs at all facilities are trained in this screen. A score of 2 means the patient did not exhibit apraxic behavior on that item. Free of apraxia if total of "6")

hammer	2	1	0
scissors	2	1	0
toothbrush	2	1	0

Aphasia:
Is the patient aphasic? Yes No Don't Know

if Y, aphasia diagnosis:

1=Broca's (agrammatic)
2=Broca's (nonfluent/nonagrammatic)
3=Conduction
4= Wernicke's
5=Transcortical Motor
6=Transcortical Sensory
7=Anomic
8= Global
9=Mixed
10= expressive aphasia
11= receptive aphasia
12= expressive/receptive aphasia
13= unspecified

Dysarthria: Yes No Don't Know Describe if possible: flaccid, spastic, mixed?

Verbal Apraxia: Yes No Don't Know Describe if possible.

Description of Speech and Language, Visual and Motor patterns:
In this section, enter summaries of the PT, OT, and ST Evaluations and give a "key-word" snapshot of the patient. You can enter summaries of the initial PT, OT and ST evaluations. We can search this field for specific characteristics later, e.g. ataxia, mis-reaching, balance problems.

Hearing Assessment:(if uncertain, copy the results of the audiogram in the patient's chart with all the decibel readings for the frequencies for both ears.)
1=**PASS-unaided**
Patient passes the standard audiometric screening test at 25dB HL bilaterally at 500, 1000, 2000 and 4000 hz (noise correction: 10 dB @ 500, 5dB @ 1000)

Or

Patient passes the Ventry protocol for elderly people (> = 65years) with audiometric screening at 40dB HL bilaterally at 1000 and 2000 hz and administration of the Hearing Handicap Index.

2=**PASS-aided**
Patient wears a hearing aid(s) and has professional follow-up at least yearly to monitor hearing level.

3=**PASS-provisionally** Patient (< 65 years) may "technically FAIL" the audiometric hearing screen as described in 1(above), however, extent of hearing loss is NOT deemed severe enough to preclude participation in research. Comprehension is adequate on a 1:1 basis. Before enrolling these patients in studies that require fine speech discrimination skills, referral to an ENT or audiologist is advised.

4=**FAIL** Patient requires ENT or audiological follow-up prior to reliable participation in a research project.
99=unknown

DATABASE ENTERING HINTS:

•Be careful with the TAB key. Sometimes, if you TAB one too many times, you will get a blank form. Just use the return TAB arrow and you should get back to your record.

•In Acute Care: after you enter facility ID, "don't know" **must** automatically appear in the first box under "consciousness" or you will not be able to continue entering information. Occasionally, it doesn't, and it necessitates that you close that page, not the database, and then reopen Acute Care. It should then be visible. The screen just needed to be REFRESHED.

PATIENT STUDY INFORMATION- SECTION 5

DEFINITION: Log of contacts to the patient to procure his/her permission for a researcher to contact them to discuss a study, as well as a log of entry and discharge dates for his/her participation in all studies of the Cognitive Rehabilitation Research Network.

Study Name: with pull down list, select a study (all listed have been approved by the Cognitive Rehabilitation Research Network.)

Contact Date: refers to the date that database personnel contacted the patient for a researcher
Record Identified: (Is out of order) refers to the date the query was run.
Patient OK Date: refers to the date the researcher contacted the patient to describe a study (note: the patient may not have said ok)
Start Date: refers to date patient entered the study
End Date: refers to date patient completed study
Study Status: gives a numerical code to either a reason that the patient did not enroll or what happened if the patient did enroll.

Reasons: code results
1=complete (patient completed study)
2=physician veto
3=distance
4=deferred
5=no response X 4 attempts (left message)
6=not interested
7=not qualified (on inspection, disqualifying condition discovered)
8=open
9=flagged
10=lost to follow up (number wrong, moved etc.)
11=withdrew prior to completing study

The program specifies contact date as a required field, therefore, enter 03/03/33 under contact date for the following reasons
5: contacted (message left) but there has been no response
7: not qualified (e.g. on inspection seizure disorder was discovered, so patient was never subsequently called)
9: flagged for condition not able to be described as per protocol (i.e. psychiatric, alchohol or drug use and abuse), so patient was never subsequently called
10=lost to follow up (patient's number was disconnected) so patient was never subsequently called

TEST UPDATES

BRAIN INJURY

Mini Mental Status Examination (MMSE)
Total Correct (score out of 30)

Paced Serial Auditory Addition Test (PASAT)
Total Correct (score out of 60)
2.4" pacing
2.0" pacing
1.6" pacing
1.2" pacing

Temporal Orientation (TO)
error score

North American Adult Reading Test (NAART)
Number of Errors
Estimated VIQ
Estimated PIQ
Estimated FSIQ

Wechsler Memory Scale-III (WMS-III)
Digit Span forward and Backward:
Digit Span forward (raw score)
Digit Span backward (raw score)
Total score (scaled)
Highest digits forward
Highest digits backward

BADS Dysexecutive Functioning Questionnaire (DEX) (Patient Version)
20 items
Total Score

Brown-Peterson Trigrams (CCC)
Control (0"delay) (Total correct of 15)
9" Delay (total correct of 15)
18" Delay (total correct of 15)
36" Delay (total correct of 15)
Total Score (total correct of 45)
Wisconsin Card Sorting Test-Computer Version (WCST)
Number of categories
Trials to complete first
Failure to maintain set
Total errors (raw score)
Perseverative responses (raw score)
Total Perseverative errors (raw score)
Total Error (corrected)
Perseverative Responses (corrected)
Total Perseverative Errors (corrected)

Stroop Test
Color Task
correct Responses
incorrect responses
score:
Color Word Score
correct Responses
incorrect responses

score:

Trail Making Test, Trials A&B (TMT)
Trial A Time (secs)
Trial A Number of Errors
Trial B Time (secs)
Trial B: Number of Errors

Five Point Test (Design Fluency) (5PT)
total responses
repetition errors
imaginary errors
total unique responses
percentage of unique responses
percentage of repetition errors

Controlled Oral Word Association (COWA)
total score
total score (corrected)
total no. repetition errors

Petrides Self-ordered Pointing Task (SOPT)
total errors (orignal format)
total errors (expanded format)

Cognitive Failures Questionnaire
self
caregiver

Rating Scale of Attentional Behavior
caregiver

California Verbal Learning Test (short form)
summary score

FRSBE (rating scale)
self-before
self-after
family-before
family-after

WAIS-III
Symbol search
total time
no. correct
no. incorrect
raw score
scaled score
Digit search
total time
no. correct
no. incorrect
raw score
scaled score

Processing Speed index

LANGUAGE TESTS

Aud.Discrimination
No Delay condition (n=40) percent correct
Filled Delay condition (n=40) percent correct

Boston Diagnostic Aphasia Examination (BDAE) (%tile rankings: 0-100)
mean of auditory comprehension tests
word discrimination
body-part identification
commands
complex ideational material
automatic sequences
repetition-single word
repetition-phrases-high probability
confrontation naming
responsive naming
animal naming
oral reading-words
oral reading- sentences
reading comprehension: word to picture matching
reading comprehension: sentences & paragraphs
writing-mechamics
writing-written confrontation naming
overall severity rating (1-5)

Boston Naming Test (BNT)
% correct

CADL-2
percentile

Gamma
Sum of Scaled Scores
IQ score
Percentile

Noun-Verb Naming
HF Nouns (n=30) % correct
LF Nouns (n=30) % correct
Verbs (n=30) % correct

Non-Word Repetition Test
(n=60) raw score
% correct

PALPA TESTS (n=20 in each)
Grammaticality Class Reading (number correct)
nouns
adjectives
verbs

functors

PALPA TESTS (n=6 in each)
Non-word Reading (number correct)
3-letter
4-letter
5-letter
6-letter

PALPA TESTS
Imageability and Frequency in Reading (number correct)
high imageability high frequency (n=20)
high imageablity low frequency (n=20)
low imageability high frequency (n=20)
low imageability low frequency (n=20)

PALPA TESTS (n=30 in each)
Spelling-Sound Regularity Reading Task (number correct)
Regular
Exceptional

PALPA TESTS
Auditory Lexical Decision: Imageability & Frequency
number correct rejections: nonwords (n=80)
number correct identifications: words (n=80)
high imageability high frequency (n=40)
high imageablity low frequency (n=40)
low imageability high frequency (n=40)
low imageability low frequency (n=40)

Philadelphia Comprehension Battery (PCB)
(% correct)
lexical comprehension-within category
lexical comprehension-across category
sentence comprehension A-reversible
sentence comprehension A-lexical
sentence comprehension B-reversible
sentence comprehension B-lexical
grammatical judgements
synonymy triplets

Philadelphia Naming Test (PNT)
(correct out of 175)
% correct at first complete response
% target related errors
% semantic errors
% no responses
% correct at final response

Philadelphia Oral Reading Test (PORT)
(n=175)

% correct at first complete response
% target related errors
% semantic errors
% no responses

Philadelphia Repetition Test (PRT)
(n=175)
% correct at first complete response
% target related errors
% semantic errors
% no responses

PNVT
(n=486)
% correct
Number of Match errors:
Number of Semantically-Close errors
Number of Semantically-Remote errors
Number of Phonologically-Close errors
Number of Phonologically-Remote errors

PPVT
Raw score

Pyramids and Palm Trees (% correct)
pictures
written word
other version

QPA Analysis
prop. wds in sentences
prop. closed class words
prop. verbs
prop. well-formed sentences
prop. narrative words to total words
mean sentence length

STM TESTING: Nadine Martin's Battery
average span
Repetition
Pointing Digits
Words

Western Aphasia Battery (WAB):
Spontaneous Speech: Information Content (0-10)
Fluency (0-10)
(AQ subscore=total of above)
Comprehension:

Auditory word Recognition (0-60)
Sequential Commands (0-80)
(AQ subscore=total/20)
Repetition:
(AQ subscore =total/10)
Naming:
Word Fluency (0-20)
Sentence Completion (0-10)
Responsive Speech (0-10)
(AQ subscore=total/10)
Aphasia Quotient (AQ=total of subscores X 2) (0.00->100)
Reading:
Writing:
Diagnostic Category (text)

APRAXIA

Grip Strength
(avg. 3 measurements)
Left, Right (3 trials, average)

Dexterity
(#repetitions in 10 sec.)
Left, Right (2 trials, average)

Tactile Sensation
(impaired +/not impaired -)

Transitive gesture to sight of object
(Total % score)
Left

Proprioception
(No. correct in 5 trials)
Left, Right

Meaningless Analogs
(% correct)
Transitive, Intransitive

Meaningful gesture to imitation
(% correct)
Transitive, Intransitive

Reaching/grasping
(avg mm.)

Body imagery
(% correct)

Target pointing task
(mm)

Left, Center, Right

Optic Ataxia Test
(mm)
Left, Right

NEGLECT TESTS

The Bell Cancellation Test
Total (% correct)
L % correct
R % correct

The Letter Cancellation Test
Total (% correct)
L % correct
R % correct

Rivermead Behavior Inattention Test
Line Bisection Subtest:
average deviation in mm.

Visual Field Cut/ Visual Extinction Examination
Unilateral trials
(n=5): left (no correct)
(n=5): right (no correct)
Bilateral trials
(n=5):

DATABASE COORDINATOR JOB TASKS:

1.Train and supervise recruiters in their duties.

2. Run weekly meeting with recruiting staff:
    a. Review currently active cases for problems.
    b. Target patients for particular studies.
    c. Gather consents to be filed and sign them as investigator designee.
    d. Update NIH stats (gender and ethnicity).
    e. Insert "Current Neuro Status" code in registry.
    f. Make high priority notes in "note field" and demographics page about patient availability and/or special circumstances impacting calls.

3. Run quarterly meeting for Research Institute PIs and team members to review procedures, present new programs and problem solve.

4. Statistics: Monthly, make a copy of the current month's patients on the three screening logs minus any outstanding contacts. Outstanding contacts on the 30/31st of any month are transferred to the next month's list. Do statistical reports from these numbers.

Do 11 statistical reports:
    a. Cumulative numbers (grant 1 plus 2) of screened/approached etc.
    b. Cumulative failures (grant 1 plus 2)
    c. Grant 2 only-numbers by sites/pathways
    d. Grant 2 only-numbers by recruiters
    e. Grant 2 only-line graphs for recruitment per recruiter
    f. Grant 2 only-numbers of screened/approached etc.
    g. Grant 2 only-failures
    h. Quarterly web report with cumulative stats including usage by site and diagnosis
    i. Quarterly web report for grant 2 stats only including usage by site and diagnosis
    j. Yearly NIH progress reports
    k. Yearly IRB progress reports

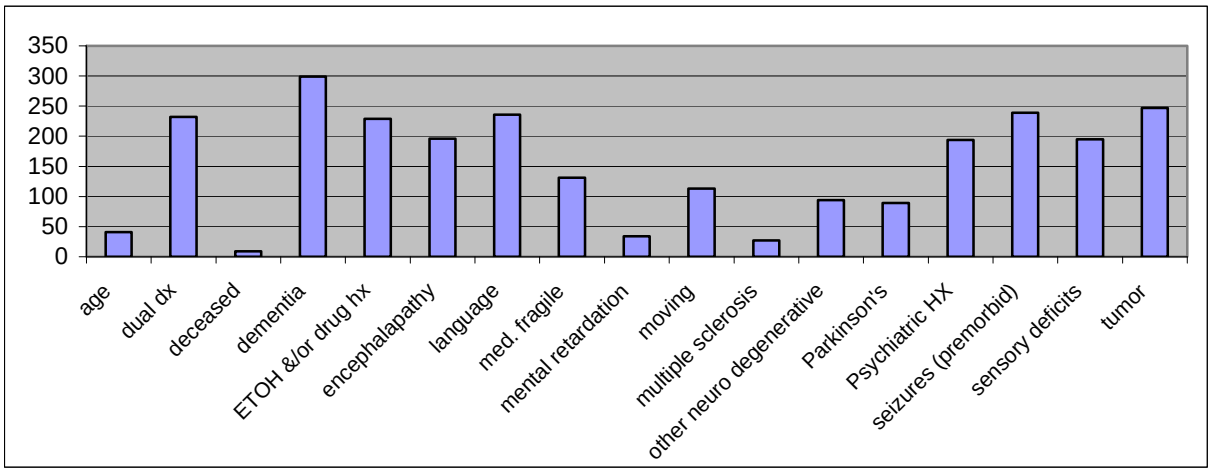
e.g. reports a, f

	CVA																	
				Approached - "YES"										"NO"			
	No. with CVA DX	No. CVA PASS criteria	% CVA PASS criteria	Total No. Approached	% Approached	No. Consents	% Consents/ all "PASSERS"	% Consents/ approached	No. contacted X3 with no resolution	No. maybe-call after DC	No. Declines	% Declines/ all "PASSERS"	% Declines/ approached	Total No. Not Approached	No. discharged early	No. Staff advised against	messages
2/01-9/05 1st grant	1748	971	55.5	893	92	637	66	71	33	52	171	18	19.1	78	77	0	1
2005																	
10	24	14	58.3	14	100	12	86	86	0	0	2	14	14.3	0	0	0	0
11	24	16	66.7	16	100	14	88	88	0	1	1	6	6.25	0	0	0	0
12	36	22	61.1	21	95	18	82	86	0	1	2	9	9.52	1	1	0	0
2006																	
1	29	19	65.5	19	100	17	89	89	0	0	2	11	10.5	0	0	0	0
2	23	14	60.9	14	100	11	79	79	0	1	2	14	14.3	0	0	0	0
3	36	14	38.9	14	100	10	71	71	0	0	4	29	28.6	0	0	0	0
4	0	0	####	0	###	0	###	###	0	0	0	##	####	0	0	0	0
5	0	0	####	0	###	0	###	###	0	0	0	##	####	0	0	0	0
6	50	21	42	19	90	7	33	37	2	0	10	48	52.6	2	1	0	1
7	43	17	39.5	17	100	5	29	29	4	0	8	47	47.1	0	0	0	0
8	51	26	51	26	100	10	38	38	5	1	10	38	38.5	0	0	0	0
9	29	15	51.7	14	93	4	27	29	4	0	6	40	42.9	1	0	0	1
10	36	16	44.4	16	100	7	44	44	3	1	5	31	31.3	0	0	0	0
11			####		###		###	###				##	####				
12			####		###		###	###				##	####				
No.	2129	1165	54.7	1083	93	752	65	69	51	57	223	19	20.6	82	79	0	3

e.g. reports b, g

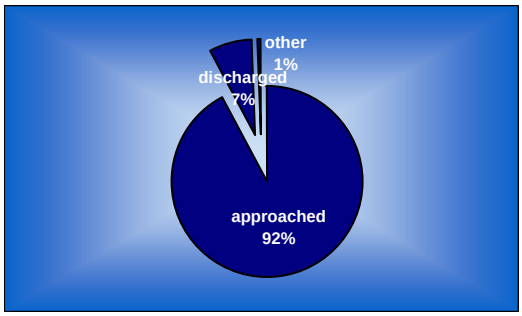
		MossRehab					Failures to meet criteria						CVA					
	age	dual diagnoses (TBI & CVA)	On list/ deceased while in rehab	Dementia	ETOH/ Drug abuse	Anoxc/metabolic enceph.	Language Barrier	Medically Fragile	Mental Retardation	Moving permanently out of area	Multiple Sclerosis	other neurodeenerative condition	Parkinson's	Psychiatric History	Seizure disorder	Sensory Disturbance	Tumor
No.	2	42	3	75	75	46	109	38	10	29	10	0	11	22	52	75	54	124
2005																		
10		2		2			2						1		1	1	1	
11		1		1			3							1			1	1
12		1		2	1		3	2		1				2		2		
2006																		
1		1					5									4		
2	3						2			1				1		1	1	

e.g. reports h, i



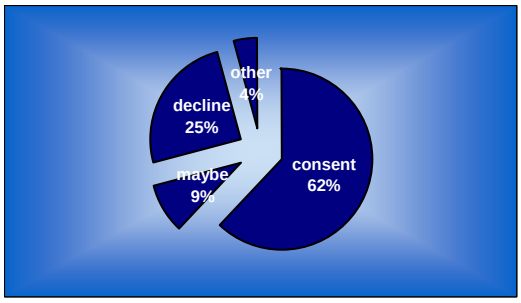
What happened to the 3928 patients who passed criteria for admission to the patient registry?

approached	3622
discharged	284
other	22



What was the outcome from the 3622 patients who were approached about participating?

consent	2246
maybe	319
decline	906
other	151



Total Enrollment: 2246

CVA	TBI
1,663	583

5. Maintain NIH Log: When the subject has been assigned a number and has been logged on the screening logs:
    a. File the original Consent (lateral files)
    b. Enter subject into NIH stats log

(W) Withdrawn codes: H=health, D=distance, INT=interest, FC=NOW FAILS CRITERIA,	NAME	C/A	W code	add "1" if DEL	Date of withdraval or death	DC	Am In/ HS	Alas	As	Haw /Pac	Bl	W	>1	UK ara	NON HS	n/ Ala s	AS	Haw /Pac	Bl	W	>1	arabic	UK	
	MG0001	C/A				1	0								1				1					1
	MG0002	C/A			9/15/2006	1	0								1					1			1	
	MG0003	C/A			6/15/2006	1	0								1					1			1	

Enter:

- Subject's name LN, FN (far left); ID code; Subject's name FN LN; Subject DX
- Enter a "1" for the appropriate race within the appropriate ethnic category (Hispanic vs Non-Hispanic) and indicate gender [see sample]
- Return to form when new info is received as to status: e.g. if withdrawn(W), opted to be deleted, deceased, lost to follow-up. Enter a date if known so that the yearly IRB report is easier.
- Form automatically tallies counts
- These data will be used for the annual IRB progress summary and for the yearly NIH progress report.

6. Assign patients to studies and maintain statistics relating to usage by teams: Identify patients for studies-either at time of enrollment or by a monthly query. Distribute lists to recruiters with specific instructions on calling. Follow-up on the resolution of the calls with the recruiters. Make sure information gets transferred correctly to team logs.
7. Train team members in methods to check for research ID codes and how to update logs and send final update forms to the registry office.
8. Assign a research code to patients using the program that assigns a code whether or not patients are Moss patients.
9. Do a yearly review and update all policies and procedures.
10. Meet with researchers as needed to modify their criteria and discuss patient usage etc.

PROCEDURES FOR RECRUITERS FOR THE RESEARCH REGISTRY:

SUBJECT IDENTIFICATION and TRACKING

• Screen charts of all new admissions with a diagnosis of CVA (Cerebrovascular accident) or TBI (Traumatic Brain Injury).

• A **CHART REVIEW FACE SHEET** is available to assist your work in screening patient's charts.

• Complete the network version of the **PATIENT SCREENING LOGS for Stroke (CVA) or Traumatically Brain-injured (TBI)** at the end of each screening day. The log identifies patients by name, so you can keep track of who you have approached and the disposition on each. Column 1 (far left) captures the overall enrollment status for each chart screened (8 choices):

MRXXXX- Patient number if enrolled

FAIL (Patient fails criteria to be enrolled in the Registry)

DECLINED

ER DC or AMA (discharged to acute care within 8 days or discharged self against medical advise)

MAYBE

PASS-NO RESOLUTION (discharged after 8 days without contact or without disposition if contacted)

ALREADY ENROLLED

SCREENED ON PRIOR ADMISSION

General Criteria for Stroke (CVA) or Head Injury (TBI) participation in the Patient Registry:

Inclusions:

c. Diagnosis of CVA (etiologies: thrombosis, hemorrhage or ruptured aneurysm)

d. Diagnosis of TBI (etiologies: blunt or penetrating)

e. Age: >16 years (upper limit-80 years)

Exclusions:

1. *Psychiatric History:* exclude patients with a previous medical history of schizophrenia or other major psychosis (e.g. disabling depression, bipolar disorder) that required multiple hospitalizations. DO NOT exclude if psychiatric symptoms first occurred AFTER a stroke or head injury.
2. *Significant Sensory Deficits:* exclude patients with confirmed blindness in BOTH eyes and patients who are confirmed as profoundly deaf and would not be able to hear the examiner state the task instructions. (Sensory deficits of lesser degrees will be evaluated by each researcher at time of screening for a particular project).
3. *Degenerative CNS disease:* Exclude patients with diagnoses such as: Multiple Sclerosis, Parkinson's, or Alzheimer's.
4. *Developmental Disorders:* e.g. syndromes with Mental Retardation as a characteristic.
5. *Prior CNS insult or Other Condition:* Cerebral Palsy, Childhood or longstanding Epilepsy (not just seizure disorder that is idiopathic), Meningitis, Anoxic, Viral or Metabolic Encephalapathy,
6. *Brain tumor/cancer:* (both non-metastatic and metastatic) are excluded.
7. *Dual Diagnoses:* History of Non-Concurrent (prior) CVA is an exclusion for TBI, but not CVA registrants. History of Non-concurrent (prior) TBI is an exclusion for CVA, but not TBI registrants.
8. *Miscellaneous:* Patients may be excluded for other reasons including: moving permanently beyond the Northeast Region with no ability to return to participate, little or no English language comprehension and lack of an available translator, status at discharge from rehab is determined to be "medically fragile" (e.g. complicating medical conditions e.g. renal or heart problems prevent the patient from sustaining an outpatient session).
9. *Patients are NOT excluded for history of Alcohol or Substance Abuse:* Determination of ability to participate in research will be made on an individual basis by each research team at the time of enrollment.

• Use the network **Patient Screening Logs** 1) to note a brief reason if a new admission failed to meet criteria; 2) declined to participate and why e.g. “I don’t have any interest in this.”; 3) to note if a patient was discharged prior to your ability to meet with them; 4) to note if you met with the patient, but could achieve no resolution prior to the patient's discharge; 5) or to indicate if a patient said “maybe”, that is, he/she agreed to a call in 4-6 months; or 6) to log a consented patient, along with their ID code. If there are outstanding patient names on the **Screening log A** at the end of the month (Admitted patients whose charts you have not yet screened or patients who are not discharged, but still "in process" with you), TRANSFER their names to the next month's list.

OBTAINING WRITTEN INFORMED CONSENT-INPATIENTS

(The following text is taken directly from the PRC guidelines for the consenting process.)

Getting written informed consent from a subject prior to placement in the “Patient Registry” is a critical step in the research process. Authorities on the ethics of biomedical research maintain that the competence to give truly informed consent is evidenced by the ability to: (a) describe the experiment or protocol; or if, nonverbal (b) demonstrate understanding of the conditions of the study or protocol through a “yes”/”no” response; (c) describe expected outcomes with or without experimental therapy, if appropriate; and (d) be able to remember the protocol over time.

For our diagnostic groups (e.g., inpatient stroke or TBI), the judgement that the patient is mentally/cognitively competent to give informed consent is inevitably open to dispute. (Note that we are not referring to the legal definition of ‘competence’ but whether the potential subject has the capacity to understand the purpose of the study, the methods involved, etc.) For such patients, even professionals will disagree as to the answer. Family members will have their own point of view on the matter. Consequently, an involved family member should *ALWAYS* be “involved” when consent is sought from a patient with a diagnosis of stroke or TBI. This DOES NOT mean the family must be present when the patient signs. It DOES mean they must be aware that you approached the patient and what the patient consented to do. (In some cases, however, a competent patient may request that no one from the family is involved

and that should be respected. However, always concur with the patient's physician that the patient is decisionally-competent, and document that in the patient's chart.)

RECRUITING PATIENTS FOR RESEARCH PROJECTS:

When recruiting inpatients for the "Patient Registry", the following procedures should be followed:

Site recruiters should use at least three measures to determine a patient's decision-making capacity to comprehend the informed consent process prior to introducing the Research Registry: (1) chart documentation; (2) interviews with staff members; and, (3) multiple, if necessary, informational interactions with the patient. If the patient is clearly not competent to make decisions (i.e. disoriented, unable to attend, remember or comprehend simple sentences due to cognitive impairment), the procedure is terminated until a family member or surrogate decision -maker is available, preferably in person, but acceptably by phone. If a site recruiter is unable to make contact with a designated decision-maker, that patient is NOT ABLE to enroll in the Patient Registry.

Informed Consent Process

TBI and CVA-INPATIENTS

PATIENT IS CLEARLY NOT DECISIONALLY-COMPETENT

1. If the patient is clearly not competent, do NOT approach the patient for consent except in the presence of a family member. Do NOT leave a brochure in the patient's room.
2. Plan to contact a family member about a week into the patient's hospital stay, but always check first to be sure: *who the appropriate family member is, and if it is a good time to contact the family.* There is always the possibility that the family is too stressed to hear from us at the present time, in which case we can defer approach until after discharge from the acute care program. **TBI – Drucker unit 4th floor**: Patients are assigned to one of two teams- either Dr. Cho or Dr. Pelensky. Weekly we receive an update from Caron Morita re: when we can approach patients for the Registry. We

always defer our approach until AFTER the TBI teams have approached the patients for the Amantadine and Model Systems studies. Caron will alert you to any family issues that you need to be aware of. **CVA- 2nd, 3rd floors:** Check with one of two social workers assigned to inpatients on the units via any method. They are equally amenable to e-mail, voicemail or in-person check-in visits. The social workers will direct you to the appropriate attending or resident, if either of them is unable to answer your questions about the family situation.

3. Once appropriate timing is confirmed, call the family member at various times up to 3X before leaving a message. Only leave a maximum of 2 messages on a voicemail.
4. When you reach the family member, explain the Registry briefly and offer to meet with the family member, along with the patient, at his/her convenience, to enroll the patient if they are interested.
5. If he/she agrees to meet you, make an appointment (be very specific about day and time), or explain and obtain their proxy consent over the phone first (You can then approach the patient to attain "assent" to the idea of being involved in the registry, if the patient is capable of interacting with you). In addition, ask that family member whether there is another family member closely involved with the patient's care who would also wish to be contacted; obtain verbal proxy consent from that additional individual.
6. If the family member gives verbal proxy consent over the phone, you must wait until they come into the hospital to actually sign the consent form *before* placing the patient's name in the patient registry. Family member(s) should sign the consent form in the designated spot for "consent".
7. REMEMBER: If a patient is deemed *incompetent* to provide informed consent *(disoriented, can not comprehend sentence length speech, or can not remember what they have been told for the duration of the visit),* and you are unable to make contact with a family member, the patient will not be able to enroll in the patient registry.
8. If the family member does NOT want the patient to be involved, say *"That's fine. I'll leave the brochure in _____'s room in case you want to pursue this at a later time."*
9. If the patient has no family or no one acting as power of attorney, it is not possible for that patient to participate.

THE NEED TO ATTAIN ASSENT

Research ethics dictate that in addition to the formal "consent" document, you should always try to solicit "assent" from patients if;

(1)they are adults who are deemed incapable of making the primary decision; or,
(2) if they are under 18 years of age, and a parent or guardian is making the primary decision. Complete the "Children's Assent" form with children under 18 years of age. This form attempts to elicit assent with age appropriate language regarding the study. If a child under 18 is incapable of responding to the "assent" form at the time of research registry enrollment, continue the consent process with the parent or guardian. Then, at a later date, the child will have the opportunity to register assent prior to participating in a study, when more cognitively aware.

PATIENT IS CLEARLY DECISIONALLY-COMPETENT

1. If the chart review results in a judgement that the patient is 'decisionally-competent', proceed as follows (if during this process, the patient appears to not be 'decisionally-competent', revert to the previously described procedures.)
2. The project and the consent form is discussed with the competent patient first approximately one week after the patient's admission. Query him/her for the level of understanding of the main points (e.g. "What did you understand from what I just read to you?"). If the patient has a speech output deficit (e.g., aphasia), questions may be structured to maximize responses (e.g. yes/no questions). With respect to the requirements of being able to recall the research protocol over time, the expectation is that minimally, the patient should be able to recall this information for the duration of the informed consent interview, so that they recall why they are signing the consent form. Patients with specific memory deficits are not expected to recall this information over longer time periods.
3. Inform the patient that it is standard procedure to 'involve' a family member in the consent process as a courtesy to let them know that you have been in to see the patient. If the patient agrees, take the following steps. Contact the family member by phone. Inform the patient that it is standard procedure to 'involve' a family member in the *inpatient consent process* as a courtesy to let them know that you have been in to see

the patient. (This is the case with all activities at MossRehab. The culture in our institution is very family-oriented.)

4. Ask the patient if this is okay with him/her. If the patient agrees, contact the family member by phone to describe the Registry and notify them of the patient's desire to participate and obtain a verbal "assent". (NOTE: This is not "co-consent" or proxy consent. In this case, we are notifying the family that the patient wants to participate, NOT asking the family if it is okay.) However, family members may want to have more information, or a chance to discuss this with the patient and be actively involved in the decision. In some cases they may argue against participation for the patient, due to prior bias, or simply because they feel they can't get involved in the transport. It is always best to anticipate this and pre-empt any concerns.
5. If the family member is in agreement, the recruiter can consent the patient without a family member present. If the family member does not want the patient to be involved with the Patient Registry, say *"That's fine. I will leave a brochure with _____ in case you want to pursue this at a later time."* It is clearly not worthwhile to engage in a battle to enroll a patient. You will most likely have future opportunities to enroll the patient when they begin OP treatment or return for a Physiatry appointment
6. Leave a brochure with the patient. Be sure NOT to say anything disparaging about the family member, just that they didn't want to pursue it at this time. Point out to the patient that a recruiter can always be contacted at a later time (contact information can be found in the brochure.)
7. <u>Note:</u> *If a clearly-competent patient with a mild TBI or CVA specifically asks you NOT to contact a family member, ask the attending physician to clear the patient's ability to make this decision; document that the physician gave the okay to proceed; and then enroll the patient. Have the patient sign the waiver of notification on the consent form.*
8. Written consent is obtained from the patient in the presence of a witness, who signs on the designated line. This witness must be someone other than a family member. The minimum standard is that the witness be able to attest to the fact that the patient did indeed sign. The higher and more desirable, standard is for the witness to be able to attest to the fact that a good faith attempt at full disclosure was made and that the patient made an informed voluntary decision to participate. The competent patient may

be entered into a study or the **"**Patient Registry" as soon as he/she has signed the consent form.

9. If the competent patient does not want to participate, the family is not called. Log that the patient has declined.
10. Complete the physician notification letter that the patient was approached and either agreed or refused to participate.

COMPETENCY IS UNKNOWN OR UNCLEAR

Follow all procedures for the "incompetent patient".

TBI AND CVA OUTPATIENTS

Follow all procedures as described above for inpatients. It is always preferable to involve a family member. A copy of the consent form and Einstein Authorization are always given to the patient, and it has been our experience that the legalese in these forms is often open to misinterpretation by family members.

INFORMED CONSENT PROCESS FOR MAIL-IN ENROLLEES

In cases where a patient/family member initiates a request to enroll (e.g. through our outreach flyers to area hospitals), the entire process can be completed by mail, after the initial phone contact. It is not necessary to speak to a family member if only the patient has initiated the call. The form that is mailed designates where a family member's signature is required.

• When you are speaking to families about the consent, be sure to ask the designated questions relating to demographic information and medical history that are unlikely to be found on the chart. These have an **"F"** preceding them on the **Patient Registry Data Form**.

Reminders: This process can be tedious and time consuming, but it is extremely important for obvious ethical reasons. Please consult the Registry Coordinator if you have any questions. Remember we are under a time constraint for inpatients. Approach new patients early in their stay (within the first week). Always approach patients with a smile and a comforting attitude.

Introduce yourself and tell them your title, and if at all possible shake their hand. A good way of getting patient and family consent at the same time is in the late afternoon (just before or after dinner). Families are more likely to be present at the hospital for visiting hours around these times. However, you may find that the most efficient way to meet the family is to schedule an actual appointment.

The Patient Registry consent form:

All consent must be in writing on the specific IRB-approved consent form.

1.Explain the registry briefly and enthusiastically in a few sentences. (See written script for further verbal approach suggestions) Describe the Registry as an effort to coordinate thousands of Philadelphia-area volunteers who wish to participate in research projects. Talk about how these studies are trying to increase understanding of how abilities like speech, attention, memory and action are affected by a stroke or brain injury, and what changes go along with recovery. Stress that if the patient accepts the invitation to participate, they are not obligated to participate in any studies, but will be notified by telephone of all new studies for which they qualify. They can make the decision about whether or not they wish to participate at the time they are called. They will be paid for their participation to cover travel expenses.

2.At this point ask the patient if they would be interested in participating.

3.If they are not, you may wish to ask why they are not willing, so that if it's simply because they have a misunderstanding with what you are asking them to do, you can explain in more detail. If they are not willing to provide a reason, that is fine. Later, mark the patient as a "no" on the **Patient Screening Log** sheet. If they are interested in placement in the Registry, continue.

RECORDING APPROACH AND PARTICIPATION

When a patient agrees to participate in the Patient Registry:

1. Explain (not necessary to read verbatim) the consent form paragraph by paragraph stressing the Confidentiality section which contains the HIPAA-related language. The patient is given a copy of the signed consent form, and the Moss Privacy Notice.

2. If the patient is under 18 years of age, explain and complete the "Children's Assent" form.
3. Store the signed original(s) in a secure location for later transfer (see TRANSMISSION OF DATA).
4. Regardless as to whether the patient consents or declines to participate in any project, the attending physician is sent a letter documenting this transaction (place on the front of the medical record.
5. A progress note is then entered into the medical record. An example of the chart entry follows: (entry must be indented)

DATE/ Neuropsychology Research

Patient X has agreed to participate in the Patient Research Registry under the direction of Dr. Myrna Schwartz. Consent form has been signed and a copy placed in the front of chart. If there are questions, please contact Adelyn Brecher at extension 6-9985.

Name_____ _____

Research Assistant Extension

If the patient/and or family does not consent, write the same chart note as above substituting "declined" for "consented" and delete the second line "a copy…", and cross out the second paragraph of the physician notification letter. If there are any special consenting conditions, include these in your note e.g. if a patient refused to involve family members, but was cleared to self-enroll by the attending physician.

6. If the patient and family consent to participate in the Patient Registry, proceed to collect data variables.

DATA COLLECTION:

• Complete the **PATIENT REGISTRY DATA FORM**.

PARTS 1 & 2 (Demographics and Medical History) can be completed from review of the patient chart and also supplemented at the time of the family interview during the consent process. When completing PART 3 (Clinical Information Variables), supplement or clarify information, if necessary, by locating the acute care transfer file and/or attending the weekly or

bi-weekly team conference meetings. If available, photocopy and attach any MRI or CT report found in the acute care or rehab records. If available for patients with aphasia, photocopy and attach the initial speech therapy evaluation so we have a " clinical language snapshot" of the patient.

• Legibility is EXTREMELY important.

WHAT TO DO WITH THE DATA?

1. Complete the networked screening logs as often as you have updates.
2. Shred the Chart Review Face Sheets when the patient's case has been resolved.
3. Original consent forms (signed by all parties), Privacy Notice, and the Children's Assent Form (if necessary) - are kept in a file cabinet at Tabor Road right now, but will eventually be filed at Elkins Park. Keep these secure. Weekly, bring them to the staff meeting for Adelyn's signature.
4. Patient Registry Data Forms are needed to input data into the database, then they are shredded.
5. FIM admission and discharge scores will not be available on the chart, but can be accessed at a later date.

Dear «patientname»,

We wish you the very best on your birthday. May your coming year be filled with health and happiness.

Sincerely,
The Neuro-Cognitive Rehabilitation Research Network:
MossRehab, Bryn Mawr Rehab and
Magee Rehabilitation Hospitals

As an enrolled member of the Patient Research Registry, you are still eligible to participate in Cognitive Rehabilitation Research. We may have already contacted you about a study. If not, it means we have not had a study for which you qualified since you enrolled. We thank you for your continued interest, and will contact you if any appropriate, new study is added.

KEEP IN TOUCH!

Please make sure we know your current address and phone number. Call Adelyn Brecher at (215) 456-9985 if you move, or if your phone number changes.

If you no longer wish to participate, call Adelyn and she will remove your name from the list.

SAMPLE SCRIPT

<u>This is a guideline only.</u> Modify the language level to maximize each patient and/or family's ability to fully understand. Speak in a slow and relaxed manner. There is a lot of information to get across.

For use with Inpatients:

Try to precede a long information session with a short introduction about a week earlier.

Hi, Mr./Mrs./Ms_____. My name is_____. I'm from the Research Institute. It's my job to evaluate everyone who is admitted with a (stroke/head injury) to see who qualifies to hear about our research projects after they are discharged, and you are eligible.

<u>If patient is decisionally-capable:</u> I'm just going to leave some information with you right now (brochure) and I'll stop back in a few days to answer any questions you may have. Feel free to share it with your family. (If patient looks interested at this point-you can proceed, but in general, it's best just to make the first contact brief).

<u>If you sense patient is decisionally-impaired:</u> (DO NOT leave brochure-contact family)

For use when:

1. **Approaching a decisionally-capable patient**
2. **Notifying a family member of a decisionally-capable patient about the Registry**
3. **Contacting a family member for their proxy consent, when a patient is decisionally-impaired**

Hi, Mr./Mrs./Ms_____. My name is_____.

I'm from the Research Institute at MossRehab. In addition to its strong therapy programs, Moss has an extensive research network as well. I wanted to tell you about a particular program that (you, "patient's name") qualify for. Is this a good time?

If no,…[determine when to return or when to call back]

If yes,…

It's my job to evaluate everyone who is admitted with a (stroke/head injury) to see who qualifies to hear about our research projects, and (you, "patient's name") have/has been identified as a good candidate to enroll in our patient research registry. So, what is our registry? Well, we established the patient registry 6 years ago as a way of maintaining contact with our patients, so that they can be alerted to research projects <u>for which they qualify</u> after they leave Moss.

It's a list of over 2,000 people now, who are entered into a computer along with information about your (stroke/brain injury). If you decide (you'd like to/ you'd like to have him/her join), (you/he/she) will be added to the list so that we can match you to studies that might interest you and notify you about them **(PERSONALIZE)** For example If a study on (speech /memory/arm movements) starts up four months from now, we'll know we have your permission to call (you/him/her) and let you know about it.

(Your/his/her) participation is always voluntary.

It's not tied into (your/his/her) medical care or medical insurance.

(You/he/she) will be paid to participate if (you/he/she) decides to enroll in a clinical trial. Is this something that would interest you?

If NO, (Most of the time, patients and/or family members will tell you the reason they are not interested. Some are overwhelmed with the newness of the illness. They can't conceive that they will be able to arrange transportation etc. Others have a negative preconceived notion about research in general. Try to determine if there are any questions you can answer that will allay their fears.)

Okay… I am always here to answer any questions you may have in the future? Would you like me to leave the information for you to review? This way if you ever decide that you might like to hear more about it, you will be able to contact me. Thank you for time today.

If YES, Great**,**

In order to participate, you'll need to review the project with me and sign a consent form so that we're able to add (your/his/her) name to the call list and gather some information for our records so that we can match you to studies.

(If on phone with a family member)

When are you planning to visit next? Do you have a conference scheduled?

(Re: conference- If yes, try to come in before or after the conference when they will be there.)

When we meet, I'll give you some additional details about how all of this works.

[an alternative]

We can do the consent process over the phone if you like, but you will have to come in to actually sign the forms before we can place _____'s name in the Registry.

(In person with patient and/or family member)

We can review the form and you can sign it now or, **(PREFERABLY)** we can review it and you can opt to keep and look it over; share it with others in the family; and then I can come back.

During the actual consent form review:

Point to INTRODUCTION AND PURPOSE paragraphs

• The Patient Registry is funded by a grant from the National Institute of Health to organize research efforts to see how abilities such as speech, memory and movement are affected by a stroke and head injury; what treatment approaches work best and what changes go along with recovery.

Point to PROCEDURES

• This section lists the type of information we add to your computer file: Some of (your/his/her) medical history: e.g. what side of the body the stroke affected, results of CT and MRI scans, and other social information such as your birthdate, former occupation etc. We identify you and your information by a number. Only the people who work in our office have access to your real name and phone number. It's important to remember that by signing this, you are ONLY giving us permission to call you to ask if you want to "hear" about a study. Then, when we call you, we're going to tell you about the study and ask you if you want the researcher to call you and schedule an appointment with you. You are NOT signing up for a particular study right now.

You're never obligated to say YES. You can say "no, not this time, but keep me on the list", or you can decide you're not interested anymore and opt out totally. In that case, all your information will be permanently deleted.

Point to RISKS

• The only risk that we have identified is that you may get a phone call. It works out that patients are called 2-3 times a year at most, and in fact some are never called. There's NO guarantee.

Point to BENEFITS

- Treatment by leading researchers- often when insurance benefits have run out

- Access to treatments that aren't readily available
- Helping to improve the quality of rehabilitation to everyone who experiences a brain injury or stroke.
- Assured of being notified for projects that may benefit him/her directly
- compensation for time and travel costs

Point to RIGHTS

It's clearly stated here that (you/he/she-- are/is) a volunteer. This has nothing to do with medical insurance or medical care. (You/he/she) can be taken off the list at any time.

Do you have any questions?

(Question patients on the main points- particularly, if you have any sense that they are confused. e.g. Do you understand that you will only be called when you qualify for a study?)

Point to CONFIDENTIALITY AND HIPAA AUTHORIZATION

Confidentiality is our primary concern. This section describes what information we collect so that we can match (you /him/her) to a study, why that information is needed, and who can view the information. You are only authorizing us to use your information for the purposes of the Research Registry.

(Explain as much of this word for word as is necessary for each family and patient.
Patient & Family must physically sign the form. While a family member may give a verbal authorization over the phone, at some point, that family member will have to actually sign it, or the patient CAN NOT be enrolled. The decisionally-capable patient, who signs for him/herself, may opt to forego having a family member sign as having been "notified" of his/her intent and still enroll.)

Introduce THE PRIVACY NOTICE when you get to this sentence

Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. A copy of the Notice will be provided to you.

(Give the patient and/or family member the Notice. They do not have to sign separately for it.

By signing the consent form, the patient and/or family member is confirming that they received a copy of the Privacy Notice.)

• Photocopy consent form when all signatures are acquired and leave a copy for the patient and/or family member.

The Neuro-Cognitive Rehabilitation Research Network

Clinical Trials

Patient Recruitment Brochure

What is Cognitive Rehabilitation?
Each year, thousands of people experience problems with cognition- attention, memory, language, and action initiation- as a result of stroke or traumatic brain injury (TBI). Cognitive rehabilitation is designed to help improve these impairments and restore as much function and independence as possible. Cognitive rehabilitation research is an important part of the recovery process as new treatments are developed. However, without clinical trials there is very little proof of the effectiveness of these treatments.

About the Research Network
Moss Rehabilitation Research Institute (MRRI) was awarded a grant by the National Center for Medical Rehabilitation Research to enhance the impact of the successful regional network it established for cognitive rehabilitation research in February 2000. The Neuro-Cognitive Rehabilitation Research Network (NCRRN) is a joint effort between Moss Rehabilitation Research Institute and the University of Pennsylvania.

This brochure will provide information about participation in cognitive rehabilitation clinical trials and answer common questions about making a decision whether to participate.

We hope to make it easier for potential research volunteers, in the Jefferson Health system and elsewhere, to learn about ongoing research opportunities that may benefit them or others, and to insure that no interested patient is lost to follow-up.

The Neuro-Cognitive Research Network (NCRRN)
The goal of NCRRN is to enhance the quality, efficiency and level of cognitive rehabilitation nationally by:

- analyzing the most promising advances in cognitive rehabilitation research,
- communicating this information to researchers who are actively developing treatments; and
- building collaborative bridges among scientists in allied fields.

The NCRRN also maintains a Patient Registry of individuals recovering from stroke or TBI who have specified an interest in participating in research.

Joining the NCRRN Patient Registry
As an inpatient or outpatient, you may be contacted by a Research Recruiter and asked to join the Patient Registry. The Registry is a database of patients who want to be kept aware of studies for which they qualify. In the Patient Registry, you are identified by a patient number. Along with your number, there will be information about your diagnosis, rehabilitation course, and social information, such as age and occupation. However, your name and other identifying information will be kept confidential from all but key Network and Registry staff.

Participation in Specific Clinical Trials
Once enrolled in the Patient Registry, the Registry Coordinator's office may contact you about a study for which you qualify and ask if you are interested in participating. If you are interested, the coordinator will arrange for you to speak to the study team to learn more. You are under no obligation to participate in a study. You can say no at any time; it will not affect your medical care or rehabilitation program.

Frequently Asked Questions

What is a clinical trial?
Clinical trials are studies conducted by research teams of healthcare professionals to find out whether promising treatments really work. Clinical trials conducted by NCRRN test the effectiveness of treatments of cognitive impairments that are caused by stroke or TBI.

Who is eligible to participate in the NCRRN Patient Registry?
People eligible to participate in the Patient Registry include those age 16 years or older who have sustained a stroke or TBI. Those with co-existing psychiatric or other neurological conditions may not be eligible to participate.

Who is eligible to participate in a particular clinical trial?
Members of the Patient registry are only invited to participate when they meet the specific eligibility requirements of each study. For this reason, some registry participants may be called to participate in several clinical trials, whereas other participants may never be called.

Why should I participate in a clinical trial?
Potential benefits include treatment by leading clinical researchers, access to therapeutic interventions not widely available, continuation of therapy after your insurance benefits have been exhausted, close monitoring of your health status, and the potential for improved quality of life. You can also help improve treatments that are given to future patients.

How do patients participate in a clinical trial?
If you are enrolled in the Patient Registry and you meet the eligibility criteria for a particular trial, the Registry Coordinator's office will call you to discuss the study and obtain your permission to have a member of the research team contact you. Then a member of the research team will meet with you and your family to describe the clinical trial and obtain your consent to participate. The informed consent process provides you with more detailed information including: what treatments are involved, time commitments, risks and benefits, and how confidentiality will be insured. Remember as a member of the Patient Registry, you are under no obligation to participate at any time. Only you can decide if a clinical trial is the appropriate choice for you.

How is confidentiality insured?
Many steps are taken to safeguard confidentiality. Access to the Patient Registry is restricted to researchers of projects that are approved by oversight committees and that are conducted under the direction of NCRRN. If you would like additional information about the Patient Registry or NCRRN, please contact Adelyn Brecher, the Database Coordinator, at (215) 456-9985 or Myrna F. Schwartz, PhD, the Director of the Patient Registry project, at (215) 456-5921.