GETTING YOU THROUGH THE RESEARCH REVIEW COMMITTEE

Avoid these common problems with Research Review Committee submissions!

- The study is closely related to, or based on, a submitted grant application, but the grant is not attached to the application.
- The study is closely related to another study that is already IRB approved (it may be appropriate to amend the existing protocol).
- Co-investigators, Dr. Gans, or Dr. DeLuca were asked to sign the application at the last minute (they need time to look over and perhaps discuss the application with you or other staff).
- Application was brought to Dr. Barrett for her to sign as Chair of the RRC, but the RRC has not yet reviewed and approved the study.
- The study needs to start in less than three months' time (allow at least three months for processing and approval)
- The study requirements for participant recruitment exceed available resources or time available.
- Consent form is filled out carelessly (page formatting is disrupted; filler material was left in).
- RRC presentation wasn't prepared or rehearsed to be both informative AND concise.
- Mentor or co-investigators with vital knowledge didn't attend RRC meeting, and some RRC questions could not be addressed.

SUBMISSION CHECKLIST

PI CHECKLIST FOR SUBMITTING A RESEARCH APPLICATION

☐ **Initial Submission Includes:**
- ✓ IRB Initial Application Consent form (if consenting subjects)
- ✓ HIPPA and NOPP form (if consenting subjects)
- ✓ HIPAA Waiver form (ie. chart review studies)
- ✓ Research Proposal Outline/Protocol
- ✓ CITI Course Certificate(s) for all investigators on the study protocol
- ✓ Copy of Grant (for grant funded study)

☐ **Determine the Review Category of your project** (*the final determination will be made by the IRB; see Attachment A, Section I for instructions and Attachment B, pages 1 and 3 for citations).*

☐ **Write your Proposal.**

☐ **Fill out the Initial Application form and obtain the following signatures:** Principal Investigator, Co-Investigators, study staff, Lab Director, Dr. Gans (KIR personnel on the project) and Dr. DeLuca (KF personnel on the project)

☐ **If your project falls under either the Full Board or Expedited category, prepare a Consent Form**. *See Attachment A, Section II.A.4 for instructions and Attachment B, pages 5-7, for federal regulations pertaining to informed consent.*

☐ **Research Review Committee (RRC)** – Unfunded study protocols will be reviewed by this committee. Provide comments from a researcher other than the mentor.

☐ **MRI Study Protocols** – Requires MRI Committee to review prior to the RRC and IRB

☐ **For Expedited and Full Review protocols** submit your application to the IRB Coordinator or Assistant Coordinator (see forms for number of copies)

☐ **Submit hard and electronic copy of your entire application via email** Microsoft Word format; submit your application to the IRB Coordinator or Assistant Coordinator (see forms for number of copies)

☐ **Read carefully the document describing Responsibilities of Investigators and retain a copy for your files** (see Attachment C).

☐ **The PI is required to attend the Research Review Committee and IRB meetings at which your protocol is to be reviewed.** You may appoint a co-investigator to represent you.

☐ **Collaborative Institutional Training Initiative (CITI)** and **UMDNJ HIPAA certification** All members of the study team are required to submit certification.
CITI Course: www.citiprogram.org
UMDNJ HIPAA course:
http://www.umdnj.edu/complweb/forms/forms_02webctnonumdnj.htm

IRB Coordinator: Malica Dock, B.A.
Phone: 973.243.6972 mdock@kesslerfoundation.org

EXPEDITED, EXEMPT, OR FULL?

ATTACHMENT A

I. INSTRUCTIONS FOR DETERMINING REVIEW CATEGORY OF APPLICATION

The Institutional Review Board (IRB) serving Kessler Foundation is required by federal and institutional regulations to review all proposed research projects involving human participants prior to initiation of research.

Research is defined as "a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge".

Human subjects means "a living individual about whom an investigator ... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information...".

See CITATION 46.102 (d) and (f) for complete definitions *(Attachment B, page 2)*

REVIEW CATEGORY

Exempt Activities: Certain research projects, for example those involving human participants in educational settings or the study of existing data, may be considered exempt from IRB review. To avoid confusion, refer to the federal regulation cited below. An investigator requesting such exemption is still required to submit a complete application packet for review by the Research Committee and for verification of exempt status by the IRB. The cover form must point to the specific regulation that justifies the exemption from IRB review.

See CITATION 46.101(b) *(Attachment B, page 1)*

Expedited Activities: Research involving no more than minimal risk and in which human subject involvement is strictly defined may be eligible for an expedited IRB review. Refer to the CITATION listed below for a complete understanding of this category. An investigator requesting expedited review must submit a complete application packet for review by the Research Committee and for expedited approval by the IRB. The cover form must point to the specific regulation that justifies the expedited IRB review.

See CITATION 46.110 *(Attachment B, page 3)*

Full IRB Review: All research projects not covered by expedited or exempt activities must be reviewed by the Research Committee and the full Institutional Review Board at its monthly meeting.

II. INSTRUCTIONS FOR SUBMITTING A RESEARCH APPLICATION

A. SUBMITTAL REQUIREMENTS

1. For project under "**Full IRB Review**", the original and 14 copies of the research proposal are required for submittal to the committee. For protocols that can be categorized as "**Exempt**" or "**Expedited**" research activities, the original and 1 copy of the entire application packet should be submitted. In addition to the required hard copies, the entire packet (cover form, research protocol, and informed consent form) must be submitted in electronic format via email. This will allow accurate entry of the project into the research database.

2. All required forms are available on the IRB website

http://kesslerfoundation.org/researchcenter/institutionalreviewboard.php. Please call the IRB Office at973-243-6972 for any additional questions or concerns.

3. Be sure to complete all sections of the Initial Application Form. Incomplete forms will be returned to the principal investigator.

4. An informed consent form must be included in the application packet unless the project falls within the IRB Exempt category.

5. One "Project Approval Signature Form" (the last page(s) of the initial application form) is necessary for each facility at which the research project will be conducted. The signatories include:

   a) Department Directors: Directors whose departments (personnel/equipment/ space) would, in any way, be involved in the research project must be informed of the potential research project and indicate their approval by signing the form.

   b) Laboratory Director: If the project will be conducted in collaboration with a specific program within Kessler Foundation, appropriate signatures must be obtained:

   c) Chairperson, Research Committee (After approval by the Research Review Committee)

   d) Chief Medical Officer, KIR (all new PIs from KIR)

6. If desired, research applications may be reviewed for completeness by the IRB Coordinator prior to final submittal.

B. REVIEW PROCESS

Review of research applications is a two-stage process. Research protocols, if not funded by a pharmaceutical sponsor, are first reviewed by the Research Committee which determines the scientific integrity of the research methodology, then by the IRB to ensure that the rights and welfare of the human subjects are protected. The following procedures are used in the review process:

1. All research applications are due to the IRB Coordinator by 4:00 P.M. on the last second of each month.(See IRB deadlines and Meeting dates)

2. Research Committee review takes place on the first Tuesday of every month. The Principal Investigator presents the protocol to the Committee at the meeting and answers any questions before being excused from the meeting.

3. Upon review by the Research Committee, a protocol is either:

   a) Approved as it stands;
   b) Approved pending minor changes to the research methodology; or
   c) Tabled due to requirement for major revisions.

4. Depending on the outcome of the Research Committee Review, the following actions take place:

   a) If the protocol is approved as written, the Project Approval Signature Form is signed by the chairperson of the Research Committee and the application is forwarded to the Institutional Review Board for review of human subject issues.

   b) If **minor** changes are required, a memo is sent to the principal investigator outlining the necessary changes. In order to meet the particular monthly deadline for IRB review, the revised protocol requiring full committee review must be returned to the Chair of the

Research Committee or to the IRB Coordinator as soon as possible. If the changes are found to be adequate, the chairperson of the Research Committee signs the Project Approval Signature Form and the protocol is reviewed at the IRB meeting which takes place on the last Wednesday or Thursday of the month.

c) If **major** changes are required, a memo is sent to the principal investigator outlining the necessary changes. The revised protocol is then due by the last working day of the month for re-review at the next meeting of the Research Committee. If the changes are adequate, the Project Approval Signature Form is signed by the Chairperson of the Research Committee and the protocol is forwarded to the IRB for review. Otherwise, it is returned to the investigator for further work.

5. The IRB review may result in one of five courses of action:

a) *Approval*: A notification of approval is sent to the applicant within one week of the expedited IRB review (for exempt and expedited proposals) or one week of the IRB meeting (for full proposals).

b) *Approval pending minor revisions*: The Principal Investigator is apprised of the required changes via memo. Upon submission of the revised protocol, the revisions are approved by the IRB Chair. An approval notice is then sent to the PI.

c) *Approval with revisions and re-review by a subcommittee*: A memo is sent to the PI outlining the requested revisions. Upon receipt, these changes are forwarded to the designated subcommittee. When the subcommittee approves the protocol, an approval notice is sent to the PI.

d) *Project tabled due to major concerns regarding participant safety*: A letter is sent to the PI with the committee's review and recommendations requesting resubmission of a new application. The new application is due on the third Monday of the following month so that the protocol can be re-reviewed by the IRB.

e) *Disapproved*: A letter is sent to the PI requesting resubmission of a new application. This debriefing letter outlines the reasons why the application was disapproved and suggests that major principles of the protocol be changed for the application to be reconsidered.

EXEMPT ACTIVITIES

PROTECTION OF HUMAN SUBJECTS

CODE OF FEDERAL REGULATIONS

TITLE 45 PART 46.101(b)

EXEMPT ACTIVITIES

§ 46.101

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED ACTIVITIES

PROTECTION OF HUMAN SUBJECTS
CODE OF FEDERAL REGULATIONS
TITLE 45 PART 46.110

EXPEDITED ACTIVITIES

§ 46.110

Research activities involving no more than minimal risk *and* in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure.

(1) Collection of: hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection or excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

SAMPLE COVER LETTER

KESSLER
FOUNDATION
RESEARCH CENTER

1199 Pleasant Valley Way West Orange, NJ 07052-3390 973.324.3571 T 973.324.3516 F www.KesslerFoundation.org

To the IRB:

Enclosed please find one original and 14 copies of our IRB proposal entitled *Evaluation of the effectiveness and outcomes of a comprehensive, outpatient cognitive rehabilitation program.* The study procedures described within are part of the Cognitive Rehabilitation Program (CRP) of the Kessler Institute for Rehabilitation. Dr. Tremaine and I have long discussed examining the effectiveness and outcomes associated with the program and are seeking IRB approval for such.

Please note that this study is not a proposed, new intervention, but is an examination of what is considered standard clinical care for individuals enrolled in the CRP and is what participants will undergo regardless of their participation in the study. We are primarily asking them to allow us to use their de-identified data for research purposes. The only exception to this is the control participants, who will be asked to complete a series of questionnaires and brief cognitive test battery, despite not being enrolled in the CRP. However, as a benefit for doing so, they will be provided feedback as to their progress over the three month study period and be administered a brief, repeated neuropsychological evaluation.

Our colleague, Dr. X., read and commented on the study prior to this submission.

Should you require any further information, please do not hesitate to contact me. Thank you in advance for your time.

KESSLER
FOUNDATION
RESEARCH CENTER

1199 Pleasant Valley Way West Orange, NJ 07052-3390 973.324.3571 T 973.324.3516 F www.KesslerFoundation.org

To the IRB:

Enclosed please find one original and a copy of my IRB proposal entitled *Unemployment in Multiple Sclerosis (MS): The role of personality, coping, and health-related behaviors*, which is a study pending funding with the National Institutes of Health as part of a larger Mentored Patient Research Career Development Award (K23).

My colleague, Dr. Y, provided review and feedback on the proposal before this submission. A copy of his comments is attached.

Please also note that the title included on the consent form and brochure is a modified version of the study title. This was changed in hopes of reducing bias in part of potential participants.

Should you require any further information, please do not hesitate to contact me. Thank you in advance for your time.

SAMPLE
INITIAL
APPLICATION

KESSLER FOUNDATION RESEARCH CENTER
INSTITUTIONAL REVIEW BOARD

APPLICATION TO UNDERTAKE RESEARCH INVOLVING HUMAN PARTICIPANTS

IRB # *(for use by administrator)* –

Submission Date: *3/12/12*

Proposed Start Date of Project: *4/1/12*

Target Completion Date of Project (i.e. publication submission): *4/1/13*

Title of Proposed Project: *Evaluation of the effectiveness and outcomes of a comprehensive, outpatient cognitive rehabilitation program*

Description of Project: The objective of this study is to evaluate the effectiveness of the Cognitive Rehabilitation Program (CRP) at Kessler Institute for Rehabilitation (KIR) in improving cognition, ability to perform complex activities of daily living, psychological health, and overall quality of life in individuals with neurological insult and/or disease and concomitant cognitive dysfunction. More specifically, the aims of the proposed investigation are: (1) To determine whether CRP is effective in improving cognitive function among individuals who participate in a 12-week program; (2) To determine whether CRP is effective in improving functional outcomes upon discharge (e.g., employment, driving); and (3) To determine whether CRP is effective in improving overall quality of life, caregiver burden, psychological health, and awareness of cognitive deficits associated with one's injury or disease. These research aims will be addressed by identifying individuals who are referred for CRP by KIR staff. Individuals who decide to enroll in CRP (treatment group) and those that are either denied or self-deny treatment (control group) will undergo a comprehensive assessment examining their cognition, awareness and perception of deficits, community integration, productivity, psychological health, and overall quality of life at baseline and following a 12-week time period (or intervention period). It is anticipated that the findings of this investigation will also inform the CRP team as to the effectiveness of the program and outcomes associated with the intervention. More specifically, findings may reveal information as to: (1) who is most likely to benefit from cognitive retraining; (2) the components of the program that result in positive outcomes; and (3) areas of weakness in the protocol that may benefit from modification to ensure quality control and improve expected outcomes; the ultimate goal being improved quality of care and overall well-being of individuals with neurological insult and/or disease.

Principal Investigator (full name, degree): *Monique Tremaine, Ph.D & Lauren Strober, Ph.D.*

Contact Information for PI: *Monique Tremaine, Ph.D.*
1199 Pleasant Valley Way, West Orange NJ 07052 & 300 Executive Drive, Suite 70, West Orange NJ 07052
973-414-4713 & 973-324-8459
MTremaine@selectmedical.com & lstrober@kesslerfoundation.org

Percentage of time to be devoted to project: *5-10%*

_____ _____

Signature of principal investigator ***(required)***

Application To Undertake Research Involving Human Participants
(Initial IRB Application)

Full name, Degree	*Co-Investigator (Co-I) or Study Coordinator (SC)*	*Department or Institution*	*Phone no., ext. (include area code)*	*Email address*	*Signature (required)*
Lauren Strober PhD	Co-PI	Kessler Foundation	973-324-8459	lstrober@kesslerfoundation.org	
Olga Nikelshpur PhD	Co-PI	Kessler Foundation	973-324-8391	onikelshpur@kesslerfoundation.org	

I. Project Description ***(check all that applies):***

☐ Is part of a grant proposal that will be/has already been submitted to a funding agency?

Name of Funding Agency: _____

Grant Application Deadline Date:

Amount of Funding Requested: _____

Time Period of Funding: _____

Grant no.: *insert grant study number or indicate 'does not apply'*

I certify that the research protocols submitted to the IRB and to the funding agency identified above are identical. If the protocols submitted to the IRB and the funding agency are different, please explain.

Signature _____ Principal Investigator

☐ Is a dissertation proposal and has been approved by the dissertation committee

☐ Is a collaboration with another institution (IRB approvals for all collaborating institutions will be required)

indicate names of all collaborating institutions

☐ IRB approval copy *attached*, or provide explanation _____

☐ Pilot project

☐ Clinical trial

Pharmaceutical sponsor name: _____

Sponsor protocol no.: *insert sponsor study number or indicate 'does not apply'*

☐ Form 1572 copy *attached* (required for clinical research studies involving drugs or devices regulated by the FDA, investigator's agreement to perform the study according to applicable federal regulations)

☐ IND copy *attached* (Investigational New Drug filing with FDA)

☒ None of the above *provide a description of project*

II. IRB FEES – *a fee of $2500 may be applied* to all protocols reviewed by the Kessler Foundation Research Center IRB and is due once the protocol has been approved and the contract or grant has been finalized; continuing review fee of $750 will be applied annual. An exemption may be applied for through the IRB Administrator.

☐ Grant proposal for which an internal transfer of funds will be authorized (att. appropriate invoice memo)

☐ Industry sponsored study (att. appropriate invoice memo)

☒ Exemption - IRB fee does not apply, e.g. Federal grant, IRB fees are part of indirect costs
provide explanation

III. Type of Review Requested ***(check only one box)*:**

☐ EXEMPTION FROM FULL IRB REVIEW
45 CFR 46, SECTION 46.101(b)*
PARAGRAPH *cite paragraph reference of Federal Guidelines for certification of exempt status*

PARAGRAPH (9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subjects. COMPLETE FROM ATTACHMENT A

☒ EXPEDITED REVIEW
45 CFR 46, SECTION 46.110*
PARAGRAPH

☐ FULL IRB REVIEW

**See APPENDIX B for citation from the Code of Federal Regulations*

IV. Facility at which the Research is to be conducted (*check all that apply*):

☒ West Orange ☒ Saddle Brook
☐ Welkind ☒ Other *Chester*

V. Research Population *(check all that apply)*

☐ Amputee
☐ Chronic Fatigue Syndrome (CFS)
☒ Multiple Sclerosis (MS)
☐ Pain Management
☒ Traumatic Brain Injury (TBI)
☒ Other *brain tumor, epilepsy, MCI, anoxic brain injury*
☒ Cerebrovascular Accident-Stroke (CVA)
☐ Huntington's Disease (HD)
☐ Orthopedic (hip, knee replacement)
☒ Spinal Cord Injury (SCI)
☐ Healthy Volunteers

VI. Human subjects to be involved in the proposed research (*check all that apply*):

☐ Minors*
☒ Cognitively impaired
☐ Non-English speaking
☐ Prisoners
☐ Pregnant women
☐ Genetic material
☒ Minorities

**Minors - Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402(a)]. "Unemancipated minor" means a person under the age of 18 years who is unmarried and is not currently serving active duty in one of the military services of the United States of America, or someone for whom a guardian has been appointed pursuant to N.J.S.A. 3B:12-25 because of a finding of incompetence.*

VII. Recruitment process: *outline process for recruitment*

☐ Advertisements, brochures, flyers, website, letters (*ATTACHED*) – Attach if necessary

☐ Databases, hospital or clinic records (logbooks, schedules) – Notice of Privacy Practices (NOPP) Subject Certification FORM is required

☐ Word of mouth

☒ Other Referral by KIR staff to CRP

VIII. Study procedures (*check all that apply*):

☐ Invasive procedures
☐ Exposure to radiation
☐ None of the above
☐ Investigational drug or device*
☐ Questionnaire with sensitive information**

**Attach FDA approval and/or Letter of Indemnification, copy of form 1572*
*** "Sensitive information" is defined as information: 1) about personal use of alcohol, illegal drugs or other addictive products; 2) about the subject's sexual activities and orientation; 3) that could damage an individual's financial standing, employability, or reputation within the community; or 4) that could lead to social stigmatization or discrimination. The IRB must review and approve in advance any questionnaire that collects sensitive information from subjects enrolled in an IRB-approved study. Note: Sensitive information about a subject may be recorded as part of subject recruitment into a protocol, when such information has previously been approved by the IRB as part of the protocol's inclusion/exclusion criteria.*

IX. Conflict of Interest Statement *(refer to policy #5016)*

Do any of the investigators have a direct or indirect personal financial or other interest or advisory relationship to the sponsor, manufacturer or to the owner of any test article being used in this research? Yes ☐ No ☒

If yes, please explain _____

X. Certification of Study Team Members:

Starting January 2008, the Kessler Foundation Research Center's IRB has required that all participants in IRB-approved studies obtain certification by the Collaborative Institutional Training Initiative (CITI) by passing the CITI Course in the Protection of Human Research Subjects. Researchers should contact the IRB office for instructions on how to access the CITI web-based course. CITI certification is provided for a three year period; investigators will be reminded by CITI 90 days before their anniversary date and will be required to renew their certification at that time. For general information on the CITI program see: www.citiprogram.org

Beginning April 2003 the IRB has required that all participants in IRB-approved studies complete the UMDNJ Office of Ethics and Compliance course on the Health Insurance Portability and Accountability Act (HIPAA). Researchers should contact the IRB coordinator for instructions on how to obtain certification using this web-based course. HIPAA certification is valid for a three year period; investigators must be re-certified every 3 years. For information on the UMDNJ HIPAA course see: http://www.umdnj.edu/complweb/forms/forms_02webctnonumdnj.htm

☒ Training certifications for study team members – *ATTACHED*

XI. HIPAA

The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires authorization to be obtained from subjects prior to their participation in research. At Kessler Foundation Research Center an application (Authorization to Use and Disclose Protected Health Information for Research Purposes) needs to be reviewed an approval provided by the Privacy Officer.

☒ Application "Authorization To Use and Disclose Protected Health Information for Research Purposes" – *ATTACHED*
☐ Application "HIPAA Waiver of Authorization" – *ATTACHED*

PROJECT APPROVAL SIGNATURE FORM

PROTOCOL NUMBER *(for use by administrator):* ____-____-____

NAME OF PRINCIPAL INVESTIGATORS: Monique Tremaine, Ph.D & Lauren Strober, Ph.D.

PROJECT TITLE: Evaluation of the effectiveness and outcomes of a comprehensive, outpatient cognitive rehabilitation program.

BRIEF DESCRIPTION: *This is a prospective investigation examining the effectiveness and outcomes of the Cognitive Rehabilitation Program (CRP) and Kessler Institute for Rehabilitation (KIR). Individuals referred for CRP and who either decide to enroll or deny participation will undergo a comprehensive evaluation assessing their cognition, awareness and perception of deficits, community integration, productivity, psychological health, and overall quality of life at baseline and following a 12-week time period.*

PROJECT APPROVALS

NAME *(printed)*	SIGNATURE	DATE
**PRINCIPAL INVESTIGATOR		
**LABORATORY DIRECTOR *(if applicable)*		
Anna Barrett, M.D. *CHAIRPERSON, RESEARCH COMMITTEE *(or designee)*		
Richard Greene, M.D., Ph.D. *CHAIRPERSON, IRB *(or designee)*		
John DeLuca, PhD VICE PRESIDENT OF RESEARCH *(or designee)*		
Bruce Gans, M.D. ****CHIEF MEDICAL OFFICER, KIR(or designee)*		

* SIGNATURE REQUIRED for Exempt studies (Chair-IRB)

*SIGNATURE REQUIRED for all non-funded studies (Chair-RRC)
** SIGNATURES REQUIRED for all studies, PRIOR TO submission of the application to the IRB Office
***SIGNATURE REQUIRED for all new PIs from KIR, PRIOR TO submission of the application to the IRB Office

SAMPLE

FLYER

UMDNJ
University of Medicine & Dentistry of New Jersey
Protocol #:

Stony Brook University Medical Center
Protocol #:

Kessler Foundation Research Center
Protocol #:

Employment and multiple sclerosis (MS)

If you are:

- ✓ Diagnosed with definite multiple sclerosis (MS)
- ✓ Between the ages of 18 to 50
- ✓ Have no other neurological illness
- ✓ Are gainfully employed OR considering leaving the workforce...

You are invited to participate in a new study examining the factors associated with employment status in multiple sclerosis

What does it require?

One study visit consisting of approximately three hours to complete various self-report questionnaires and undergo a brief cognitive assessment battery

****You will be compensated for your participation****

For more information, please contact:

Lauren Strober, Ph.D.
Kessler Foundation Research Center
300 Executive Drive Suite 70
West Orange NJ 07052
(973) 324-8459

Principal Investigator: Lauren Strober, Ph.D.

RESEARCH PROPOSAL OUTLINE

OUTLINE FOR RESEARCH PROPOSALS

YOUR PROPOSAL SHOULD INCLUDE ALL OF THE INFORMATION THAT FOLLOWS.

1. ABSTRACT:

A half-page abstract should be prepared for the lay reader with a glossary of technical terms. All units of measurement should conform to the S.I. system (Système International d'Unités) of reporting with explanation as appropriate.

2. OBJECTIVE OF THE STUDY:

List the objectives in outline form to reduce wording and also in order of priority.

- *State briefly the reason for doing the study.*
- *What question(s) is the study designed to answer and why is the question being asked?*
- *If enough background information has been gathered (through an effective review of the literature) to allow prediction of results, then state hypotheses for the proposed research.*
- *If the study is prototypical or exploratory in nature, it is more appropriate to state objectives.*
- *Include references if appropriate.*

3. SIGNIFICANCE OF THE STUDY:

This section is a justification for undertaking the study.

- *Briefly explain the magnitude of the problem and why time and effort should be spent on this research.*
- *Provide supporting evidence for the practical or theoretical importance of the research by presenting an argument as to what the study is expected to contribute to the problem or to a certain body of knowledge.*

4. REVIEW OF THE LITERATURE:

Present only the most pertinent research studies supporting your argument and discuss only the highlights of the cited studies.

- *Outline the information in a logical sequence (chronologically, if applicable) to demonstrate a knowledge of previous research.*
- *Detail how previous research has not answered your specific research question nor tested your stated hypothesis.*
- *Point out any technical flaws detected in previous research.*
- *If any current studies overlap the problem in your proposal, show how your prospective research differs from these studies and how it will complement them.*
- *If little or no previous work can be found in the area of the proposed study, cite those studies most closely related to the proposed research.*

5. METHODOLOGY:

A. Participants

- *Give a brief description of the participants (sex, age, physical or mental status, and ethnicity), method of selection (random, stratified, convenience sample, etc.) and approximate number of participants to be studied in all experimental and control groups.*
- *Indicate the criteria for the selection of the proposed kinds and numbers of participants.*

- *If populations at special risk (children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons) are to be studied, provide the reason(s) for their inclusion.*
- *Specify population groups to be excluded (e.g., pregnant women).*
- *Provide details on how the sample size was determined and the likelihood of finding statistically significant results, if you can.*
- *If possible, provide an estimate of the magnitude of your experimental effect and the normal variation in your dependent measures. The Research Department will help you make these calculations, if needed.*
- *State, in adequate detail, any anticipated physical, mental, or emotional risk to the subjects and the degree of likelihood that it may occur. If no such risk is anticipated, state why this is so.*
- *Describe, in adequate detail, what measures will be taken to protect the confidentiality of the data to be obtained and the subjects' rights to privacy.*
- *Indicate and justify the type and/or amount of payment to subjects and controls. Provide copies of any advertisements to be used for subject recruitment.*
- *Informed consent (State whether it is planned to obtain informed consent from each subject of the research activity. If informed consent will be obtained, use Attachment D as the model. If it is not planned to do so, provide a thorough justification for its omission. (Note: Federal regulations provide that written informed consent be obtained from each subject of a research activity, but this requirement may be waived by the IRB under specific circumstances; see Attachment B, pages 6-8.)*

B. Research procedures

- *Concisely describe how the study will be conducted by elucidating the variables involved, units of measurement, measuring instruments or equipment, techniques and conditions as well as controls to be used.*
- *Indicate how data are to be gathered, recorded, stored, retrieved and used.*
- *If the study is to be conducted according to a detailed protocol of a pharmaceutical company or other outside agency, include a summary in this section and attach the full protocol as an appendix.*
- *If the study involves the use of an attitude scale, questionnaire, or structured interview, attach the text of such instruments as appendices.*
- *Drugs (provide specific information on proposed dosage levels and schedules. Include both the generic and commercial name of each drug and summarize available information on efficacy and side effects. If none is to be administered, enter this statement: "No drugs will be given.")*
- *Blood sampling (state the volume to be drawn on each occasion and the frequency of sampling from the same subject. If none is to be drawn, enter this statement: "No blood will be drawn.")*
- *Radioactive isotopes (give the identity and dose of each isotope. If none is to be administered, enter this statement: "No radioactive isotopes will be given.")*

C. Analysis

- *The statistical design to be used should be stated by name; for example, "a two-tailed, paired t-test at the 5 percent level of significance". Data should never be collected and then some statistical design found to fit the data - always fit the data to the pre-selected design.*
- *Briefly give the procedures for analyzing and synthesizing the data.*

6. WORK SCHEDULE:

This section pertains to the administrative planning for the project.

- *Give a brief estimate of the time requirements for each phase of the study. This information may be presented in a Gant Chart.*
- *Particular attention should be paid to the expected rate at which subjects will enter the study.*

7. COST ANALYSIS (BUDGET):

Prepare a budget for the proposed research project keeping in mind the various costs incurred: salaries of personnel; equipment and supplies; computer time for analysis of data or costs for a statistician to analyze the data; art work for illustrations; slides for presenting the findings; consultants; literature searches when computers are used for the search; reprints; travel locally or to national meetings; rental of space or renovation of rooms; and construction of equipment not commercially available. Also to be included in the budget are the total costs for overhead. Note: Neither the Research Committee nor the IRB approves funding.

8. PUBLICATION OF RESEARCH:

The investigator must also ensure that the research proposal includes:

- *A timeline on when the research paper will be published;*
- *The name of the journal to which it will be submitted; and*
- *A designation of primary and secondary authors as well as individuals to be acknowledged in the article.*

9. REFERENCES:

References cited should be listed in alphabetical order in standard medical reference format (Index Medicus). If the journal to which the investigator intends to submit the article requires references in another format this may be used instead.

SAMPLE RESEARCH PROPOSAL

1. ABSTRACT

Declines in cognition, quality of life, well-being, and overall functioning are common following neurological insult and/or disease. Efforts to improve the overall functioning and quality of life of such individuals are paramount. The Cognitive Rehabilitation Program (CRP) at the Kessler Institute for Rehabilitation (KIR) is a comprehensive rehabilitation outpatient program which utilizes a client/family centered, multidisciplinary rehabilitation team approach to maximize potential for independence in persons with cognitive deficits due to neurological insult or disease. The program is designed to serve the unique needs of individuals at different levels of severity and stages of recovery. The *traditional* cognitive rehabilitation group program serves a mildly to moderately impaired population with realistic goals of return to work or community functioning. The *fundamentals* cognitive rehabilitation group program serves a more severely impaired population with more acute family education and caregiver needs. Individual therapies are provided for both group participants and clients with specialized needs. Comprehensive cognitive rehabilitation programs such as CRP are commonly recommended for individuals with such injuries and associated impairments in cognition and/or functioning. However, the outcomes and effectiveness of such programs have not been extensively investigated to date. The purpose of the proposed investigation is to examine the outcomes among individuals enrolled in the CRP at KIR. Pre- and post-treatment evaluations of cognition, well-being, psychological health, community participation, quality of life, productivity, and caregiver burden will be conducted among individuals enrolled in the CRP and a comparable control group to determine the effectiveness of individuals' participation in this important program.

2. OBJECTIVE OF THE STUDY:

The objective of this study is to evaluate the effectiveness of the Cognitive Rehabilitation Program (CRP) at Kessler Institute for Rehabilitation (KIR) in improving cognition, psychological health, ability to perform complex activities of daily living, and overall quality of life in individuals with neurological insult and/or disease and concomitant cognitive dysfunction. To date, the cognitive and functional outcomes of this treatment program have not been extensively investigated in detail. Knowledge pertaining to such outcomes will help identify: (1) those who are most likely to benefit from cognitive retraining; (2) components of the program that result in positive outcomes, and; (3) areas of weakness in the protocol that may benefit from modification to ensure quality control and improve expected outcomes. In particular, the proposed investigation has the following specific aims:

Aim 1: Determine whether CRP is effective in improving cognitive function among the individuals who participate in a 12-week traditional program.

Aim 2: Determine whether CRP is effective in improving functional outcomes upon discharge (e.g., employment, driving).

Aim 3: Determine whether CRP is effective in improving overall quality of life, caregiver burden, psychological health, and awareness of cognitive deficits associated with one's injury or disease.

3. SIGNIFICANCE OF THE STUDY

Neurological injury and/or disease are a substantial concern. For instance, among the general population, approximately 1.7 million individuals sustain a traumatic brain injury (TBI)[1] and stroke occurs in an estimated 795,000 individuals each year.[2] Reports also suggest that there are nearly 12,000 new cases of spinal cord injuries (SCI) in the Unites States; [3] Finally, multiple sclerosis (MS) affects approximately 250,000 to 350,000 individuals in the United States with more than 10,000 new cases being reported each year.[4] Detriments in cognition, quality of life, well-being, and overall functioning are common following such neurological insult and/or disease. Cognitive impairments, including but not limited to those in attention, processing speed, memory, language, decision-making and reasoning frequently result in decreased independence, as they affect ability to perform such activities of daily living as management of medication regimen and handling personal finances, shopping, and driving among others. These deficits may also result in difficulty maintaining employment, increased financial, psychological, and physical burden on caregivers, and ultimately increased cost to society. Although non-pharmacological interventions are widely used in rehabilitation of such deficits, evidence base for the effectiveness of these interventions is limited, at best. The proposed investigation aims to examine the effectiveness and outcomes of an existing rehabilitation program for individuals who have sustained such injury and or illness and have documented cognitive, functional, and psychosocial impairments. While the specific aims are to examine the components and outcomes of the treatment, the overarching goal of the investigation is to better the lives of individuals seen in CRP.

4. REVIEW OF LITERATURE

General background and significance of the problem. Individuals who sustain a neurological insult and/or disease have been shown to have significant declines in overall quality of life, well-being, participation in home and community, productivity, and independent living. Specific functional changes following neurological insult or disease may include impairment in handling finances,[5] difficulty maintaining employment,[6] and returning to driving.[7] The majority of these detriments can be attributed to the cognitive, psychological, and physical symptoms associated with various neurological conditions. Depending on the nature of the neurological insult or disease, cognitive changes may include, but are not limited to, declines in attention/concentration, processing speed, memory, language, visual skills, or executive functioning. Additionally, psychological distress, particularly depression and anxiety are common among those with a neurological insult or disease. For instance, depression is reported in 10% to 77% of individuals with a TBI,[8] 27% to 54% of individuals with MS,[9] and 25% to 79% of individuals post-stroke.[10] While there are several immutable factors associated with one's illness, rehabilitation aimed at improving cognitive functioning (particularly the development of compensatory strategies), psychosocial functioning, awareness and appreciation of deficits, acceptance of one's condition, and overall well-being and psychological health in the face of illness or injury is purported to result in improved outcomes following neurological insult or disease.

Given this, rehabilitation programs have been designed and implemented to both improve physical and cognitive functions as well as psychological health, quality of life, and participation and re-integration into the community. In particular, the aim of rehabilitation is "to restore patients to their greatest potential and maximum independence, hopefully resulting in independent functioning, the return to their own home and participation in society."[11] While the research evaluating comprehensive rehabilitation programs such as provided by KIR is limited given several methodological concerns and known hurdles of clinical research, several reviews to date suggest that individuals who receive evidence-based cognitive rehabilitation treatment demonstrate better long-term outcomes as compared to those who are not treated.

Effects of rehabilitation on cognition in neurological conditions. Comprehensive reviews of hundreds of studies have demonstrated substantial evidence to support the use of cognitive rehabilitation in patients with stroke and TBI.[12,13] More specifically, Cicerone et al.'s (2005)[13] review of nearly 87 studies investigating various interventions targeting memory, attention, and functional communicational deficits suggested that individuals receiving cognitive rehabilitation have significantly better outcomes than those engaged in cognitive or psychosocial treatment, pseudotreatment, conventional rehabilitation programs, or no treatment. Additionally, while there were methodological issues in some of the studies investigated, Geusgens et al.'s (2007)[11] review of 41 studies examining the transfer of cognitive rehabilitation efforts to non-trained items, daily tasks, of daily living suggested that cognitive rehabilitation is beneficial. For brevity, a selected review of literature of the effectiveness of cognitive rehabilitation techniques in use with individuals of various etiologies is provided within.

Sohlberg et al. (2000) examined the effects of a structured, manualized, 24 hour, 10-week intervention aimed at rehabilitating attention function (Attention Process Training; APT) in a small sample of individuals with acquired brain injury.[14] Compared to placebo control, which involved 10 weeks of 1-hour sessions of psychotherapy, brain injury education, and relaxation techniques, participants in the active intervention group exhibited improvement in memory and attention on both objective neuropsychological measures and subjective self-report questionnaires assessing their cognitive functions. However, participants in the placebo control group reported improvements in psychosocial functioning. These findings underscore the importance of engaging the participants in the multimodal intervention such as CRP. Cicerone (2002) evaluated the effectiveness of intervention in rehabilitation of attention deficits in a small sample of individuals with mild traumatic brain injury (mTBI).[15] The study compared active intervention group with the demographics- and time post-injury-matched controls recruited from individuals referred for treatment but unable to enter the program for financial or geographic reasons. The treatment was administered during weekly one hour sessions over a period of 11-27 weeks. During initial sessions participants received feedback regarding the nature of their attention deficit and education about the need for treatment as well as the relationship between various components of attention and the relationship between attention deficits and subjective sense of fatigue and irritability. In subsequent sessions participants received instruction in use of strategies aimed at efficient allocation of attention, such as rehearsal, self-pacing, anticipating demands, and verbal mediation. Feedback was provided with regard to pacing and the number of errors. The results of the study showed significantly greater improvement on objective neuropsychological measures of attention and reduction in subjectively perceived attention deficits in treatment group compared to control group.

Other domains of cognition have also shown improvement following intervention. Deficits in executive functioning, including initiating the use of strategy, are among the most common consequences of TBI and frequently limit the utility of compensatory memory techniques acquired through rehabilitation. More specifically, Ownsworth & McFarland (1999) examined the effects of the instructional program directed at improving the use of compensatory memory strategy (i.e. diary use) in a sample of individuals with chronic acquired brain injury.[16] Results suggested that the active treatment group, which was trained in effective diary use benefitted to a greater extent from this commonly used compensatory strategy than the comparison group who were asked to use the diary but did not receive such instruction. The same technique was evaluated by Lawson and Rice (1989) in improving the initiation of strategy use in a case study of closed head injury.[17] They found that their participant exhibited increased use of acquired memorization strategies immediately and six months post-treatment and showed evidence of sustained improvement on the functional memory tasks. Further, the investigators reported increased spontaneous utilization of other strategies not specifically taught during the program.

Finally, Levine et al. (2000) investigated the effectiveness of the goal management training (GMT) as compared to a non-cognitive skill training program (motor skills training; MST) in a sample of individuals with chronic moderate TBI and in a case study of an individual recently recovered from encephalitis.[18] The training was administered in a single one-hour session. The investigators reported a significant improvement in accuracy on tests of attention and categorization in the GMT group whereas the MST group exhibited an insignificant reduction in accuracy on these tasks. Furthermore, the GMT group was found to spend more time working on a given task after the training, which may be interpreted as an improvement in self-monitoring and increased attention to the task; participants who were assigned to the MST program spent less time on the tasks after the training. Further investigation of this program when utilized to improve an instrumental activity of daily living (IADL) (i.e., meal preparation) in a post-encephalitic patient found that the program was beneficial in rehabilitating functional skills in real life situations. The patient reported a significant improvement in this functional skill that was maintained to a limited extent at three months post-treatment.

In sum, this brief review suggests that cognitive interventions, particularly those aimed at attention and memory functions, two of the most common cognitive deficits associated with neurological insult and/or disease, hold great promise in rehabilitating those who sustain such injury or disease.

Effects of rehabilitation on functional outcomes, quality of life, integration, caregiver burden, and psychological functioning. While improvement in cognitive functioning is a clear goal of cognitive rehabilitation programs such as KIR's, it is not the sole priority. Several outcomes are as vitally important. These include improvements in functional outcomes (e.g., employment, driving), community integration, psychological health, and overall quality of life. Additionally, among individuals with more severe impairments, improvements in instrumental activities of daily living (IADLs), awareness of deficits, and reduction in caregiver burden are also a priority. Burden has been reported among caregivers' of individuals with chronic neurological disease, including significant effects of physical, social, and emotional burden.[19] Again, while the

literature is limited with regard to the effectiveness of such programs on these outcomes there is some evidence to suggest that cognitive rehabilitation and associated interventions can result in improved outcomes. A brief review is provided within.

Return to work (RTW) is considered one of the most important goals of rehabilitation. It is estimated that between 18% and 88% of individuals with a TBI are unemployed following injury[20] and rates of RTW following a stroke varies from 4% to 75%.[21] Predictors of RTW following TBI include psychosocial impairment, cognitive impairment, significant physical disability, and alcohol use.[22] Many suggest that these impairments are more predictive of RTW than the severity of injury itself. Evidence also suggests that there is strong correlation between one's self-awareness and positive vocational outcomes.[23] Thus, enhancing one's awareness of their deficits, developing compensatory strategies, and improving one's psychosocial functioning is likely to result in better outcomes with regard to RTW. Additionally, more specific interventions of vocational rehabilitation such as worksite assessment, onsite job coaching, work trial assessment, vocational counseling, intensive individualized work skill rehabilitation, placement in sheltered workshops, and assisted placement with transitional support are also likely to better indentify, monitor and improve one's skills that are necessary for reintegration into the workforce. Studies have shown that those engaged in such vocational intervention have a sooner RTW than those who do not.[24]

Instrumental activities of daily living (IADL) are also a common target of rehabilitation. In a large sample of 2,832 elderly individuals, IADLs and cognition were assessed following their involvement in a memory training intervention, reasoning training intervention, processing speed training intervention, or control condition.[25] It was found that individuals in all training groups reported less difficulty than controls in completing their IADLs nearly five years later; though this was only statistically significant among those enrolled in the reasoning training intervention. With regard to cognitive functioning, immediate improvements were found in the specific cognitive ability trained and following booster sessions at 11 and 35 months, these effects were found to be maintained five years later.

With regard to community integration, it has been shown that psychological factors such as depression and anger and impaired social pragmatics affect one's ability to reintegrate into the community among individuals with a TBI.[26] Evidence suggests that interventions aimed at addressing the latter are effective in improving the social functioning of individuals following brain injury. More specifically, interventions involving interpersonal process recall, social communication skills, and emotion perception training have all been shown to be beneficial.[27]

Finally, improvements in individual's quality of life and reductions in caregiver burden have been shown among individuals with mild Alzheimer's disease who underwent a multidisciplinary rehabilitation program consisting of physiotherapy, physical training, memory retraining, cognitive stimulation, and expressive activities. Additionally, depression was found to decline for both patients and their caregivers.[28]

5. METHODOLOGY

A. Participants

Participants will be recruited from the pool of individuals seen for either inpatient or outpatient neuropsychological evaluation at all campuses of KIR who are subsequently referred to participate in individual and/or group cognitive rehabilitation given an impairment in cognition and/or function. Based on current standard practices, approximately 18 to 20 patients per month are referred for CRP. Given this, we estimate a pool of approximately 216 to 240 participants to recruit from over the course of 12 months. Of this pool, it is anticipated that nearly half will either be denied insurance benefits to participate in the program or decline participation. Such individuals will be asked about their willingness to serve as a control group to the intervention and will undergo a follow-up evaluation (described below) and be provided a written report of their progress over the three month period as part of their participation. **Controls will be identified as either a control to the Traditional program or Fundamentals program based on their initial CRP referral.** Assuming an 80% response rate, approximately 173 to 192 participants may be enrolled in the study. Kessler Institute for Rehabilitation serves an ethnically diverse population with a broad range of socio-economic status and our sample will be representative of this population.

Inclusion Criteria: participants will be included in the study if they meet the following criteria:

1. Age 18 or older
2. Have a documented neurological insult and/or disease, including but not limited to, traumatic brain injury, spinal cord injury, stroke, multiple sclerosis, tumor resection, anoxia related brain injury, post-infection encephalopathy.
3. Have a cognitive and/or functional impairment documented by neuropsychological evaluation
4. English proficiency

Exclusion Criteria: individuals will not be eligible to participate in the study if the following criteria are met:

1. Cognitive impairment that would preclude participation even in the *fundamentals* program.

Risks to subjects:

Emotional Risks: Although participation in cognitive rehabilitation may result in some degree of emotional discomfort for the participants, all care will be taken to treat every participant in a sensitive manner to prevent any emotional or psychological trauma. Participants are seen by highly trained neuropsychologists, rehabilitation psychologists, speech and language therapists, and vocational rehabilitation specialists who understand emotional sequelae associated with neurological insult or disease and psychological challenges that may arise in the process of rehabilitation. In addition, participants will be allowed to withdraw their agreement to participate in the study at any time.

Inclusion of vulnerable participants: Although our sample consists of cognitively compromised individuals, particularly those whose cognitive impairment was severe enough to necessitate enrollment in the *fundamentals* program, all efforts will be made to assure their consent, safety, and ultimate care while participating in the program. Additionally, a requirement of the *fundamentals* program is 50% family participation. As such, continued consultation with designated health care proxies will be sought in all efforts to maintain patient's autonomy, diginity, and well-being.

Protection of Confidentiality

All members of the team have received HIPAA training and will strictly abide by the HIPAA laws to protect participants' confidentiality. Participant's information will not be discussed outside of the research team. All data will be kept in locked cabinets and password-protected, secure computer files and will not leave the premises of Kessler Institute for Rehabilitation and Kessler Foundation Research Center. In the datasets, participants will be identified only by assigned ID numbers. A separate password-protected computer file will contain their identifying information.

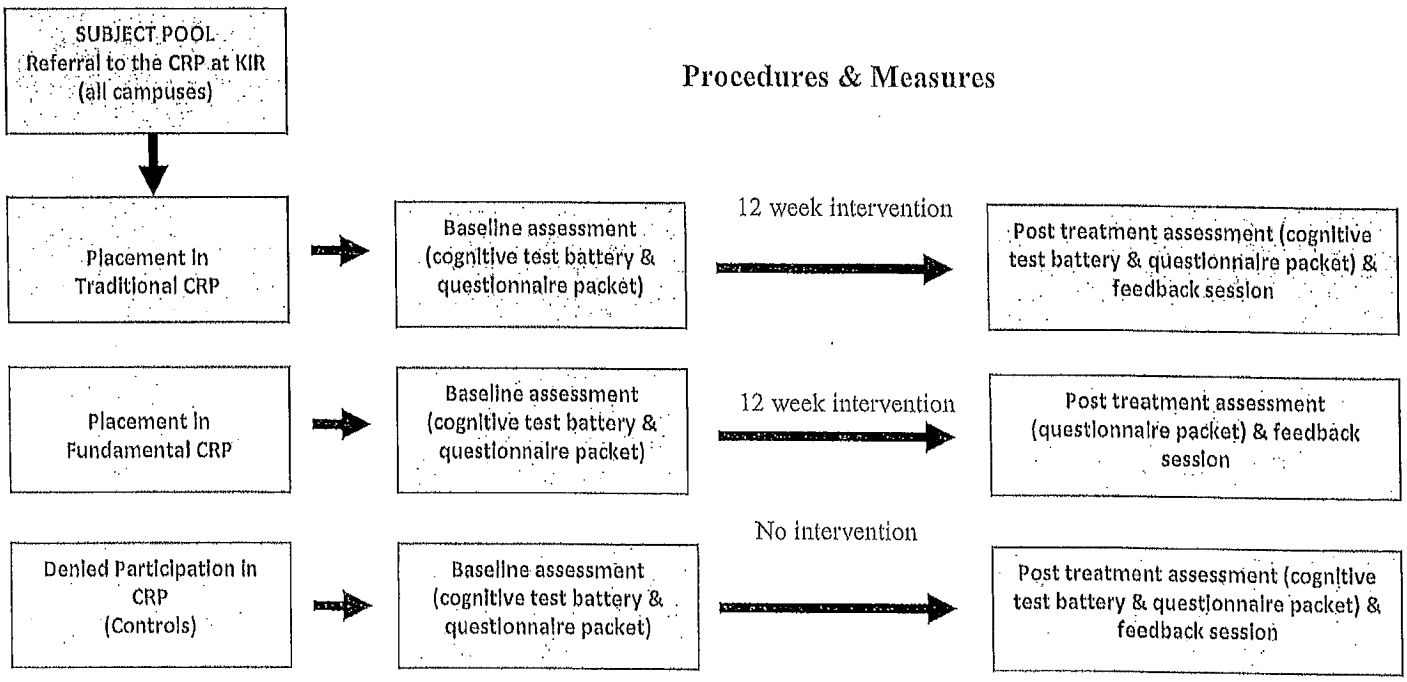
Informed consent procedure

Signed IRB approved informed consent will be obtained from all prospective participants who were deemed capable of providing such consent prior to participation in the study. Those not capable of providing informed consent (such as in the case of the *fundamentals* program) will be verbally assented (with written documentation) and only enrolled in the study if their designated health care proxy gives IRB approved written consent on behalf of the participant.

B. Research Procedures.

Below is a schematic outlining the procedures described below.

Participants



Procedure and measures:

Participants enrolled in the ***traditional*** **CRP and** ***traditional*** **CRP control participants** will complete the following questionnaires at **baseline** and **12 week follow-up**:

Domain	**Measure**
History & Background Information Form (Including Goal Identification & Satisfaction)	**Personal background information, occupational status, driving status, goal planning, satisfaction with program**
Self-report of cognitive impairment	Frontal System Behavioral Scales (self & other)
Awareness of cognitive deficits	Awareness Questionnaire (self & other) Perceived Deficits Questionnaire
Activities of daily living	The Functional Behavior Profile (self and other) Community Integration Questionnaire
Quality of life	Satisfaction with Life Scale Quality of Life after Brain Injury
Psychological functioning	Beck Depression Inventory-Second Edition (BDI-II) Beck Anxiety Inventory (BAI)

Participants enrolled in the **fundamental CRP and** ***fundamentals*** **control participants** will complete the following questionnaires at **baseline** and **12 week follow-up**:

Domain	**Measure**
History & Background Information Form (Including Goal Identification & Satisfaction)	**Personal background information, occupational status, driving status, goal planning, satisfaction with program**
Self-report of cognitive impairment	Frontal System Behavioral Scales
Awareness of cognitive deficits	Awareness Questionnaire
Activities of daily living	Activity card sort
Quality of life	Satisfaction with Life Scale
Psychological functioning	Beck Depression Inventory-Second Edition (BDI-II) Beck Anxiety Inventory (BAI)
Caregiver burden	Caregiver Burden Interview

Participants who have completed their neuropsychological evaluation at KIR will have already received the following cognitive measures as part a comprehensive neuropsychological evaluation. In the interest of eliminating practice effects and burden, their data will be accessed retroactively from their clinical file per IRB approval. Individuals who underwent their neuropsychological evaluation more than three months prior to their enrollment in CRP or baseline evaluation (if enrolled as a control), will be re-administered the cognitive tests to obtain the most current estimate of their cognitive functioning. The measures consist of:

Cognitive domain	**Measure**
Estimated premorbid intelligence	Wechsler Test of Adult Reading (WTAR) Wechsler Adult Intelligence Test-Fourth Edition (WAIS-IV)

Language	Boston Naming Test Delis Kaplan Executive Functioning Systems (DKEFS) Verbal fluency
Attention	WAIS-IV Digit Span WAIS-IV Arithmetic
Information Processing Speed	WAIS-IV Coding WAIS-IV Symbol Search
Visual Spatial Skills	WAIS-IV Block Design Rey Osterrieth Complex Figure Test (RCFT) Copy
Verbal Learning & Memory	California Verbal Learning Test-Second Edition (CVLT-II)
Visual Learning & Memory	RCFT Immediate and delayed recall
Executive Functioning	DKEFS Trail Making Test DKEFS Color Word Interference DKEFS Verbal Fluency WAIS-IV Similarities WAIS-IV Matrix Reasoning

Participants will then receive 12 weeks of individual and/or group cognitive rehabilitation if enrolled in CRP or maintain care as usual if enrolled in the control group.

The CRP at KIR is a comprehensive neuropsychologically driven outpatient program which utilizes a client /family centered, multidisciplinary rehabilitation team approach to maximize potential for independence in persons with cognitive deficits due to acquired and traumatic brain injuries. Specific goals may include return to independent living, return to productive work or vocational activity, and to promote quality of life within the home and community. The program is designed to serve the unique needs of individuals at different levels of severity and stages of recovery. Our *traditional* program serves a mildly to moderately impaired population with realistic goals of return to work or community functioning. The *fundamentals* cognitive rehabilitation group program serves a more severely impaired population with more acute family education and care giving needs. Individual therapies are provided for both group participants and clients with specialized needs. The appropriate distribution of group and individual sessions is determined on the basis of a comprehensive neuropsychological evaluation as well as initial evaluation by the rehabilitation staff.

The rehabilitation team includes neuropsychologists, case management, occupational therapists, speech language pathologists, certified rehabilitation counselors, and vocational therapists. Client and caregiver meetings are held on a routine basis, led by a neuropsychologist and attended by a CRP case manager and CRP team members, to communicate goals, progress and discharge planning. Conceptually, all programs serve to: (1) augment the natural healing process and promote the re-emergence of cognitive skills; and (2) provide skilled training in adaptive strategies and problem solving across naturalistic and functional settings. As such, the content of the program is intended to promote recovery of basic cognitive functions in the context of simulated naturalistic exercises. The program model utilizes both group and individual settings in order to deliver relevant treatment, integrating various stages of recovery to enhance awareness of deficit and promote mentorship and peer support.

A. Cognitive Rehabilitation (*Traditional* Program)

The majority of participants will be enrolled in the *traditional* group cognitive rehabilitation program intended for persons with mild to moderate impairments. Initial treatment follows a psychoeducational/cognitive skills training protocol. Group modules include: Goal Setting (self generation and maintenance of functional short term goals); Reasoning and Problem Solving, Cognitive Strategy Development, Personal Growth and Adjustment, Communications and Relations, and Brain Injury Education. Clients are assigned to group modules based on individual needs. Throughout each group, the focus is on improving arousal, attention, conceptualization, reasoning skills, capacity for generalizing learning to novel situations and executive functioning. Group treatment also emphasizes behavior management, pragmatic/awareness skills enhancement, and ultimately, long-term psychosocial adjustment and redefinition of self within the context of the injury. The group program runs 3 days per week for 5 hours per day. Participation varies based on clinical need. As a client progresses through the program, treatment focus is modified toward reintegration into community and vocational settings. While most patients continue to attend 3 days per week, their schedule is modified to incorporate functional skills groups which meet 2 days per week/5 hours per day. These groups are highly individualized and include treatments that simulate targeted community, school and work environments. Average length of stay in the group program ranges from 3 to 6 months. Individual length of treatment varies depending on client need and financial/managed care realities. Initially, treatment is focused on maximizing functional independence at a level within the home, family adjustment and family skills training, as well as to provide resources and long term planning strategies for patients who may not achieve independence.

B. Cognitive Rehabilitation (*Fundamentals* Program)

The fundamental cognitive rehabilitation program serves clients with more severe impairments. Individuals with a neurological insult or disease may experience severe cognitive and memory impairment, behavioral dysregulation, and heightened caregiver dependency. A family member or caregiver is therefore encouraged to attend a minimum of 50% of the treatment sessions to promote generalizability of cognitive strategies, to provide community resources and to instruct families in management of challenging behaviors. Group modules consist of Cognitive Skills (i.e., orientation, attention, memory, executive functioning, visual/auditory processing); Relational Skills (expressive and receptive language, pragmatics); Daily Living Skills, and Behavioral Management. Patients are assigned to group modules based on individual needs. Within each group, the focus is on caregiver training, environmental and task restructuring, compensatory skills training, and environmental safety and supervision evaluation. Ultimate goals are to promote the client's best level of functioning in daily living skills. Attention is paid to behavior management, improving insight and awareness and facilitating realistic expectations and long-term psychosocial adjustment. The group program runs two days per week for two hours per day, for duration of 12 weeks. Participation varies based on clinical need.

C. Individual Cognitive Rehabilitation.

Most participants will participate in individual treatment regardless of group placement. Individual therapy provides an opportunity to target and refine remaining treatment goals as a client transitions out of the group therapy program. Individual therapy may also be recommended

from the start of treatment as it can be geared toward clients that require therapy focusing on higher level cognitive skills for work/school and complex independent activities of daily living (IADL). Appropriate clients are scheduled for one to three hours per week in individual- and cognitively-oriented occupational, speech, and vocational therapies targeted at specific problem areas that are best remediated on an individual basis. Such therapies may include remediation of cognitive linguistic, visual spatial, or individual vocational/community re-integration needs. For clients participating in the *fundamentals* CRP, individual therapy provides an opportunity for intensive IADL training and to promote maximum independence. In addition, individual treatment may include intensive caregiver training for improving client's safety and independence with basic everyday tasks. Individual treatment is also provided for those clients with milder injuries who would not otherwise benefit from group programming.

Following 12 weeks of CRP (or care as usual for the controls), participants referred to the *traditional* CRP will complete the following brief cognitive battery:

Cognitive domain	Measure
Language	Delis Kaplan Executive Functioning Systems (DKEFS) Verbal fluency (Alternate form)
Attention	WAIS-IV Digit Span
Information Processing Speed	WAIS-IV Coding WAIS-IV Symbol Search
Verbal Learning & Memory	California Verbal Learning Test-Second Edition (CVLT-II) (Alternate form)
Executive Functioning	DKEFS Trail Making Test

As part of standard clinical care, participants will receive a written report documenting their progress over the three months. Clinical staff will provide this during a feedback session with the participant and/or their family. Controls will also receive feedback as to their progress over the 12 week period.

Data will be entered into the password protected datasets accessible only by the members of the research team.

Cost of Treatment: participants will not incur any additional costs associated with their participation in the study.

Data Analysis: data will be analyzed using Predictive Analytic Software (PASW, formerly known as SPSS) version 18. Data will be subjected to correlational and linear regression analyses to establish cognitive and functional correlates and predictors of positive treatment outcomes and repeated measures ANOVA to determine the effects of cognitive intervention on various constructs examined over the course the 12 week period. More specifically, the following analyses will be conducted to address the following study aims and related hypotheses.

Power Analysis: It is estimated that 173-192 subjects will be eligible for the study based on census data from CRP. Taking a conservative estimate, we predict that 175 individuals will be enrolled. Based on these numbers we will certainly have a large enough sample to

conduct the primary analyses (Repeated measures ANOVA). In particular, in setting α at 0.05, we can achieve power of 0.80 and obtain a medium effect size (f = 0.25) with a minimum sample size of 34. However, with regard to regression analyses, to obtain a power of .80 with α at 0.05, we would need an approximant sample of 172 to obtain a small to medium effect size (f =.10) when using six predictors in the model.

Aim1: Determine whether CRP is effective in improving cognitive function among the individuals who participate in a 12-week traditional program.

Hypothesis 1: Individuals enrolled in the traditional CRP will demonstrate an improvement in their cognitive functioning compared to controls

Proposed analyses: Two factor repeated measures ANOVA will be employed with cognitive test variables as the primary outcome variables and time and group as independent factors.

Aim 2: Determine whether CRP is effective in improving functional outcomes upon discharge (e.g., employment, driving).

Hypothesis 2: Individuals enrolled in the CRP will demonstrate greater improvements in their functioning following a 12 week period than controls.

Proposed analyses: Initial Chi-square analyses will conducted to determine whether a greater proportion of individuals enrolled in CRP have returned to work or driving. Subsequent logistic regression analyses will be conducted to determine which factors at baseline and follow-up may be most accountable for improvement in functional outcomes.

Aim 3: Determine whether CRP is effective in improving overall quality of life, caregiver burden, psychological health, and awareness of cognitive deficits associated with one's injury or disease.

Hypothesis 3: Individuals enrolled in CRP will exhibit an improvement in their overall quality of life, psychological health, and awareness of deficits. Additionally, caregivers of participants in the fundamentals group will demonstrate a reduction in caregiver burden.

Proposed analyses: Two factor repeated measures ANOVA will be employed with quality of life, psychological factors, awareness measures, and caregiver burden as primary outcome variables and time and group and independent factors.

Work Schedule:

Study Initiation: April 2012

Screening: 18-20 participants per month

Recruitment: 14-16 participants per month

End recruitment: April 2013

Data Analysis: March 2013-May 2013 - March 2013

Publication: June 2013 or later.

Cost Analysis: No additional cost is anticipated as the study encompasses the already established treatment protocol that participants would have engaged in whether or not they participated in the study.

Publication of Research: We expect that this study will produce scientifically significant results. Preliminary results will be ready for publication and presentation at the professional conferences upon projected completion of data analyses in March 2013.

References

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HIPAA & NOPP TEMPLATES

KESSLER FOUNDATION RESEARCH CENTER

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Sponsor: [Name Of Funding Organization And Grant No.]

Investigator-Name, Address and Phone No:

Study Title and Number: [study name and IRB no.]

Research, Privacy, and the new Health Insurance Portability and Accountability Act (HIPAA)

1. *What is the purpose of this form?*

We would like to use your health information for research. This information includes data that identifies you during the process of data collection. The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires us to get your approval to use health information about you that identifies individuals. This approval is called an Authorization.

By signing this Authorization form, you are giving permission for the use of your protected health information for research purposes. This information may include data that identifies you. Please carefully review the information below. If you agree that we can use your protected health information, you must sign and date this form to give your approval.

2. *What protected health information do the researchers want to use?*

The researchers want to copy and use the portions of your medical record that will be needed for their research. If you participate in this research study, information that will be used and/or released may include the following: [state what protected health information will be used/disclosed for the study (use common terminology) - you must include all protected health information to be accessed for the research study]. ***[Example - REMOVE if not applicable]*** We will use your information from your medical records, results of laboratory tests and case report forms, both clinical and research observations made while you take part in the research. Clinical information collected will include any new diagnoses, reported symptoms, changes in body appearance, how well you feel physically and emotionally, what medications you are prescribed and how many times you have missed taking your prescribed study medication, and any problems you may be having that are related to taking your study medication. Blood will be collected at each study visit and the results of those tests will also be recorded.

3. *Why do the researchers want my protected health information?*

In enacting HIPAA, Congress mandated the establishment of Federal standards for the privacy of individually identifiable health information. The Privacy Rule establishes

safeguards to protect the confidentiality of medical information and provides guidelines for research organizations such as Kessler Foundation Research Center to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. We believe that the protection of identified medical information will facilitate medical research because research participants know that their information is protected in accordance with the Privacy Rule.

4. ***Who may see your protected health information for this research study:***

Your health information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. We may share this information with others who are in charge of the research, who pay for or work with us on the research or those who make sure that we do this research properly. This authorization form will explain how your protected medical information will be used and shared (disclosed) in this research study.

To meet regulations or for reasons related to this study, the study team may share a copy of this approval form and records that identify you with the following people:

- The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
- Auditors from this institution (the Kessler Foundation Research Center), the sponsor or government agencies responsible for the conduct of research to make sure we are following regulations, policies, and study plans.
- Members of the study team, including [insert study team member names]
- If applicable, the Finance Dept. of the Kessler Foundation, who will prepare subject payments for participation in the study
- Other organizations: [list all study-specific agencies, divisions, companies, labs, etc. who may see research data or PHI-if none, state 'NONE' or select/remove from following]

  FDA (United States Food and Drug Administration) - the government agency that reviews all research information for approval of new drugs and treatments for the public. ***[REMOVE if not applicable]***
  DHHS (Department of Health and Human Services) - the government agency that oversees and funds research involving human beings. ***[REMOVE if not applicable]***

You have the right to look at your study information at the study doctor's office and to ask (in writing) for corrections of any of your information that is wrong. [Language for blinded study-REMOVE if not applicable] Because this is a blinded study (neither you nor your doctor will know if you are receiving study drug or placebo, a sugar pill), you may not see your study information or request corrections to your study information until the study is completed.

We will make every effort to keep information we learn about you private. However, research involves gathering, recording, and transferring information that needs to be verified and other people may need to see the information (these others are listed on this form). Some of these people may share your health information with someone else. If they do, the same laws that the hospital, clinic or institution must obey to protect your health information may not apply to these other people or institutions.

5. ***What happens if I sign this Authorization?***

If you agree to give approval to use and share your protected information as described in this form, your authorization will not expire unless you cancel it. The information collected during your participation for this study will be kept [state time it will be kept - if there is no expiration, state "indefinitely"]. By signing this approval form, you give us permission to use and share your protected health information.

6. ***What happens if I do not sign this approval form?***

If you do not sign this approval form, you will not be able to take part in the research study for which you are being considered.

7. ***If I sign this form, will I automatically be entered into the research study?***

No, you cannot be entered into any research study without further discussion and a separate consent form. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research approval (Informed Consent) form.

8. ***What happens if I want to remove my approval?***

You can change your mind at any time and remove your approval to allow your protected health information to be used in the research. If this happens, you must remove your approval in writing. Beginning on the date you remove your approval, no new protected health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your approval.

If after signing this form, you want to remove your approval, please contact the person(s) below. He/she will make sure your written request to remove your approval is processed correctly.
[Insert Contact Person Name, their Title, Address, Phone and Fax numbers-include ONLY names associated with the study team]

9. ***How long will these approvals last?***

If you agree by signing this form that researchers can use your protected health information, this approval has [state time it will be kept, should match what is stated in sect. 5 - if there is no expiration or indefinite, state "no expiration date"]. However, as stated above, you can change your mind and remove your approval at any time.

Questions should be directed to the research staff person who is reviewing this form with you. You can also call the Kessler Foundation Research Center Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572*

SIGNATURE PAGE

This form does not replace the Informed Consent to participate in research. It provides additional information related to the use and disclosure of your protected health information. Your signature means that you are giving approval (authorization) for the use and disclosure of your protected health information for research purposes, as described in this form. You will be given a copy of this form to keep.

Signature of Research Participant (Date)	**Printed Name of Research Participant**
Signature of Investigator Obtaining Approval (Date)	**Printed Name of Investigator**

KESSLER FOUNDATION RESEARCH CENTER

HIPAA WAIVER OF AUTHORIZATION***

Date:
IRB Protocol #:
Title:

The use or disclosure of Protected Health Information (PHI)* involves no more than a minimal risk to the privacy of individuals because: [provide explanation]

The alteration or waiver will not adversely affect the privacy rights and the welfare of individuals because: [provide explanation]

The research could not practicably be conducted without a waiver because: [provide explanation]

The research could not practicably be conducted without access to and use of the PHI because: [provide explanation]

The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research because: [provide explanation]

Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access. [describe plan]

All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research. [describe procedure used to destroy all (PHI) data collected during study 9electronically, paper, audio, video, photography, other) which may be use to identify individuals] [alternative language, REMOVE if not applicable: The identifiers collected during the study will not be destroyed because [provide explanation]]

Provide a detailed list of the PHI to be collected and a list of the source(s) of the PHI. [provide list of PHI and source of PHI]

The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives. [provide explanation]

The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria.

I assure the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time
I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB/Privacy Board.

Signature of Principal Investigator _____ Date: _____

Name (typed):

_____

*PHI: individually identifiable health information transmitted and maintained in any form (electronic means, or paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.

**Note: Research staff is defined as ALL study personnel (including PI) that are involved in the research.

***HIPAA Regulations allow Privacy Boards to issue a Waiver of Authorization if all of the criteria listed above are met.

KESSLER FOUNDATION RESEARCH CENTER

NOTICE OF PRIVACY PRACTICES - HUMAN SUBJECT ASSURANCE FORM

IRB # _____

Name of Research Study:

Name of Principal Investigator (complete printed name):

Address of Principal Investigator (complete address):

Future participation in research studies ***(please initial one):***

_____ Please contact me about participating in future studies. I understand that checking this space means that any researcher at Kessler Foundation Research Center may contact me about future research.

_____ Please DO NOT contact me about participating in future studies

This is to certify that I have received a Notice of Privacy Practices for the above named research protocol, pursuant to the Department of Health and Human Services Health Insurance Portability and Accountability Act (HIPAA) 45 CFR 164.520.

Subject Name	**Subject Signature**	**Date**
Witness Name	**Witness Signature**	**Date**

FORM INSTRUCTIONS:
NOPP policy (attached) should be discussed and a copy provided to subject; this Human Subject Assurance Form should be signed and kept in PI study files.

Notice of Privacy Practices

PURPOSE OF THIS NOTICE

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully. If you have any questions about this Notice, please contact the Kessler Foundation Research Center site and/or personnel that provided your services. For your convenience, a listing of contacts is provided with this Notice.

This Notice of Privacy Practices describes how Kessler Foundation Research Center may use and disclose your protected health information in the conduct of research, payment or for other purposes that are permitted or required by law. Kessler Foundation Research Center shall be referred to collectively as "Kessler Foundation" or "we" in this Notice.

It also describes your rights to access and control your protected health information. "Protected health information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health condition and related health care services.

We are required to abide by the terms of this Notice of Privacy Practices. We may change the terms of our Notice at any time. The new Notice will be effective for all currently maintained protected health information.

Upon your request, we will provide you with any revised Notice of Privacy Practices. You may access our website at **www.kesslerfoundation.org** for a current Notice of Privacy Practices, or you may contact the appropriate Kessler Foundation Research Center representative listed in this Notice. This Notice is effective as of April 14, 2003.

OUR PLEDGE REGARDING YOUR MEDICAL INFORMATION

In accordance with Kessler Foundation Research Center's institutional mission of research, training, and education in rehabilitation, the research program seeks to improve quality of patient care through introduction of research into ongoing clinical activities and the involvement of treatment staff on research teams.

Kessler Foundation Research Center understands that medical information about you and your health is personal and confidential and we are committed to protecting your medical information. We create a record of your participation in research projects at Kessler Foundation Research Center, which is necessary to maintain documentation of research activities and to promote the highest scientific and ethical standards. Records are also maintained to provide you with quality care, to comply with certain legal requirements, and where applicable, for payment purposes, i.e. participation in a research protocol is subject to a stipend in some cases.

This Notice applies to all records of your protected health information generated by Kessler Foundation Research Center.

SECTION 1 – YOUR RIGHTS

The following is a statement of your rights with respect to your protected health information and a brief description of how you may exercise these rights.

You have the right to inspect and copy your protected health information.
This means you may inspect and obtain a copy of protected health information about you that is contained in a designated record set for as long as we maintain the protected health information.

Reasonable costs for producing copies of your medical records will be charged in accordance to applicable law. A "designated record set" contains medical and billing records.

Under federal law, however, you may not inspect or copy the following records: psychotherapy notes; information compiled in reasonable anticipation of, or use in, a civil, criminal, or administrative action or proceeding, and protected health information that may be restricted from disclosure by law. We may decline to disclose certain protected health information in cases where the disclosure might have an adverse effect on the safety and health of a participant. Depending on the circumstances, a decision to deny access may be applicable. In some circumstances, you may have a right to have this decision reviewed. You may direct any questions about access to your medical record by contacting the facility contact personnel provided at the end of this Notice.

You have the right to request a restriction of your protected health information.
This means you may ask us not to use or disclose any part of your protected health information. You may also request that any part of your protected health information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this Notice of Privacy Practices. Your request must be **in writing** and cite the specific restriction requested and to whom you want the restriction to apply. We are not required to agree to a restriction that you request. For example, if your physician believes it is in your best interest to permit use and disclosure of your protected health information, your protected health information will not be restricted. If your physician does agree to the requested restriction, we may not use or disclose your protected health information in violation of that restriction unless it is needed to provide emergency treatment. You may direct any request for restrictions **in writing** to our facility contact personnel listed at the end of this Notice. In the event you have provided us with inconsistent directions concerning restrictions on the use or disclosure of your protected health information, we will attempt to abide by the most recent directions you have provided.

You have the right to request to receive confidential communications from us by alternative means or at an alternative location.
We will accommodate reasonable requests. We may also condition this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request **in writing** to our facility contact personnel listed at the end of this Notice.

You may have the right to have an amendment of your protected health information.
This means you may request **in writing** an amendment of protected health information about you in a designated record set for as long as we maintain this information. In certain cases, we may deny your request for an amendment. If we deny your request for amendment, you have the right to file a statement of disagreement with us and we may prepare a rebuttal to your statement and will provide you with a copy of any such rebuttal. Please contact our facility contact personnel if you have questions about amending your research record.

You have the right to receive an accounting of certain disclosures we have made, if any, of your protected health information.

This right applies to disclosures for purposes other than research, treatment or payments made for research participation or payments made to receive medical care for any injuries sustained in conjunction with the research as described in this Notice of Privacy Practices and disclosures we may have made to family members or friends involved in your care, or for notification purposes. You have the right to receive specific information regarding disclosures that occurred after April 14, 2003. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations.

Complaints:
You may complain to us or to the Secretary of Health and Human Services if you believe your privacy rights have been violated by us. You may file a complaint with us by notifying our site contact personnel listed at the end of this Notice.

SECTION 2 – USES & DISCLOSURES OF PROTECTED HEALTH INFORMATION

The following section describes the different ways that we may use and disclose medical information. For each category of uses and disclosure, we will explain what we mean and give some examples. All of the ways we are permitted to use and disclose information will fall within one of the sections. The sections listed below are not optional, and in some instances uses and disclosures are mandated by regulation. Your protected health information may be transmitted in various formats including, but not limited to mail, telephone, facsimile and electronic formats.

Uses & Disclosures of Protected Health Information Based Upon Your Written Consent
You will be asked to sign a consent form. Once you have consented to use and disclosure of your protected health information for research, treatment or payments made for research participation or payments made to receive medical care for any injuries sustained in conjunction with the research by signing the consent form, we will use or disclose your protected health information as described in this Section 2.

Your protected health information may be used and disclosed by the principal investigators and others involved in the research study within Kessler Foundation Research Center; and outside of Kessler Foundation Research Center, for the purpose of providing health care services to you, and in order to preserve the health and safety of our personnel. Your protected health information may also be used and disclosed to pay your health care bills and to support the operations of Kessler Foundation Research Center. The following are examples of the types of uses and disclosures of your protected health care information that are permitted to be made once you have signed our consent form. These examples are not meant to be exhaustive, but to describe the types of use and disclosure that may be made.

Treatment:
We will use and disclose your protected health information to provide, coordinate, or manage your health care and any related services. This includes the coordination or management of your health care with a third party that has already obtained your permission to have access to your protected health information. For example, we would disclose your protected health information, as necessary, to a home health agency that provides care to you. We will also disclose protected health information to other physicians or therapists who may be treating you when we have the necessary permission from you to disclose your protected health information. For example, your protected health information may be provided to a physician to whom you have been referred to ensure that the physician has the necessary information to diagnose or treat you.

In addition, we may disclose your protected health information from time-to-time to another physician or health care provider (e.g., a specialist or laboratory) who, at the request of your physician, becomes involved in your care by providing assistance to your physician with your diagnosis or treatment.

Payment:
Medical therapy will be arranged by Kessler Foundation Research Center for any physical injuries sustained as a direct consequence of participation in research. Your health insurance carrier or other third party payer will be billed for the cost of this medical therapy. Your protected health information will be used, as needed, to obtain payment for your health care services. This may include certain activities that your health insurance plan may undertake before it approves or pays for the health care services we recommend for you such, as: making a determination of eligibility or coverage for insurance benefits, reviewing services provided to you for medical necessity, and undertaking utilization review activities. For example, obtaining approval for treatment purposes may require that your relevant protected health information be disclosed to the health plan to obtain approval for the treatment.

Where applicable, we will provide your name and address to the Kessler Foundation, this organization will arrange for any available payments for your participation in a research study.

Healthcare Operations:
We may use or disclose, as needed, your protected health information in order to support the business activities of Kessler Foundation Research Center. These activities include, but are not limited to: quality and performance assessment activities, employee review activities, training of medical, post-doctoral or other students and/or therapists, licensing and regulatory activities. For example, we may disclose your protected health information to medical school students, psychology interns or student therapists. In addition, we may use a sign-in sheet at the registration desk where you will be asked to sign your name. We may also call you by name in the waiting area when your healthcare provider is ready to see you. We may use or disclose your protected health information, as necessary, to contact you to remind you of your appointment. We will share your protected health information with third party "business associates" that perform various activities (e.g., transcription services). Whenever an arrangement between Kessler Foundation Research Center and a business associate involves the use or disclosure of your protected health information, we will have a written contract that contains terms that will protect the privacy of your protected health information. We may use or disclose your protected health information, as necessary, to provide you with information about treatment alternatives or other health-related benefits and services that may be of interest to you.

Uses and Disclosures of Protected Health Information Based upon Your Written Authorization
Other uses and disclosures of your protected health information will be made only with your written authorization, unless otherwise permitted or required by law as described below. You may revoke this authorization, at any time, **in writing**, except to the extent that we have taken an action in reliance on the use or disclosure indicated in the authorization.

Other Permitted and Required Uses and Disclosures That May Be Made With Your Consent, Authorization or Opportunity to Object
We may use and disclose your protected health information in the following instances. You have the opportunity to agree or object to the use or disclosure of all or part of your protected health information. If you are not present or able to agree or object to the use or disclosure of the protected health information, then we may use professional judgment to determine whether the disclosure is in your best interest. In this case, only protected health information that is relevant to your health care will be disclosed.

Others Involved in Your Healthcare:
Unless you object, we may disclose to a member of your family, a relative, a close friend or any other person you identify, your protected health information that directly relates to that person's involvement in your health care. If you are unable to agree or object to such a disclosure, we may disclose such information as necessary if we determine that it is in your best interest based on our professional judgment. We may use or disclose protected health information to notify or assist in

notifying a family member, personal representative or any other person who is responsible for your care, of your location, general condition or death. Finally, we may use or disclose your protected health information to an authorized public or private entity to assist in disaster relief efforts and to coordinate uses and disclosures to family or other individuals involved in your health care.

New Findings:
Unless you object, we may use your protected health information during the course of the study to contact you about any new findings that might affect your willingness to remain in the study. Such information might include treatment options, health care-related services and products, therapy and research initiatives, settings of care and other health and/or wellness related issues.

Research:
Unless you object, we may disclose your protected health information to researchers at Kessler Foundation Research Center and other institutions when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your protected health information. We may disclose your protected health information to researchers at Kessler Foundation Research Center in advance of a research project, or to researchers who are attempting to find participants who may be suitable for research participation, so they may contact you to determine whether you are willing to participate in research. Kessler Foundation Research Center conducts rehabilitation research that will improve health and lead to cures for persons with physical disabilities, musculoskeletal and neurological conditions that help all racial and ethnic minorities achieve optimal health, dignity and independence.

Institutional Review Board:
If you consent to participate in a research study at Kessler Foundation Research Center, your protected health information may be disclosed to the institutional review board, the committee that is responsible for the safety of human participants in research.

Sponsors of Research:
If you consent to participate in a research study at Kessler Foundation Research Center, your protected health information may be disclosed to the organization (or its designated representative) sponsoring the research.

Other Permitted and Required Uses and Disclosures That May Be Made Without Your Consent, Authorization or Opportunity to Object
We may use or disclose your protected health information in the following situations without your consent or authorization as required by law. The use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law.

Emergencies:
We may use or disclose your protected health information in an emergency treatment situation. If this happens, your physician and/or therapist will try to obtain your consent as soon as reasonably practicable after the delivery of treatment. If your physician or another physician in the practice is required by law to treat
you and the physician has attempted to obtain your consent but is unable to obtain your consent, he or she may still use or disclose your protected health information to treat you.

Public Health:
We may disclose your protected health information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for controlling disease, injury or disability. We may also disclose your protected health information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases:
We may disclose your protected health information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight:
We may disclose protected health information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the health care system, government benefit programs, other government regulatory programs and civil rights laws.

Abuse or Neglect:
We may disclose your protected health information to a public health authority that is authorized by law to receive reports of child abuse or neglect. In addition, we may disclose your protected health information if we believe that you have been a victim of abuse, neglect or domestic violence to the governmental entity or agency authorized to receive such information. In this case, the disclosure will be made consistent with the requirements of applicable federal and state laws.

Food and Drug Administration:
We may disclose your protected health information to a person or company in conjunction with the Food and Drug Administration to report adverse events, product defects or problems, biologic product deviations; track products; to enable product recalls; to make repairs or replacements, or to conduct post marketing surveillance, as required.

Department of Health and Human Services:
We may disclose your protected health information to a person or company required by the Department of Health and Human Services to report adverse events or research problems and to comply with regulations for the protection of human subjects in research.

Legal Proceedings:
We may disclose protected health information in the course of any judicial or administrative proceeding, in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), in certain conditions in response to a subpoena, discovery request or other lawful process.

Law Enforcement:
We may also disclose protected health information, so long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include (1) legal processes and otherwise required by law, (2) limited information requests for identification and location purposes, (3) pertaining to victims of a crime, (4) suspicion that death has occurred as a result of criminal conduct, (5) in the event that a crime occurs on the premises of the practice, and (6) in the event of a medical emergency (not on the premises) where it is likely that a crime has occurred.

Coroners, Funeral Directors, and Organ Donation:
We may disclose protected health information to a coroner or medical examiner for identification purposes, to determine cause of death, or for the coroner or medical examiner to perform other duties authorized by law. We may also disclose protected health information to a funeral director, as authorized by law, in order to permit the funeral director to carry out his or her duties. We may disclose such information in reasonable anticipation of death. Protected health information may be used and disclosed for organ donation purposes.

Criminal Activity:

Consistent with applicable federal and state laws, we may disclose your protected health information if we believe that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose protected health information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security:
When the appropriate conditions apply, we may use or disclose protected health information of individuals who are Armed Forces personnel: (1) for activities deemed necessary by appropriate military command authorities; (2) for the purpose of a determination by the Department of Veterans Affairs of your eligibility for benefits; or (3) to foreign military authority if you are a member of that foreign military service. We may also disclose your protected health information to authorized federal officials for conducting national security and intelligence activities including for the provision of protective services to the President or other legally authorized persons.

Workers' Compensation:
Your protected health information may be disclosed by us as authorized to comply with workers' compensation laws and other similar legally established programs.

Inmates:
We may use or disclose your protected health information if you are an inmate of a correctional facility and your physician created or received your protected health information in the course of providing care to you.

Required Uses and Disclosures:
We will disclose information about you when required to do so by federal, state or local law.

This Notice of Privacy Practices applies to Kessler Foundation Research Center

Notice of Privacy Practices -- Contact List
If you have a question regarding subject privacy complaints, medical records access, restrictions to use and disclosures of protected health information, amendments to protected health information or an accounting of disclosures of protected health information, please direct your inquiries to the appropriate contact at the facility or provider where services were received.

Kessler Foundation Research Center
1199 Pleasant Valley Way
West Orange, NJ 07052-1499

John DeLuca, Ph.D., ABPP
Privacy Officer
(973) 324-3572 or email jdeluca@kesslerfoundation.org

CONSENT FORM TEMPLATE

KESSLER FOUNDATION RESEARCH CENTER

INSTITUTIONAL REVIEW BOARD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

(Please DO NOT change the margins of this document as sufficient space is needed for applying the IRB approval stamp on each page)

TITLE OF STUDY:

RESEARCH STUDY #:

I, _____, have been asked to participate in a research study under the direction of Dr(s)._____. Other professional persons who work with (*him/her/them*) as study staff may assist or act for (*him/her/them*). All research projects carried out at Kessler Foundation Research Center are covered by the rules of both the Federal Government and Kessler Foundation Research Center.

The Information provided may contain words I do not understand. I will ask the study doctor or the research staff to explain any words or procedures that I do not understand.

PURPOSE:

The purpose of this research study is. . .

*(State the purpose/objectives of the research **in lay language using 8th grade English**)*

DURATION:

My participation in this study will last for about _____.

PROCEDURES:

I have been told that, during the course of this study, the following will occur:

*Describe in lay language using 8th grade English, step by step **(in first person)**, what will happen to the participant. This description should include, but not be limited to, such items as:*

- *The overall design of the study.*
- *Methods and probability of assignment, randomization, controls and placebos.*
- *Brief summary of blinding procedures, if applicable.*

(For use by IRB Administrator)

- *Procedures to be performed, including frequency and follow-up.*
- *Distinction between those procedures that are experimental and those that are part of standard care.*
- *Medications (including placebo) to be administered and the method, dose, and frequency of administration.*
- *Number, frequency and duration of visits, or time required of participants already on site.*
- *Specimens to be collected, including frequency and size/amount.*
- *Specific requirements of the research participant, e.g., post-treatment follow-up, diary cards, questionnaires, etc.*

PARTICIPANTS:

I will be one of about _____ *(number)* participants in this study.

State the total number of participants to be enrolled in the study, the number for each site if a multicenter study, and the number in each arm of the study. State any specific requirements of the participant for inclusion in the study (e.g., age, sex).

INCLUSION CRITERIA:

Provide a summary, in lay language, of the criteria for enrollment in this study.

EXCLUSIONS:

If any of the statements below apply to me, I need only tell the researcher that one or more of the statements pertain to me. To ensure my privacy and confidentiality, I need not reveal which of the statements apply to me. If I choose to tell the investigator which of the statements apply to me, the information will be kept strictly confidential.

I will inform the researcher if any of the following statements apply to me:

*(List study exclusion criteria in **lay** language)*

RISKS/DISCOMFORTS:

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

I have been told that the study described above may involve the following risks and/or discomforts:

(For each procedure/intervention, describe the potential, immediate and long-term discomforts, hazards, and risks - include physical, psychological, social, and reproductive risks. If the incidence of these risks or discomforts is known, it should be stated.)

(If applicable) If I become pregnant during the course of the study, I should notify the principal investigator of this fact as soon as possible since the risks to the fetus or me are unknown.

There also may be risks and discomforts that cannot be foreseen.

BENEFITS:

I have been told that the benefits of participating in this study may be:

(Describe potential benefits, to the individual and to society in general, that might result from the research. If the individual participant will receive NO DIRECT BENEFIT, this must be stated.)

However, I may receive no personal benefit from participating in this study.

(OR)

I have been told that I will receive no direct benefit from my participation in this study, but the information obtained from this investigation may help the researchers to better understand . . .

ALTERNATIVES:

The following alternative procedures or treatments are available if I choose not to participate in this study:

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

(State the course of treatment that will be available if the subject does not choose to participate in the study. If there are no alternatives, state that the only alternative is not to participate in the study.)

NEW FINDINGS:

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

CONFIDENTIALITY:

Every effort will be made to maintain the confidentiality of my study records. Officials of Kessler Foundation Research Center, the sponsoring company - *(name of company)*, and the U.S. Food and Drug Administration *(if applicable)*, will be allowed to inspect sections of my medical and research records related to this study. If the findings from the study are published, I will not be identified by name. My identity will remain confidential unless disclosure is required by law.

CLINICAL TRIALS:

(The following section should be included in the consent form if this is a clinical trial. IRB Policy 5036 requires that all IRB approved trials be registered on the web site <ClinicalTrials.gov>. The definition of a clinical trial is any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. Medical intervention, as used here, means any intervention used to modify a health outcome.)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

FINANCIAL COSTS TO THE PARTICIPANTS:

(For use by IRB Administrator)

Version Date:

Participant's Initials: _____

PROTOCOL NUMBER:

I understand that my participation in this study may incur the following (increased/decreased) costs to me. Some of these costs may be covered by my health insurance provider.

(Indicate who is to bear the expense of tests, procedures, hospitalization, etc., done solely for research purposes. If participation increases/decreases the cost to the subject, so state.)

(OR)

I understand there will be no cost to me for my participation in this study.

PAYMENT FOR PARTICIPATION:

I have been told that I will receive $_____ for my participation in this study according to the following schedule:

(Include this statement if subjects are to be paid or reimbursed for participation. Specify the dollar amount and the payment schedule or other forms of reimbursement. Address the matter of prorating payments if the participant withdraws or if the investigator terminates the study.)

MEDICAL THERAPY FOR INJURY:

(Choose the appropriate paragraph below)

FOR RESEARCH INVOLVING NO GREATER RISK OF PHYSICAL INJURY THAN THAT ENCOUNTERED IN EVERYDAY LIFE:

Medical therapy will be arranged for me by the Principal Investigator for any physical injuries sustained as a direct consequence of my participation in this research. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical therapy. All claims for unreimbursed expenditures for medical therapy should be made to the Principal Investigator. I understand that there

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

will be no cost to me for the therapy. No financial compensation will be provided to me other than the reimbursement of my out of pocket medical expenses for care for physical injuries sustained as a direct consequence of my participation in this research.

FOR RESEARCH ON VOLUNTEERS INVOLVING MORE THAN MINIMAL RISK (for unsponsored research and sponsored research where the sponsor does not agree to reimburse subjects' out of pocket medical expenses for care for study-related physical injuries):

If I participate in this study, I will be exposed to certain risks of physical injury. Medical therapy will be arranged for me by the Principal Investigator for any physical injury to me that occurs as a direct result of my participation in this research. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical therapy. I understand that I will be responsible for any portion of the cost of therapy not paid by my insurance or managed care provider. No financial compensation is offered to me in the event of physical injuries sustained as a direct consequence of my participation in this research.

FOR RESEARCH ON VOLUNTEERS INVOLVING MORE THAN MINIMAL RISK (for industry-sponsored research where the sponsor agrees to reimburse subjects' out of pocket medical expenses for care for study-related injuries):

If I participate in this study, I will be exposed to certain risks of physical injury. Medical therapy will be arranged for me by the Principal Investigator for any physical injury to me that occurs as a direct result of my participation in this research. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical therapy. (*Name of sponsoring company*) will provide reimbursement for the reasonable costs of medical therapy to the extent that my health insurance, managed care provider or other third party payer does not cover such costs. All claims for unreimbursed expenditures for medical therapy should be made to the Principal Investigator, who will remit the claims to (*name of sponsoring company*) for payment directly to me. No financial compensation will be provided to me other than reimbursement for my out of pocket medical expenses for care for physical injuries sustained as a direct consequence of my participation in this research.

RIGHT TO REFUSE OR WITHDRAW:

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

I understand that my participation is voluntary and I may refuse to participate, or may discontinue my participation at any time, without penalty or loss of benefits to which I am otherwise entitled. I also understand that the investigator has the right to withdraw me from the study at any time.

(Describe the medical consequences [if any] of the participant's decision to withdraw from the research. Indicate the procedures for an orderly termination of participation by the subject.)

INDIVIDUAL(S) TO CONTACT:

If I have any questions about my treatment or the research procedures, I can contact:

(List the name, phone number, and office address of the investigator or other responsible individual who can be contacted by the participant in the research activity.)

(The principal investigator may include the paragraph below if he/she believes it is applicable to this study.)
If you have medical questions pertaining to this study, there is a resident physician on-call available at the Kessler Institute of Rehabilitation who can be reached at 973-731-3600. Please be aware that this on-call physician is not a part of the study team and will not be familiar with the study, but will be able to direct your study-related medical questions to the appropriate member of the study team.

If I have concerns only regarding my **rights as a research participant**, I may contact Malica Dock, B.A., IRB Coordinator, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to participate in this research study.

_____ Participant's Initials

SIGNATURE OF PARTICIPANT

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name:_____Signature:_____

Date:_____

SIGNATURE OF WITNESS

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) signed this document.

Witness Name_____Signature_____
Date: _____

VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTION TO COMFORTABLY WRITE

_____ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. He/She has also given me permission to initial each page of the consent form with his/her initials as we review it. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

Person Obtaining Consent:

Name:_____Signature:_____

Date: _____

Witness Name:_____Signature:_____

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

Date:_____

SIGNATURE OF INDIVIDUAL PROVIDING SURROGATE CONSENT IF PARTICIPANT IS COGNITIVELY IMPAIRED *(remove if not applicable)*

I, (*name of surrogate*)_____, as the (*relationship to patient*) of (*name of patient*) _____, do consent to the participation of the above person in this research study. I further state that all good faith effort has been made to contact all others in my level of priority to review this decision with them, and that no dissenting opinion exists among them.

Signature:_____Date:_____

SIGNATURE OF PARTICIPANT IF 7 - 17 YEARS OLD *(remove if not applicable)*

I have read this entire form, or it has been read to me, and I have had all of my questions answered to my satisfaction. I agree to participate in this research study. I understand that, because I am a minor, my parent/legal guardian must also agree to my participation. I also understand that I will not be enrolled in this study without my signature on this form. I may withdraw at any time, with or without my parent's/guardian's permission, by notifying the investigator.

Minor's Name:_____Signature:_____

Date:_____

SIGNATURE OF PARENT OR LEGAL GUARDIAN

I am the ☐ parent or ☐ legal guardian *(check one)* of this participant,_____ *(name)*. I agree to the above statement, and agree to my child's participation in this research study.

Parent/

(For use by IRB Administrator)

Version Date:

Participant's Initials: _____

PROTOCOL NUMBER:

Guardian Name:_____Signature:_____

Date:_____

SIGNATURE OF READER/TRANSLATOR IF THE PARTICIPANT DOES NOT READ ENGLISH WELL

The person who has signed above, _____, does not read English well. I read English well and am fluent in *(name of the language)* _____, a language the participant (his/her parent/legal guardian) understands well. I have translated for the participant (his/her parent/legal guardian) the entire content of this form. To the best of my knowledge, the participant (his/her parent/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and that these questions have been answered to the complete satisfaction of the participant (his/her parent/legal guardian).

Reader/
Translator Name:_____Signature:_____

Date:_____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge, the participant, _____, (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant's questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name:_____Signature:_____

Date:_____

(For use by IRB Administrator)

Version Date:

Participant's Initials: _____

PROTOCOL NUMBER:

ATTACHMENT – POLICY ON SUBSTITUTED (SURROGATE) CONSENT (*remove if not applicable*)

2.3 Individuals Able To Provide Effective Surrogate Consent for Participation In Research Studies

2.3.1 The following individuals may be considered capable of providing surrogate consent, in the following descending order of priority:

(1) the health care representative of the subject pursuant to an advance directive for health care;
(2) the legal guardian of the subject who has the authority to make health care decisions for the subject;
(3) the spouse of the subject;
(4) the subject's domestic partner or partner of a civil union ;
(5) an adult son or daughter of the subject;
(6) a custodial parent of the subject;
(7) an adult brother or sister of the subject;
(8) an adult grandchild of the subject;
(9) an available adult relative with the closest degree of kinship to the subject.

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

VERIFICATION OF SPOUSE OR DOMESTIC PARTNERSHIP STATUS

(*remove if not applicable*)

With respect to an individual from whom an investigator seeks to obtain surrogate consent to enroll a subject in a research study, and who claims to be a spouse or domestic partner but has a different last name than the subject, the investigator is responsible for verifying that such individual qualifies as a spouse or domestic partner for purposes of this policy. Spouse or domestic partnership status shall be verified by obtaining three (3) of the following pieces of supporting documentation:

1. Joint mortgage or lease ( )

2. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary under a life insurance policy ( )

3. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary of retirement benefits ( )

4. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary under a will ( )

5. Joint ownership of an automobile, joint bank account or joint credit account ( )

Notwithstanding the foregoing, an individual may verify that he or she is the spouse of the subject by providing a valid marriage certificate without the need for the investigator to obtain copies of three of the above-listed documents. ( )

In the case of a same-sex domestic partnership, domestic partnership status may be demonstrated by obtaining a copy of an Affidavit of Domestic Partnership from a Local Registrar of Vital Statistics in any municipality in the State of New Jersey (without the need to obtain copies of three of the above-listed documents), under which each domestic partner confirms joint responsibility for each other's common welfare and the sharing of financial obligations. ( )

(For use by IRB Administrator)

Participant's Initials: _____

Version Date:

PROTOCOL NUMBER:

Copies of the documents obtained as part of the process of verifying spouse or domestic partnership status shall be maintained in the research records, along with a copy of this Verification form which contains check-offs for each document that has been obtained and which has been signed and dated by the investigator and the spouse/domestic partner.

Investigator Print Name	Spouse/Domestic Partner Print Name
Signature of Investigator	Signature of Spouse/Domestic Partner
Date	Date

(For use by IRB Administrator)

Version Date:

Participant's Initials: _____

PROTOCOL NUMBER:

SAMPLE

CONSENT

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Evaluation of a comprehensive cognitive rehabilitation program

RESEARCH STUDY #: E-730-12

I, _____, have been asked to participate in a research study under the direction of Dr(s).Tremaine and Strober. Other professional persons who work with them as study staff may assist or act for them. All research projects carried out at Kessler Foundation Research Center are covered by the rules of both the Federal Government and Kessler Foundation Research Center.

The Information provided may contain words I do not understand. I will ask the study doctor or the research staff to explain any words or procedures that I do not understand.

PURPOSE:

The purpose of this research study is to examine the outcomes following rehabilitation interventions such as those conducted in the Cognitive Rehabilitation Program (CRP) at the Kessler Institute for Rehabilitation.

DURATION:

My participation in this study will last for approximately 12 weeks.

PROCEDURES:

I have been told that, during the course of this study, the following will occur:

I will be seen for two visits (baseline and 12-week follow-up). At my baseline visit, I will complete questionnaires relating to my thinking skills, psychological health, quality of life, and community participation. I will also be asked about certain background information and information relating to my employment status, driving status and other activities of daily living. I may also be asked to complete a brief testing battery consisting of paper and pencil tests assessing attention/concentration, thinking speed, language, learning and memory, and problem solving. An identified significant other will also complete questionnaires related to my thinking skills and overall well-being. After approximately 12 weeks, I will be re-evaluated to determine my progress. At this follow-up visit, I will again be asked to complete a series of questionnaires and

(For use by IRB Administrator)

complete a brief cognitive assessment battery consisting of paper and pencil tests assessing attention/concentration, thinking speed, language, learning and memory, and problem solving. An identified significant other will also complete questionnaires related to my cognition and overall well-being.

PARTICIPANTS:

I will be one of about 175 participants in this study.

INCLUSION CRITERIA:

Eligible participants for this study must be:

- Age of 18 or older
- Have a documented brain injury or neurological disorder
- Have an impairment in thinking skills documented by neuropsychological evaluation
- Be proficient in English

EXCLUSIONS:

Given the nature of the study, there are no exclusionary criteria. All individuals referred for participation in CRP are eligible to participate.

RISKS/DISCOMFORTS:

I have been told that the study described above may involve the following risks and/or discomforts:

Distress/frustration throughout the paper and pencil testing component of the evaluation or discomfort in providing personal information on self-report questionnaires. I understand that every effort is made by the experimenters to minimize frustration or discomfort that may occur during testing. I may also experience fatigue and/or discomfort in completing questionnaires. I have been informed that I will be provided the option of taking the questionnaires home to complete and/or given breaks during the study visit.

There also may be risks and discomforts that cannot be foreseen.

(For use by IRB Administrator)

Participant's Initials: _____

BENEFITS:

I have been told that the benefits of participating in this study are that I will receive verbal and written feedback as to my progress over a 12 week period. Additionally, the information obtained from this investigation is likely to have an impact on the quality of care individuals receive in the CRP as well as increase our knowledge as the recovery process of individuals with brain injury or neurological disease. Ultimately, the goal is to develop a better understanding as to how individuals recover and ways in which cognitive rehabilitation may help in the process.

ALTERNATIVES:

The only alternative is not to participate in the study.

NEW FINDINGS:

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

CONFIDENTIALITY:

Every effort will be made to maintain the confidentiality of my study records. Officials of Kessler Foundation Research Center and Kessler Institute for Rehabilitation will be allowed to inspect sections of my medical and research records related to this study. If the findings from the study are published, I will not be identified by name. My identity will remain confidential unless disclosure is required by law.

FINANCIAL COSTS TO THE PARTICIPANTS:

I understand there will be no cost to me for my participation in this study.

MEDICAL THERAPY FOR INJURY:

Medical therapy will be arranged for me by the Principal Investigator for any physical injuries sustained as a direct consequence of my participation in this research. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical therapy. All claims for unreimbursed expenditures for

(For use by IRB Administrator)

medical therapy should be made to the Principal Investigator. I understand that there will be no cost to me for the therapy. However, no other financial compensation is offered to me in the event of physical injuries sustained as a direct consequence of my participation in this research.

RIGHT TO REFUSE OR WITHDRAW:

I understand that my participation is voluntary and I may refuse to participate, or may discontinue my participation at any time, without penalty or loss of benefits to which I am otherwise entitled. I also understand that the investigator has the right to withdraw me from the study at any time.

INDIVIDUAL(S) TO CONTACT:

If I have any questions about my treatment or the research procedures, I can contact:

Monique Tremaine, Ph.D.
1199 Pleasant Valley Way
West Orange NJ 07052
973-414-4713

Lauren B. Strober, Ph.D.
300 Executive Drive Suite 70
West Orange NJ 07052
973-324-8459

If I have concerns only regarding my **rights as a research participant**, I may contact Malica Dock, B.A., IRB Coordinator, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to participate in this research study.

_____ Participant's Initials

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name:_____Signature:_____

Date:_____

(For use by IRB Administrator)

Participant's Initials: _____

SIGNATURE OF WITNESS

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) signed this document.

Witness Name_____Signature_____
Date: _____

VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTION TO COMFORTABLY WRITE

_____ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. He/She has also given me permission to initial each page of the consent form with his/her initials as we review it. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

Person Obtaining Consent:

Name:_____Signature:_____

Date: _____

Witness Name:_____Signature:_____

Date:_____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

(For use by IRB Administrator)

To the best of my knowledge, the participant, _____, (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant's questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name:_____Signature:_____

Date:_____

(For use by IRB Administrator)

Participant's Initials: _____