



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):

Initial all that apply:

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

_____ Please DO NOT contact me about participating in future studies

_____ Please DO NOT contact me regarding donation purposes.

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 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 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 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 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'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 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, which is necessary to maintain documentation of research activities and to promote the highest scientific and ethical standards. Records are maintained to provide you with quality care in the context of certain research studies, 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.

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 the principal investigator 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 the principal investigator 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; and outside of Kessler Foundation, 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. 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.

Payment:

Medical therapy will be arranged by Kessler Foundation 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, Kessler Foundation, 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. 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 a member of the research team 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 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 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 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 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, 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, 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, the principal investigator will try to obtain your consent to disclose protected health information to the clinicians treating your emergency. If the principal investigator 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 the clinicians treating 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 the principal investigator created or received your protected health information in the course of the research study in which you participated.

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.

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
1199 Pleasant Valley Way
West Orange, NJ 07052-1499

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