KESSLER FOUNDATION

INSTITUTIONAL REVIEW BOARD

APPLICATION TO UNDERTAKE RESEARCH INVOLVING HUMAN PARTICIPANTS

IRB # *(for use by administrator)* –

Submission Date: _____

Proposed Start Date of Project: _____

Target Completion Date of Project (i.e. publication submission): _____

Title of Proposed Project: _____

Description of Project: *brief summary of study-objective, significance, methodology*

Principal Investigator (full name, degree): *print name*

Contact Information for PI: *print name*
mailing address
telephone number (including area code)
email address

Percentage of time to be devoted to project: _____ *%*

_____
Signature of principal investigator *(required)*

Co-Investigators and Study Coordinators

Full name, Degree	***Co-Investigator (Co-I) or Study Coordinator (SC)***	***Department or Institution***	***Phone no., ext. (include area code)***	***Email address***	***Signature (required)***

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: _____

Project Title:_____

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 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)*

☐ EXPEDITED REVIEW
45 CFR 46, SECTION 46.110*

☐ FULL IRB REVIEW

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

☐ West Orange ☐ Saddle Brook
☐ Chester ☐ Other *provide description of facility*

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

☐ Amputee
☐ Chronic Fatigue Syndrome (CFS)
☐ Multiple Sclerosis (MS)
☐ Pain Management
☐ Traumatic Brain Injury (TBI)
☐ Other *indicate research population treatment category*
☐ 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 (please choose below)
  ☐ Intellectually impaired – impaired decision making
  ☐ Specific cognitive deficits – intact decision-making, but some deficits on certain cognitive test
☐ Genetic material
☐ Non-English speaking
☐ Prisoners
☐ Pregnant women
☒ 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*)

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

☐ Word of mouth

☐ Other (*description*)

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

☐ Invasive procedures
☐ Exposure to radiation
☐ None of the above
☐ MRI
☐ 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. Consent Forms

Provide the number of participants.

_____

Provide the number of consent forms attached.

_____

XI. Certification of Study Team Members:

Starting January 2008, the Kessler Foundation'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

☐ Training certifications for study team members – *ATTACHED*

XII. 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 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 "HIPAA Waiver of Authorization" – *ATTACHED*

PROJECT APPROVAL SIGNATURE FORM

NAME OF PRINCIPAL INVESTIGATORS: _____

PROJECT TITLE: _____

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NAME *(printed)*	PROJECT APPROVALS SIGNATURE	DATE
_____ ****PRINCIPAL INVESTIGATOR**	_____	
_____ ****LABORATORY DIRECTOR *(if applicable)***	_____	
	_____	
John DeLuca, PhD *****SENIOR VICE PRESIDENT OF RESEARCH (*or designee)***	_____	
Bruce Gans, M.D. *******CHIEF MEDICAL OFFICER, KIR(or designee)***	_____	

**** SIGNATURES REQUIRED for all studies, PRIOR TO submission of the application to the IRB Office**

***** SIGNATURES REQUIRED for all studies, AFTER IRB approval (For IRB Administration)**

******SIGNATURE REQUIRED for all new PIs from KIR, PRIOR TO submission of the application to the IRB Office**