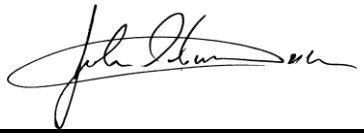
KESSLER FOUNDATION

Policies and Procedures Manual
IRB

SUBJECT: Off-Hours Coverage of Research Participants Involved in Interventional Clinical Studies	**POLICY #** **2054**
APPROVED: **Richard J. Greene, M.D., Ph.D.** **IRB Chair**  **John DeLuca, Ph.D.** **Senior Vice President for Research** 	**EFFECTIVE DATE:** **September 11, 2007** **REVISED DATE:** **April 10, 2014**

PURPOSE

To ensure that appropriate physician coverage is available evenings, nights, and weekends for participants in interventional clinical research studies approved by the Kessler Foundation IRB.

RATIONALE

In accordance with appropriate standards for the proper conduct of interventional clinical research studies, coverage by Principal Investigators (PIs) or their designees must be available 24 hours a day seven days a week.

POLICY

1) All after-hours calls, questions and visits from research participants will be directed to the resident on call at the Kessler Institute for Rehabilitation - West Orange Campus. All operators and staff at all Kessler Institute for Rehabilitation campuses will be informed that they should contact the resident on call at West Orange should any research participant contact them either by telephone or in person for questions that cannot wait till the next working day.

2) The resident on call will then perform an initial assessment, and based on this will triage according to the severity of the presenting clinical problem. Management options include:

    a. Immediate referral to a local emergency room for an urgent or emergent problem, whether or not the problem is study-related.

b. Referral to the participant's primary or other physician for non-study related non-urgent problem management.
c. Referral back to the study team for follow–up. After telephone consultation with the PI or his/her designee, the participant will be given an appointment with a member of the study team either on the next business day or on the next scheduled visit, depending on the acuity of the problem.

3) The resident is expected to see the patient in person only if a circumstance arises where the patient physically presents to the hospital, rather than calling by phone.

4) The resident on call will contact the principal investigator or his/her designee to facilitate the decision-making process if there is any question of a significant study-related issue. The principal investigator or his/her designee must be called immediately if there is a possible risk to the participant's safety or any significant adverse event that can possibly be attributed to the study intervention. The PI contact information will be available for the resident on call for all interventional clinical studies. The PI or his/her designee will be available via beeper, pager, cell phone, home phone, or a 24/7 physician contact service. The progress note generated by the resident regarding the interaction should be included as part of the documentation of the study participant's research records. The progress note will be sent to the Principal Investigator within 2 business days of the telephone contact.

5) While this system is designed as a support for the principal investigator in providing coverage to insure participant safety, it is not meant to replace the principal investigator's ultimate and final responsibility for the participant's safety and wellbeing.

6) For each clinical intervention study, the IRB will determine if a licensed physician should be included as a co-investigator and if this licensed physician should be the point of contact for the resident on call if he/she needs to discuss an emergent medical problem with a member of the study staff
   a. It is expected that all pharmaceutical studies will have a physician as a co-investigator on the study team.
   b. All fMRI studies should include the resident on call phone number on the subject consent form.
   c. Study PIs are encouraged to provide wallet-sized laminated cards and/or refrigerator magnets with the same relevant contact information as in the consent form.
7) To provide information about interventional clinical protocols approved by the Kessler Foundation IRB, the IRB Coordinator will maintain a notebook for the resident on call that will include the PI's study summary (from page 1 of the initial IRB application) and the page containing Individual(s) to Contact from the Consent Form. Over time, this hard copy information will be replaced by a database that will link research subjects to the protocol(s) in which they are enrolled and provide summaries of the protocols and contact information for study staff.

The IRB Coordinator is responsible for updating the Notebook with information on newly IRB-approved studies.

8) This policy will be implemented in coordination with the Executive Vice President & Chief Medical Officer and the Medical Director of Kessler Institute for Rehabilitation.