

# KESSLER FOUNDATION

## *Policies and Procedures Manual Administration/Conduct of Research/IRB*

<b>SUBJECT: Human Subjects Research: Protection of Human Subjects</b>	<b>POLICY # 2004</b>
<b>APPROVED:</b>	<b>EFFECTIVE DATE:</b>
<b>Richard J. Greene, M.D., Ph.D. IRB Chair</b> 	<b>February 13, 2004</b>
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### **PURPOSE**

To set Kessler Foundation policy that will ensure that the conduct of human subjects' research (1) by Kessler Foundation staff, investigators, trainees, visiting professors and other agents, or (2) conducted on Kessler Foundation premises, or (3) otherwise under Kessler Foundation auspices, is in conformance with all applicable Federal and other regulations (including 45 CFR 46 [DHHS] and 21 CFR 56 [FDA], and with the Federalwide Assurance (FWA00001357) filed by Kessler Foundation with the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services. Kessler Foundation's mission includes dedication to the pursuit of excellence in research, including human subjects' research. The broader purpose of this policy is to foster and help ensure the attainment of excellence in human subjects' research.

### **ACCOUNTABILITY**

The President of Kessler Foundation (President) will be responsible for enforcing this policy and the Senior Vice President (VP) for Research (Senior VP for Research) of Kessler Foundation will be responsible for implementing the policy.

### **APPLICABILITY**

This policy will apply to (1) human subjects' research sponsored by Kessler Foundation; (2) human subjects' research directed or performed by any Kessler Foundation researcher, student, volunteer, or other agent in connection with his or her institutional responsibilities or educational program, whether or not the research is carried out on Kessler Foundation premises; (3) human subjects research conducted by any individual, regardless of institutional affiliation, using any property or facility of Kessler Foundation; (4) human subjects' research using Kessler Foundation's non public information to identify or contact human research subjects or prospective subjects, regardless of

affiliation of investigator or location of the research. This policy will apply to all such research, regardless of sponsorship.

## **DEFINITIONS**

Human Subject: a living individual, about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.

Research: a systematic, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

## **POLICY**

- A. Kessler Foundation is responsible for the compliance with all applicable laws and regulations of human subjects' research to which this policy applies (see Section III above). Therefore, Kessler Foundation and its administrative officers must maintain adequate administrative involvement with and oversight of all policies and procedures relating to this research. This administrative oversight will be vested in the office of the President and delegated to the Senior VP for Research.
- B. All purposed human subjects' research to which this policy applies (see Section III above) must be reviewed and approved by the Kessler Foundation's Institutional Review Board (IRB) as established under the Kessler Foundation's FWA filed with the OHRP. With the approval of the IRB Chair, the Senior VP for Research and, the President, Kessler Foundation may enter into cooperative agreements with another institution whereby the Kessler Foundation IRB will provide review and oversight for a single research protocol or multiple protocols from that institution. The cooperating institution must have its own FWA. The Kessler Foundation IRB reviews and provides oversight for all research protocols carried out at Kessler Institute for Rehabilitation (KIR) under KIR's FWA (FWA00016290).
- C. Through the Senior VP for Research, Kessler Foundation will exercise administrative oversight of all policies and procedures involved in reviewing, approving, conducting, monitoring and documenting human subjects' research in order to ensure that the rights and welfare of human subjects are being protected and that Kessler Foundation is in compliance with its FWA. This administrative oversight will consist of the following activities and responsibilities:
  1. The Senior VP for Research will be responsible for the development, and regular review and revision of written policies and procedures, including applicable forms, for the conduct of human subjects' research by Kessler Foundation staff, research trainees, visiting scientists and others on its premises, and will publicize these to all individuals proposing and/or performing such research. These Kessler Foundation-specific policies and procedures will adhere to the requirements for human subjects' research set forth in Federal regulations, in this Policy, and by the IRB.
  2. The Senior VP for Research will ensure the orientation and training of investigators proposing and conducting human subjects research at Kessler Foundation. Training designed to enhance the development of high quality protocols will be encouraged and training in good research practices and in methods of minimizing risk should be

provided. In addition, the Senior VP for Research will communicate widely to other department directors, KIR clinical care staff, and appropriate institutional officials Kessler Foundation's policies and procedures for protecting human subjects. A statement of principles for human research subject protection, from the Belmont Report, will be included in material used in orientation and training and will be made part of Kessler Foundation's policies regarding human subjects' research.

3. The Senior VP for Research will:
  - i. Be responsible for the establishment of an IRB, under Kessler Foundation's FWA, to review and approve all human subjects' research as defined above, with the members of the IRB being acceptable to the President.
  - ii. Ensure that IRB membership is in accordance with Federal regulations, and that the IRB functions autonomously in accordance with all applicable regulations. The Senior VP for Research will advise the IRB concerning its adherence to these regulations and will work with the IRB Chair to ensure these regulations are being observed. (If the Senior VP for Research is unable to ensure compliance of the IRB, he or she will inform the President.)
  - iii. Ensure the appropriate initial orientation and training as well as periodic continuing education of current and new IRB members in human subjects' research regulations, institutional policies and procedures, and other relevant matters. The Senior VP for Research will encourage and support the attendance of IRB members at workshops and other educational opportunities focused on IRB functions.
  - iv. Ensure the preparation of written procedures and guidelines to be followed by the IRB when conducting its initial and continuing review of research and for reporting its findings and actions to the investigator.
  - v. Be responsible for providing the IRB with sufficient meeting space and staff to support its review and record-keeping duties. Designated, confidential storage space to maintain IRB records will be provided.
  - vi. Ensure the adequate documentation of IRB activities, including maintenance of all research protocols reviewed (including informed consent documents), agenda and minutes of IRB meetings, records of continuing review activities, protocol amendments, adverse event reports and copies of all IRB correspondence.
  - vii. Ensure that all records pertaining to an IRB-approved protocol are accessible when appropriate to the study investigators, to IRB staff members, to authorized representatives of the sponsor (if any) of the research, and to appropriate Federal regulatory agencies.
4. New applications from investigators wishing to undertake human subjects research, applications for continuing approval and proposed changes to ongoing protocols will be forwarded to the IRB Chair by the IRB Coordinator. The decisions of the IRB and the administrative status of applications will be communicated, in writing, to the investigators by the IRB Coordinator.

The Senior VP for Research will require that applications for human subjects' research be reviewed, approved, and signed by 1) the

investigator's department director, 2) the coordinator of the Research Program within which the research will be conducted, 3) the Medical Director of a cooperating medical facility, and 4) the Administrative person responsible for that facility. After approval of the research proposal by the IRB, the IRB Chair will sign the Project Approval Form.

5. The IRB Chair will inform the Senior VP for Research promptly of any significant or material finding or action with regard to the human subjects' research being conducted by Kessler Foundation individuals, including but not limited to injuries to human subjects or other unanticipated problems involving risks to human subjects or to others. The VP for Research will promptly inform the President of such findings or actions. If of sufficient seriousness, the President will inform the OHRP, and the research sponsor, if any.
  6. Allegations and complaints regarding inappropriate conduct of human subjects research and/or noncompliance with Federal regulations, institutional policies or IRB requirements by investigators will be reported to the Senior VP for Research and to the IRB Chair and will be documented in writing. The IRB Chair will investigate the facts of any allegation. At the end of the fact-finding process, a determination will be made of the merits to the allegation. If, after fact-finding, the allegation demonstrates merit, the IRB Chair will inform the Senior VP for Research and a full inquiry will be undertaken by the Senior VP for Research and the IRB. After the inquiry and investigative process, if a finding of serious noncompliance is determined, the Senior VP for Research will report such finding to the President, the OHRP and the research sponsor, if any.
  7. The Senior VP for Research will promptly be informed by the IRB Chair of a suspension or termination of any human subjects research by the IRB. The Senior VP for Research will report any suspension or termination of human subjects' research project by the IRB, or by Kessler Foundation or a medical facility at which Kessler Foundation research is conducted, to the President and the research sponsor, if any.
  8. The Senior VP for Research will ensure that procedural and record keeping internal audits are conducted periodically for the purpose of detecting, correcting, and reporting administrative and/or material breaches in the protection of the rights and welfare of human subjects as required by Federal regulations and institutional policies. The Senior VP for Research will ensure the establishment of written internal audit procedures to accomplish this responsibility. Written reports describing the results of internal audits will be sent to the IRB Chair, and the President.
- D. Infractions of Federal regulations or of institutional policies and procedures for human subjects' research can result in immediate, temporary, or permanent termination of the research by the IRB Chair, Senior VP for Research, or President. The Senior VP for Research will refer these infractions, if appropriate, to the President. Infractions of IRB requirements will be investigated by the IRB and a report will be submitted to the Senior VP for Research. There may be additional administrative action under the policies of cooperating medical facility.
- E. All human subjects' records, especially those containing subjects' names or other identifying information, will be kept confidential within the limits of the law.