

KESSLER FOUNDATION

Policies and Procedures Manual IRB

1. INTRODUCTION

The Institutional Review Board (IRB) is established by Kessler Foundation to review and approve all human research undertaken at this institution according to regulations of the U.S. Department of Health and Human Service (DHHS) including the Food and Drug Administration (FDA).

Kessler Foundation has provided a Federalwide Assurance (FW A0001357) to the Secretary of Health and Human Services (DHHS) that all human subjects research at this institution will be carried out in compliance with all Federal regulations that protect the rights and welfare of human research subjects. Kessler Institute for Rehabilitation (KIR) has provided a similar Federalwide Assurance (FW A00016290) to the Secretary of DHHS, designating the Kessler Foundation's IRB as its IRB of record.

The Policies and Procedures in this Manual provide the details of how human research carried out under the auspices of the Kessler Foundation IRB meets the highest ethical standards and is in compliance with Federal and State laws on human research.

2. PRINCIPLES and POLICIES

ETHICAL PRINCIPLES AND INSTITUTIONAL POLICIES GOVERNING RESEARCH INVOLVING HUMAN SUBJECTS

Applicability:

With the exception of research exempted or waived under HHS regulations 45 CFR 46.101, Part 1, these policies and procedures are applicable to all human subjects research carried out under the auspices of Kessler Foundation's IRB, if:

The research is sponsored by Kessler Foundation, or

The research is conducted by or under the direction of any employee or agent of Kessler Foundation in connection with his or her institutional responsibilities; or

The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution; or

The research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects; or

The research is conducted by employees or agents of another institution that enters into an agreement with Kessler Foundation to 1) utilize the Kessler Foundation IRB to review and approve its human research protocols and 2) provide its own Federalwide Assurance to the Secretary of DHHS and 3) abide by these policies and procedures in carrying out its research.

Ethical Principles Governing Human Subjects Research

All human subjects research carried out at Kessler Foundation is guided by the ethical principles set forward in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the Belmont Report – Federal Register April 18, 1979). These principles include:

Respect for Persons:

Subjects must give informed consent to participate in research.

The dignity and autonomy of research subjects is respected.

Vulnerable persons must be given additional protection.

Research subjects' privacy and confidentiality will be protected.

Beneficence:

Research risks must be justified by expected benefits of the research.

Research shall maximize benefits and minimize harm to subjects.

The researchers must be qualified to carry out the research.

There must be a valid research design.

Justice:

There must be an equitable distribution of research burdens and benefits.

Research subjects must be chosen equitably.

The policies and procedures for human subjects research included in this manual operationalize the ethical principles of the Belmont Report.