

APPENDIX C

STUDIES REQUIRING IRB REVIEW

To assure the protection of human subjects and to comply with federal law, the institution name requires that, prior to initiation, all research projects involving humans as subjects or human material be reviewed and approved by the Institutional Review Board. This policy applies, regardless of the source of funding and location of the study, to all biomedical and behavioral research involving human subjects conducted by faculty, staff and students of the University. If the study is part of an application to a Sponsoring agency, the human protocol must be submitted for Committee review before or when the application is processed in the Office of Regulatory Affairs.

Definition of Human Subjects

"Human subject" means 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. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between Investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Definition of Human Research

The boundary between research and innovative care is a complex and controversial issue. However, for the purposes of this Committee, human research is any activity that has the intent of securing information from humans for the purpose of advancing generalizable knowledge. Such activity may or may not differ in a significant way from customary medical or other professional practice. A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The protocol may include therapeutic and other activities intended to benefit the subjects, as well as procedures to evaluate such activities. Research objectives range from understanding normal and abnormal physiological or psychological functions or social phenomena, to evaluating diagnostic, therapeutic or preventive interventions and variations in services or practices. The activities or procedures involved in research may be invasive or non-invasive and include surgical interventions; removal of body tissues or fluids; administration or application of chemical substances or forms of energy; modification of diet, daily routine or service delivery; alteration of environment; observation; administration of questionnaires or tests; randomization of subjects; review of records, etc.