Activities that Require IRB Review

The KUMC Institutional Review Board (IRB) must give prior approval to activities that qualify as human subjects research. Federal regulations define *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *Human subjects research* occurs when an investigator interacts or intervenes with a living individual, or uses the individual's identifiable data or specimens for research purposes. Examples of activities that need IRB approval include, but are not limited to:

- Clinical trials of a drug, device or biologic product
- Research involving surveys, interviews or focus groups
- Collection of data obtained from clinical procedures
- Certain non-standard medical practices (see page 2)
- Research on behavioral interventions
- Queries of identifiable health records that are designed to answer a research question
- Banking of tissue, blood or other specimens for future research
- Research using non-invasive procedures, such as MRI, X-ray or ECG
- Research on educational practices
- Research involving data collected through chart reviews
- Research on food, food supplements, vitamins or herbs
- Certain quality improvement interventions (see below)
- Certain program evaluations (see page 2)
- Pilot studies
- Feasibility studies that use the same or similar procedures, or a similar group of subjects as those that will be used in a future research study
- Student research projects
- Research conducted by KUMC personnel at other institutions
- Collaborative projects involving human data or specimens
- Use of human data or specimens transferred from a faculty member's former institution
- Systematic modifications to surgical technique, not directly related to the patients' benefit

The following non-research activities also may become human subjects research under certain conditions:

Quality Improvement versus Research

Health care professionals frequently conduct activities that are designed to measure and improve the quality of care for patients. Most quality improvement (QI) activities do not constitute human subjects research; however, clinicians are responsible for obtaining IRB approval if research is involved. The federal Office for Human Research Protections has guidance that is helpful in determining whether or not quality improvement is also research that requires IRB oversight.

In general, QI projects involve implementing a practice known to be effective in improving the quality of patient care and collecting patient or provider data to evaluate implementation in the local setting. According to federal guidance, those types of activities would not be classified as human subjects research even if the results were later presented or published.

By contrast, some QI projects involve introducing an untested clinical intervention and examining how well the intervention achieves the intended result. If the project uses a novel approach, or if patients or providers are randomly allocated to one of several conditions, then the project would be considered human subjects research and would require prior IRB approval.

Program Evaluations

Program evaluations are designed as a management tool to improve the provision of services to a specific population. Results of program evaluations are shared only with the program and entity in which the program operates; the activities are not intended to have any application beyond the specific organization in which they are conducted. Typically, program evaluations are performed under a contract for services, and the program being evaluated is the owner of the evaluation data, results and reports.

Program evaluation becomes a research activity if it assesses a new, modified or previously untested intervention, service or program to determine effectiveness and potential for use in other settings. Assigning program participants into groups to compare outcomes also constitutes a research activity. Additionally, a systematic comparison of standard or non-standard interventions is considered to be research. Finally, program evaluations may become research if the KUMC faculty member keeps the evaluation data for presentations, further analysis or future grant proposals.

Off-label Use or Non-Standard Medical Practices

Off-label use of a marketed drug or device, or non-standard medical or surgical practices, may be pursued with the sole intent of enhancing the well-being of an individual patient. Off-label use and non-standard medical practices are subject to hospital policy.

Off-label use or non-standard practices may become a research activity when one or more of the following is true:

- There is a clear intent, before treating the patient, to systematically collect data on a series of patients receiving similar treatments;
- The physician keeps separate data sheets for reviewing patient outcomes or has other organized methods of gathering data;
- Extra tests are performed that are not directly related to the patient's benefit;
- The care under consideration is delivered consistently across a series of patients according to an "unwritten" protocol in order to keep processes and procedures uniform.

Single Case Reports

A report of a small number of cases (generally not more than three), created for presentation or publication, are not considered research if the following conditions exist:

- The report is compiled by persons already involved in the patient's care;
- The information is presented in de-identified form; and
- No changes were made in the patient's care or diagnostic testing for the sake of reportability.

Case reports become a research activity if any of the previous three stipulations are not met, or if multiple cases are systematically analyzed for presentation or publication or to test a hypothesis.

Faculty, staff and students are encouraged to contact the IRB Office with questions about activities that may qualify as human subjects research. The IRB Office also can review an activity and issue a non-human subjects determination letter, when appropriate, if such a determination is required for a grant application, presentation or journal submission.