

## Frequently Asked Questions about Scientific Review for Human Research Studies

### **1. What is the requirement for scientific review?**

Beginning with submissions for the February 27, 2007 meeting, the Human Research Protection Program will require documentation of scientific review on new proposals for expedited and full-committee review. The review process has been implemented to fulfill accreditation requirements of the Association for Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP standards require that institutions develop mechanisms to coordinate the scientific and ethical review of research. Departments will be responsible for ensuring that scientific review has occurred prior to submission to the Human Subjects Committee (HSC).

### **2. What is the purpose of the scientific review?**

The purpose of the scientific review is to ensure that proposals reflect an acceptable level of scientific rigor and merit prior to ethical review. Ensuring scientific merit is a key component in protecting the rights and welfare of our human research participants. Through the scientific review process we ensure that the study is well-designed and has adequate resources so that we do not expose research subjects to unnecessary harms.

Specifically, accreditation standards require the scientific review to confirm the following:

- a) the research uses procedures consistent with sound research design, which do not unnecessarily expose subjects to risk;
- b) the research is likely to answer the proposed question; and
- c) the knowledge reasonably expected to result from the research has scientific importance.

### **3. Which studies need scientific review?**

Any study requiring “expedited” or full-committee review must demonstrate prior scientific review. There is no requirement for scientific review of exempt research.

### **4. What are the options for accomplishing scientific review?**

If an external peer review process (such as NIH) has been accomplished, or if there are plans for review by the KMCRI Protocol Review and Monitoring Committee or GCRC Advisory Council, then the scientific review requirement is met. A Master’s Thesis or Doctoral Dissertation Committee will provide the scientific review for graduate students. If none of the above situations apply, then the scientific review must be accomplished at the departmental level.

### **5. Who can perform the departmental scientific review?**

Each department may decide whether the review occurs by the department chair, by a designee or by a departmental research committee. Departments are given the discretion to arrange the review in a manner that best suits the needs of the department. Any colleague with relevant expertise can perform the review, provided he/she is not on the

study team. For studies that represent high-risk to subjects or a novel area of investigation, departments should consider review by more than one individual.

**6. How is scientific merit evaluated for pilot studies?**

Pilot studies must meet standards for sound rationale, minimized risks, clear objectives, and measurable outcomes. While not statistically powered to definitively answer the research question, the pilot study should be designed to contribute important knowledge about whether further studies are justified.

**7. How should non-interventional studies (such as those using questionnaires, interviews and focus groups) be evaluated?**

Non-interventional studies should be evaluated for sound rationale, minimized risks, clear objectives and measurable outcomes. While these studies may not pose a risk of physical harm, reviewers should consider any psychological, social, legal and economic risks that might be involved in study participation. Steps should be taken to minimize those risks, and any remaining risks should be reasonable in relation to the potential benefits of the study.

**8. Is a scientific review still required for industry-sponsored multi-center clinical trials?**

Yes. While it is recognized that multi-center clinical trials have already undergone one or more levels of scientific review, the departmental review still should confirm the overall soundness of the study. For example, reviewers would use their knowledge of best practices to confirm that appropriate comparators are being used in a randomized trial of a new drug's efficacy. In most cases, the departmental review of multi-center trials will focus on whether or not the study is appropriate for KUMC. Reviewers should consider the expertise of the local PI, the availability of appropriate and sufficient research subjects, facilities, and expertise of ancillary services in order to ensure the safe conduct of the research.

**9. When should the scientific review occur?**

The scientific review should occur before the department chair or center director signs the HSC application (unless the project is being referred to PRMC or GCRC). For studies using the services of the RI Clinical Trials Division, investigators should only submit the study to the RI when they have the final version of the protocol. All protocols should be labeled with a version date.

**10. What paperwork does HSC need?**

The last page of the new HSC application form asks the department chair to indicate how the scientific review process is being accomplished. If the review has not been done by external peer review, PRMC, GCRC or an MS/PhD committee, then a departmental review will be required. The HSC submission should include a copy of the departmental checklist as well as any **correspondence** between the PI and the scientific reviewer. The correspondence about scientific issues may facilitate HSC deliberations.

**11. What form should be used for the departmental review?**

Departments should use a scientific review checklist they have created for their own purposes. The Human Research Protection Program provides a sample template for departments to adapt, or departments can develop their own forms. Specific questions can be directed to the HRPP Director at 588-0942.

**12. If I have an internal grant from the KUMC Research Institute, do I still need departmental review?**

If you have a clinical research pilot funded by the Research Institute, those projects have undergone a peer review by external experts prior to approval for funding. The HSC would not require a departmental review. The HSC application form should indicate that the scientific review has already been accomplished by an external review process.

**13. How will scientific review benefit departments?**

The scientific review process offers departments an opportunity to improve the quality of research in several important ways. The process facilitates mentoring of young researchers, identification of synergies among related lines of investigation, and knowledge of current research that can support plans for departmental growth.