University of Minnesota
Contract for Services (RFP)

External Review of Clinical Research on Human Subjects

On December 5, 2013 the Faculty Senate approved a resolution requesting an external review of clinical research on human subjects at the University of Minnesota. Specifically the Senate resolution stated:

BE IT RESOLVED that a panel external to and independent from the University of Minnesota be constituted for the purpose of conducting an inquiry examining current policies, practices, and oversight of clinical research on human subjects at the University, in particular clinical research involving adult participants with diminished functional abilities. The administration, in collaboration with appropriate faculty governance committees, shall initiate the constitution of such an independent panel and shall support its inquiry. The panel shall have authority to obtain any records it deems necessary for a thorough inquiry, to the extent consistent with applicable law. At the conclusion of the inquiry, the panel shall issue a report that will be made publicly available, within the limitations of regulations governing the protection and privacy of individuals, including research participants, and the results will be reported back to the Faculty Senate so that senators have an opportunity to ask questions and discuss the report.

Rationale for Requesting Services:
The intent of this review is to ensure that the University’s processes for clinical research on human subjects meet or surpass the established best practices and norms and to instill confidence among faculty and the public that the University Minnesota research is beyond reproach. It is to be forward looking, productive, transparent and independent review of current practice by an external expert panel.

Objectives:
1) obtain an independent, external assessment of the current policies, practices and oversight of clinical research on human subjects at the University of Minnesota – in particular clinical research involving adult participants with diminished capacity to provide consent.
2) select an external contractor/vendor with widely recognized expertise and experience in clinical research on human subjects to manage the review process. External contractor selected will empanel an independent team of no less than three experts who will conduct a thorough, professional, independent and transparent review and issue a report that will be made publically available.
3) seek recommendations for any changes, if needed, to policies, practices and oversight of clinical research to align with best practices nationally.

Outcomes Needed:
We expect the contractor selected in response to this RFP to define and manage the process of an expert review of the current policies, practices and oversight of clinical research on human subjects at the University of Minnesota – in particular clinical research involving adult participants with diminished capacity to provide consent.

The expert review must include a review of relevant standard operating procedures and an assessment of compliance with regulations and other applicable law. A detailed report outlining the strengths and weaknesses of current policies, practices and oversight of clinical research involving adult participants
University of Minnesota
Contract for Services (RFP)

External Review of Clinical Research on Human Subjects
with diminished capacity to provide consent is required. If any deficiencies in our current practices are found, the review should include recommendations for remediying them.

The contractor will select and empanel an independent team of no less than three experts to include an MD who will conduct a thorough, professional, independent and transparent review. The review must examine policies, practices and oversight of clinical research on human subjects at the University, in particular clinical research involving adult participants with diminished functional abilities. At least one member of the panel should be prepared to speak publicly to their process, findings and any recommendations for improvement.

The contractor will develop a plan for identifying the data needed, gathering the data and producing a final report that will be public.

The contractor will orchestrate site visits and acquisition of materials and data to conduct the review.

Key audiences for the results of this review include: University President, Board of Regents, University Faculty Senate, IRB and external stakeholders. The report will also be made publically available.

University of Minnesota Obligation:
The University of Minnesota will ensure that the panel has appropriate access to information, resources and individuals needed to meet their charge.

Timeline:
Final report delivered by July 1, 2014. Timeline may be adjusted depending on acceptance of proposal date.