

Regenstrief and IU develop innovative ethics-based model for academia-industry collaboration

September 22 2015

In an era of declining federal government funding for medical research, researchers from the Regenstrief Institute and the Indiana University Center for Bioethics have developed a set of principles and benchmarks for ensuring that academic-industry partnerships can be conducted with the highest ethical standards.

"Industry Support of Medical Research: Important Opportunity or Treacherous Pitfall?," an article that outlines the issues raised by [industry](#)-academic collaborative research and describes a strategy for ensuring ethically credible partnerships between industry and university-funded research, appears online ahead of print publication in the Perspectives section of the *Journal of General Internal Medicine*.

"Industry currently funds more biomedical research than the National Institutes of Health and other government entities combined, and industrial support is growing," said article lead author William M. Tierney, M.D. "Working together academicians can help industry spend their research dollars wisely producing answers the public can trust."

"Academic-industry relationships can be ethically credible when specific principles are followed that minimize the risk that industry funding will bias the planning, conduct or reporting of studies. Good academic-industry relationships are not only possible, they are desirable." Dr. Tierney is president of the Regenstrief Institute and associate dean for

clinical effectiveness research at Indiana University School of Medicine.

"To rule out industry support of [biomedical research](#) because of the potential for conflicts of interest would be wasting valuable resources as well as collective knowledge," said bioethicist and article co-author Eric Meslin, Ph.D. "As long as rigorous ethical guidelines are followed, the private sector can be an important source of both funding and expertise to support high-quality, important academic research.

"We are confident the collaborative research model we've developed—with specified principles and benchmarks—enables industry, academic investigators, individual patients and populations to benefit. Excluding commercial support of research would squander valuable resources that society can ill afford to waste." Dr. Meslin is the director of the Indiana University Center for Bioethics and associate dean and professor of bioethics at the IU School of Medicine. The Center for Bioethics was commissioned to review the Regenstrief Institute's collaborative research model and develop the principles and benchmarks.

The nine ethical principles of the model include: academic freedom, a defined and managed conflict of interest policy, effective governance, protection of human subjects, and transparency. Twenty-three benchmarks are used to assure compliance with these principles including annual assessment of efficiency, effectiveness and achievements of the partnership, training of researchers in responsible conduct of research and related ethical issues, and manuscript publication in a peer-reviewed journal.

"We found that the scientific and ethical safeguards employed in the Regenstrief industry collaborative model provide not only a valuable way to deal with the thorny issue of private sector support for research, but also an efficient and effective way to take advantage of joint expertise,"

Dr. Meslin said.

Employing this model, the Regenstrief Institute is in the fourth year of a five-year collaboration with Merck Sharp & Dohme to develop and conduct mutually interesting and beneficial research projects.

Researchers from the Regenstrief Institute, Indiana University and Merck propose collaborative one-year projects. A review committee of three senior investigators reviews and ranks the proposals. Merck decides on its annual funding allocation for the joint endeavor. Projects are funded in rank order until all allocated funds are expended. To date 32 projects in a wide variety of areas including heart failure, chronic kidney disease, cognitive impairment and osteoporosis have been funded by the pharmaceutical manufacturer under its collaborative agreement with the Regenstrief Institute.

With more than two decades of experience with research collaboration with industry, the Regenstrief Institute has launched an Industry Research Office known as IndRO that facilitates conversations with prospective industry funders, identifies Regenstrief Institute and Indiana University principal investigators and co-investigators, helps design protocols and write proposals, manages communication and contracts, and follows the principles and benchmarks for a wider range of investigators, funders and studies. The overriding goal of IndRO is to provide Regenstrief Institute and Indiana University academic researchers with alternative sources of funding for their research as federal sources of support diminish.

"Academics' interests and of those of industry scientists can be aligned," Dr. Tierney said. "As a clinician-scientist, my obligation is to discover new ways of helping my patients, but that work has to be paid for. As US government funding sources are dwindling, I feel an obligation to search for alternative ways of funding. With a model that enables us to evaluate relationships for ethical and scientific fidelity,

collaboration with industry is an attractive ethical option."

Provided by Indiana University

Citation: Regenstrief and IU develop innovative ethics-based model for academia-industry collaboration (2015, September 22) retrieved 10 April 2024 from <https://medicalxpress.com/news/2015-09-regenstrief-iu-ethics-based-academia-industry-collaboration.html>

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