

Title of proposed program: Bioethics and Science

Submitting Source: NIH

What is the major obstacle/challenge/opportunity that the Common Fund should address? What would the goals of the program be?

A major shift is occurring in clinical research. The growth of genetic research, community engagement efforts, international collaborative partnerships, and data mining of related electronic health records and mega biologic specimen repositories highlights the new paradigm of how clinical research is conducted. As this new era is embraced, ethical requirements must keep pace ensuring that subjects are treated with respect and their rights and welfare are protected as they contribute to the research process and social good. A program that reshapes the contours of clinical research ethics creates an opportunity to meet this challenge. The goal of this program is to establish bioethics as a mainstream science in an effort to generate a new body of knowledge that will lead to development of evidence-based practices that address bioethical challenges facing the current clinical research enterprise, anticipate the evolution of bioethical issues, and inform policy discussions as they emerge.

Why is a trans-NIH strategy needed to achieve these goals? What initiatives might form the strategic plan for this topic?

NIH promotes novel, cutting edge science that has potential to broaden the boundaries of ethical guidance. A trans-NIH strategy that focuses on the study of high priority national and international bioethical challenges and issues will ensure that NIH-conducted research is conducted in the most ethical manner possible.

Initiatives that might form the strategic plan for this program include:

- Leveraging existing Centers of Excellence to develop cores in Bioethics that provide network support for empirical research addressing bioethical issues emanating from global advances in the clinical research enterprise.
- An international consortium that creates a data-driven repository of evidence-based ethical practices and outcomes of bioethical consultative services that promote policy and guidance
- A program to train and promote career development of bioethics researchers

If a Common Fund program on this topic achieved its objectives, what would be the impact?

A Common Fund investment in *Bioethics and Science* in the short term will propel the science of bioethics in new directions and accelerate the growth of an empiric body of knowledge capable of supporting the creation of accepted policies and practices for respecting and protecting research participants both nationally and globally. In the long term, a new cadre of bioethics scientists and a centralized bioethics data repository will ensure the continued evolution of the science of bioethics.