

## 50 years of ethics: Scientists navigate an increasingly challenging field

October 7 2022, by Krista Conger

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Paul Berg, who won a Nobel Prize in Medicine in 1980 for his work in recombinant DNA, paused his research into a gene-editing tool in the 1970s so he and other scientists could consider its implications. Credit: Jose Mercado/Stanford News Service

It was a breakthrough discovery: a protein that cuts DNA at precise points, leaving overhanging sticky ends ready to glom onto a matching partner. Using the protein, researchers could cut and paste genetic sequences from one species into another as easily as a word processing program can rejigger a sentence.

These genetic gymnastics, first [reported](#) in 1972 by researchers at Stanford Medicine and UC San Francisco, launched a field known as recombinant DNA technology. But within months of the discovery, the research was halted—at the researchers' request.

The technology, scientists feared, could lead to "Frankencells" that are antibiotic resistant or toxic or that incite cancer-causing proteins when the hybrid molecules were introduced into living cells. The scientists called a partial moratorium on this promising field of study—the first time researchers had voluntarily done such a thing.

"[This is] the first time that I know of that anyone has had to stop and think about an experiment in terms of its social impact and potential hazard," said Paul Berg, Ph.D., the Robert W. and Vivian K. Cahill Professor of Cancer Research, Emeritus, then chair of biochemistry at Stanford Medicine. Berg, who was a leading figure in the nascent field, went on to share the Nobel Prize in Medicine in 1980 for his work with recombinant DNA.

Berg and some 150 like-minded researchers and lawyers came together at a seminal meeting at the Asilomar conference grounds in Pacific Grove, California, in 1975 to align on reasonable guidelines for the technology. The day after the meeting ended, the director of the National Institutes of Health initiated the formation of the Recombinant DNA Advisory Committee, which would be tasked with establishing guidelines for future research during the coming decades—a move that served as a kind of model for handling edgy research in genetics and genetic engineering.

## **New research, new responsibilities**

Since the discovery, scientists have repeatedly been called on to navigate a field fraught with ethical tripping hazards: [human embryonic stem cells](#)

, self-propagating genes that spread among species, human gene therapies, genetically engineered babies, [human organs](#) or cells growing (and functioning) in the bodies of animals. In some cases, national legislation has tied their hands—in 1995, Congress banned the use of federal funds for research that destroys human embryos. But more often, it's researchers who decide how and when to avoid crossing an ethical line that is moving, largely invisible and subjective.

Fortunately, researchers facing such dilemmas have help. From that moment in 1972, organizations like the National Institutes of Health and the National Academy of Sciences, as well as [academic institutions](#) like Stanford Medicine, have marshaled resources and created guidelines to support the ethical conduct of research in biology.

"Worrying about these issues is important," said Hank Greely, JD, the Deane F. and Kate Edelman Johnson Professor in Law and director of Stanford University's Center for Law and the Biosciences. "It's critical that researchers are open about what they are planning and why it is important, and that they understand the instrumental value of involving ethicists and discussing ethical issues."

Greely is a member of Stanford Medicine's Bedside Ethics Consultation Service, or BECS, which launched in 2005 after operating informally for years. The service is available to researchers within and outside of Stanford Medicine, offering confidential, written feedback from experienced bioethicists.

"BECS helps researchers who are doing something really novel that has ethical or societal implications, and who want advice about how to incorporate those concerns into their research plans," said Mildred Cho, Ph.D., professor of pediatrics and an associate director of the Stanford Center for Biomedical Ethics. The center was established in 1989 and was one of the first to be designated by the NIH as a Center for

Excellence in Ethical, Legal and Social Issues in Genetics and Genomics.

"Stanford Medicine was one of the first institutions to offer this type of service; now there is international interest in establishing similar groups around the world," Cho said. Members of BECS work on two to three consults each month, Cho estimated, including some from local or even international biotech companies seeking expert advice.

## Research dilemmas

Why, exactly, does scientific and medical research so frequently bump up against scales of morality we often can't clearly articulate? In many cases, the problem is the unavoidable need for ever more realistic models of human biology, be they cells, tissues or living animals.

Human embryonic stem cells can generate any cell type in the body, and they are isolated from [human embryos](#) donated for research after in vitro fertilization procedures. Growing human organs or tissues in laboratory animals gives scientists a clearer picture of how they function (or don't, in the case of inherited diseases or missing genes) and could relieve shortages for organ transplantation. It opens a door to studies and drug testing that could never be done in human subjects and also promises to vastly expand our clinical knowledge in ways that could save lives.

"It's a dilemma, particularly in neuroscience," Greely said. "When researchers study a living human brain in a living human person, there are strong ethical boundaries about what they can do. They can't put in or take out a gene to see how it affects a person's behavior. So we use models. But the more similar to a human your model is, the more you risk backing into an ethical quandary."

Greely is a member of the Stanford Brain Organogenesis Program, a group of researchers who study functional [human brain](#) tissue in the lab

and in the brains of mice—something they expect will dramatically advance our understanding of psychiatric and genetic diseases affecting neural function. In 2021, the National Academies of Science issued [a report](#) noting the potential benefit for people struggling with Alzheimer's and Parkinson's diseases, autism, schizophrenia and depression.

Scientists also need to realize it is important not to conduct their experiments in a vacuum, Greely says. The media and the general public play important roles in how research is perceived.

"Researchers need to be open. Explain the frameworks and guidelines in place to address ethical issues and avoid secrecy. Talk about experiments and findings even before publication. Don't surprise people," Greely said. "And help the public understand that the work holds potential for scientific or medical value, that these experiments are being done for a good reason."

Broadly acknowledging the importance of coming to a consensus on tricky research is critical to responsible advancement in scientific and medical knowledge, Greely said. And the challenge is growing.

"The difference between Asilomar and now is that, at the time, only a dozen or so labs in the world were equipped to move forward with the recombinant DNA experiments," Greely said. "Today we see a vast range of experimental protocols pursued by research groups around the world. Our job as bioethicists is to encourage scientists to be self-aware and to initiate conversations about important topics. Very few people want to be remembered as Dr. Evil; they want to be heroes in their own movie. We can help them think through how their research might be perceived, and ways to avoid ethical pitfalls."

Provided by Stanford University Medical Center

Citation: 50 years of ethics: Scientists navigate an increasingly challenging field (2022, October 7) retrieved 20 April 2024 from

<https://medicalxpress.com/news/2022-10-years-ethics-scientists-increasingly-field.html>

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