

'Science' article has implications for all rapidly developing fields

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Global climate change and other fast-developing scientific fields can take a cue from a prolonged process that eventually led to a workable compromise regarding the release of new data by human genome researchers.

A new study by a Washington University in St. Louis School of Law professor in the July 23 issue of the journal "*Science*" chronicles a 15-year struggle around the competing needs inherent in data-release decisions.

In the first comprehensive examination of its kind, Jorge Contreras, JD, explains that the U.S. government must weigh the rights of <u>researchers</u>, also called data producers, against those of data users. The scientific community needs the latest data as soon as possible in order to drive further research. But researchers may want time to prepare for publication and apply for patents.

The result is a balancing act between the interests of these two groups. Although Contreras' study focuses on human genome research, the same dilemma holds true for research in many other areas of study.

"I think you must have a compromise. Otherwise these commons, or bodies of data, aren't going to be created," Contreras says.

NASCENT FIELD DEMANDS NEW POLICIES



At the dawn of human genome research two decades ago, more than 1,000 researchers were working around the globe. To facilitate knowledge sharing, the U.S. government sought to coordinate their efforts.

In the past, government-funded human genome researchers had a 12-to-18 month latency period between the generation of data and its required release.

In 1992, the National Institutes of Health (NIH) and the Department of Energy (DOE) reduced that period to six months. Four years later, government and scientific leaders determined that six months was still too large a gap.

They then decided that human genome research findings must be released prior to publication, within 24 hours after generation. The legacy of that determination, called the "Bermuda Accord," still affects genomic research projects today and makes it difficult for data generators to publish their findings before competitors who have free access to their data.

"While it would be preferable, from a pure scientific advancement standpoint, to have every piece of data released immediately to the public, that doesn't give data-generating scientists the opportunity to publish and advance their careers through publication," Contreras says.

The agreement also inhibits the ability of researchers to obtain patents, as patents cannot be obtained on information that is already known to the public.

COMPROMISE RESOLVES SOME PUBLISHING ISSUES, STILL THWARTS PATENTING



With the arrival of the 21st century, genomic research began to evolve from sequencing to associating variants in the genome with specific traits and conditions, known as genome-wide association studies (GWAS). This development brought about a 2007 compromise decision, in which the NIH again altered its rules.

The newer policy, which applies only to GWAS, still requires quick data release but it also prevents users from publishing the data or presenting related information for up to 12 months. The shift is significant in that GWAS now make up a large portion of human genome research.

Still in effect, this set of rules allows GWAS researchers time to publish their own work. In the meantime, other scientists can use the data for their research and future publications.

The 2007 policy does not improve the likelihood of scientists patenting their work, but that issue is secondary to publication for most researchers, according to Contreras.

Contreras sees implications for his study in numerous scientific fields beyond genomics, including not only global climate change, but also chemistry and astronomy.

"As policy makers begin to develop commons in different areas, rather than going back to the drawing board and starting from scratch, they'll be able to look at this systematic analysis of how timing variables have played a role in genome science, and take it from there," Contreras says.

Provided by Washington University in St. Louis

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