



**Section:**  
**Communication and Ethical, Legal, and Societal Issues**



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Prepared by  
Biological and Environmental Research Information System  
Oak Ridge National Laboratory  
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# Communication and Ethical, Legal, and Societal Issues

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### ELSI Pilot: Assessing and Mitigating the Risks of Large-Scale Metabolic Engineering

J. Geller,<sup>1</sup> S. Lee,<sup>1</sup> D. Tarjan,<sup>1</sup> C. Wu,<sup>1</sup> T. Torok,<sup>1</sup> T.C. Hazen,<sup>1</sup> A.P. Arkin,<sup>1,2,3</sup> and **N.J. Hillson**<sup>1,2\*</sup> (njhillson@lbl.gov)

<sup>1</sup>Lawrence Berkeley National Laboratory, Berkeley, Calif.; <sup>2</sup>Joint BioEnergy Institute, Emeryville, Calif.; and <sup>3</sup>University of California, Berkeley

**Project Goals: Establish methodologies for assessing and mitigating the risks of future large-scale metabolic engineering microbial projects, including those extending beyond the bioreactor.**

The DOE EERE-funded Advanced Biofuel Process Development Unit (ABPDU) houses two 300 liter microbial fermentation tanks. In the extremely unlikely event that the ABPDU's post-fermentation microbicidal protocol (e.g. base treatment and neutralization) should catastrophically fail, broth harboring viable genetically engineered micro-organisms could be purged directly to downstream waste-water treatment processes. This Ethical, Legal and Social Implications (ELSI) pilot study seeks to quantitate the risks associated with this scenario, by measuring the viability of the engineered microbes (and perhaps more importantly, their embedded genes) in mock sewage reactors that mimic the conditions and microbial communities found in real-world waste water treatment plants. Furthermore, investigation of how differential genetic backgrounds (e.g. gene deletions) impact survival and gene transmission to sewage sludge communities will guide subsequent forward-engineering efforts to further reduce risk. This pilot study establishes methodologies (leveraging only recently available technologies) for assessing and mitigating the risks of future large-scale metabolic engineering microbial projects, including those extending beyond the bioreactor.

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### Managing the Risks of Synthetic Biology: Assessing the U.S. Regulatory System

Sarah R. Carter<sup>1\*</sup> (scarter@jcvl.org), Michael Rodemeyer,<sup>2</sup> and **Robert Friedman**<sup>3</sup>

<sup>1</sup>J. Craig Venter Institute, Rockville, Md.; <sup>2</sup>University of Virginia, Charlottesville; and <sup>3</sup>J. Craig Venter Institute, San Diego, Calif.

**Project Goals: (see below)**

The Coordinated Framework for the Regulation of Biotechnology was established in 1986 as a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products." (51 FR 23302) This framework has evolved over time (CEQ/OSTP, 2001), both as the Federal government has gained experience with biotechnology products and as the technology has advanced. However, with the advent of synthetic biology and other new technologies, new questions arise about the applicability of these rules and regulations to future biotechnology products (Rodemeyer, 2009). Synthetic biology refers to a set of techniques that together provide scientists and engineers with far greater capabilities to modify organisms than current techniques allow. The term "synthetic" comes from the relatively new ability to synthesize long pieces of DNA from chemicals, increasing both the power and precision of genetic engineering. Both the departure from older genetic engineering techniques and the broader type and scale of genetic changes may create challenges for the regulatory system.

The goal of this project is to assess how well the current Federal regulatory framework for biotechnology applies to the anticipated products of synthetic biology, and to provide options for addressing any gaps or shortcomings. This will include an analysis of the authorities that are used by regulatory agencies (primarily USDA, EPA, and FDA) as well as the risk assessment challenges that the agencies are likely to face. This is a two-year project that includes two workshops as well as multiple consultations with experts both within and outside the Federal government. The final report should be available by late 2012.

The first workshop will be held in January, 2012, and will focus on assessing the regulatory framework for likely synthetic biology products based on a case study approach. The four product case studies will be: cyanobacteria and microalgae for biofuel production; microbes for use as drugs or cosmetics; and modified plants for use as alcohol-fuel feedstock. By bringing together outside experts and Federal regulators, we hope to get a better understanding of the agencies' regulatory authorities, their capabilities to perform risk assessments, and where any gaps in the regulatory framework may occur.

#### References

1. CEQ/OSTP Assessment: Case Studies of Environmental Regulation for Biotechnology (2001). 66 FR 7905.
2. OSTP: Coordinated Framework for Regulation of Biotechnology (1986). 51 FR 23302.
3. Rodemeyer M. (2009). *New Life, Old Bottles: Regulating First-Generation Products of Synthetic Biology*. Washington, D.C.: Woodrow Wilson International Center for Scholars.

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### Choices and Challenges in Translating Science and Technology from Concepts to Realities

Amy K. Wolfe<sup>1\*</sup> (ami@ornl.gov), David J. Bjornstad,<sup>1,2</sup> W. Christopher Lenhardt,<sup>1</sup> Barry Shumpert,<sup>1</sup> and Stephanie Wang<sup>1</sup>

<sup>1</sup>Oak Ridge National Laboratory and <sup>2</sup>University of Tennessee

Knowledge generated by modern science and technology (S&T) must be “translated” from individual ideas and discoveries to organized production blueprints and business plans if the fruits of knowledge generation are to lead to socially valuable products and processes. Whether by institutional design or the efforts of individual actors, this translation process must support a confluence of inputs—science, technology, technology transfer and entrepreneurship activities—and take place at a number of stages during the science-to-product chain. This poster describes our preliminary research findings into the process by which large S&T centers can develop programs and procedures to help convert the scientific and technical concepts they develop into the uses that entrepreneurs can nurture for societal benefit.

Our research is beginning to identify the implications of different ways that S&T institutions organize the conduct of science, both for how research is conducted and for research translation. A number of frameworks have been used to describe how information and products flow from laboratory toward use. We draw elements from these frameworks and from data we have collected to propose a different conception that we term “ushering.” Ushering entails purposeful actions designed to move the information and products of S&T toward use, effectively extending the point at which scientists or organizations typically consider their work “done.” Thus, institutions purposefully would create an environment that not only facilitates, but expects flows of information to occur within and between organizations. Within the organization, information flows may link fundamental to basic activities, basic to fundamental activities, or may involve other activities, such as technology transfer. Outside the organization, information flows may provide assistance to downstream entrepreneurs or organizations that help them gain access to needed scientific and technical knowledge in an organized manner or to other types of information exchange.

The scientists, science managers and administrators, and personnel involved in intellectual property, technology transfer, and commercialization we have queried typically agree on the importance of translation. However, they also recognize that their participation in the ushering process is governed by a variety of internal business practices and external drivers. These practices and drivers can provide

information, mechanisms, and incentives to participate in the translation process, but they can also create barriers that discourage participation. Our inquiries have identified instances where practices created to achieve other goals have the effect, perhaps inadvertently, of competing or conflicting with research translation goals.

The research described in this poster is being carried out by the ORNL Ethical, Legal, and Social Issues Scientific Focus Area. It focuses, in part, on identifying the components of and resources needed for the ushering process and on analyzing the implications of alternative organizational rules and practices for science and research translation. Data for our translation work are drawn from structured discussions with individuals and from a day-long workshop involving 26 individuals from diverse areas of science and technology, management, and technology transfer. Our initial project efforts are focused on translating S&T toward use, within and beyond the community of scientists. Later work will expand the current set of ushering topics into broader types of support, mechanisms for providing this support, and experiences at other S&T institutions.

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### Biological and Environmental Research Information System: A Multifaceted Approach to DOE Systems Research Communication

Jennifer L. Bownas, Kris S. Christen, Holly L. Haun, Brett Hopwood, Sheryl A. Martin, Marissa D. Mills, Judy M. Wyrick, and **Betty K. Mansfield\*** (mansfieldbk@ornl.gov)

Biosciences Division, Oak Ridge National Laboratory, Oak Ridge, Tenn.

**Project Goals: Develop and distribute programmatic materials to help build the multidisciplinary community needed to advance systems research for DOE energy and environmental missions. The Biological and Environmental Research Information System group works with program managers and the scientific community to help develop and communicate key scientific and technical concepts for scientific community and public discourse. Ideas are welcome to extend program integration and improve communications and thus represent BER’s research more comprehensively.**

Concerted communication is key to progress in cutting-edge science and public accountability. Our goals focus on three objectives: (1) facilitate science planning, research, and communication; (2) inform a broader audience about Department of Energy (DOE) research projects, progress, and significance to science and society; and (3) respond to outreach and information exchange needs of related DOE projects.

The Biological and Environmental Research Information System has focused on presenting all facets of genom-

ics research for DOE's Office of Science (22 years). The materials we produce have helped ensure that scientists can participate in and reap the bounty of the genome revolution, that new generations of students can be trained in genomics and systems biology, and that the public can make informed decisions regarding genetics issues.

In 2009, our scope was extended to include all programs within the Office of Biological and Environmental Research (BER), which conducts frontier research in climate, subsurface biogeochemistry, and genome science within the Office of Science. These programs explore scientific complexity at temporal and spatial scales requiring contributions from teams of interdisciplinary scientists, thereby necessitating an unprecedented integrative approach both to the science and to research communication strategies. Because each scientific discipline has different perspectives and languages, effective communication to help foster information flow across disciplines and translation of scientific discovery into appropriate DOE mission areas is critical to BER's success. We work with DOE staff and the research community to produce and disseminate information in various formats: technical reports, roadmaps, websites, brochures, databases, technical compilations, presentations, exhibits for scientific meetings, text, graphics, and posters. We staff the BER and Genomic Science exhibits at more than 10 scientific meetings each year and maintain the searchable BER Research Highlights database ([public.ornl.gov/hgmis/bernews/](http://public.ornl.gov/hgmis/bernews/)). We also assist with the outreach efforts of DOE grantees—especially the Bioenergy Research Centers, Joint Genome Institute, Environmental Molecular Sciences Laboratory, and Atmospheric Radiation Measurement Climate Research Facility—to help increase their reach and impact.

**Biological Systems Science Division—completed and ongoing projects include:**

- Genomic Science program website <http://genomic-science.energy.gov>
- DOE Genomic Science Awardee Meeting X, February 26–29, 2012 (this abstracts book)
- Applications of New DOE National User Facilities in Biology Workshop Report (February 2012)
- Switchgrass Research Group: Progress Report (January 2012)
- Biosystems Design: Draft Report from the July 2011 Workshop (Web HTML, January 2012)
- Plant Feedstock Genomics for Bioenergy Joint Awards (August 2011)
- Revealing the Role of Microbial Communities in Carbon Cycling (July 2011)
- Projects Underpinning Knowledgebase Development (May 2011)
- Biological Systems Science Division Overview (revised May 2011)
- Genomic Science Program brochure (May 2011)
- DOE User Facilities: Advanced Technologies for Biology, Structural Biology brochure (May 2011)
- DOE BER Joint Genome Institute brochure (revised May 2011)

- Joint Meeting 2011: Genomic Science Awardee Meeting IX and USDA-DOE Plant Feedstock Genomics for Bioenergy Awardee Meeting, April 10–13, 2011, abstracts book, 238 pp., April 2011

**Climate and Environmental Sciences Division (CESD)—completed and ongoing projects include:**

- Subsurface Biogeochemical Research website (in development)
- Subsurface Biogeochemical Research Contractor-Grantee Workshop, April 30–May 2, 2012, abstracts book (in development)
- Subsurface Biogeochemical Research brochure (October 2011)
- Terrestrial Ecosystem Science brochure (October 2011)
- Climate and Environmental Sciences Division Overview (October 2011)
- GOAmazon2014 Workshop Report summary brochure (October 2011)
- GOAmazon2014 Workshop Report (September 2011)
- DOE BER Environmental Molecular Sciences Laboratory overview brochure (revised May 2011)
- DOE BER ARM Climate Research Facility overview brochure (revised May 2011)

We also continuously update and enhance websites, paying particular attention to navigation and increasing functionality and accessibility. These sites include:

- Genomic Science website ([genomicscience.energy.gov](http://genomicscience.energy.gov)). In addition to describing program research, the site provides information on how to access DOE user facilities and the DOE Systems Biology Knowledgebase.
- BER image gallery ([public.ornl.gov/site/gallery/](http://public.ornl.gov/site/gallery/))
- BER Research Highlights Database ([public.ornl.gov/site/bernews/](http://public.ornl.gov/site/bernews/))
- Subsurface Biogeochemical Research (in development)

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