# Translational Governance Research for Synthetic Biology

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Synthetic biology (SB) involves multiple techniques and tools to design and engineer complex or artificial biological parts, devices, and systems to achieve useful or novel properties. It resembles other "big science" fields like nanotechnology and genome sequencing in that it garners significant investment from the federal government and is drawing attention to not only its promise for addressing societal problems, but also to concerns about its potential impacts and its focus on "re-engineering life'. Categories of synthetic biology include, but are not limited to, synthesized or artificial genes, systems of engineered biological parts, and synthetic organisms. Although there are not clearly recognizable products of synthetic biology in the market yet, microorganisms with highly-engineered metabolic pathways to produce industrial or pharmaceutical compounds are now in use. More radical applications of SB, such as de-extinction of species or the creation of artificial cells, are emerging in the literature as successful in proof-of-concept stages. The ability to transform life is upon us, yet making societal decisions about what applications of SB are desirable to whom and under what conditions remains almost entirely in the hands of funders, the "free" market, and companies. Many citizens and scholars have argued that decision-making processes need to be open to a wider range of experts, stakeholders, and interested parties, especially in democracies. It is in this context that ethical, legal, and societal issues (ELSI) research becomes crucial to our future with synthetic biology.

ELSI research is primed to play an important role in societal decision-making process for SB. Through disciplinary, multi- and inter-disciplinary work, it can inform processes and methods for the design and implementation of governance systems and the choices made within them. However, historically, this potential has not been realized. Other ELSI programs such as those associated with the National Nanotechnology Initiative or Human Genome Initiative, have had marginal, ad-hoc influences on debates and courses of action, but have neither been integrated into decision-making processes nor had long-lasting, transformative impacts on those scientific fields. Although ELSI research efforts have yielded a mass of data, information, and better understandings of socio-technological relationships, they have not been given equal standing to natural science or engineering research and have not focused on practical and complex problems requiring decisions at the researcher, company, local, national or international levels. Simply put, the vast majority of ELSI research was neither translational nor integrated into society. ELSI researchers have been operating as the biological sciences did 30+ years ago, by doing research in "labs" without putting their ideas into the "marketplace" for useful purposes. For example, even public engagement efforts have been primarily used for research and not designed to have input into important and current societal decisions. With a few exceptions, there remains disconnect between ELSI findings and information and what to do about the future of technology, specifically synthetic biology.

This is not entirely or even largely the fault of the ELSI research community. Practically-inspired work does not traditionally get funded or rewarded. In the social sciences and humanities, "industries" do not exist to carry the ball for use-inspired research and develop products or processes. Yet, if we want to better inform and potentially improve our future with emerging technologies, it is important that we conduct ELSI research that is translatable and integrated into decisions about funding, governance, communication, R&D, and technological deployment.[1]

Whether this translation occurs is a two-way street. Societal decision-makers at all levels and in multiple institutions should be receptive to learning from ELSI research. In turn, ELSI researchers should

[1] I do not believe that *all* of ELSI research should be use-inspired or translational. Some basic ELSI research on theory and hypothesis testing needs to remain. It will be a balance. Perhaps start with a 50:50 split?

listen to the needs of practitioners and go out on the limb of engaged scholarship. Along these lines, I propose the following work to set the stage for ELSI research to better inform society, and in turn for ELSI research to be better informed by society: 1) host a series of pre-funding conversations among multiple relevant interested and affected parties (citizens reps, subject-matter-experts, stakeholders, groups) about what kind of ELSI knowledge and information matters to them and could be used for decision-making at multiple levels (this workshop may be a start), 2) identify the broad kinds of research that can best gather that knowledge and information, innovating with methods and cross-disciplinary approaches as needed, and 3) develop routinized and long-lasting governance systems to integrate ELSI research into societal decision-making in *timely, meaningful, and concrete ways*[2]. In additional to laying the groundwork for translational ELSI work, these three areas also inspire research such as exploring mechanisms for conducting dialogues, developing mixed methods, and testing innovative governance systems.

In addition to the foundational work, I propose the following research areas for translational research. This list represents policy sciences work on governance systems, which currently has little place in the federal funding portfolio, yet it might be most important for making appropriate choices about SB:

- *Historical Analyses of Governance Systems—*
  - Explore the use of multiple natural & social science and ethical criteria and how to integrate them to analyze historical cases of governance and uncover patterns or features that are indicators of systems that lead to desirable outcomes for multiple stakeholders.
- *Experiments with Governance Systems*[3]*—*
  - Test ways to anticipate and prepare for future technologies in governance systems with side-by-side comparisons of different features for these systems.
  - Explore alternatives for engaging "interested and affected parties" within these systems.
- *Methods to Deal with Uncertainty and Ambiguity in Governance.*
  - Improve upstream methods within governance systems to explore a broad range of harms and benefits and characterize uncertainty.
  - Test decision-science and future-studies approaches (scenario planning, Bayesian approaches, systems mapping, etc.) in governance systems.
- *Improve Ways to Explore Claims and Counterclaim in Contested Areas*
  - Develop balanced and more inclusive approaches for determining "weight of evidence" and for ways to minimize bias in interpretations of evidence.
  - Understand and acknowledge values behind multiple perspectives and interpretations of evidence.
  - Explore assumptions, contradictions, and correlation arguments on multiple sides of controversies.

Policy sciences and governance systems research is a tough sell, especially in the context of declining federal funding and animosity for political science research, which could be associated with ELSI governance work. However, SB is an area of technological development that not only has the ability to greatly impact society, but also the ability to fundamentally alter living things at their very core. There will be no stronger imperative for better integration of ELSI inquiry and research into societal decision making.

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[2] Note this does not mean ELSI researchers should "vote" on societal decisions as in direct democratic fashion, but rather should have input into decisions—in other words, be seen and respectfully heard by those with power before decisions are made.

[3] These exercises do not need to be "legally binding", at least initially in the experimental stage, but should mimic conditions for direct input into decision-making authorities.