DESIGNING INSTITUTIONS AND PROCESSES TO ENABLE INTEGRATIVE PROGRAMS ON THE SOCIETAL ASPECTS OF BIOLOGICAL RESEARCH

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The National Science Foundation's (NSF) Directorate for Biological Sciences (BIO) recently requested ideas from on fundamental biological research questions and topics poised for major advances, as part of their program to create Integrated Institutes for Cross-Cutting Biology (NSF 19-027). The request for information posed three questions:

What fundamental biological research question is poised for breakthroughs by collaboration across biological subdisciplines? Why is this question important? While NSF's call focused on supporting collaborative teams of researchers in subdisciplines of biology, an integrated environment to prepare for next generation biological science should also address foundational questions concerning the environmental, economic, health, safety, security, ethical and governance aspects of biotechnologies. Many of these issues arise across programs supported by the BIO directorate, from sole investigator grants through to multi-university centers. These topics cannot and should not be addressed in isolation from these future integrative institutes.

Why is now a particularly good time to address these questions? Questions about the purposes, methods and potential implications of biological research begin at the very earliest stages of research. Biology's current rapid rate of advance is coupled with high public awareness and debate addressing foundational social, ethical and behavioral questions of both research design and implications. Engagements with these aspects of biotechnologies supported by BIO should take place early enough to allow researchers to identify key uncertainties and initiate research to fill gaps in knowledge, and to modify designs and conduct tests with benefit of feedback from regulators, insurers, firms and civil society.

What types of resources, in terms of expertise and infrastructure, would facilitate answers to these questions? The remainder of this memo focuses on the design of institutions and processes to enable collaboration among biologists, biological engineers, social scientists, and humanists in pursuit of these ends.

Part I considers issues of institutional design. Part II considers process design issues, with emphasis on roles, resources, and reporting systems. It offers design principles that NSF might use to foster collaborative research of practical value in assessing and addressing broader aspects and implications of emerging technologies while advancing the state of the art in relevant parts of the social sciences, humanities and engineering.

I. INSTITUTIONAL DESIGN

This memo compares two institutional models that supported work by social scientists and humanists in partnership with technologists: the NSF Synthetic Biology Engineering Research Center (Synberc), of which we were all Investigators, and the NSF-supported Centers for Nanotechnology and Society (CNS), which were part of the National Nanotechnology Initiative (NNI) and overlapped in timing with Synberc. CNS differed markedly on the degree of separation of technical and scientific work from the social sciences and humanities, on the extent to which social scientists and humanists had autonomy in choosing research topics, and on the levels and duration of funding for research. We consider alternatives, such as relying on unfunded advisory panels to offer commentary on funded technical work, as too ephemeral to sustain meaningful and integrative work.

SEPARATE BUT EQUAL MODEL- NANOTECHNOLOGY: In addition to several science and engineering centers set up under NNI, NSF set up Centers for Nanotechnology and Society at ASU and UCSB to address societal and policy issues, and later funded environmental work at other universities. Social scientists and humanists at CNS enjoyed significant autonomy in choosing research directions and operated with large budgets that were assured over multiple years, allowing for significant scholarly work within their disciplines. However, by virtue of their geographic separation from natural scientists and engineers, social scientists and humanists were less aware of impending fundamental developments and emerging applications in nano-technology and therefore unable to influence the trajectory of those developments.

INTEGRATED BUT UNEQUAL MODEL- SYNTHETIC BIOLOGY: NSF opted to integrate social sciences and humanities work into Synberc through dedicated and collaborative research thrusts and programs instead of creating separate centers. This allowed policy-relevant research on key governance challenges (e.g. CRISPR enabled gene drives, opiate synthesis, synthesis screening and human gene editing) and practical work on intellectual property regimes, risk governance and organizational management (e.g. within Synberc management processes and those of efforts it catalyzed, such as the international Genetically Engineered Machines (iGEM) competition). It took years of dedicated effort for relationships among social scientists, technologists, firms, regulators and civil society to develop, and these relationships outlasted Synberc into collaborative research and industry efforts. Synberc's funding for social science and humanities work was substantially less in dollar amounts than NNI, but initially comparable in terms of percentage of overall program funding (in Synberc this percentage grew over time, from ~10% to ~25% of NSF funds). Even with this extra percentage of funding, Synberc social science and humanities researchers had to secure external funding and relied heavily on an industrial advisory group that understood the need for serious engagement with issues of risk and governance to give internal credibility to their efforts.

We recommend integrating social science and humanities work within large research projects along the lines of Synberc but with more autonomy and higher levels of support along the lines of CNS.

II. PROCESS DESIGN RECOMMENDATIONS

In 2014, NSF funded a Workshop on Research Agendas in the Societal Aspects of Synthetic Biology (Grant #1445903) focused on the need to create a productive environment for research that integrates social, natural, and engineering approaches to rapidly advancing scientific areas. The workshop report favored an embedded model where social scientists contribute not only to addressing questions defined by the scientific priorities of the project, but also to the formulation of questions the project addresses. Our process recommendations focus on ways that this model might be instituted through adjustments in the way the NSF structures its solicitations, peer review process, management of awards, and review structure.

A. **Calls for submissions** should begin with a pre-proposal process that includes a social scientist or humanities co-PI. The pre-proposal should describe appropriate integration of social science and humanities expertise in each step of project development, including research design, budgeting, and oversight of work. Calls for submission should note that a team including NSF staff and reviewers associated with multiple programs and Directorates will work with authors of promising pre-proposals to develop stronger proposals that integrate work in the humanities, social sciences, sciences and engineering. Funding should also not come from the BIO Directorate alone. Ideally, the participation of other units within NSF through funding and staff would enhance the quality of Integrated Institutes from the perspective of biologists and social scientists.

B. In **reviewing awards**, **NSF review panels should be cross-directorate.** Discussion of broader effects should occur in general meetings, and not be confined to Social, Behavioral, and Economic (SBE) subsets of panels. Once awards are determined, NSF Site Visit Teams (SVTs) should include social scientists, humanities scholars, scientists and engineers with experience conducting integrated work and with sensitivity to how the specifics of projects may limit the direct transferability of their experience. Formal reporting to SVTs should, where possible, be done by mixed teams of humanities, social sciences, engineering, and science. The requirement of integrated reporting may improve the prospects for genuinely collaborative research activities. The SVT should assess the degree to which the social science and humanities findings are useful in the design and strategy of the project as a whole.

C. **In managing awards,** NSF and PIs should expect and embrace persistent and fundamental tensions regarding the relevance of social science and humanities research agendas. Tensions may well exacerbate as technologies and investments mature. Acknowledging and creating space to explore and (re)balance tensions may help protect against polarization and gridlock. Interdisciplinary teams should be co-located when possible to help foster relationships, and funding should be allocated for specific people to work as brokers between disparate fields of expertise. Social science and humanities funding within Integrated Institutes should be structured to enable diverse activities. In Synberc these included: assessing and addressing safety, security and environmental risks; analyzing policies on intellectual property regimes IPR, techno-industrial policy, and risk regulation; conducting ethical and ethnographic research, and knowledge brokering.