



October 30, 2023

BY ELECTRONIC SUBMISSION

ARPA-H-ELSI@arpa-h.gov

Re: Request for Information: Design and Development of ARPA-H Ethical, Legal, and Social Implications (ELSI) Initiative

I am writing on behalf of the [Association of Bioethics Program Directors \(ABPD\)](#) in response to the Request for Information (RFI) on the Design and Development of the ARPA-H ELSI Initiative. We understand that ARPA-H is seeking unique and creative ideas to help the agency develop a well-informed, comprehensive, and actionable Ethical, Legal, and Social Implications (ELSI) of research framework that will guide, clarify, justify, and evaluate ARPA-H investments toward the development of high-impact health solutions.

The ABPD represents the leadership of approximately 100 academic bioethics programs across North America and exists to serve the needs of the programs led by our member directors. Our association's work helps to foster the development and success of bioethics programs housed in academic institutions and healthcare systems by creating information of use to program directors, acting as a clearinghouse for information, and hosting conversations among peers about issues that are important for those in leadership positions. Many of the faculty, staff, and trainees in our members' programs receive grant support for bioethics research from the National Institutes of Health (NIH), the National Science Foundation, the Greenwall Foundation, and other funders, including the ELSI program at the National Human Genome Research Institute (NHGRI). An important goal of the ABPD is to be a voice for a bioethics of the future, based on collaborations with stakeholder organizations.

Our response to the RFI centers on the importance of community engagement. **We encourage ARPA-H to require community engagement as a fundamental component of the ELSI research program.** Effective technology development and implementation must begin with a recognition of the communities it aims to serve. This requires integrating the expertise of communities through equitable collaboration with technology developers, ELSI scholars, scientists, policymakers, and others involved in ARPA-H projects. The now three-decades-long history of the ELSI program in genomics suggests that engaging communities is critical to increasing trust, reducing potential harms, and optimizing the potential for more beneficial science.^[1] This will require investments in community engagement that go beyond the specific timelines of individual projects and foster community engagement in long-term relationships. Dedicating funding sufficient for engaging the appropriate expertise, developing effective mechanisms for integrating community members, and assessing the impact of relationship-building will be critical in addressing potential concerns about the societal effects of emerging technologies.



Drawing on the experience of many of our members involved in ELSI research in genomics, artificial intelligence, and other emerging biotechnologies, **we encourage ARPA-H to create flexible structures for ELSI research that include funding for both embedded and independent projects.** We encourage the integration of ELSI research and consultation into Requests for Proposals (RFP) to ensure ELSI is addressed from the beginning and throughout a project. There are several examples of effective embedded ELSI research in which ELSI researchers function as team members on projects and are positioned to address emergent ELSI questions in real-time. Examples of this model include the NIH Pragmatic Clinical Trials Collaboratory and the NIH/NHGRI Clinical Sequencing Evidence Generating Research consortia, in which ELSI researchers are integral to the ethics and regulatory cores that function as a general resource for addressing emergent issues.

In addition to the embedded ELSI approach, **we underscore the importance of ARPA-H support for independent, investigator-initiated ELSI research that provides opportunities for raising and addressing ELSI questions.** For example, mechanisms for independent research can frame ELSI activity as supporting a range of potential innovative health solutions, including non-technology-based approaches, and whether and how technologies should be implemented. Independent ELSI research is critical for an ELSI program to represent public interests, and for ELSI researchers to have the intellectual freedom and budgetary independence to surface questions and issues that bear on the ethical, legal, and social implications of emerging technologies.

It is critical that ARPA-H invest in training programs across career stages and disciplines to support the next generation of ELSI scholars and scientists. This should include a palette of funding mechanisms at the predoctoral, postdoctoral, early career, and transition to independence stages that invites individuals from a range of fields, including the social sciences and humanities. Recruiting and retaining appropriate and effective expertise in the development of the ARPA-H ELSI workforce is crucial. This workforce must be inclusive of scholars and scientists who bring lived experience and understanding of the interests of the diverse communities ARPA-H seeks to engage.

We encourage ARPA-H to develop mechanisms for sharing and disseminating ELSI research products across projects to stakeholders, including ELSI researchers, communities, technology developers, and policymakers. This will ensure population representation in research, thereby building trust and transparency with the communities. Real-time dissemination of ELSI research to appropriate stakeholders is essential to increasing its value and benefit. Transparency about partnerships and their implications may be a particularly important area for the ELSI initiative. For example, institutional policies, processes, and practices that govern public-private partnerships can significantly impact equity and access, and may have downstream consequences on the distribution of benefit and public trust; these areas have been historically understudied in ELSI research. **ARPA-H should invest in empirical research into the terms and impact on equitable access of partnerships between academic centers and commercial entities, including cost-sharing arrangements, ownership of intellectual property, data access, and decision-making authority.**



We encourage ARPA-H to develop mechanisms for ongoing consultation with the ELSI and bioethics research communities in the form of an ELSI Council or Advisory Board.

This body could advise ARPA-H on programmatic and research developments in ELSI across disciplines, institutions, and federal agencies. The growth of ELSI in the US and globally provides an opportunity for ARPA-H to leverage the experience of programs in developing its ELSI initiative. Representation from bioethics-focused organizations and funders, such as the Greenwall Foundation, the Hastings Center, and the ABPD, in addition to funders of ELSI research such as the NHGRI, National Center for Advancing Translational Sciences, Genome Canada, and Wellcome Trust, would allow ARPA-H to draw on the collective experience of ELSI research and scholarship.

For more than a decade, ABPD leadership has met quarterly with NIH leadership (Office of Science Policy and Trans NIH Committee on Bioethics Research and Training) to share information about initiatives and activities of mutual interest, and to discuss the specific opportunities and constraints of bioethics programs to support ELSI research. An early aspect of this communication was for ABPD to articulate the process by which bioethics scholarship can impact policy.^[2] **Engaging** ABPD members who lead bioethics programs in education, research, and clinical translation in early conversations may be helpful as ARPA-H creates and implements its ELSI initiative. **We welcome ARPA-H to engage ABPD as a conduit for communication and a sounding board for ideas and approaches for developing the ELSI program.**

Sincerely,

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^[1] Dolan, D.D., Lee, S.S.J. and Cho, M.K., 2022. Three decades of ethical, legal, and social implications research: Looking back to chart a path forward. *Cell genomics*, 2(7).

^[2] Mathews DJ, Hester DM, Kahn J, McGuire A, McKinney R Jr, Meador K, Philpott-Jones S, Youngner S, Wilfond BS. A Conceptual Model for the Translation of Bioethics Research and Scholarship. *Hastings Cent Rep*. 2016 Sep;46(5):34-9.