

December 6, 2024

Response to NSF RFI on CHIPS and Science Act, Section 10343

Today, COGR filed the following response to the <u>NSF Request for Information (RFI)</u> seeking public comment on ways in which to "incorporate ethical, social, safety, and security considerations into the agency's merit review process and to develop strategies for mitigating the potential harms of scientific research and amplifying societal benefits from such research." Responses were collected via the use of an electronic form that did not permit the uploading of attachments. Accordingly, COGR's responses were submitted using that form and are copied below.

The responses were developed by members of COGR's <u>Research Ethics and</u> <u>Compliance Committee</u>. As noted below, the group did not respond to every question in the RFI.

If you have any questions regarding this matter, please contact Kris West, Director, Research Ethics and Compliance at <u>kwest@cogr.edu</u>.

Question 1: Describe ethical, social, safety, and/or security risks from current or emerging research activities that you believe might be of concern to the community, profession, or organization with which you are connected.

The broad categories of "ethical, social, safety, and/or security risks" are both distinct and overlapping, and research activities may present one of more of these types of risks depending on how they are defined. In developing policies regarding the process for considering these risks, we urge NSF to employ consistent definitions for these terms.

For example, does the term "security risk" refer to risks to the United States' national security or to data security risks that put human subjects' privacy and confidentiality at risk? In some cases, there are existing laws and regulations, at both the federal and state level, which address these risks, and it may be helpful if NSF were to begin by conducting an inventory of existing requirements and how they are presently being addressed.

Further, in considering ethical risks, there are numerous ethical frameworks that may be applied (e.g., utilitarianism, deontology, etc.). Depending on the framework



employed, different risks may be identified and/or prioritized. A more fruitful approach may be to have stakeholders first develop or adopt an ethical framework and then employ that framework in developing regulations. One example of this approach was the drafting of the <u>Belmont Report</u>, an ethical framework developed by a commission formed pursuant to the <u>1974 National Research Act</u>. The Belmont Report was then used to inform the development of the federal Common Rule [45 C.F.R. Part 46] on human research regulations, which NSF grantees must follow.

Given that NSF is seeking "input on ways to incorporate ethical, social, safety, and security considerations into the agency's merit review process," we urge NSF to clearly define the terms "ethical, social, safety, and/or security risks" and, when possible, to align these definitions with any currently existing federal definitions. We also encourage NSF to develop or provide guidance on the ethical lenses that it desires reviewers to employ.

Question 2: Which products, technologies, and/or other outcomes from research do you think could cause significant harm to the public in the foreseeable future?

Each new product or technology, or new use of an existing product or technology, presents a range of risks and benefits, which may change over time. In addition, products and technologies may be inherently risky, but often those risks are already subject to appropriate controls through existing regulations, training, and other means. Accordingly, generating a list of these items and the risk/benefits they present has limited utility because both items and risks/benefits can change dramatically over time.

We encourage NSF to instead take an alternate approach in which it begins by inventorying the processes and frameworks currently in place at federal agencies for performing risk/benefit assessments of research activities and then partnering with the agencies that use those tools to evaluate their adaptability in addressing emerging risks. For example, the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) recently held an <u>exploratory workshop</u> that considered ethics and governance principles for the use of AI in human subjects research, including application of existing ethical frameworks (e.g., Belmont Report and Common Rule).

Additionally, NSF must consider current processes for detecting and reporting noncompliance. These processes will continue to play an important role, as no set of regulations can provide universal assurance that a wrongdoer who is intent on violating the rules will always be stopped. Finally, given that the sharing of research



results is critical to the conduct of science, asking researchers to anticipate what a hypothetical wrongdoer may do with the results of their research may not be practical.

Question 3: Describe one or more approaches for identifying ethical, social, safety, and/or security risks from research activities and balancing such risks against potential benefits.

As noted in our response to Question 2, we encourage NSF to evaluate existing risk assessment processes and determine how those processes can be leveraged and/or refined to address new and emerging risks. In addition to the noted example of the Belmont Report and the Common Rule, the <u>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and the PHS Policy on Humane Care and Use of Laboratory Animals, and related publications, provide ethical principles and processes for the review of research using animal research (although current requirements for Institutional Animal Care and Use Committees do not mandate ethics reviews). More recently, the Office of Science and Technology Policy published the revised <u>United States Government Policy for</u> Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and associated <u>Implementation Guidance</u>, which sets forth a risk assessment framework for use in the areas of biosafety and biosecurity. We note that NIST is also engaged in a process regarding artificial intelligence and its risks, and NSF may want to consider how this work can inform its efforts.</u>

Each of the foregoing review processes provides principles and frameworks to evaluate the risks and benefits associated with various types of research. We encourage NSF to leverage these existing processes in its merit review process, as opposed to inventing yet another layer of potentially duplicative and burdensome review. Further, in developing any new guidelines, we urge NSF to engage stakeholders from multiple areas, including researchers, to ensure that risks and associated controls are appropriately calibrated and do not stifle the United States' ability to continue to drive innovation.

Question 4: Describe one or more strategies for encouraging research teams to incorporate ethical, social, safety, and/or security considerations into the design of their research approach. Also, how might the strategy vary depending on research type (for example, basic vs. applied) or setting (for example, academia or industry)?

Not answered.





NSF's Approach to Ethical, Social, Safety, and Security Considerations

Question 5: How might NSF work with stakeholders to promote best practices for governance of research in emerging technologies at every stage of research?

Not answered.

Question 6: How could ethical, social, safety, and/or security considerations be incorporated into the instructions for proposers or into NSF's merit review process? Also, what challenges could arise if the merit review process is modified to include such considerations?

The NSF "Broader Impacts" statement that researchers complete as part of their NSF funding applications already requires researchers to discuss how the proposed activity benefits society or advances desired societal outcomes. Rather than requiring every applicant to similarly address ethical/social/safety/security risks in this section, NSF may want to consider adopting a risk-based approach in which NSF identifies higher risk programs for which applicants are required to provide a more detailed assessment of these risks in their proposals. For programs that present lesser risks, NSF could consider the use of a default statement by which the applicant acknowledges that they have considered potential ethical/social/safety/security risks and concluded that the program does not present significant risks. This approach could also incorporate an optional section for describing any unusual situation in which an unexpected risk may have been identified.

If NSF does modify the merit review process to include risk assessment considerations, we urge NSF to also consider the training required for both applicants and reviewers. Specifically, current training for the responsible and ethical conduct of research (RECR) may need to be modified to incorporate material on identifying and assessing societal risks posed by various types of research, and institutions will need support in developing these training resources. Additionally, reviewers will need instruction on how they should assess risks and weigh risk/benefit ratios, so as not to penalize researchers who propose high risk/high reward research. Finally, we urge NSF to avoid requiring researchers and reviewers to assess risks for which they possess inadequate information to consider. This is particularly true in the area of risks posed to research by malign foreign influence. Researchers and reviewers do not have access to all pertinent information necessary to identify and evaluate potential threats to national security.



Question 7: What other measures could NSF consider as it seeks to identify and mitigate ethical, social, safety, and/or security risks from research projects or other activities that the agency supports?

We urge NSF to consider the impact on innovation and the STEM pipeline. Federally funded researchers already must comply with a multitude of regulations and guidance documents designed to address widely accepted ethical and safety risks associated with the conduct of their research. They are then committed to the broad sharing of that research as part of the scientific process. Adding additional requirements (such as the impossible task of trying to predict what an unknown malfeasor may do with the results of basic research) to researchers' increasingly burdensome list of proposal requirements, may have the unintended, and undesirable, effect of discouraging scientists from pursuing research that poses any risk. And, as with the growth of AI, working solely with the private sector, which is subject to fewer of these rules, may become the preferred path for our brightest scientists.