PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

August 10, 2022

Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine
Board on Health Sciences Policy
National Academy of Medicine
500 Fifth Street, NW
Washington, DC 20001

RE: Recommendations for creating a governance framework for managing risks, benefits, and implications of emerging science, technology, and innovation in health and medicine.

Submitted via email to CESTI@nas.edu

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to provide input to the National Academy of Medicine (NAM) Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

Below is PRIM&R's input for the Committee's consideration:

Ethical principles to undergird a new framework
PRIM&R strongly endorses the Committee's intent to develop a framework that is founded on the ethical principles of justice, equity, and fairness, and exhorts the Committee to also take into consideration diversity and inclusion at all levels in emerging science, technology, and innovation (ST&I)—idea development, funding decisions regarding initiatives, workforce development, product testing and impact, access to novel products as well as oversight functions.

Impact of evolving societal norms on ST&I ethics
Efforts to develop a framework for governance of emerging ST&I in health and medicine need to be situated within the larger context of

emerging technologies as an integral part of everyday life. The rapid pace at which innovative technologies are being developed and adopted by the public has had a tremendous impact on societal norms. For example, as a result of the ubiquity of digital technologies, societal norms regarding issues such as privacy and consent are evolving and are currently in a state of flux. The right to privacy is not as equitably distributed as it was in the pre-digital age and is most accessible to those who are savvier about the use of emerging technologies. Given the pervasiveness of digital technologies and the variety of entities involved in developing and using them, adequate governance of emerging ethical challenges will require coordinated efforts involving public and private stakeholders (including scientists, technology developers, institutional review boards/ethics committees, federal oversight agencies, community members, and patient advocates) across the research, technology, and innovation enterprise, as well as sustained dialogue with the public.

Shortcomings of current governance systems

As the committee thinks about governance frameworks for emerging ST&I in health and medicine, it would do well to consider the shortcomings of current governance approaches. First, the current regulatory oversight system for the research that undergirds technological innovation is ill-suited to address all of the ethical issues arising around emerging ST&I. More specifically, the Federal Policy for the Protection of Human Research Subjects (the Common Rule) explicitly and unequivocally proscribes institutional review boards (IRBs) from taking into consideration possible downstream impacts of the knowledge gained from the research on society, when weighing risks and potential benefits of the research. As a result, researchers are discouraged from even considering potential negative ethical or societal implications of their research, in general. Furthermore, the current research oversight system is designed primarily to address the possibility of immediate physical risks/harms, and is not therefore well-equipped to deal with the full range of potential harms involved in modern research (for example, research on medical practice, big data, citizen science), including risks to privacy, dignitary harms, and access and use of personal information and data for commercial or other purposes without explicit consent

One effort to address these gaps in oversight is a program within the Ethics, Technology, and Society Hub at Stanford University entitled *Ethics and Society Review (ESR)*[1]. The mission of ESR is to help researchers "in mitigating negative and societal aspects of their research… ." Grant funding is predicated on researchers including in their proposal to an interdisciplinary ESR Board details about potential downstream harms of the proposed study not only to participants and their communities, but to society at large, as well steps that would mitigate those risks. The ESR program could serve as model for creating a framework for governance of ST&I, such that both public and private funders of ST&I make it mandatory for researchers and developers, as a condition for obtaining funding, to

[1] See https://casbs.stanford.edu/ethics-society-review-stanford-university

provide a detailed narrative describing ethical and society implications of their research and their mitigations strategies.

Second, the patchwork nature of current oversight systems leaves important gaps in governance of research and development of ST&I. The multi-sectoral nature of ST&I today involves myriad old and new players, including academic researchers, public and private funders, biotech companies, tech start-ups, and more. By statute, federal agencies are charged with regulatory oversight of publicly funded ST&I, typically conducted by academic researchers. For example, the Department of Health and Human Services Office for Human Research Protections oversees the research with human subjects to ensure the protection of the rights and welfare of the subjects, and the FDA regulates research activities by various entities, if they are in the service of developing a drug, device, or biologic for the market. Thus, academic and some industry researchers developing ever more sophisticated technologies for health and medicine are required to comply with federal policies for the protection of human subjects in research. However, technology companies that develop health apps and sell them directly to consumers often fall outside the purview of the federal oversight system and are virtually unregulated, even if other aspects of the business are regulated by agencies such as the Federal Trade Commission. In short, given that privately funded entities are playing a much bigger role in ST&I, it is imperative that these other actors also be held to the same standards of compliance and accountability as those in the public sector.

We believe that there needs to be a concerted and coordinated effort across federal agencies to ensure that issues and entities that are not covered by the current patchwork of regulatory oversight mechanisms are adequately addressed. There are different ways that such a system might be structured. One possibility is the creation of an interagency group to regulate ST&I at the federal level, based on one or more legislative statutes (in case public and private require separate statutes), with one federal agency responsible for enforcement and oversight—similar to separate safety programs for public vs private industry overseen by the Department of Labor Occupational Safety and Health Administration. Another possibility is a harmonization effort across different relevant agencies (akin to the Common Rule).

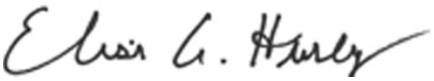
Enhanced and expanded training in scientific ethics

PRIM&R also wants to emphasize the role of education about scientific ethics as a lever for enhancing good governance of emerging ST&I in health and medicine. The education and training of researchers in the biomedical, behavioral, and social sciences typically equips them to be sensitive to and to incorporate ethical considerations in the design and conduct of their research. Academic programs in fields related to the development of digital technologies, such as information sciences, computer sciences, and engineering, on the other hand, do not typically include training in research ethics. Thus, there is a pressing need to incorporate into training of the next generation of both scientists and technology developers, ensuring that consideration of ethics is integral to the process of designing innovative technologies in health and medicine.

Inequities in access to ST&I in health and medicine
Finally, we remind the Committee that it is critically important that a governance framework for emerging ST&I in health and medicine take into account a fundamental shortcoming of the current US healthcare system, specifically in terms of justice, fairness, inclusion, and access. The costs associated with our current health care system threaten to put emerging ST&I in health and medicine outside the reach of broad sections of the public, specifically those individuals and groups who are medically disenfranchised. This in turn would exacerbate prevailing inequities in health and wellbeing. It is imperative that any governance framework for this domain not only not further exacerbate problems of systemic racism and classism, for instance by instituting superficial requirements, mechanisms, and processes that tokenize groups and communities; it should also serve to mitigate inequities in access and applicability.

Thank you again for the opportunity to provide input to the Committee as it develops a governance framework for emerging ST&I in health and medicine. We hope our comments will be useful to the Committee in its ongoing deliberations on this important issue. PRIM&R stands ready to provide any further assistance or input that might be of use. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Sincerely,



Elisa A. Hurley, PhD
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors