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*Elisa A. Hurley, PhD
Executive Director*

3/30/20

Comments submitted via email.

RE: Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for FYs 2021-2025

To whom it may concern:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the NIH Request for Information Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for FYs 2021-2025.

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, including members and staff of human research protection programs and institutional review boards (IRBs), investigators, and their institutions. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise understand the central importance of ethics to the advancement of science.

We appreciate the NIH's willingness to take heed of community input as it charts its course for advancing the best possible science over the next few years. When NIH solicited comment on its 2016-20 strategic plan framework, PRIM&R urged the agency to ensure that the plan "emphasizes the centrality that ethics plays in the research enterprise by elevating ethics to a unifying element within its framework." We are therefore very pleased that Objective 3 of the new framework takes a step in this direction by emphasizing scientific integrity, public accountability, and social responsibility in the conduct of science. Elevating these issues to an overarching objective represents a clear sign of NIH's commitment to the idea that good science is responsible science.

While this commitment is commendable, we believe it will be substantially strengthened by elaborating on some key elements of responsible and accountable science, and the role of various

stakeholders, beyond scientists themselves, in ensuring that science is responsible. We elaborate on some ways to achieve this emphasis below.

First, we urge the NIH to clarify what is involved in “a culture of good scientific stewardship,” as mentioned under Objective 3. We assume the NIH means at least in part the attitudes and practices that foster responsible stewardship of the many types of resources required to conduct good science. We therefore believe that NIH’s strategic plan should articulate, under the umbrella of stewardship, an explicit commitment to the protection of the rights, interests, and welfare of the human beings who contribute their selves, their bodies, and, increasingly, their data to the advancement of science.

Furthermore, as data becomes one of the most valuable contributions a participant can make to science, it is critical that the enterprise recognize it as such. To that end, NIH should explicitly include the stewardship of *data* as an element of good scientific stewardship, and in the full Strategic Plan, committing to responsible, respectful use and handling of participant-contributed data. We have previously [submitted comment](#) about how this vision for data should be operationalized.

We also urge NIH to make clear that fostering a culture of good scientific stewardship intersects with ongoing efforts, within NIH and elsewhere, to advance rigor and reproducibility in preclinical research involving animals and animal models, while maintaining the highest standards of animal welfare.

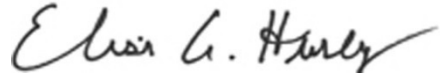
Second, we turn to the cross-cutting themes. PRIM&R endorses the framework’s cross-cutting themes as representing important considerations spanning the plan’s specific objectives. We are especially pleased to see NIH’s commitment to supporting and enhancing diversity, broadly, and to addressing health disparities, as these commitments are key to ensuring that the benefits of science are widely, and fairly, shared.

With respect to the cross-cutting theme of “promoting collaborative science,” however, we hope it is intended to go beyond scientists collaborating with other scientists to include additional stakeholders in the research enterprise, such as oversight bodies, the public, and research participants. Not only are partnerships with these other groups crucial to driving science forward, leveraging them is also key to meeting the framework’s third objective. The scientific enterprise will not succeed or advance without the trust of the public, as consumers of, funders for, and potential participants in, that endeavor. To that end, we urge NIH in further iterations of its strategic plan to make clear that accountability is to not only the principles of good science but also the populations whom science is meant to serve and on whom it relies.

As a global leader in advancing the scientific enterprise, the NIH is to be commended for elevating issues of integrity, accountability, responsibility, and diversity in its next strategic plan. The suggestions we have made here are offered in the spirit of helping NIH deliver on its commitments to these important values. PRIM&R stands ready to provide any further

assistance or input that might be useful during this process. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Respectfully submitted,

A handwritten signature in black ink, reading "Elisa A. Hurley". The signature is written in a cursive style with a large, sweeping initial 'E'.

Elisa A. Hurley, PhD
Executive Director

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