Comments from
The FUTURE OF PRIVACY FORUM
To the NATIONAL INSTITUTES OF HEALTH
Office of the Director

NOT-OD-20-064
Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for FYs 2021-2025

Submitted to:
NIH via website form available at: https://grants.nih.gov/grants/rfi/rfi.cfm?ID=101
Email: nihstrategicplan@od.nih.gov

Dr. Rachele Hendricks-Sturrup, Health Policy Counsel
Dr. Sara R. Jordan, Policy Counsel, Artificial Intelligence
THE FUTURE OF PRIVACY FORUM
1400 I St. NW Ste. 450
Washington, DC 20005
www.fpf.org

On February 12, 2020, the Office of the Director for the National Institutes of Health (NIH) published a Request for Information and feedback on the NIH-Wide Strategic Plan covering fiscal years 2021-2025. We thank the Office of the Director for the opportunity to submit comments.

The Future of Privacy Forum (FPF) is a non-profit organization that serves as a catalyst for privacy leadership and scholarship, advancing principled data practices in support of emerging technologies. FPF is supported by the privacy officers of more than 150 companies and by leading foundations, with an advisory board of academic, civil society and industry members. We bring together industry, academics, consumer advocates, and other thought leaders to explore the challenges posed by technological innovation and develop privacy protections, ethical norms, and workable business practices.[1] FPF supports the work of the NIH to address the cross-cutting themes identified in the RFI.

We write to comment on: 1) overall cross-cutting themes; 2) RFI Objective 2 (Supporting Research Resources and Infrastructure); and RFI 3) Objective 3 (Fostering a Culture of Good Scientific Stewardship). FPF recommends:

- The NIH should consider “balancing health data privacy with data access and use” as an additional cross-cutting theme;
- The NIH should support research resources and infrastructure with ethical review models and tools. In particular, the NIH should consider adopting or working with FPF to refine

[1] The views herein do not necessarily reflect those of our supporters or our Advisory Board.

our ethical review tools, which could help the NIH identify, consider, and mitigate privacy risks raised by the terms of use and re-use of data held in the NIH repositories; and

- The NIH should foster a culture of good scientific stewardship around consent to data use. This is particularly important given that health data is no longer exclusively generated or processed by health care providers and insurers.

1. The NIH Should Consider "Balancing Health Data Privacy with Data Access and Use" as an Additional Cross-Cutting Theme

FPF supports the NIH's continued commitment to advancing the health of the American people and the global population. We encourage the NIH to consider "balancing health data privacy with data access and use" as a cross-cutting theme. FPF encourages the NIH to include the following components to the proposed cross-cutting theme:

1. Ensuring fidelity to a risk-adjusted consent framework;
2. Developing a clear and privacy-preserving and responsible data use guidance; and
3. Promoting a privacy-centric approach to health data sharing and use across sectors and stakeholders.

We believe that by adding this additional cross-cutting theme, a balance might be achieved between the NIH's drive to advance health and preserving the privacy of individuals who offer their data for the development of new medical procedures, products, pharmaceuticals, and devices. This would include the use and processing of patient data from traditional health records, consumer- and/or patient-reported data, and consumer-generated health data.

2. Supporting Research Resources and Infrastructure with Ethical Review Models and Tools

The NIH is the premier agency from which exceptional health data can be drawn for secondary use. Creating effective tools to facilitate use of data in the NIH repositories, such as adoption of a clear-language approach, with robust verbal and symbolic descriptions of restrictions and use permissions, should be incorporated into all institutes' guidance on secondary data use. FPF has developed infographics that describe data on a spectrum of fully identified to fully anonymized on which we have received excellent user feedback regarding interpretability and explicability.[2] We encourage adoption of our model as one mechanism for description of datasets and terms of their use. Including language that outlines the potential privacy risks for reuse of the data, including results from a well-designed open data risk-benefit assessment, will clarify boundaries to privacy respecting reuse of the data.[3]

---

[2] Finch, K. (2016). A Visual Guide to Practical Data De-Identification. https://fpf.org/2016/04/25/a-visual-guide-to-practical-data-de-identification/

[3] Finch, K. (2018). FPF Publishes Model Open Data Benefit-Risk Analysis. https://fpf.org/2018/01/30/fpf-publishes-model-open-data-benefit-risk-analysis/

Secondary uses of health data, including recombination of the NIH funded data with non-research data sources, present issues for all divisions of the NIH, researchers funded by the NIH, and users of data held by the NIH. FPF welcomes the opportunity to work with the NIH to develop policies and procedures necessary to implement an oversight group that can be responsible for reviewing secondary data use requests on behalf of companies using the NIH data repositories and other repositories storing human subjects data. FPF is implementing the objectives of a grant received for the express purpose of designing an ethical review process for data sharing between corporations and research organizations.[4] We have committed to development of an ethical data sharing review board that broadly meets the third objective described in this RFI. The FPF Ethical Data Sharing Review Committee will provide a framework for review that is compatible with the research ethics and research integrity infrastructure that already governs federally funded research projects.[5] This body will serve as an independent body to provide review of data sharing arrangements made between for-profit and not-for-profit, non-profit, academic, and other organizations when those data sharing arrangements are made for the specific purpose of research. Our expertise in corporate data sharing practices[6,7] privacy risks for machine learning systems[8] and embedding data protection principles for machine learning[9] puts our organization in an ideal place to serve as a reliable partner for oversight of data use requests.

3. Foster a Culture of Good Scientific Stewardship Around Consent to Data Use

---

[4] Leong, B. (2019). FPF Receives Grant to Design Ethical Review Process for Research Access to Corporate Data. https://fpf.org/2019/10/15/fpf-receives-grant-to-design-ethical-review-process-for-research-access-to-corporate-data/

[5] Jordan, S.R. (2019). Designing an AI Research Review Committee. https://fpf.org/wp-content/uploads/2019/10/DesigningAIResearchReviewCommittee.pdf

[6] Harris, L. & Sharma, C. (2017). Understanding Corporate Data Sharing Decisions: Practices, Challenges, and Opportunities for Sharing Corporate Data with Researchers. https://fpf.org/2017/11/14/understanding-corporate-data-sharing-decisions-practices-challenges-and-opportunities-for-sharing-corporate-data-with-researchers/

[7] FPF Staff. (2019). Ethical and Privacy Protective Academic Research and Corporate Data. https://fpf.org/2019/06/07/fpf-companies-academics-developing-best-practices-on-data-sharing/

[8] Stalla-Bourdillon, S., Leong, B., Hall, P., & Burt, A. (2019). WARNING SIGNS: The future of privacy and security in an age of machine learning. https://fpf.org/2019/09/20/warning-signs-identifying-privacy-and-security-risks-to-machine-learning-systems/

[9] Stalla-Bourdillon, S., Rossi, A., & Zanfir-Fortuna, G. (2019). Data Protection by Process: How to Operationalize Data Protection by Design for Machine Learning. https://fpf.org/2019/12/19/new-white-paper-provides-guidance-on-embedding-data-protection-principles-in-machine-learning/

Given that consent is an essential component to the protection of health data privacy, we would like to caution that consent may be an appropriate mechanism for protecting the privacy and data rights of research participants in many cases, but not in all cases, especially given that health data is no longer exclusively generated or processed by health care providers and insurers. Guidance from the European Data Protection Board (EDPB) reminds that consent may be less appropriate when there is an imbalance of power between data subjects and researchers.[10] FPF encourages the NIH to fund all institutes' development of a nuanced approach to requirements for fidelity to consent that acknowledge the limitations to consent in each disciplinary area and reinvigorates the use of consent documents to outline which research purposes conform to participants' privacy expectations.

We are particularly concerned that the NIH's strategic plan encourages each institute to evaluate its approach to individual consent and broad consent with a perspective that merges disciplinary concerns with global privacy concerns.[11,12,13] Broad consent requirements give investigators the latitude to request that subjects consider future unknown uses of their data and give consent to those unknown future uses, within the restrictions that they must set out for the period of time the data may be stored, maintained, or used. Under these terms, investigators do not need to re-approach subjects to notify them if clinically relevant research results emerge from secondary use under broad consent.

Conclusion

Several footnotes herein contain links to FPF resources that the NIH may find useful or as a starting points for possible FPF-NIH collaboration to create institute wide guidance on balancing privacy and data use consent (health data or otherwise). We believe that a FPF-NIH collaboration would be timely and meaningful to adapt to and within the current landscape of using traditional and nontraditional health data, and/or combining such data with other data (e.g. location/movement data), to support and advance socially-beneficial research. Specifically, FPF would enjoy collaborating with the NIH to develop and/or refine existing tools needed to achieve

---

[10] Article 29 Working Party (2018). Guidelines on Consent under Regulation 2016/679. https://ec.europa.eu/newsroom/article29/document.cfm?action=display&doc_id=51030

[11] Federal Ministry of Justice and Consumer Protection. (2020). Opinion of the Data Ethics Commission. Federal Government of Germany. January 22, 2020. https://www.bmjv.de/SharedDocs/Downloads/DE/Themen/Fokusthemen/Gutachten_DEK_EN_lang.html;jsessionid=088D6FC6594FF0130AEC723D7A82FEC1.2_cid334?nn=11678512

[12] European Data Protection Supervisor (EDPS). (2020). A Preliminary Opinion on Data Protection and Scientific Research. January 6, 2020. https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

[13] Office for Human Research Protections. (2018). Revised Common Rule Q&As. July 30, 2018. https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#broad-consent-in-the-revised-common-rule

this objective and successfully ensure that our recommendations herein are implemented to the benefit of stakeholders engaged in leveraging data for good.