Dear Members of the Genomic Data Sharing Policy Team,

Public Responsibility in Medicine and Research (PRIM&R), a nonprofit educational and professional development organization, appreciates the opportunity to submit comments on the National Institutes of Health (NIH) draft Genomic Data Sharing Policy, as requested in the September 20, 2013 Federal Register notice.

For 39 years, PRIM&R has been dedicated to advancing the highest ethical standards in the conduct of research. We accomplish this goal by serving the full array of individuals and organizations involved in biomedical, behavioral, and social science research, particularly the members and staff of human research protection programs and institutional review boards (IRBs). Through conferences and other educational activities, PRIM&R provides balanced, thorough, and accurate information on a range of ethical and regulatory issues affecting research.

PRIM&R agrees that making genomic data available for broad research has the potential to provide important public benefits. As a research ethics education organization, rather than an organization that conducts, oversees, funds, or otherwise has a direct stake in research using such data, our comments focus on dimensions of the Policy that could help to ensure this work is conducted in the most ethically defensible way.

Before we move into our specific recommendations and comments, we wish to make a preliminary point. We strongly urge NIH to clarify that this proposed Policy covers only data and data sharing, and not the collection or sharing of biospecimens. The draft Policy refers in several places—notably in section C.4 on informed consent—to “clinical specimens” and “cell lines.” Though these are presumably references to data derived from clinical specimens and cell lines, and not to the specimens/cell lines themselves, the mention of biological source materials may lead to confusion. It is essential that NIH make absolutely clear that this Policy applies solely to data, to avoid confusing guidelines dealing with data and guidelines dealing with specimens. In accord with this clarification, our comments refer only to data sharing, and not to specimen collection or sharing.
Below, we make one broad recommendation, and then add two narrow requests for further guidance and clarification.

I. Informed Consent as an Educational Opportunity

The draft Policy presents a number of requirements regarding informed consent as a condition of submitting data to the appropriate databases. Two of PRIM&R’s guiding principles are that protecting the rights and welfare of human research subjects is of primary importance, and that a robust informed consent process is a principal mechanism by which such protection is operationalized. However, the activity discussed in this draft Policy does not qualify as human subjects research under the Federal Regulations codified at 45 CFR 46, because it solely involves the submission of de-identified genomic data to a database. Therefore, as long as these data are truly de-identified and the proposed uses do not constitute human subjects research, PRIM&R urges NIH, as it considers the infrastructure needed to promote responsible genomic data sharing, to move away from a model that focuses narrowly on what consent documents for discrete studies say about the collection, de-identification, and secondary use of any research data generated. Nevertheless, the ethical principle of respect for persons (as described in the Belmont Report and elsewhere) supports the contention that those who provide genomic information for research purposes be told that their genetic material or data is going to be so used; we do not suggest otherwise. Rather, we urge NIH to utilize these data sharing possibilities as opportunities to educate the general public, as potential sources of specimens and data, about genomic research and research in general, and to adopt a model of disclosure for data that has this broad educational goal at its core.

More specifically, we suggest that NIH create, or underwrite the creation of, a toolkit of understandable, accessible, layperson-friendly information about how and why biological specimens and genomic data are being collected and shared.¹ This toolkit should be provided to all investigators who might be required to submit information to a database, as well as to clinicians who must be aware that data and specimen obtained in routine clinical care may be used in research. The toolkit might involve a script for investigators with visual aids for potential donors, a brochure to review, and/or a short video to discuss. It should be generic, rather than specific to any particular study or data repository, so that it could be used by any NIH-supported researcher in conversation with any individual whose de-identified data might be collected and shared.

The goals of this conversation, as facilitated by such a toolkit, should be (1) to inform individuals in the research setting that their genomic and phenotypic information from discrete research studies may be used for additional research in the future; (2) to inform patients in the clinical setting that information and specimens obtained for their clinical care may be used for research; (3) to explain to all potential donors why such information sharing is an important part of the research enterprise and public health; and (4) to encourage all individuals to accept the collection and retention of their

¹ While the collection of clinical biospecimens is beyond the scope of this policy, we acknowledge that it is difficult to dissociate the collection of specimens and the collection of the genomic information derived from them. A layperson-friendly communications toolkit about data sharing will likely need to provide information about the source materials from which those data are derived.
genetic information for research. It should not be to solicit their consent for research, as such, though a mechanism should be available for individuals to opt out.

We suggest that NIH consult with health communications specialists to determine how the relevant information can be best communicated. Below are some points we think it would be important to clearly communicate in any educational materials created, and some suggestions for the scope of the language that might be used:

- The National Institutes of Health (NIH) stores genetic information from people who have been in research.
- If researchers can use this information it will help us better understand the role that genes play in human health.
- It is routine to send genetic information to the NIH.
- None of the information sent to the NIH will include your name or other identifying information.
- Researchers must receive permission from the NIH to use the information for research.
- If you do not want us to send your genetic information, just let us know.
- Do you have questions?

Again, this is just a rough sketch of the kind of information we think ought to be communicated. The development of an effective communications toolkit will require assembling individuals who are skilled in health communication and adult education in order to create materials with the appropriate tone, level of clarity, and scope to be understandable to the average person. Such experts will be essential because few clinicians and investigators have the training to facilitate this type of conversation.

We strongly urge NIH to seize this opportunity to educate the public about the emerging research landscape and the role each person can play in the advancement of scientific knowledge, by investing in the creation of a general communications toolkit.

We now offer two additional points focused on aspects of the draft Policy that require further clarification.

II. Guidance Regarding “Compelling Scientific Reasons” to use Tissue Without Consent

The following language appears in section IV.C.4 of the draft Policy:

For studies proposing to use cell lines or clinical specimens, the NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified. If there are compelling scientific reasons that necessitate the use of cell lines or clinical specimens that were created or collected after the effective date of this Policy and that lack consent for research use and data sharing, investigators should provide a justification for the use of any such materials in the funding request. (78 FR57862, emphasis added)
It is unclear what would count as a “compelling scientific reason” to use the data derived from cell lines or specimens collected without consent for research purposes, or who is expected to make the determination that there are such reasons. If the Policy intends for an institution to determine that the research is scientifically compelling enough to conduct without consent, prior to the submission of a funding application to NIH, then the Policy should make clear who is charged and authorized to make such determinations. NIH should also develop a plan to assure this exception to the rule is not abused. Further, more detailed criteria for the application of this exception need to be created to both guide and limit its use. This guidance is absolutely necessary even if the NIH believes that this is a role for the IRB.

III. Clarification Around “General Research Use”

Our final comment is a recommendation for clarification and consistency within the proposed Policy. In Section IV.C.5, regarding institutional certification, the draft Policy states that,

Institutions should indicate in the certification whether aggregate genomic data from datasets with data use limitations may be appropriate for general research use…. If so, the aggregate genomic data will be made available through the controlled-access compilations of aggregate genomic data to facilitate secondary research.” (78 FR 57862-63)

This statement seems inconsistent with other points in the Policy that indicate that research uses of genomic data must be consistent with what is indicated in the informed consent document signed by the individual whose genomic information it is. If a person has given consent to use his or her genomic information for specified purposes only, such as for research on a particular disease, rather than for future research broadly, then on what basis would an IRB decide that the “general research use” of such data is “appropriate”? What are the boundaries around such “general research uses,” and how—from the perspective of an individual who has allowed use of his or her information only for a specified set of purposes—would allowing that person’s information to be used for “general research” be relevantly different from using it in research the person has explicitly ruled out?

Perhaps another way to articulate what is perplexing here is to ask how the category of “general research use” is distinct from the category of research uses to which information that is designated as “open-access” would be put. If it is not different—and we admit that we do not understand, as written, how it would be—then it seems that no data accompanied by data use limitations could appropriately be used for such “general research uses” since the person, by not electing “open-access,” presumptively meant to remove his or her data from use in such “general research.” At the very least, NIH needs to clarify these categories, to provide better reasons why general research uses would not routinely be ruled out by the limitations placed on research uses during the consent process, and to specify by whom determinations that such uses are “appropriate” may be made.

IV. Conclusion

We hope that our recommendations regarding a communications toolkit, and our requests for further clarification and rethinking, provide useful direction to NIH as it further develops its
genomic data sharing policy. We welcome the opportunity to collaborate with NIH on the
development of the toolkit, should that be of interest, and, more broadly, on promoting the goal
of responsible genomic data sharing that is so important to all stakeholders in the research
enterprise.

Respectfully Submitted,

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Cc: Board of Directors, Public Policy Committee