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Dear NIH Genomic Data Sharing Policy Team,

The Genomic Data Sharing Policy provides an excellent opportunity for the NIH to establish methods to engage research participants in a truly participant-centered approach to genomic medicine. The participant consent process provides an opportunity to engage individuals and their families, to explain the intentions of research, and to initiate dialogue about the participant's role in the research process.

First, we believe more emphasis should be put on Fair Information Practice Principles, so that the burden of engagement is not placed upon informed consent alone, and particularly not upon a form, rather than a process.

Second, we believe that the proposal to adopt a "broad consent" approach undermines the NIH's focus on ensuring that participants are appropriately informed about the research to which they are contributing. NIH wishes to engage participants and the public in a much broader understanding of biomedical research, and those who 'raise their hand' to participate in biobanks, registries and clinical trials are prime stakeholders in this engagement.

Instead, we propose that NIH adopts at least a dynamic consent approach, and perhaps a granular (allowing sharing of specific subsets of information) and dynamic consent process. Using dynamic consent will empower participants to understand the potential of the proposed research, improve their level of engagement, and provide input in the process. The recent Institute of Medicine recommendations for the Centers of Translational Science Awards (CTSA) highlighted community engagement as an essential element of the research enterprise. NIH welcomed those recommendations, and it would be inconsistent for the agency to use broad consent instead of dynamic and participatory consent.

The deficiencies of broad consent are considerable and well articulated. Participants cannot make genuinely informed decisions when sharing and decisions about secondary use of their data is beyond their reach and control. Broad consent is effectively consenting to have all the important decisions made by other people—its primary effect in practice is to marginalize and trivialize the trust and involvement of donors in research. Dynamic consent will provide an opportunity for researchers to gain participant input as the research field develops and progresses, and will enable participants to receive timely information about the research that is being undertaken.

The primary argument for broad consent—that it relieves researchers from having to engage in expensive, time-consuming recontact and re-consent of participants—is limited by the fact that broad consent does not protect research from changes in law and regulation, from innovative

new technologies that permit novel and un-anticipated uses of data, or from changing demands from publics or policy makers. Further, it diminishes the power of the connection between individuals and their data and samples. Only by integrating the whole of the individual, their family and their community into the research enterprise will researchers have the data they need to understand stratified medicine, and the contribution of the environment and microbiome.

In an era of participant-centered innovation and increased public engagement in science, research that treats participants as 'subjects' rather than participants, and static paper-based consent models, are becoming increasingly out-dated and unfit for the purpose of patient consent.

Dynamic consent is an alternative to broad consent that addresses the changing nature of biomedical research. Dynamic consent maintains and upholds participant respect by actively producing research as an ongoing partnership between participants and researchers. To achieve this, dynamic consent uses information technology to place patients and research participants at the center of decision–making. These technologies are ubiquitous in other sectors, but new to biomedical research. It makes what seemed onerous and impossible in the past, possible and simple.

There are advantages in employing a dynamic consent system.

1. This participant-centered paradigm of consent recognizes user autonomy and tailors the experience to meet individual needs.
2. Engaging participants promotes scientific literacy, transparency, and trust in research as participants become more informed about the research carried out on their samples and information.
3. An engaged and dynamic consent process creates an online, responsive, and highly engaged cohort of participants for researchers to contact regarding further studies or further collection of information.
4. A dynamic participatory process allows research governance to respond to changes in law and regulation, new scientific techniques and capabilities, and changing social perspectives by engaging with participants to discuss the changes rather than making assumptions about what patients 'would probably be comfortable with.'
5. It makes the consent process meaningful and allows for nuanced consent choices that avoid the 'all or nothing' flaw of broad consent.
6. In this age of abundant information, an engaged dynamic consent process meets the highest international ethical and legal standards for consent in a world where data protection laws are changing.

In 2007, the NIH conducted a public consultation to gather comments relating to the policy for sharing of data obtained in NIH supported or conducted Genome-Wide Association Studies (GWAS). The Notice outlining the result of this exercise stated that the *'NIH recognizes that the ethical considerations relevant to GWAS data sharing are complex and dynamic*.' Consent was a specific area of concern for respondents, with the Notice stating that efforts to address the complex nature of these issues would include *'discussion of the optimal methods for communicating with participants about relevant issues through the informed consent process for prospective studies.'* It also conceded that *'[t]he NIH anticipates that a number of GWAS proposing to include pre-existing data or samples may require additional consent of the research*

participants,' providing a clear example of the difficulty involved in setting up a system of broad consent that adequately caters to future research developments.

While this previous exercise specifically focused on GWAS studies, many of the concerns raised are directly applicable to the data sharing issues discussed in the Genomic Data Sharing Policy. The white paper produced by the global alliance states: "Within research, there are a number of participant-centric initiatives (PCIs) that use social media tools, offering new ways to engage with research participants. These can enable on-going communication, allowing individuals to give consent to research, specify personal privacy levels and to become partners in the research process in ways that have not been possible before. By enabling control over personal information and the potential to give on-going consent in real time, these initiatives meet international legal standards for the protection of privacy. Active engagement with the public and relevant governmental and regulatory officials will be needed to encourage the use of PCI and promote beneficial research while providing adequate privacy protections. In the long term, there needs to be greater transparency in data handling, commensurate punishment for mishandling of data, and governance procedures that include public input...". Renowned experts produced this white paper after much deliberation.

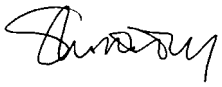
Genetic Alliance has developed the Platform for Engaging Everyone Responsibly (PEER), which uses cutting edge technology to give individuals to share their genomes, and other data, as they wish. They chose, after guidance from one of three members of their community, their own sharing, privacy and data access preferences. Open access repositories are part of the choices, and varying levels of de-identified to identified sharing are available. We believe that we can and must make the governance mechanisms and processes even more transparent and participant-centric given the personal nature of decisions and preferences in context[1]. As characterized by members of our Ethics Team and elsewhere, the shift to participant-centric models involves several important elements [2-7]. One is recognition that respect for persons requires asking permission and providing guidance to make meaningful discreet choices[8]. As many public opinion surveys have shown, there will not be a consensus regarding how comfortable people are with sharing personal health information, and with whom[9; 10]. The premise of the granular consent approach built into PEER is that we can move beyond "one size fits all" to tailored access preference management. Second, by integrating participants into every layer of decision-making and implementation, biomedical research will allow for an adaptive and responsive governance approach that makes context-specific decisions as needed, recognizing that the needs of the individual, the investigator and the biomedical research enterprise evolve over time[3]. With participants involved throughout the governance processes, we can move closer to trustworthy systems, and avoid making decisions on behalf of someone's interests unless deputized to do so[11].

Finally, in addition to the inherent participant-centric focus and design, PEER also follows best practices as outlined by disease advocacy-run biobanks and research registries[12]. These include keeping all decisions mission-focused with the mission defined as those actions and activities that advance positive impacts on human health. Other practices include being flexible and creative with partnerships and forging collaborative efforts with a full range of public-private partners who share and value the common purpose of advancing health. Combined with the adaptive approaches utilized by participant-centric designs, PEER works creatively to respond to

opportunities and find solutions when barriers are met. Our tool is ready to be put to use, and has already been deployed in a series of campaigns and activities:
https://www.reg4all.org
https://www.trialsfinder.org
http://www.free-the-data.org
and 8 sites for a patient focused drug development initiative to support FDA in PDUFA V activities.

This is an opportunity for NIH to lead on behalf of participant-centric solutions.

Sincerely,



Sharon F. Terry, MA
President and CEO
For Genetic Alliance Council and Staff

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