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Overvaluing individual consent ignores risks to tribal participants

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Abstract

Genomic studies often rely on individual-based consent approaches for tribal members residing outside of their communities. This consent model fails to acknowledge the risks to small groups such as tribes, which can implicate the community as a whole.

Guidelines for engaging Indigenous people[1] in genomics are based on community-based participatory research (CBPR) models that are consistent with Indigenous communitarian ethics[2]. However, ‘big data’ studies consistently rely on individual-based consent approaches for tribal members residing outside of their communities, which can circumvent CBPR and bypass tribal sovereignty.

Increasingly larger genomic data sets are being used to study disease. However, the inclusion of Indigenous people — including American Indians, Alaska Native groups and Native Hawaiians — remains a contentious topic for several reasons that include research harms perpetrated on tribal communities and recent concerns about open data-sharing policies. Efforts to involve Indigenous participants by large-scale consortia such as the eMERGE Network and the International HapMap Project have been unsuccessful, as shown by low recruitment numbers[1]. However, the All of Us initiative has, as of mid-February 2019, already amassed a representative sample of genomic and health record data from Native Americans, presumably by recruiting from large cities with high concentrations of Indigenous individuals and without a formal partnership with the recruited individuals’ tribes[3]. This practice of recruiting Indigenous individuals from urban centres is not new; state epidemiological databases such as the Surveillance, Epidemiology, and End Results (SEER) Program, the Million Veteran Program, hospital-based studies and universities partnered with direct-to-consumer genetic testing companies have long utilized and

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overprioritized individual consent models to passively or actively recruit populations that include Indigenous persons without tribal consultation. While this practice may be easier than engaging tribes, it is not without concern.

Individual consent ignores group risk

Individual informed consent is the prevailing model for obtaining a prospective participant's permission to partake in a biomedical research study. Its context arose out of a doctor–patient dyad and, due to an emphasis of individual autonomy in 'Western' medical ethics, forms the basis for the ethical principles of the Belmont Report and the Federal Policy for the Protection of Human Subjects ('Common Rule') in the United States. This consent model foregrounds the individual as the sole recipient of potential benefits and harms, which might not be appropriate for a member of a tribal community. Especially with small populations, there is a risk that an individual's genomic information can be used as a representative sample to make statistical inferences about his or her community. Indeed, this has been the source of many controversies occurring recently in genomics studies within tribal nations[1]. While many researchers acknowledge that 'de-identified' individuals can be bioinformatically re-identified, this is a greater issue for members of small tribes, despite data safeguards. If All of Us is, in fact, asking participants to indicate their tribal affiliation[3], then re-identification of tribes is a certainty. For Indigenous people, these risks implicate the communities as a whole, which thus transfers potential risks onto the group. If group risk is not adequately disclosed to the tribal member who is consenting to participate in a study, then we must ask if consent is truly informed or if it is being obtained from an under-informed participant.

Recent updates to the Common Rule uphold federally recognized tribes' sovereign ability to regulate research being conducted within their tribal communities. These updates correctly heed treaty law, international law and US constitutional statute. Although Indigenous researchers encourage active partnerships with tribal communities[1], in actual practice the time and resources spent building new trust relations with tribal partners may seem daunting to outsiders. Time is needed to navigate tribal governance structures, which are unique to each tribal nation. Many tribal community members live in remote areas and are geographically mobile, which can make recruitment, consenting and reconsenting, and subsequent follow-up protocols challenging. According to the 2010 US Census, more than three-quarters of American Indian and Alaska Native people live outside of tribal areas and reside in large, metropolitan cities[4]. Notwithstanding inflation due to multiracial individuals, this statistic illuminates the relative ease of recruiting Indigenous individuals who reside outside of their tribal communities.

Although this apparent migration could be interpreted as a trend away from tribally centred geographies, in actuality it more likely reflects a constant flux between urban areas and tribal ones as imposed by socio-economic factors — a long-term effect of the USA's previous assimilation and termination policies. Regardless, neither scenario argues against the extension of group protection; rather, this phenomenon should be seen as a need for cultural cohesion and preservation of Indigenous peoples' ways of life. Furthermore, if the goal of precision health and genomics research is to reduce health disparities, then a look at the structural barriers to health that overburden these communities, and not just the individual, would certainly provide a more holistic and accurate representation of health status. Unfortunately, many ‘big data’ projects aim to primarily collect large data sets of longitudinal electronic health records — a resource that is rare for US Indigenous groups with referentially less access to health care — and look for associations with genomic data that might be prone to population stratification issues depending on group identification. Given that these issues may predict less-tangible benefits for tribes participating in these projects, many tribal nations might be left to wonder whether their involvement outweighs the risks.

Towards community-based genomics

Nearly two decades ago, the Navajo Nation instituted a moratorium on genomics research within its tribal community, which they are now considering amending. In more recent years, individual tribes have developed their own policies and Institutional Review Boards for regulating research within their communities. Examples include but are not limited to the Collaborative Research Center for American Indian Health (CRCAIH), which encourages tribes in North and South Dakota to develop their own research infrastructures (expanding on governance frameworks from tribes in Oklahoma and Arizona) and the recently established US Indigenous Data Sovereignty Network. With the National Centre for Indigenous Genomics serving internationally as a model for directing health research and storing biospecimens for Australia’s First Peoples, it is only a matter of time before US tribes are able to more fully assert genomic data sovereignty within their own communities. Unfortunately, these tribal-based approaches, albeit certainly more equitable, have been and will likely continue to be circumvented by researchers’ recruitment of urban Indigenous individuals. Our hope is that calling attention to this issue can either give researchers pause long enough for tribes to develop autonomous research processes over their own data or inspire researchers to properly partner with tribal communities.

Underlying many of the complex issues touched upon here is a fundamental lack of acknowledgement of risk to groups in standard informed consent procedures. While the focus has been on tribal groups, these concerns extend to other, non-Indigenous groups as well. Especially in this era of third-party genomic databases, the risk of re-identification of linked individuals in, most famously, the Golden State Killer case points to a need to reconsider our valuation of risk on groups and not just individuals. Although these privacy concerns are generally examined in the context of European-descended dominant populations, the likelihood of re-identification is presumably the same or greater for Indigenous populations and similarly sized researched groups such as the Amish, Hutterite and Latter-Day Saints.

Central to this issue is a need to reconceptualize individual versus communal domains in precision medicine endeavours such as All of Us. While genomic research touts personalized medicine innovations in diagnostics and treatments unique to each individual, stratified medicine is the more likely outcome at best, with patients grouped by genomic profiles into likely responders to potential treatments[5]. Given the state of US Indigenous health disparities, proximal group interventions are sorely needed. Thus, for many underrepresented populations, precision medicine itself is not really about individuals, and a model of purely individual consent is doubly inadequate: it fails to recognize the risks to small communities such as tribes, and it does not match the true nature of stratified medicine. Mismatch of objectives aside, at the very least, researchers should consider impact beyond individual-level informed consent and focus on the immediate socio-political impact of their research on the communities they propose to help.

References

1. Claw KG et al. A framework for enhancing ethical genomic research with Indigenous communities. Nat. Commun 9, 2957 (2018). [PubMed: 30054469]
2. Reardon J Race to the Finish: Identity and Governance in an Age of Genomics 99–125 (Princeton Univ. Press, 2004).
3. Kaiser J Million-person U. S. study of genes and health stumbles over including Native American groups. Science 10.1126/science.aay2081 (2019).
4. Norris T, Vines PL & Hoeffel EM Report number C2010BR-10: the American Indian and Alaska Native population: 2010. United States Census Bureau https://www.census.gov/library/publications/2012/dec/c2010br-10.html (2012).
5. Juengst E et al. From “personalized” to “precision” medicine: the ethical and social implications of rhetorical reform in genomic medicine. Hastings Cent. Rep 46, 21–33 (2016). [PubMed: 27649826]