

NHGRI Meeting on: Ethical Issues Associated with the Creation and Use of Induced Pluripotent Stem Cell (iPSC) Lines Derived from NHGRI-Supported Sample Collections

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Executive summary

Induced pluripotent stem cell (iPSC) lines from diverse populations are a powerful resource to better understand human gene and variant function. NHGRI and others have developed and are continuing to develop large and diverse sample collections with broad consent for projects such as the International HapMap Project (HapMap) [1,2], the 1000 Genomes Project (1000 Genomes) [3], and the Human Pangenome Reference Consortium (Pangenome) [4]. This meeting brought together experts in iPSC lines, genomics, and Ethical, Legal and Social Implications (ELSI), including researchers with connections to communities represented in these sample collections.

The meeting, on December 1, 2021, addressed the importance and scientific value of iPSC lines developed from diverse sample collections, the elements of the consent process that would allow existing samples to be made into iPSC lines, some potential limits on the research use of such iPSC lines, and considerations for consent processes and governance structures for the development of iPSC lines from diverse population samples collected in the future.

A broad consensus-building process, the “Deriving Induced Stem Cells Using Stored Specimens (DISCUSS)” project [5], was previously undertaken to consider the consent elements that would allow existing samples to be made into iPSC lines. The HapMap and 1000 Genomes consent forms [6, 7] include specific language on all the elements of broad consent and biobanking governance that DISCUSS identified as consistent with production of iPSC lines. Thus it is likely that these samples could be used for iPSC research as long as appropriate research use limitations and governance structures are established.

The meeting participants agreed that explicit consent is required for the commercial use of products from samples or iPSC lines; the creation of iPSC lines for producing gametes or embryos; or use of the samples, iPSC lines, or their products for therapies, including transplantation. Meeting participants noted that societal and cultural concerns may vary and therefore explicit consent may also be required for using samples to develop neural organoids or human-animal chimeric tissues.

For future prospective collections, consent processes should be developed that describe the production of iPSC lines and potential research uses, now and in the future, such as organoids. Explicit consent should be obtained for specific research uses that some participants may find objectionable or concerning, such as the production of human embryonic stem cells (hESCs), embryos, gametes, gamete-producing tissues, or neural tissues. Although not a goal of the NHGRI projects listed above, other uses such as providing material for therapies or transplantation would also require explicit consent.

The importance of robust and trustworthy governance processes was stressed. For research resources that are expected to last a long time, governance structures need to be developed that will last decades. The planning for long-term research resources should consider possible future uses and mechanisms to maintain trust and ensure follow through on commitments.

Overview of meeting topics

1. Scientific value and use of iPSC lines, currently and in the future.

Discussion focused on the scientific and medical questions that iPSC lines address, the value of population diversity, the state of the field, and likely future uses of iPSC lines [8].

2. ELSI considerations for existing samples with broad consent

Discussion focused on how to determine whether previously collected samples may be used to derive iPSC lines, in particular for the HapMap and 1000 Genomes samples. Discussion included what restrictions on use or distribution of cell lines for producing iPSC lines are appropriate [5].

3. ELSI considerations for future samples

Discussion included where the field of iPSC research is going, what kinds of uses could be envisioned, and what consent processes and elements should be used. Although consent documents and processes include descriptions of potential future uses, additional considerations or restrictions may be appropriate depending on the population, proposed use, or other factors [9, 10]. Discussion also included whether particular governance structures should be developed.

Full report of the meeting

Background and goals of the meeting - Lisa Brooks

For broad biomedical research use, NHGRI supported the collection of many samples from diverse populations, including the HapMap [1], HapMap3 [2], and 1000 Genomes Projects [3]. DNA and cell lines from these samples are available to researchers, from the NHGRI Sample Repository for Human Genetic Research at the non-profit Coriell Institute for Medical Research [11]. Coriell requires that users describe the planned research use of the samples and Coriell monitors this information. These samples do not have clinical phenotype or disease data associated with them.

These samples were collected to support the discovery of common genetic variants and their haplotype patterns in 28 global populations, as well as to study other questions related to genetic variation and biology. They have been extensively genotyped and sequenced. The cell lines are used for studies that relate genotypes to molecular and cellular phenotypes, such as how variants result in differences in response to cancer drugs and in gene expression. Because of the accumulation and public release of many types of variation and functional data on the same sets of samples, and the ancestral geographic diversity of the samples, these data and samples are a major resource for the human genetics community.

When the HapMap samples were collected, starting in 2001, the HapMap Samples and ELSI Group developed community consultation processes and broad consent language [6, 12, 13]. Each community had a consultation process and issues were addressed that were specific to that community. The samples for the 1000 Genomes Project were collected by clinical research groups with close ties to their communities, using consent forms with the same elements as for the HapMap samples [7].

The participants in these projects are anonymous and they provided broad consent, including for public release of sequence and variation data and distribution of cell lines to researchers around the world, including government and commercial researchers. Research participants consented to their data being used in many ways, including population relatedness and studies of gene products. The consent forms tried to be forward thinking on where the science would go and included the production of cell lines. The HapMap consent form [6] said: “researchers will also use the samples to look for differences in the amount and form of the products that genes make, called RNA and proteins”. The 1000 Genomes consent form [7] said “Future researchers may use the samples to study many other questions, such as how genes and genetic variants affect the way genes work and the products that genes make (these are called “gene expression” or “proteomic” studies).”

iPSC lines, where cell lines are used to create pluripotent cells that can be differentiated into specific cell types, were not envisioned when the HapMap and 1000 Genomes samples were collected. There is now interest in developing iPSC lines from these samples because of their ancestral diversity, the availability of the variation data, and the accumulation of information from many studies of these samples. However, it is not clear whether the consent language is sufficient to allow the production of iPSC lines from these samples, or more generally from other samples with broad consent. Also, some uses may raise specific issues.

The HapMap and 1000 Genomes samples do not have associated phenotypes or disease information. The value of iPSC lines from these samples thus would not be for studying disease processes in samples from patients with those diseases, as most iPSC studies do. Instead, the value of iPSC lines from these samples would come from studying how variants affect molecular processes by examining many diverse samples. This would be basic research that is applicable to many diseases.

Other efforts supported by NHGRI will collect samples from additional populations for the Pangenome project and eventually other projects. Given the now widespread use of iPSC lines, consideration is warranted as to how these samples should be collected to enable such research.

The first major question for this meeting is whether there should be any conditions on the creation or use of iPSC lines from already-existing samples. The other major question is what are considerations for the consent and use of samples to be collected in the future, where there is the opportunity to develop new consent processes.

The scientific value and use of iPSC lines - Sandra Engle

Induced pluripotent stem cells (iPSCs) can be produced from cell samples and then differentiated into specific cell types [8]. These cell lines allow studies of the tissue- or cell type-specific functions of genes and their variants. Gene expression can vary a lot among cell types and cell states.

A resource of iPSC lines is valuable, since individual researchers may not be able to collect the needed samples and it takes months to produce iPSC lines and differentiate them. An available iPSC resource allows many researchers to study the same cell lines and thus accumulate rich data on the samples. Human iPSC lines are needed for research because animal models do not always have similar biology to humans, and human models are needed to develop therapies.

As an example, genetic variants substantially affect how individuals respond to drugs. To make effective drugs that work for people around the world, many populations need to be studied to understand how variants and genetic backgrounds affect drug metabolism. Most current iPSC lines are from people of European ancestry. Diverse samples are essential for including more variation in drug response that is important for various global populations. Separating genetic effects from other effects depends in part on having sufficiently large sample sizes. The 60-200 samples per population in the HapMap and 1000 Genomes samples are valuable for studying variants and haplotypes within diverse populations.

iPSC lines are being used for tissue and disease modeling, drug discovery, cell therapy, and the production of therapeutic materials. Future uses will include many more specific cell types and the development of spheroids, organoids, tissues, and organs.

Discussion - Moderated by Evan Snyder

Existing iPSC lines are available from only a handful of repositories, containing fewer than 500 lines. Genetic diversity beyond European ancestry is minimal. The HapMap and 1000 Genomes samples would be valuable as iPSC lines because of their broad consent, deep characterization, wide range of ancestral diversity, and the many samples from each population. This enables researchers to choose specific samples to study based on the genetic variants and functional data.

An iPSC product for cell therapy has to be of the highest quality if being used to treat patients, while uses of iPSC lines for drug discovery or disease modeling have more flexibility. iPSC lines should be annotated as coming directly from primary somatic tissue from a patient or from EBV-transformed cell lines. The HapMap and 1000 Genomes samples are EBV-transformed lymphoblastoid cell lines from blood samples. Frozen peripheral blood mononuclear cells (PBMCs) are available, although limited, for many of the samples. The EBV transformation affects the cells, although genetic background has a much larger influence on gene expression. The reprogramming to differentiate iPSC lines into cell types erases much of the environmentally-induced epigenomic changes.

While the HapMap and 1000 Genomes samples do not have the consent or phenotype information to be used to develop products for cell therapy, they are valuable for studying how variants affect gene expression and other molecular phenotypes. The sample sizes per population are large enough to distinguish real effects from the random effects of individual samples.

The NHGRI Repository at Coriell requires that researchers who order the samples list their research intent, with an official institutional signature. The samples may not be repurposed for other uses or shared with researchers not involved in the approved project. Coriell checks these research intents and does not provide samples to researchers who propose to use samples in ways that are not allowed. The consents for the HapMap and 1000 Genomes samples allow use by commercial researchers but prohibit the selling of products derived from those samples, such as therapies.

Outline of Ethical, Legal and Social Implications (ELSI) – Nicole Lockhart

Important ELSI considerations include informed consent, possible restrictions or limitations on use, and governance. While the meeting did not seek to write consent forms, general guidance on the kinds of language or topics that should be included to allow derivation of iPSC lines was sought. Conversely, examples of consent language that preclude the derivation or particular uses of iPSC lines would be instructive. For future samples, there may be research uses for which specific consent is recommended. In addition to the informed consent document itself, consideration of the process used to obtain informed consent from participants is also important. Meeting participants recognized that it may be appropriate to establish different standards for samples that were already collected compared to future samples.

Another key consideration for meeting participants was related to governance. What systems, processes and oversight would be required to uphold the principles described in the consent forms and who should be responsible for establishing and maintaining any such structures? Consideration of whether existing governance systems are sufficient or additional approaches might be needed for future samples was welcomed.

ELSI considerations for existing samples such as in HapMap and 1000 Genomes - Rosario Isasi

When samples have already been collected and the participants cannot be reconsented, the focus is on whether the derivation of iPSC lines is consistent with the original consent used for sample collection. The “Deriving Induced Stem Cells Using Stored Specimens (DISCUSS)” project [5] was a collaboration to develop consensus on the responsible use of existing human biospecimens for derivation of iPSC lines. The DISCUSS project included published points to consider, fora with international participants involved in human specimen research and biobanking, and a revised set of points to consider in response to feedback. The DISCUSS project recognized the scientific value of samples that are well characterized and come from diverse populations that would be hard to replicate as resources for the research community.

The overarching conclusion of the DISCUSS project was that procedural and governance mechanisms should guide the use of biospecimens and decisions related to the potential derivation, use and distribution of iPSC lines. The focus should be establishing trustworthy processes and avoiding strictly legalistic review. Such procedures would include a review to ensure that iPSC derivation was not precluded by or in conflict with the original informed consent document and process. The DISCUSS project identified several informed consent elements that could be considered consistent with the derivation, use, and distribution of iPSC lines: consent for broad research use, including the study of many diseases; sharing of biospecimens with other researchers; and description of a “best-science approach” in the use of samples. DISCUSS participants noted that silence on a particular issue in the consent document does not necessarily preclude that particular use. The procedural and governance structures in place for the biospecimen collection will help determine what a reasonable participant could have understood about how their biospecimen would be used, although meeting participants noted that different institutional review boards or other bodies may arrive at different decisions. The DISCUSS group endorsed specific or explicit consent for some uses, including the deposition of individual-level genomic data in open databases, the development of cell lines or derivatives as commercial products, and studies seeking to characterize the ancestry of research participants. The HapMap and 1000 Genomes consent documents include specific language related to all of these elements of broad consent and biobanking governance.

The DISCUSS project recognized that societal concerns related to how biospecimens are used exist and should be addressed. Uses that would likely be unanticipated by participants should not be allowed for the samples or the iPSC lines derived from them without explicit consent, including use of the samples, iPSC lines, or their products for human transplantation; or the development of embryos, egg cells, sperm cells, or tissues that make gametes.

Discussion - Moderated by Bartha Knoppers

In developing the guidelines, the DISCUSS group considered the beneficence interests of the participants, the values of equity and inclusion for participants, and the importance of governance processes to support participant trust in the consent for broad use.

Neural organoids are a specific potential use that may raise concerns for some people. While there is much potential value in using neural organoids to study brain disease, there may be instances in which participants would not have consented to the use of their biospecimen if they had known such research was a possibility. Another topic of possible concern is using samples to form human-animal chimeras.

The samples for the HapMap Project were collected in consultation with a Community Advisory Board (CAB) for each community [12, 13]. These CABs were responsible for ensuring participant protections and that specific community concerns were addressed. The samples for the 1000 Genomes Project were collected by clinical research groups with close ties to their communities. It is important to recognize that negative outcomes from use of the samples could affect not just the participants but also their communities, leading to stigma or other dignitary harms. In the twenty years or so since the CABs were set up, many are no longer active (e.g., Japan, China) although some still are. The CAB for the Yoruba population is still active and has replaced some

members over the years. Coriell sends quarterly reports to the PIs who collected the HapMap samples for distribution to the CABs as well as to the PIs of the 1000 Genomes sample collecting. These reports include the use of that community's samples and articles about the medical research uses of the HapMap and 1000 Genomes samples and data. The quarterly reports allow the CABs to monitor the uses and raise any questions with Coriell.

Active CABs could provide an opportunity to discuss issues related to developing iPSC lines from the HapMap and 1000 Genomes samples. Individual participants cannot opt out of the collection since the samples are anonymous and participants were promised that attempts to identify them would not be allowed. However, a population could decide to withdraw their samples if they considered the uses of the samples inconsistent with the broad set of uses described in the informed consent form. Although meeting participants thought it would be interesting to discuss iPSC lines with existing CABs, they did not think this was a requirement before the production of iPSC lines.

ELSI considerations for prospective collection – Debra Mathews

Dasgupta and colleagues conducted focus groups with adult patients who had received medical care at the Johns Hopkins Hospital to assess their perspectives on the donation of biospecimens for the derivation of iPSC lines [9]. In this study, patients were generally supportive of the use of their tissues for iPSC research. Participants' primary concerns related to privacy and the use of non-anonymized samples or reidentification of genetic data, inappropriate uses of immortalized cells, commercialization, the creation of gametes, and cloning. Most focus groups mentioned the Henrietta Lacks story and the HeLa cell line. Despite some concerns, patients also identified mitigating factors such as robust informed consent and transparency in the use of samples. Participants' willingness to provide samples is based on trust in the person or institution asking them to participate. Most patients expressed greater trust in academic and government researchers than researchers at pharmaceutical or other commercial entities. US participants generally trust researchers and institutions in the US to do governance right but are less certain about researchers in other countries.

Bollinger and colleagues conducted a series of interviews with a diverse group of Johns Hopkins patients and parents of pediatric patients to assess views on organoid research [10]. This study found similarly high levels of support and similar concerns about organoid research as for iPSC lines. In addition, the majority of participants expressed specific concern about brain organoids as needing greater scrutiny. Given the significant health impact of brain diseases, one approach might be to prohibit research uses related to making brain models in any state approaching consciousness, rather than restricting all research on neural tissues.

In addition to the concerns expressed by potential research participants, several general concerns are described in the bioethics and ELSI literature. There is an increasing ability to re-identify samples due to porousness between sectors that hold data (e.g., clinical data, law enforcement, direct-to-consumer companies). Some feel that science is outpacing current human subjects protections. For example, non-scientists are surprised to discover that informed consent is not required for the use of deidentified samples. There is ongoing concern about the well-established lack of diversity in research studies and the downstream effects of such biases.

Special consideration may be needed for samples collected from children, including whether children will need to consent at the age of majority if their biospecimens or derivatives will be used for ongoing or long-term research. Biospecimens from rare disease populations may face additional risks related to re-identification. Finally, there is a pressing need to acknowledge the problematic history between the research community and indigenous groups and increasing calls for data sovereignty.

In 2021 the International Society for Stem Cell Research (ISSCR) issued revised Guidelines for the Field of Stem Cell Research and Regenerative Medicine [14]. These guidelines contain several recommendations related to informed consent for derivation of iPSC lines and organoids. There are also examples of consent language used by Coriell and academic institutions.

Discussion – Moderated by Rich Sharp

Informed consent

The types of samples that are the focus of this meeting were collected to create research resources. The informed consent process for the HapMap and 1000 Genomes projects stressed that the samples would contribute to developing a resource to be used by researchers all over the world. This also applies to the samples to be collected for the Pangenome project. Meeting participants agreed that framing such collections as research resources is useful, although it can be challenging to describe the possible future uses of samples due to advances in technology.

The need for greater clarity and precision when using terms such as “commercial research” in consent documents was highlighted by multiple meeting participants. “Commercial research” could include the development of therapeutics or other products for commercial use but could also include basic research conducted by commercial researchers to understand biomedical processes. While multiple studies have shown that research participants tend to have less trust in commercial entities, additional nuance describing potential uses of samples and the distinction between basic research performed by commercial entities and selling of tissues or derivatives may improve understanding by potential research participants.

Meeting participants described possible models for the informed consent process. One option could be tiered consent, where participants can opt-in to some research types and opt-out of others. Another option is dynamic consent, where participants provide ongoing consent to various types of studies or where participants can change their consent preferences over time. The ability to change preferences or privacy settings in other applications has led some research participants to question why participation in research requires a one-time consent instead of a fluid or iterative approach. However, systems that would allow changes in consent status would require the collection and maintenance of identifiers to implement any requested changes. Also, systems that would enable changing privacy or consent settings can be expensive to implement and maintain and are not broadly available in low- to medium-income countries. Further, once research data are distributed, such as in a database or publication, participants could not practicably stop the use of their data, although the participant could request no further release of samples or derivatives from a biobank if identifiers were collected.

Samples that are available for broad use and unlimited time are often more valuable scientifically than samples with limitations on use. If samples are broadly available and the resultant data are shared, then various types of data on the samples will accumulate over time, making the samples especially useful to address many biomedical questions. However, some constraints on broad use may allow the inclusion of samples from specific diverse population that have concerns about broad consent. For example, different communities and populations have different relationships with the research community due to historical mistreatment or broken promises of science delivering benefit to the community. To continue to structure systems in ways that explicitly prioritize the needs of scientists feels unbalanced to some people and will likely perpetuate the overrepresentation of European-ancestry populations and other groups with more trust in research.

Community perspectives

There are strong scientific and equity justifications for the value of samples from diverse populations, such as those in the HapMap, 1000 Genomes, and Pangenome projects, for producing iPSC lines. Generally, fresh cells are used to develop iPSC lines, but banked cells can also be used, especially given the value of the diversity of the existing and to-be-collected samples. Researchers need to develop consent processes and governance structures that support the participation of diverse communities so that people feel comfortable participating.

A variety of approaches could be used to understand the views and potentially concerning issues for different groups of people. Processes of patient and public involvement, such as used in Japan and the UK, are partnerships between lay people and researchers. Educating potential research participants can help them understand the science and issues; they become more informed for making decisions, although they will not necessarily agree to join the research. Deliberative democracy approaches convene a group of interested stakeholders, provide them with large amounts of information and differing views on a particular topic, and facilitate deliberation and debate on possible policy approaches. By providing a forum for in-depth education and discussion, deliberative democracy approaches can help researchers understand what might be driving specific concerns of participants, and how possible policy approaches might mitigate the concerns. Due to the substantial time commitment required, participation in deliberative democracy sessions may not be feasible for many community members. Other social science research methodologies such as focus groups, interviews, or surveys can be used in a complementary manner depending on the needs and research question at hand. In addition, just as science evolves over time, public attitudes can also shift and there may be differences across groups. For example, some younger people may have a different conception of privacy compared to older generations and people with rare diseases may have more concerns about identifiability but also higher enthusiasm for participation and data sharing.

When researchers engage with participants, they need to be prepared to listen and act on the advice. Participants and communities must be able to say no. When a large proportion of community members object to a research project or proposed use, then it is best to not use samples from that community for the project. However, learning the reasons for the objections may help improve the research plans, communication about the project, and the consent forms, possibly leading to greater acceptance of the project or modifications to allowed uses.

Researchers should not promise more than they can deliver, such as for privacy protections or data use. In addition, researchers should consider how to make decisions when the community views are divided.

There are specific concerns about sample collections from indigenous peoples, given the long history of inappropriate use and problematic interactions with the research community. These concerns include issues related to data sovereignty and ancient DNA and extend to samples or remains that are unidentified or anonymous.

Governance

For research resources that are expected to last a long time, governance structures need to be developed that will last decades. An advantage of prospective collections is that such structures can be designed and developed at the start of the project. One model is adaptive governance, where a governance board stands in for participants to address new issues as they arise. The planning for long-term research resources should consider possible future uses and mechanisms to maintain trust and ensure that commitments are followed through on. The future research uses of the samples require oversight and careful consideration, to minimize results that are stigmatizing or are used for discrimination and perpetuating inequities.

Concluding summary

The high-level goal of hearing perspectives on these issues from the meeting participants was achieved. A strong case was made for the importance of diverse and broadly available samples, such as HapMap and 1000 Genomes samples, for the derivation of iPSC lines, and for the inclusion of additional diverse individuals in future iPSC resources. At the same time, there is a need to recognize cultural differences and concerns from some communities that must be grappled with to reach the goal of greater diversity and equity. Approaches such as those used in the DISCUSS project may serve as a framework when considering whether existing samples align with iPSC research. In some cases, research participants might object to specific research uses, such as neural organoids, derivation of gametes, or commercial use, and it is vital to understand the origin of such objections to ensure the intent of such research in the informed consent document and process is clear and to respect these concerns.

The HapMap and 1000 Genomes samples were collected from anonymous participants and therefore consent for specific uses that require more consideration cannot be obtained. Since the broad consent for HapMap and 1000 Genomes samples included the production of cell lines, commercial use, and open access data sharing, it is likely that these samples could be used for iPSC research as long as appropriate research use limitations and governance structures are established. For future collections, the consent process could include the possibility of the production of iPSC lines, as well as explicit consent for research studies that may be of particular concern to the relevant community if such studies are envisioned for the samples. Meeting participants repeatedly highlighted the ongoing importance of long-term governance as a means of demonstrating trust and following through on commitments made to research participants.

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Meeting participants

Adebamowo, Clement		UMD
Brooks,	Lisa	NHGRI
Callouri,	Stephanie	NHGRI
Engle,	Sandra	Biogen
Felsenfeld,	Adam	NHGRI
Flicek,	Paul	EBI
Garrison,	Nanibaa'	UCLA
Ghanaim,	Elena	NHGRI
Hull,	Sara	NHGRI
Hutter,	Carolyn	NHGRI
Isasi,	Rosario	U Miami
Kato,	Kazuto	Osaka U
Knoppers,	Bartha	McGill U
Koenig,	Barbara	UCSF
Lo,	Bernie	Greenwall Foundation, UCSF
Lockhart,	Nicole	NHGRI
Loring,	Jeanne	Scripps Research Institute
Mathews,	Debra	Johns Hopkins U
McDougall,	Robyn	McGill U
McEwen,	Jean	NHGRI
Miga,	Karen	UCSC
Park,	Nyugen	NHGRI
Phillips,	Haleena	NHGRI
Popejoy,	Alice	UCDavis
Ramos,	Erin	NHGRI
Ramos,	Khara	NINDS
Rotimi,	Charles	NHGRI
Royal,	Charmaine	Duke U
Scheinfeldt,	Laura	Coriell
Sharp,	Richard	Mayo Clinic
Snyder,	Evan	UCSD
Turan,	Nahid	Coriell