



PEOPLE-DRIVEN THERAPEUTICS

Ethics and Community Engagement

Ethics and Community Engagement at Variant Bio

Variant Bio’s long-term goal is to identify individuals and populations who are outliers for traits of medical relevance, uncover the genes encoding those traits, and develop therapeutics and diagnostics that can make a local and global difference. This requires us to collect medically relevant data from people’s medical records or through a set of measurements (minimally invasive and non-invasive) and to collect DNA data from our partners’ blood or saliva. There are risks associated with sharing any sensitive data with researchers and private companies and we want to make sure that this document addresses how we are going to mitigate them and conduct our partnerships according to the highest ethical standards.

Variant Bio is a people-driven company. People are at the core of everything we do, whether it is identifying individuals and populations with unique traits or developing new treatments for disease. That’s why, when we started Variant Bio, the first thing we did was to work with leaders in the ethics of genetics and genomics to establish a concrete ethical framework and guiding principles for effectively engaging research partners. These are a core piece of Variant Bio’s foundation and guide every aspect of the work we do. Doing this from the onset is not only the right thing to do, but it’s the smart thing to do. We want our research partners to feel confident that their privacy, interests, and cultures are respected and that they benefit from partnering with us. Our hope is that this will empower communities that have historically been hesitant to engage in genomics research to make fully informed decisions regarding their participation in this type of research.

This document outlines our overarching ethical framework, our key principles for community and individual engagement and co-creation, specific guidelines for working with biobanks, and the process by which we ensure that all of our studies meet the highest ethical standards.

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I. Overarching Ethical Framework

At Variant, we see ethics as a core part of our mission—one that will allow us to build a research program from the ground up with ethics at its foundation, and to engage research partners more meaningfully than ever before. One of our first orders of business as a company was to establish a guiding ethical framework that will benefit and respect the people who partner with us. At the core of this framework are five simple tenets:

- 1) Respect – respecting the privacy, values, beliefs, and cultures of research partners.
- 2) Transparency – sharing what we know (and what we don't) about the research with our partners and making sure that we are available to answer questions and address concerns throughout the lifespan of the partnership.
- 3) Consent – implementing a thoughtful, holistic, and ongoing process of informed consent for all potential research partners.
- 4) Collaboration – co-constructing meaningful partnerships with both individual participants and their communities.
- 5) Benefit – providing a research process that maximizes the potential benefits and minimizes potential harms for participating individuals and communities.

Working with individuals and communities in a way that meets the highest ethical standards is of paramount importance to Variant Bio. To accomplish this, we have rooted our ethical framework in key international and national guidelines governing the access to and use of genetic data. We draw especially from the [World Medical Association's Declaration of Helsinki](#) (adopted in 1964); [UNESCO's Universal Declaration on the Human Genome and Human Rights](#) that was endorsed by the UN General Assembly in 1998 (particularly articles 1, 5[b,c], 10, 12, and 13); [UNESCO's International Declaration on Human Genetic Data](#) adopted in 2003 (particularly articles 3, 4(b), 7(a), 13, and 16); [UNESCO's International Declaration on Bioethics and Human Rights](#) adopted in 2005 (particularly articles 6, 8, 9, 12, 15); [UNESCO's Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights](#) (2015); [the Affordable Care Act](#) (section 1557); the 2015 report from the Institutes of Medicine: [Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk](#); and the 2018 National Academy of Science consensus report: [Returning Individual Research Results to Participants: Guidance for a New Research Paradigm](#). In addition, we hope to contribute to the international conversation on how to best engage and collaborate with historically marginalized populations in genomics research by sharing our experiences with the international research community.

II. Principles of Community and Individual Engagement

Both academic researchers and commercial entities have a history of building relationships with the individuals and diverse communities they work with and subsequently abusing the trust that those people and communities have placed in them. As a result, geneticists working with Indigenous populations worldwide are often referred to as “bio-colonists.” Consequently, many communities have produced detailed guidelines defining best practices for ethical research. Our community engagement framework is based on the [National Congress of American Indians \(NCAI\) AI/ AN Genetics Resource Guide](#), H3Africa's [High-Level Principles on Ethics, Governance and Resource Sharing](#), [Te Mata Ira](#) -

Guidelines for Genomic Research with Māori, QIMR Berghofer's [Genomic Partnerships: Guidelines for Genomic Research with Aboriginal and Torres Strait Islander Peoples of Queensland](#), and excellent suggestions published by the Summer internship for Indigenous peoples in Genomics (SING) consortium ([Claw et al., 2018](#)).

Each partnership will be unique and guided by the nature of the research and community. However, in all cases, Variant Bio will abide by the following principles of community and individual engagement:

1. ENGAGE WITH LOCAL COMMUNITIES IN AN INDIVIDUALIZED, ETHICAL, AND CULTURALLY SENSITIVE MANNER

Cultures around the world are as complex and diverse as our genetics, which means that cultural competency is an essential part of our community partnerships. Before we embark upon any projects, we will engage leaders and other members of our partner communities, and researchers who have experience working with those communities, to understand cultural nuances, including beliefs surrounding creation and ancestry, cultural taboos, and historical grievances related to medical research and genetic testing. By making cultural competency a priority, this will help ensure that if the community is interested in partnering with us, our research will be carried out sensitively, and in ways that avoid offending and/or marginalizing participants.

In addition to ensuring that we as a company are culturally competent regarding our partners, it is equally as important that our partners understand our company, our goals, and the exact nature of the proposed partnership. Culturally appropriate communication, transparency, and respect will allow partners to determine if our priorities are aligned, understand the research process, and thus feel confident about their decision of whether or not to partner with us.

2. PRACTICE CO-CREATION AND CONSULTATION

We will co-design all our research proposals. Co-designed research is the process whereby the communities and individuals who share their genetic data with us are actively involved in the creation of a research proposal to the extent that they want to be. This involves including community voices at every step of the process, and consulting with them as true research *partners* as opposed to “subjects.” Borrowing from the North America First Nations communities framework (see, for example, [Goodyear-Smith et al 2015](#)), key themes of co-design include dissemination, cultural competency, transparency, capacity building, community engagement, sovereignty, and research regulation.

Firstly, we will work together with community representatives to understand their goals and concerns with regards to genomics and health, and incorporate those as best we can into the research project. The co-design process does not end after the project has been created. Throughout the project's lifespan, we will continuously engage with participants and communities, to inform them of the project's progress, seek advice, and be available to answer any questions or concerns. At the conclusion of the project, it is also important to include

diverse community voices and narratives in the dissemination of the results, both within the partnering communities and to the greater public. This could take many forms, including co-authorship between Variant Bio and our partners on scientific papers, co-creation of educational materials, or joint media releases.

3. UNDERSTAND THE IMPORTANCE OF LEGAL AND REGULATORY FRAMEWORKS ON A LOCAL AND REGIONAL LEVEL

We recognize the importance of understanding and adhering to both national and local regulations for genomics research, particularly as many communities or tribal nations function as sovereign or semi-sovereign entities. These regulations will guide us in developing a specific framework for each partnering community for sample collection, biospecimen handling, and issues surrounding ownership of biological samples and data, data storage, and sample storage, return, or destruction.

The bare minimum requirement for ensuring ethical oversight of each project is to submit the protocol to the appropriate human research committee review board. However, we understand that true oversight requires the involvement of the people and communities we work with, and there may be instances where the local committee does not include a community representative. In instances where the local human research ethics committee does not have a representative from the community with whom we partner, we will strive to engage an external expert panel member to provide specialist advice. This will help to ensure that members of the partner community are involved in both the creation and approval of all projects.

Variant Bio will seek to engage with local researchers/medical doctors affiliated with academic or healthcare institutions which will likely have established Institutional Review Boards and formal approval processes. However, this will not always be the case, and we will always seek to engage with the local communities we are partnering with beyond academic institutions. Communities' approvals will be sought through local ethics board approval if they exist (e.g. Māori ethics board).

If neither an IRB nor a community ethics board can be found in the region where we are working, we will work with Variant's Ethics Advisory Board to seek appropriate approvals from an accredited external review board.

In rare cases, we might work with a sub-population that is not directly represented by the local ethics board. In this case, we work with Variant's Ethics Advisory Board in order to seek approval from the community in the most appropriate ways (e.g. through community representatives, NGOs, etc.).

In case we are only able to obtain informal approval from the community, without a formal review process by local authorities/representatives, we will work with Variant's Ethics Advisory Board to seek appropriate approval(s) from an accredited external review board.

4. ENSURE APPROPRIATE TYPE OF INFORMED CONSENT

The process of informed consent can look very different depending on the local context. There are many types of “informed consent” and it is important to be as specific as possible about the nature of consent and who is giving consent. In collaboration with the local community we are partnering with, we will establish a process that respects the community priorities, and may exclude certain research areas if required by the community. It will be made very explicit what type of consent is being sought for each partnership, and the potential consequences of each type of consent. It is also important to acknowledge and inform participants that “true” informed consent for genomics is often not possible, as future uses of data are unknown.

Cultural competency also plays a role in the process of seeking informed consent. We will determine who, exactly, should be consulted about consenting to the project. In some instances, consent by the individual participant will be sufficient, while in other instances, consent must be sought on behalf of the family, community, or larger set of interrelated communities. On a more micro-level, it will be important to be culturally competent regarding local norms and cultural behaviors around giving and declining consent. For example, people might be more comfortable having a local representative guide them through the consent process. These nuances will be discussed with the partnering communities, and determined before the process of seeking consent begins.

5. BE TRANSPARENT ABOUT SHORT- AND LONG-TERM RESEARCH GOALS AND PRACTICES

Historically, serious issues have arisen when research participants are not fully informed about the research process, including short- and long-term use of their sample, genetic testing results, and other health-related data. Offering individuals who participate in research access to significant findings is an essential part of our research model. We want our participants to be actively engaged as partners rather than as passive research “subjects” for the duration of the study and beyond. To accomplish this, we will share scientific findings in a format that is customized for each partner community and that establishes and respects individual preferences for return of results.

6. PROVIDE CLEAR GUIDELINES FOR DATA AND SAMPLE OWNERSHIP, STORAGE, AND SHARING

The methods and geographical locations for storing, analysing, and sharing of biological samples and data collected during the study will be detailed in the informed consent, and developed in collaboration with the local communities, and in accordance with local rules and regulations. Similarly, the stewardship of the biological samples during the study period will be agreed upon with the community by the joint creation of a standard operating procedure. This will include what to do with samples and data at the end of the project.

Every participant will be able to withdraw from participation at any time, and their data will not be used for any analysis going forward. Upon withdrawal, participant genetic data and any

associated information will be deleted, and samples will be destroyed or sent back as agreed during the consent process.

Our sequencing partners will never share any data with any outside party except ourselves. After the sequencing has been completed and they return data to us, they will not keep copies of it on their servers. On our end, we will never share the data with any other company without explicit permission from our partners. The data will be used for internal research purposes only and this research may lead to a discovery of novel diagnostic or therapeutic targets. Variant Bio and their commercial partners may use those targets to develop new diagnostics or therapeutics. In accordance with local regulations, all health information, sample information, and genomic data is stored on compliant encrypted servers hosted using online services with all communication occurring through encrypted networks. In addition, we will only receive and store de-identified data. In the unlikely event that data is inadvertently shared with outside entities we will immediately notify our partners.

At Variant Bio we firmly believe that genetic data itself does not constitute intellectual property, so we will not patent or otherwise commercialize any genetic variants or sequences. Instead, we will derive patentable property related to interventions that have been informed by genetic studies, for example, by identifying relevant targets for therapeutic intervention and developing drugs to match these targets.

7. MAXIMIZE BENEFITS FOR RESEARCH PARTNERS IN WAYS THAT REFLECT THEIR OWN PRIORITIES AND VALUES

We want to ensure that the communities and individuals we partner with benefit in ways that are relevant to them. To that end, we will establish an incentive plan in consultation with each community depending on their specific needs and priorities. We have developed a set of potential benefits (both short-term and long-term) that encourage engagement with our research partners. Short-term benefits will be funded immediately after the sample collection is completed. These funds will go into initiatives that support local capacity building, education, healthcare, and sustainable development, and will be decided together in consultation with the community. Our long-term benefits are tied to Variant Bio's future revenue and will support similar initiatives, yearly, starting when we first generate revenue from the therapeutics or diagnostics discovered in the database that all our partners contribute to. Long-term benefits will be managed and distributed with community input.

For return of any medically relevant results, we will involve medical professionals and genetic counselors. We will also make clear that a community's engagement in a genomic study will not necessarily result in a significant or specific health benefit to that community.

The ways in which Variant Bio may benefit from findings related to the samples and data collected in research projects will also be clearly explained and specified within the consent form.

8. WORK WITH LOCAL SCIENTISTS TO IMPROVE GENOMIC LITERACY AND INCREASE THE VALUE OF PARTICIPATION FOR DIVERSE COMMUNITIES

People around the world are excited about the potential of genetic studies to transform healthcare, but at the moment both expertise and participation in research are concentrated in North America, Europe, and parts of East Asia. At Variant Bio, we aim to actively support and engage local scholars and scientists, and promote scientific literacy within the communities we partner with. These partnerships will support capacity building around local research programs to facilitate translational use of genomic studies in the community and provide lasting benefits that incentivize increased voluntary representation of diverse populations in future studies, and ultimately, the development of research programs that seek to answer locally relevant questions.

In order to accomplish research capacity building, we will engage the local workforce (e.g. healthcare professionals and academic researchers) to aid in carrying out these projects. These efforts will also complement the benefit sharing outlined in the previous section; depending on the community's preferences, our benefit sharing agreement may also include supporting research scholarships for community members.

9. RESPECT THE PRIVACY OF RESEARCH PARTICIPANTS AND INFORM THEM OF ANY RISKS ASSOCIATED WITH GENETIC RESEARCH

Any identifying demographic information (such as name, email address, phone number, or any other information that could directly identify a participant from their samples) will always be removed from the samples at the time of collection. The samples will be de-identified and labeled with unique identifiers. Any research data will be stored separately from the identifying information, and in compliance with local regulations. All Variant Bio data is stored on secure servers in a way that is encrypted and password-protected, making it extremely secure. Only approved Variant Bio researchers and staff will have access to any participant's identifying information. There are risks related to sharing and storing genetic information and every participating individual will be informed about all of the potential risks, including security breaches, reidentification, and self-disclosure.

III. Partnering with Biobanks

Partnering with biobanks means using data that was collected prior to Variant Bio's involvement, as a part of studies whose principles of community and individual engagement may differ from our own. However, in all instances, Variant Bio will ensure that the biobanks we partner with have taken necessary measures to safeguard for:

1. Consent: Biobank partners will follow local laws with respect to informed consent and institutional oversight. Ideally, they will adopt a broad consent model that includes a strong and continuous ethical review process as well as continuous provision of information to participants (see [Broad Consent for Biobanks is Best -- Provided it is Also Deep](#)). Partner consent documents will be evaluated by our staff and ethics advisory board to ensure that we have the right to access samples and that they were collected according to the highest ethical standards.
2. Privacy: Biobank partners will align with the [Organisation for Economic and Cultural Development \(OECD\) Information Privacy Principles \(1980\)](#) as well as relevant national ethical codes to protect participants' confidentiality and privacy.
3. Governance: Biobank partners will align with the [OECD Guidelines on Human Biobanks and Genetic Research Databases \(2009\)](#) as well as relevant internal institutional governance arrangements to foster and maintain public trust.

IV. Ethics Advisory Board

All studies that Variant Bio engages in require approval by our Ethics Advisory Board (the Board) consisting of ethicists, genetic counsellors, and anthropologists. The purpose of this is to ensure that our partners are properly protected, that the engagement process ensures community participation, and that benefits are appropriate and aligned with contributions. This is especially important for instances where Variant Bio collaborates with researchers who have already collected samples and phenotypic data. In these cases the Board will determine whether the consent process was sufficient and whether participants understood that they consented to data sharing with a private, for-profit company. If not, we will seek to re-contact and re-consent participants.

The Ethics Advisory Board's process is to evaluate:

1. The study design.
2. The consent form, proposed consent implementation process, and legal protections stemming from this form (especially important for existing projects that use non-Variant Bio recruited cohorts).
3. The engagement and communication plan, which will depend on the community needs and will be implemented only in projects where Variant Bio works directly with the community.
4. The incentive plan, which will be discussed with the community (direct projects), or the researcher (indirect projects), and may involve benefit sharing.

IV. References and Further Reading

1. [Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects](#). World Medical Association. 1964.
2. [Universal Declaration on the Human Genome and Human Rights](#). UNESCO. 1997.
3. [International Declaration on Human Genetic Data](#). UNESCO. 2003.
4. [International Declaration on Bioethics and Human Rights](#). UNESCO. 2005.
5. [Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights](#). UNESCO. 2005.
6. [The Affordable Care Act](#). U.S. Congress. 2010.
7. [Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk](#). Committee on Strategies for Responsible Sharing of Clinical Trial Data; Board on Health Sciences Policy; Institute of Medicine. 2015.
8. [Returning Individual Research Results to Participants: Guidance for a New Research Paradigm](#). National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories. 2018.
9. [Genetics Research Guide](#). National Congress of American Indians (NCAI) AI/ AN. Accessed 03/25/19.
10. [High-Level Principles on Ethics, Governance and Resource Sharing](#). H3Africa. Accessed 03/25/19.
11. [Te Mata Ira](#). University of Waikato. 2016.
12. [Genomic Partnerships: Guidelines for Genomic Research with Aboriginal and Torres Strait Islander Peoples of Queensland](#). QIMR Berghofer. 2019.
13. [A Framework for Enhancing Ethical Genomic Research with Indigenous Communities. SING Consortium](#). 2018.
14. [Co-Design and Implementation Research: Challenges and Solutions for Ethics Committees](#). BMC Medical Ethics. 2015.
15. [Broad Consent for Biobanks is Best - Provided it is Also Deep](#). BMC Medical Ethics. 2019.
16. [Information Privacy Principles](#). Organisation for Economic and Cultural Development (OECD). 1980.
17. [Guidelines on Human Biobanks and Genetic Research Databases](#). Organisation for Economic and Cultural Development (OECD). 2009.

Appendix

1. UNESCO Universal Declaration on the Human Genome and Human Rights (1998), articles 1, 5[b,c], 10, 12, and 13:
 - Article 1: The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.
 - Article 5 [b,c]:
 - (b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.
 - (c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.
 - Article 10 (Research on the human genome): No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.
 - Article 12:
 - (a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

- (b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.
- Article 13 (Conditions for the exercise of scientific activity): The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.
2. UNESCO's International Declaration on Human Genetic Data (2003), articles 3, 4(b), 7(a), 13, and 16):
- Article 3 (Person's identity): Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.
 - Article 4(b) (Special status): Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established.
 - Article 7(a) (Non-discrimination and non-stigmatization): Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.
 - Article 13 (Access): No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security.
 - Article 16 (Change of purpose):
 - (a) Human genetic data, human proteomic data and the biological samples collected for one of the purposes set out in Article 5 should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or unless the proposed use, decided by domestic law, corresponds to an important public interest reason and is consistent with the international law of human rights. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) should apply *mutatis mutandis*.
 - (b) When prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an identifiable person, human genetic data may be used in accordance with domestic law or following the consultation procedures set out in Article 6(b).

3. UNESCO's International Declaration on Bioethics and Human Rights (2005), articles 6, 8, 9, 12, 15:
- Article 6 (Consent):
 1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
 2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
 3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.
 - Article 8 (Respect for human vulnerability and personal integrity):

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.
 - Article 9 (Privacy and confidentiality):

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.
 - Article 12 (Respect for cultural diversity and pluralism):

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.
 - Article 15 (Sharing of benefits):
 1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
 - (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

- (b) access to quality health care;
 - (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
 - (d) support for health services;
 - (e) access to scientific and technological knowledge;
 - (f) capacity-building facilities for research purposes;
 - (g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research.

4. The Affordable Care Act, section 1557 (Non-discrimination):

(a) IN GENERAL.—Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection. (b) CONTINUED APPLICATION OF LAWS.—Nothing in this title (or an amendment made by this title) shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or the Age Discrimination Act of 1975 (42 U.S.C. 611 et seq.), or to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a). (c) REGULATIONS.—The Secretary may promulgate regulations to implement this section.