

Ethical principles for the use of human cellular biotechnologies

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Recent developments in bioengineering promise the possibility of new diagnostic and treatment strategies, novel industrial processes, and innovative approaches to thorny problems in fields such as nutrition, agriculture, and biomanufacturing. As modern genetics has matured and developed technologies of increasing power, debates over risk assessments and proper applications of the technology, and over who should have decision-making power over such issues, have become more prominent. Recently, some scientists have advocated that ethicists “step out of the way,” whereas others have called for greater ethical scrutiny, or even for moratoria on some lines of research^{1,2}. As a community, however, we must together determine the proper application of these powerful biological tools. This paper, a consensus statement of a group of interdisciplinary delegates drawn from the top biotech-producing countries of the world, offers a set of ethical principles to contribute to the ethical conversation about human cellular biotechnological research moving forward.

In May 2015, a group of over 140 delegates from the top biotech-producing countries of the world gathered in Atlanta, Georgia, USA for a three-day conference entitled “Biotechnology and the Ethical Imagination: A Global Summit” (BEINGS). The purpose of the summit was to see whether an ideologically and culturally diverse group of stakeholders from a variety of fields and approaches could generate consensus on a set of principles to guide basic and translational science. The focus was on those biotechnologies rooted in gene editing and synthetic biology, with special attention to genetic manipulation of human cells that could have a major impact on human development, social and environmental health, and general human well-being.

The scope of BEINGS ‘stopped at the clinic door’. In other words, BEINGS did not focus on clinical issues or human experimentation. The focus instead was on basic, preclinical science and its implications as it made its initial move out of laboratories and into applied settings, including industrial settings. Many important and worthy issues, such as agriculture and food production, biomanufacturing, and animal rights, were deemed too unwieldy to address in the context

of BEINGS, and so were excluded from official consideration (for a more detailed explanation, please see **Box 1**).

The challenges related to biotechnologies have spawned conferences, white papers, and sets of guidelines, all trying to suggest ways to responsibly contain the power of biotechnologies, such as synthetic biology¹, human genome sequencing, stem cells², and reproductive germline editing³. Contributions of various kinds have been proffered by groups such as the United Nations Educational, Scientific and Cultural Organization (UNESCO; Paris)⁴, the US National Academy of Sciences (Washington, DC), the UK Royal Society (London), the Chinese Academy of Sciences (Beijing)³, and the Hinxton Group (Baltimore, MD)⁵. The BEINGS Conference Statement of Principles presented here is intended to complement, not compete with, these important statements, and emphasizes elements we believe are absent or insufficiently covered in other such statements. In the pages that follow, we give some background on the BEINGS selection of delegates, approach, and philosophy, and then propose ten principles to guide the use of human cellular biotechnologies that emerged from our discussions at BEINGS.

Delegates to BEINGS

The goal of BEINGS was to contribute to this ongoing dialog by convening a broad group of scholars who met the following criteria: (1) they were drawn from the top biotech-producing countries; (2) they represented a broad spectrum of disciplines, including philosophy, ethics, science, engineering, policymaking, advocacy, the arts, literature, law, and religion; and (3) they personified diverse ideological perspectives, from those who were wary or skeptical of biotechnological advances to those who embraced them wholeheartedly. To this end, we convened a global summit in Atlanta in 2015 with a distinguished faculty and an international delegate body. About 60 delegates volunteered to begin working in five working teams to prepare statements in their assigned topic areas, and the five resultant papers were synthesized into the current statement of principles.

To choose delegates, we identified the top 30 countries in biotech using an algorithm developed by *Scientific American* (<https://www.scientificamerican.com/article/the-worlds-best-countries-science/>) to create an intensity score for each country, which we then ranked. The rankings are based on metrics that assess a country’s accomplishments in biotech in five categories: public biotech company employees per capita, public biotech company revenues by gross domestic product (GDP), biotech patents per total patents, business expenditures on biotech R&D, and knowledge- and technology-intensive industries. The intensity measurement compares the success of larger countries while also identifying smaller countries with high biotechnological achievement.

Delegates were identified by consulting top thought leaders in the various fields and various countries, by searching the literature, and

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Received 13 December 2016; accepted 13 October 2017; published online 9 November 2017; doi:10.1038/nbt.4007

through the help of national science consulates from the identified countries. We used a multifaceted approach to identify 200 delegates to be invited to BEINGS 2015. The goal was to have a diverse set of delegates by every measure, including a spectrum of approaches and ideologies to the challenges of cellular technologies, and to draw from the sciences, religion, law, and the arts and humanities. To ensure the participation of all stakeholders, we first reached out to the countries' consulates and consulate generals in the Atlanta area and surrounding states. We contacted embassies, attachés, and national science liaisons and leaders of various National Academy of Sciences through the InterAcademy Council (Amsterdam). In addition, we selectively included organizations that advocate for and against various approaches to the challenges of cellular biotech, transnational organizations with a stake in the issues, representatives of religious organizations, regional representatives, professional societies, and advocacy groups both supportive of, and critical of, various approaches and technologies. The delegate pool reflected our goal of scientific and ideological diversity, and included scientists, policymakers, and laypeople and professionals in the sciences and social sciences as well as religion, the arts, and the humanities.

Representatives from industry, as well as industry trade organizations, were present at the meeting, and many delegates had dual roles in academia and industry; however, we recognize that the corporate world could have been better represented at the summit and among the authors of this paper. We therefore hope that this paper can be a catalyst for future conversations with the corporate sector.

To facilitate and oversee the effort, we also gathered together several advisory bodies:

- A 'University Partner's Board', whose core was 15 Georgia-based colleges and universities, including The Georgia Institute of Technology (Atlanta), Georgia State (Atlanta), University of Georgia (Athens), Morehouse College (Atlanta), and others;
- A coalition of the consulates and ambassadors of the participant countries, including their science liaisons and National Academies of Sciences;
- A 'Strategic Advisory Board' that included representatives from top civic and nongovernment organizations (NGOs), including industry trade representatives, in the greater Atlanta region;

- An 'Academic Advisory Board' to help identify delegates and faculty;
- Cooperation and consultation from the American Association for the Advancement of Science (AAAS; Washington, DC), the National Academy of Sciences, the World Health Organization (Geneva), and many smaller NGOs.

Guiding philosophy of the statement

The emergence of any powerful technology brings with it visions of both promise and peril. The fundamental challenge of any ethical or policy recommendation, whether legislative, administrative, or social, is to minimize the peril while supporting the promise. Overall, this paper is meant to be aspirational, an attempt to establish principles that will not only allow advances to proceed safely, ethically, and with greater public confidence, but also to serve as a model to guide international policy in biotech.

Ethical analyses to guide new technologies often tend to focus on potential challenges and risks, and so, to some, appear to focus on the negative or to be overly cautious or naysaying. The authors want to make it very clear that we encourage and celebrate responsible scientific inquiry into cellular biotech. We understand and believe in its great power to improve human health and to contribute to the general good. The goal of BEINGS was to carve out a path forward that can help guide the responsible inquiry into these promising technologies while avoiding or pre-empting ethical violations, unwarranted negative public reactions, or misguided regulations.

Although BEINGS was planned before CRISPR–Cas9 (CRISPR) became widely recognized through mainstream media, the publicity surrounding CRISPR^{3,4} and other gene editing tools has underscored the need to have an engaged public conversation. In addition to the organized biotech community, BEINGS delegates were concerned about the proliferation of do-it-yourself (DIY) gene editing^{6,7} and 'biohacker' communities (for example, Bento Bioworks, <https://www.bento.bio/bento-lab/>), home kits that can be used for CRISPR, home microbiome analysis kits (<http://ubiome.com/>), and even yeast-manufactured consumer drugs⁷ and clothing (<http://www.biofabricate.co/>), as well as consumer-oriented marketing of these tools to a general public that may have little or no understanding of the technology. Today's technologies bring greater ease of use, increased speed of analysis and results, with

Box 1 Scope and focus of the BEINGS meeting

BEINGS concentrated on human cellular biotechnologies, looking at the consequences of basic genetic science and research, including translational research (more details can be found at <http://www.beings2015.org>). We concentrated on technologies that manipulated human cells, but included other biotechnologies that could have an impact on human beings (such as genetically altered mosquitos). The scope of the topics covered, and thus of the main text, included five categories that were determined through analysis of existing consensus documents on genetic and synthetic biotechnologies as well as through survey responses from delegates collected before the summit. The five topic areas were: Goals and Aspirations (of science and biotechnology); Alien Organisms and New (ID)Entities; Bioerror and Bioterror; Ownership; and Donorship.

BEINGS explicitly did *not* include discussions related to agricultural applications (such as the use of genetically modified organisms for the purpose of generating food) or to nonhuman animal rights and animal experimentation, although we did discuss technologies that ultimately may have applications for these topics. BEINGS was also not about clinical medicine or human

experimentation—our discussions 'ended at the clinic door'—and did not focus on ethical/policy guidelines for human physiological or cognitive enhancement or on issues related to clinical trials (such as informed consent or first-in-human trials).

A series of cross-cutting questions were posed to consider throughout the Summit, including the following:

1. What should be the goals of biotechnology; is progress itself an ethical aim or obligation? How do we honor the sanctity of life (assuming that 'sanctity of life' continues to be a morally useful construct)? What is 'human flourishing' insofar as biotechnology can contribute to it?
2. How do we navigate the spectrum of differing perspectives on risk, such as those that take a more precautionary, risk-averse approach to those that privilege provable harm approaches?
3. How do we protect vulnerable populations, honor global cultural differences, and respect and include diverse opinions?
4. Who should ultimately regulate technologies (for example, government, private sector, self-regulation)?
5. How do we assure fairness, justice, and global sharing of the fruits of modern biotechnology?

a lower price tag than the technologies of the past, which often take the technologies out of formal scientific institutions with systems of oversight.

Divergence in global views on the use of such biological technologies has become evident. Genetic interventions in reproduction and in human embryos are especially contentious and fraught with ethical questions. Although more than 40 countries have enacted laws against human gene editing for reproductive purposes, for example, the United States has not. Additionally, China, Sweden, the UK⁸, and Japan⁹ have approved gene editing of human embryos for basic science research, whereas the US National Institutes of Health (NIH; Bethesda, MD)⁸ has issued a moratorium on funding for such research. Some countries that use the '14-day rule', governing the limits of when human embryo research is allowable, have begun discussions of reconsidering that standard⁹.

In addition, scientific progress is outpacing regulation¹⁰. The list of US Food and Drug Administration (FDA; Rockville, MD)-approved animals that are genetically engineered to produce human drug therapies¹¹ is falling behind announcements of newly engineered organisms¹². Efforts are underway to combat emerging mosquito-borne epidemics with genetic interventions, such as induced sterility¹³. These and other experiments have raised concerns about potential biosafety and biosecurity issues¹⁴. Given the speed, global scale, effectiveness, and likelihood of technical success, scientists and others involved in these new biotechnologies assume responsibility in advocating for the proper use of the technologies they help create and apply.

Guiding principles must maintain a balance between supporting the scientific pursuit of knowledge and the practical applications of findings while considering risks to human identity and health, social justice and human rights, protection of the natural world, and concerns about transitioning to certain levels and types of biotechnological consumerism. Furthermore, ethical analysis must traverse the complex terrain of multiple cultures and transnational regulatory environments.

There are clearly limitations to what we could accomplish at BEINGS and to the resultant guidelines (see **Box 2** for a description of the process used in drafting the guiding principles). First, given the intention to represent such a variety of ideological perspectives among BEINGS delegates, consensus on all points was unrealistic. We attempted to represent as many voices as possible, but there are lingering unresolved concerns

on religious and legal grounds. In addition, not all invited countries sent delegates (for example, China was notably absent), though nationals from some of these countries who now reside or work in the US were included. Implementation is a challenge worthy of an entire summit in itself, and convening such a summit might be a recommended next step. An increased representation from industry and commercial concerns in the implementation conversation is also crucial.

The following proposed ten principles should thus be seen as one contribution to an ongoing conversation about the enormous potential and the need for cautious reflection attendant to emerging cellular biotechnologies.

Principle one: The biotechnological enterprise should have as its principal goals the alleviation of human suffering and the mitigation of environmental harms, as well as the general improvement of the human condition

To say that we invest in biotech because it contributes to 'the Good', human flourishing, well-being, or happiness expresses a general aspiration but may not ultimately be helpful, as the precise meaning and scope of these concepts have been subjects of debate for millennia. Whatever the definition, the deeper question remains: should progress in biotech itself ultimately be judged, and perhaps even regulated, by whether it positively contributes to, detracts from, or has no effect on some or all of these concepts? Descriptions of 'the Good' and 'flourishing' necessarily reflect deeper assumptions about what it means to be human and what it is about 'humanhood' that ought to be preserved or nurtured, and so reliance on such broad terms often leads to sterile polemics. Even more, the very advent of new technological abilities challenges and changes our sense of these terms.

Some argue that biotechnological research should proceed without the intervention of nonscientists or regulators, in light of what BEINGS presenter Steven Pinker called the "global burden of disease"¹⁵. However, that assertion is problematic. Embedded in that claim is the assumption that scientists themselves have the skills and the standing to determine the scope, nature, goals, and underlying values of the quest for alleviation of human suffering. But these are contentious claims. First, public trust in scientists is, at best, moderate, and among some subgroups very low¹⁶. In addition, even goals like eradicating disability and disease are not

Box 2 Process for drafting of the Principles

BEINGS was designed to generate and capture as many ideas as possible in real time. Multiple modes were employed for recording divergent opinions from the faculty, delegates, and audience. We recorded audio and video, distributed note cards for comments and discussion during the summit, provided electronic (Dropbox) file folders for delegates to submit notes, had a Twitter feed, and employed multiple volunteer note takers to capture all questions and discussion.

About 60 of the international delegates ('Drafting Delegates') agreed to begin work on a consensus paper based on the BEINGS proceedings. Drafting Delegates came from both the public and private sectors. In addition, 13 delegates agreed to act as peer reviewers ('Reviewing Delegates') and read and commented extensively on the paper.

At the conclusion of the public phase of the summit, the 60 Drafting Delegates were divided into working groups based on the five topic areas of BEINGS: (1) 'Goals and Aspirations'; (2) 'Alien Organisms and New (ID)Entities'; (3) 'Bioerror and Bioterror'; (4) 'Ownership'; and (5) 'Donorship'. The Drafting Delegates each worked in a working group coordinated by individuals we termed

'Topic Leaders'. The Drafting Delegates had routine monthly teleconference and e-mails with their working groups, and Topic Leaders had routine meeting with the BEING executive team to provide status updates, troubleshoot, and share ideas.

The working groups collaborated for 18 months and each generated a set of ethical standards in their topic area for consideration by the world community. The guidelines that follow represent a synthesis of five separate manuscripts generated by the working groups. Given the intentional design to represent a variety of ideological perspectives among BEINGS delegates, even this level of consensus seems remarkable, and reflects our belief that advancing genetic cellular science necessitates and benefits from the inclusion of a range of voices from a variety of fields, disciplines, orientations, nations, and cultures.

Once synthesized, the draft was sent to the Reviewing Delegates for comment and feedback. The final manuscript was sent to the remainder of the BEINGS delegates, faculty, and a handful of other participating scholars and professionals with the invitation to sign on as Signatories if they agreed with the recommendations.

uncontested: the increasingly influential disability studies community, for example, sees conservation of certain disabilities as a “potentially generative resource rather than [an] unequivocally restrictive liability”¹⁷, and is concerned about what (or whom) it is that biotechnology is trying to eliminate. Others critique the atomistic, anthropocentric approach to human health that underlies much of the biotechnological argument, which may neglect environmental, social, economic, and other contributions to the “global burden of disease.”

Because interpreting those goals (of alleviation of suffering and mitigating harm) is more complex than often assumed, the biotechnological enterprise must promote and invest in consistent, transparent, and ongoing community engagement, in which multiple stakeholders can contribute through structured dialog to articulate continuously evolving goals and aspirations, as well as acceptable and unacceptable risks and harms.

Principle two: The biotechnological enterprise must invest time in asking questions about its assumptions and its eventual impacts on communities and individuals, and must include their voices, as well as those of other stakeholders in the scientific process

Science is a social enterprise. The questions science asks and the choices of topics it pursues are socially and culturally mediated, and the pursuit of basic science is largely possible because of public financial support. Various disciplines over the past half century have demonstrated that science is a complex social enterprise infused with often hidden values, and have challenged our understanding of who does scientific research, what kinds of questions are asked, and who and what are used as subjects and material for research. Scientific products have impact on society, and society reciprocally influences the direction of science. The scientific enterprise and its knowledge products (that is, the knowledge and materials it generates) are never culture free^{14,18,19}. Furthermore, the scientific enterprise, though often treated as apolitical, has been shown through decades of research to often reflect dominant ideological positions, while challenging or alternative viewpoints, especially from socially marginalized sources, are accused of being ‘ideologically biased’. Such perspectives on science as a social and political pursuit are often neglected both in scientific work itself and in the training of students.

If science is to serve the social good, then it must attend to such unexamined assumptions and address questions such as the following: What groups and stakeholders are included in the research? What values and assumptions are informing the research? What might be the impact of the research, especially the unintended consequences and side effects? The actual impact of specific scientific programs and applications may be unanticipated by the scientists, but may emerge from discussions that include individuals with diverse expertise (for example, social scientists, historians and ethicists) as well as communities that may be affected by the work. Scientists may also fail to consider that much of their work is supported by public taxes, and the citizenry therefore has a legitimate interest in the process of setting the general goals and directions of the science their money supports.

Principle three: A well-considered and reconceptualized precautionary approach (not to be confused with the precautionary principle as commonly understood) should guide those cellular biotechnologies with the largest capacity for harm (such as embryonic germline modifications and environmental releases) at the individual, group, social, and environmental levels

The key ethical tension of cellular biotech lies in its capacity to bring great benefit balanced with its ability to cause harm. Risk assessments are used to determine likelihood and severity of harms, but both the process

of risk assessment and the final determination of likelihood and severity contain significant value elements. In addition, a requirement of *proving* that something will not cause harm or, alternatively, that it will cause harm can set impossible standards. Clearly, a reasoned set of standards must be considered that includes potential benefits.

Although there is a range of perspectives on risk assessment and strategies in science itself, it is also true in general that the manner in which experts understand risk and harm is not necessarily consonant with how the public interprets those concepts²⁰. Examples such as genetically modified crops, climate change, or animal use in research illustrate the complexity of the differing ways in which scientists and segments of the public consider facts and evaluate risk and harm. Moreover, experts themselves often cannot fully anticipate or understand the risks—or benefits—related to an emerging technology. Technologies always operate with epistemic risk: that is, decisions are based on necessarily incomplete information and, at times, erroneous assumptions. Furthermore, risks operate at different levels, and risks can accumulate over time. Climate change is partially the result of countless industries, individual behaviors, and long-term trends each contributing incrementally to the problem, further influenced by government policy. Non-native species invasions result from actions ranging from federal programs to the releases of pets or imported plantings.

In assessing benefits and harms, feasible alternatives must be taken into account. For example, many of the goals of embryonic germline gene editing are also achievable with selective embryo screening (pre-implantation genetic diagnosis) or sperm or egg donation. On the other hand, the consequences of *not* using a technology are also important considerations for a final assessment. For example, the altering of a wild insect species, such as *Anopheles stephensi* or *Aedes aegypti* mosquitoes, may prove to be the most feasible way of combating malaria or the Zika virus, even though we are uncertain how it might alter large ecosystems¹⁴.

A sophisticated approach to assessing risk and harm is therefore imperative for technologies of such transformative power. A strict criterion of ‘provable harm’ (that is, that a technology should be allowed unless one can prove it is harmful) is too lenient when risks are highly unpredictable, potentially vast, and irreversible or enduring, or where harm may emerge in the form of unacceptable social consequences or a violation of fundamental ethical principles rather than as quantifiable economic losses. At the same time, the precautionary principle can also be constructed in ways that are too restrictive. ‘Proving’ that a technology is harmful or not harmful often typically boils down to assessing statistical risk. The threshold for relevant risk must be determined collectively, with concerned stakeholders mutually determining the levels of proof necessary to apply a technology outside the laboratory. Such a determination requires open and democratic discussions of the values underlying risk assessment, and will more likely require staged and categorized models of risk assessment rather than reliance solely on typical statistical risk models that critically depend on imputed quantification. Recommendations for expanding methods of assessing risks in a more grounded fashion include both real-time assessment and anticipatory policy approaches that rely on scenarios, prototyping, and experimental approaches to ethics.

Principle four: Scientists and other concerned parties should resist pressure to overly promote or exaggerate the impacts of their work, and responsibly communicate and interpret scientific findings and their implications to the public

Scientists, whether in the academy or industry, should be advocates of their work and should be active voices in the interpretation and promotion of good scientific products. Given the competition for media

attention and the financial and reputational advantages of publicity, however, scientists need to be reflective about pressures to speculate about or exaggerate findings and their potential impacts.

The scientific community has an ethical obligation to promote public understanding of the implications of biotech and its risks, harms, and uncertainties. Many promising lines of inquiry fail to materialize, or take much longer to bear fruit than originally anticipated (for example, gene therapy). Responsible public communication also requires self-critical reflection on the limits and applicability of a technology—including technologies still in an early phase of development; evaluation of potential dangers and side effects; and any potential cultural and environmental harms, including to nonhuman species.

The free communication of reliable scientific information requires governmental and regulatory support. Science journals and their editors are also gatekeepers who can hold scientists (and, often, a government's science policy) accountable to the kinds of ethical principles found in this report and others^{5,21}. The scientific community needs to engage and listen to the public in a deliberative process if it wants to establish meaningful avenues to gain the public's trust.

Principle five: International treaties should be used to establish international policy standards and guidelines for the just sharing of risks and benefits of technologies; the international community should sanction violators by, for example, ostracizing them from political, scientific, and biotechnological collaboration

There is currently no established global forum that enables direct participatory input into national or regional scientific policy-making. Nation-state democratic forums are often insufficient, as they are usually coalitions of specific nations or regions and so are not fully representative. Scientific agencies have knowledge about techniques and better predictive capabilities, but they often do not represent the values and interests of the global public and can be thwarted by, for example, government or commercial opposition. Finally, market mechanisms can be effective stimulators of innovation, but they are unsuitable by themselves for establishing ethical limits because they often have a short-term economic gain bias and incentives to disregard externalities, such as environmental damage.

The global impact of biotech, such as DIY synthetic biology or the genetic engineering of human embryos, necessitates more widespread consideration. Although, at present, the United Nations seems the most inclusive forum to conduct a conversation with such global implications, the creation of alternative collective bodies may be prudent, perhaps using existing organizations that provide international guidance and advising as models. Even if not enforceable, guidelines—created by international professional societies that are attempting to self-regulate or by highly visible international organizations (a process that should include diverse global public voices)—can create important social norms for conducting research¹⁷. As one model, the Council for International Organization of Medical Sciences (CIOMS; Geneva), which partners with UNESCO and the World Health Organization (WHO; Geneva), includes 49 international, national, and associate member organizations, hosts a series of working groups on biomedical research, and creates guidelines on human subjects research through a multi-year international deliberative process.

Currently, the majority of persons and nations have little voice in decisions about the use of technologies that can challenge their values and alter their heritage. Although global regulatory bodies raise problems of their own, a global advisory commission could be instrumental in providing disenfranchised groups with a voice in international policy and treaties. One possibility is that such a commission could provide certification or designation that a group, company, laboratory, or university

research effort conforms to a set of standards (for example, something akin to the LEED certification used to evaluate the environmental performance of buildings). Further deliberation would need to determine exactly what kind of advisory bodies and what kind of certification, if any, would be most effective for the international community. On this point, the BEINGS delegates did not reach consensus.

Principle six: International scientific bodies and professional societies should call for and enforce to the degree possible collective oversight over human reproductive germline engineering of the embryo and encourage international consensus and regulation

Many ethical, social justice, and human rights concerns are raised by the prospect of creating new human lives with altered genomes. Some argue in favor of such pursuits, advocating the moral obligation to prevent the transmission of genetic diseases and claiming that these germline modification technologies offer the opportunity to prevent the reproductive propagation of seriously debilitating and life-threatening diseases. Others argue that the therapeutic benefits of germline modification are tenuous, and point to the availability of safer and less socially and ethically fraught reproductive alternatives (third-party gametes and preimplantation genetic diagnosis) for those at risk of transmitting inherited diseases (the use of mitochondrial transfer in embryos to prevent disease was not discussed at BEINGS and so is not included in our definition of 'germline modification').

Given the existing safety concerns, there is a general consensus that reproductive human germline engineering of embryos must not be contemplated until primary safety and human rights issues are resolved. (Emerging germ cell technologies, such as those that modify spermatogonial stem cells, can also be considered as altering the human germline, but for our purposes we are restricting our argument to manipulations of the embryo.) The social, political, cultural, and economic consequences of reproductive human germline engineering must also be discussed and consensus achieved.

In addition, even alterations aimed at prevention of disease or disability must be considered in light of recent human history, such as the 20th century eugenics movement, with its specification of individuals and groups considered genetically inferior or diseased. The current designation of 'undesirable' genes that need to be replaced and 'desirable' genes, even in some cases for the eradication of conditions defined as 'disease,' can reflect criteria set by the economically and socially privileged, disease definitions promoted or shaped by the market and commercial interests, or standards put in place by governments or health insurers. Often these biases are unintentionally embedded in the efforts of well-meaning people and institutions with only positive intentions. Such developments must be carefully examined and evaluated by a diverse set of experts before decisions are made that will be genetically incarnated into human bodies.

Concerns have centered on the potential to distort familial and other relationships were it to become practice to alter human beings to the specifications of parents, researchers, fertility clinics, or other entities that have access to the technology. Treating human reproduction like engineering a product²¹ runs the risk of undermining the human right to bodily integrity and an open future and, to some, distorts the very nature of the human being's relationship to the natural world.

To proponents of these technologies, however, terminology such as "treating human beings like engineered products" is itself biased. It can be argued that much of medicine advances through understanding the human body as an engineering problem, and that biomedical engineering research has resulted in important devices, such as pacemakers or artificial limbs. Parents often make difficult medical decisions for their offspring, during gestation as well as after birth. If it is possible to prevent

a disease in egg cells, sperm, or developing embryos, they argue, it may well increase rather than undermine “bodily integrity.”

Given the gravity of technologies that alter the human germline, they deserve serious conversation and policies that strive for general consensus among all stakeholders²², which include the intended consumers of such technologies, as well as the general public.

Principle seven: National scientific priority planning and scientific funding strategies, especially around the engineering of nonhuman life forms released into the environment, should carefully consider the needs of developing nations and include their participation, with a conscious intention toward diminishing global disparities (in both developing and developed nations), without compromising or neglecting areas of national importance in the biotechnologically developed world

Funding agencies and foundations, scientific advisory bodies, and other professional organizations have the power to drive research priorities, implementation, and dissemination. An assessment of the impact of cellular biotechnologies, or of the creation of altered organisms, must include attention to whether they exacerbate existing inequities and disparities, in the short or long term, in both developing and developed countries.

Of equal, and sometimes countervailing, importance is recognizing that taxpayers, especially those in scientifically advanced countries, expect their taxed and donated resources to support research that is of importance to them. Introducing social and political concerns when reviewing the merit of specific scientific research projects must be done with careful sensitivity to public priorities and with an eye to the influences of commercial interests. By encouraging research that seeds new technologies, as well as research that explores ways to broaden access to existing technologies, public funding has the potential to benefit both ends of the socioeconomic ladder. The key is balance, whereby both needs are part of the planning process of funders and policymakers.

Researchers in higher-resource countries, where most biotech development occurs, also have an obligation to ensure that the risks and harms of biotech are not placed disproportionately upon countries where such research, and the capacity to regulate it, is absent. Additionally, they should strive to ensure a more equitable distribution of benefits and to assist colleagues in low-resource environments in building and maintaining a strong scientific infrastructure. Existing statements such as UNESCO’s Universal Declaration on Bioethics and Human Rights⁴ and the European Convention on Human Rights and Biomedicine²³ can serve as models for developing collaborative conversations on science policy.

Principle eight: The scientific and biotech industry communities have a duty to address potential intentional and unintentional misuse of human cellular biotechnologies through training and teaching, advocacy for appropriate external regulation, and honest self-evaluation, self-regulation, and promotion of moral behavior

Emerging cellular biotechnologies offer new opportunities and possible uses for altered organisms. It is uncertain what potential applications of biotech will eventually be developed and implemented and what concerns they will raise, because predictions regarding scientific progress have often been inaccurate. Projections seem to vacillate between utopian visions of technological progress and dystopian scenarios of doom.

While celebrating our technological achievements, we must also set up safeguards to minimize the potential for both ‘bioerror’ (the accidental release of such products, whether through incompetence, error, or inadequate safeguards) and ‘bioterror’ (the intentional and criminal use of the products of such research to threaten governments, groups,

or individuals), as well as any emergence of major unintended negative consequences. Given the potential consequences of technologies of this power, safeguards against bioerror must continue to be a priority of the international scientific community. In particular, as DIY gene editing technologies, biohacker communities, and direct-to-consumer scientific technologies become more widespread, the release of pathogens, toxins, or other health or environmental harms by amateur scientists becomes a realistic possibility. Prevention is much more difficult in those settings than in well-run academic or commercial laboratories.

In addition, we unfortunately live in a world where bioterror is a genuine possibility. A debate has ensued about the right strategy to preempt bioterror. For example, the decoding of the genome of the 1918 influenza virus led to discussions about whether the better strategy was to keep the findings as secret as possible or to publish the genome and let the entire scientific community work to create preventative and curative measures should the information be misused. Given the likelihood of others uncovering the genome independently, the decision was made to publish widely and encourage the development of a cure. The decision is still controversial among some ethicists and commentators²⁴.

An essential component of becoming a scientist and researcher is the willingness to take responsibility for one’s actions and their consequences, and the development of that quality must therefore be part of scientific training programs and graduate education. Individual scientists have an obligation to strive to identify and prevent negative consequences of their research and, in consultation with key stakeholders, be willing to carry out the following actions: (1) engage in measures to mitigate harm; (2) agree to postpone research until such time as technological or regulatory capacities make mitigation possible; or (3) in rare cases, terminate projects if those negative consequences cannot be minimized with reasonable means²⁰.

Training must move beyond standard ‘Responsible Conduct of Research’ courses and involve deeper reflection of the social and ethical implications of technologies as they are developed. Governmental agencies and funders should consider such training efforts at multiple levels of education and expertise as best practice. Furthermore, when scientists do identify and report negative consequences, regulatory and funding agencies should respond constructively and not punitively. Universities and other research institutions should work to ensure that their hiring, promotion, and compensation programs do not contribute to incentives to push ethical boundaries so as to be the first to discover, publish, or market.

Principle nine: Ownership of one’s personal, unique organic characteristics reside with the individual, including attributes that may have value to biotech, such as one’s genome, epigenome, proteome, metabolome, and microbiome

Human beings are unique, with an integrity not reducible to any of their parts. Individual humans should have ownership of their own unique organic materials and biological profile that define them as individuals, despite their value to the biotechnological enterprise. Meaningfully informed consent should therefore be obtained where appropriate, along with licensure in certain cases.

A person is not property in respect to another’s proprietary claim. Respect for individuals and their rights should be a central principle when human biological materials are procured and employed in scientific inquiry. Use of human biological materials and of information derived therefrom by researchers ought to entail not only license, but also responsibility. Such materials and information should be used in ways that also contribute significantly to the individual and group empowerment of those who donated the materials.

When human material (whether discarded or donated) is used for science, it is a principal obligation of scientists, as well as funding and regulatory agencies (who may control patient registries or tissue banks),

that the unique integrity of any identifiable individual who is linked to such material be respected, protected, and inviolable. In a rapidly changing academic and commercial scientific environment, uncertainty over future uses of human tissues makes it essential to be as clear as possible during the informed consent process and to ensure that respect for the individual and sensitivity to such things as the economic, cultural, and social environment of the donor are considered. In some cases, incorporating opportunities for ongoing communication between researchers and donors/participants is a key consideration in addressing ethical challenges. A consensus proposal to establish a standard practice of broad initial consent coupled with independent oversight and ongoing communication with donors may be one model for addressing these challenges in certain cultural contexts²⁵.

Cultural shifts are taking place in the relationship between individuals and their health information owing to the growing popularity of commercial services to sequence genomes and microbiomes. Genetic data may be considered company assets that are passed on when a business fails or is sold. With biobanks and other data repositories, new strategies of consent and research participation (in academic settings and commercial settings) and access need to be developed. Other sources of tissues, such as uses of organic waste, and the ways these and other tissues are commodified (in both academic and commercial contexts) may also need reconsideration. Identification of individuals may become easier, even through partial genomic information, as genetic information becomes more routinely used and tools more accessible. Establishing appropriate governance structures over entities such as biobanks and repositories may be an effective means of fostering an institutional culture that prioritizes this respect for research participants.

Principle ten: The modern scientific enterprise includes the obligation to proactively consider, address, and foster the wellbeing of those who are not direct participants in research, but whose rights or interests are nonetheless affected by others contributing biological materials to research

An individual's decision to contribute materials to research often implicates the interests of others who share key characteristics with the donor(s) (such as members of the same family or ethnic group or others with shared cultural identity). In addition, certain marginalized groups, often the targets of genetic research, are often also the most vulnerable to being exploited, and deserve careful and respectful consideration in such research, including participation in the research process. Examples include Arizona State University's dispute with the Havasupai tribe over a situation in which biological samples collected for one type of research were used without authorization for research considered taboo by the donors of the samples²⁶, and the general discussion around the genetic rights and genetic legacies of indigenous peoples²⁷. Here, too, documents such as The United Nations Declaration on the Rights of Indigenous Peoples²⁸ can provide a common foundation.

The harms that can come to non-donors include risk of identification of non-participants from data and samples collected from genetically linked direct participants, lack of legal or ethical controls to prevent unauthorized or inappropriate access to donated human biological samples, and risk of stigmatization of both the individual and the collective arising from disclosure or publication of the results of research authorized or consented to by donors alone. Similar concerns also emerged in relation to the publication of the HeLa cell line genome²⁹ without the consent of Henrietta Lacks or her family. As the latter case illustrates, the disclosure of genetic information belonging to an individual can have negative cross-generational impacts on family members, such as the violation of their privacy rights, stigmatizing and discriminatory effects, and impacts on their ability to control access to their health information.

Researchers should therefore consider, proactively, the implications of their research on relevant non-participant populations, particularly given the increasing potential to utilize and manipulate genetic material. Researchers should consider inclusion of a non-participant welfare impact assessment.

The inclusion of underrepresented communities in research, and the development of research resources in underdeveloped areas, should be priorities for the world research community, and not only for genetic research. It has been noted, for example, that although under-resourced developing countries bear over half of global disease burden, they lag substantially compared with resource-rich countries in developing next-generation biorepositories for innovative biotech research^{30,31}. As a result, without appropriate policies and incentives, it is possible that discoveries arising from biobanks “will not sufficiently benefit those living in developing countries”³². A similar divide has been observed in the “unfolding revolution...in designer pharmacogenomics” enabled by the sequencing of the human genome³³. Biomedical researchers must develop and implement ethical norms that promote broad and inclusive participation in and distribution of the potential benefits of biotechnology. At the same time, great care must be taken that calls for ‘inclusion’ and ‘diversity’ are not used to unduly pressure participation in biobanks or DNA databases.

Conclusions and recommendations

The delegates to BEINGS believe that a deliberative, reflective, and collaborative set of recommendations, with the aim of encouraging and supporting biotechnological progress while protecting individuals, communities, and the environment, and reflecting shared values, is crucial to our shared future and to the continuation of biotechnological science as a shared social enterprise. As an international community of scientific researchers, policymakers, scholars, public interest advocates, and public stakeholders, we must be watchful of developments in human cellular and genetic biotechnologies. As a concerned and involved set of colleagues and observers, we must stay abreast of the most recent developments and work to anticipate the potential consequences and applications of these technologies in the laboratory, the clinic, and the consumer realm. And, recognizing the commercial nature of the modern scientific enterprise, we must partner more closely with the biotech and pharmaceutical sectors to work collaboratively to develop and maintain these collective principles over time.

Scientific values and goals are culturally and socially contingent. Biotechnologically sophisticated societies should be sensitive to how their research impacts and is shaped by the cultural, social, and physical environments of their own subpopulations and that of other societies, and should seek the participation of these groups in the setting of standards and principles. Valuable insights lie in the collective experience—the science and philosophy and the art and literature—of different communities and cultures, including tribal and indigenous populations, and they should be active in helping shape the conversation.

The assessment, communication, and management of risk and harm are some of the most fundamental challenges to specific biotechnologies and are the issues of most concern to critics and the public. Although risk analysis is a sophisticated science, it is also hindered by limited data, as well as by the scientific and ethical judgments inherent in the process, and so requires collaboration between those who generate the analyses and those who use them³⁴.

A mechanism for global community engagement must be created with representatives from diverse communities of various economic statuses and cultural perspectives. Importantly, traditionally uninvolved stakeholders must have a voice at the table. Voices from such groups should be integrated into decisions about the directions of research and included in

emerging means of knowledge dissemination. Disciplinary diversity is also key, as was shown at BEINGS, where the dialog between scientists, ethicists, and policy specialists; representatives of the social sciences, arts, and humanities; and general community stakeholders and patients contributed in important ways to the outcome. More than just including or tolerating such voices, we must recognize that we, as a scientific community manipulating technologies of great power, need the collective wisdom and innovative thinking of as many different fields, cultures, philosophies, and perspectives as possible.

We also must cope with the fact that scientific research and its products today are often commercialized and privatized and therefore may bypass academic and governmental scrutiny and control. Consumers will be making decisions about which services and products to use, which necessitates that efforts be improved to increase scientific literacy; to deepen understanding of the social, economic, and political implications of different scientific and technological applications and trajectories; and to provide educational resources that can empower future creators and consumers of biotech. These efforts will also allow citizens to make informed and well-considered contributions to decisions about policies and regulations, as well as contribute to the conversation around proper boundaries for such work. In our radically shrinking, connected world, individual governmental actions have an increasingly limited reach over biotech, necessitating greater international collaboration and the involvement of an informed global citizenry. We see our effort as a complementary contribution to a continuing global conversation as we navigate the powerful, rapidly evolving developments in human cellular technologies.

ACKNOWLEDGMENTS

BEINGS was made possible by grants from the Coca-Cola Foundation, Emory University, The Marcus Foundation, Georgia Research Alliance, Wipro Limited, King & Spalding Law Firm, the Metro Atlanta Chamber of Commerce, Southwest Airlines, Sanofi, Air France, The Embassy of the Republic of France, the Atlanta Clinical and Translational Science Institute, Central Atlanta Progress, and Biofaction. Academic partners included the Georgia Institute of Technology, the University of Georgia, Kennesaw State University, Brenau University, Mercer University, Agnes Scott College, Columbia Theological Seminary, Georgia College, Georgia Gwinnett College, Georgia State University, Morehouse School of Medicine, University of Northern Georgia, Oglethorpe University Savannah College of Art and Design, and the University of West Georgia.

COMPETING FINANCIAL INTERESTS

The authors declare competing financial interests. Details are available in the [online version of the paper](#).

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