The Need for Early Engagement with Interested Groups on Advanced Biopreservation

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Abstract: Research on advanced biopreservation — technologies that include, for example, partial freezing, supercooling, and vitrification with nanoparticle infusion and laser rewarming — is proceeding at a rapid pace, potentially affecting many areas of medicine and the life sciences, food, agriculture, and environmental conservation. Given the breadth and depth of its medical, scientific, and corresponding social impacts, advanced biopreservation is poised to emerge as a disruptive technology with real benefits, but also ethical challenges and risks. Early engagement with potentially affected groups can help navigate possible societal barriers to adoption of this new technology and help ensure that emerging capabilities align with the needs, desires, and expectations of a broad range of interested parties.

Introduction

Research on advanced biopreservation technologies is proceeding at a rapid pace, promising to impact many important areas of medicine and the life sciences, including organ and tissue transplantation, as well as food, agriculture, and environmental conservation. Broadly speaking, advanced biopreservation is a constellation of innovative platform technologies which offers effective new ways to safely reach sub-freezing temperatures and to rapidly rewarm large and/or complex biologics, including solid organs, complex tissues, and whole organisms. Together, these innovations allow researchers to slow down biological time dramatically by suppressing or pausing metabolism, and by doing so, transcend traditional geographical and chronological constraints that limit where and when

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complex biologics can be distributed and used.[1] In medicine, for example, biopreservation technology could be used to enable much longer preservation and wider transportation of human organs and tissues for transplantation. Similarly, biopreservation might enhance the development, storage, and distribution of new cell-based therapeutics. In the life sciences, applications can range widely — from preserving whole multicellular organisms for scientific study, to improved aquaculture for food production, to environmental conservation through, for instance, the creation of large-scale faunal biobanks to protect biodiversity.

Given the breadth and depth of its potential medical, scientific, and corresponding social impacts, advanced biopreservation is poised to emerge as a disruptive technology with real benefits, but also ethical challenges and risks. In such circumstances — especially given the large role that public funding has played in the development of the technology — we believe early engagement with potentially affected parties can help both to identify and to navigate possible societal barriers to adoption of a new technology and help to ensure that emerging capabilities align with the needs, desires, and expectations of a broad range of interested groups. As some of us have argued elsewhere, coordination across otherwise-siloed communities of researchers, regulators, stakeholders, and the public is necessary to standardize terminology and protocols and to develop effective oversight strategies, both in terms of anticipatory governance and midstream modulation aimed at ongoing responsible innovation.[2] Building from that essay, which articulated broad engagement as a core strategy for coordinated governance, we focus here specifically on the need for engagement during the research and development process. As the collective of researchers, developers, and potential regulators is now taking shape in this field, a wider range of possible partners and collaborators is needed to help inform the development and application of advanced biopreservation to build accountability and trust. Science museums are especially well positioned to play an important role. Below we outline the ethical and practical justifications for engagement with interested parties, offer examples of the need for broader

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I. The Need for Engagement with Interested Parties and Its Challenges

In August 2023, the US President's Council of Advisors on Science and Technology published a Letter to the President advocating for advancing public engagement with the sciences.[3] In that letter, they stated, "We must, as a country, create an ecosystem in which scientists collaborate with the public, from the identification of initial questions, to the review and analysis of new findings, to their dissemination and translation into policies."[4] This statement was made to help ensure public trust and effective policies associated with emerging capabilities. However, engagement with interested parties early in the research and development process is increasingly seen as important for ensuring that new scientific advances and technologies serve society and benefit diverse groups while avoiding hurdles or harms that may otherwise be avoidable.[5] Given the potential of advanced biopreservation technologies to profoundly impact society and individual lives, early engagement will be an important part of the technology's responsible and successful development. And, given the breadth of advanced biopreservation technologies and approaches to engagement with potentially affected parties, it is crucial to understand what engagement might mean and entail within this specific context.

First, depending on the particular research context at hand (e.g., medicine, basic science, food production, or species conservation) there are quite different groups that might be implicated, such as physicians and patients, institutional regulators, funders, policy makers, consumers, and industry partners. And each of these interested groups may have their own ambitions, regulatory models, and ethical standards. We do not presume they will be aligned. In fact, likely they will not. Thus, the catch-all term "publics" could be criticized as being imprecise at best, and at worst, overly inclusive in a way that dilutes the voices of those most directly affected by the technological advances in question.

Second, recommending the need for early engagement is further complicated by the fact that there is disagreement among public engagement researchers and science and technology studies (STS) scholars regarding key concepts, such as the meaning of "engagement" (i.e., *communication* vs. *consultation* vs. *participation*), the engagement mechanisms that should be employed (e.g., opinion polls, focus groups, citizen advisory groups, or consensus conferences), and how to gauge the "effectiveness" of the engagements.[6] Furthermore, some STS commentators argue that mainstream approaches to public engagement operate under "residual realist" assumptions about both participation and various publics — that is to say, they question whether the "public" is problematically treated under these mainstream approaches as singular and external to the scientific process.[7] For example, this "residual realist" approach appears to characterize public engagement as distinct from the scientific practice itself and views engagement as being conducted well only if it is inclusive, representative, and has an impact on how science is done. Others argue that mainstream approaches to public engagement tend to be limited to engagement mechanisms that are promoted by sponsors; these critics urge that public engagement should instead include more spontaneous forms of participation like public mobilization, local protests, social movements, and patient associations influencing research.[8]

Although we cannot in this essay settle these important debates amongst public engagement researchers and STS scholars, we have benefited from this discourse in our consideration of the issues below. Importantly, we aim to identify non-scientific interested groups, rather than solely referring to "publics," to avoid "residual realist" assumptions. Additionally, we focus on sponsored engagement activities, not because we deny the legitimacy or the need for "spontaneous" forms of participatory science, but rather because advanced biopreservation technologies are so new that one cannot reasonably presume patient groups and other non-scientific interested parties are aware of their developments and potential — at least not to the degree that spontaneous or unsponsored mobilization is likely at this time. For example, patient associations are currently unlikely to take the initiative to influence the direction of biopreservation research.

Given the rich complexities and dynamic scholarship surrounding broad engagement in science — controversies that typically relate to disagreements about conceptual starting points, measurement, and other empirical, methodological issues — it is important not to lose sight of the central ethical reasons for promoting it. Broad engagement between scientists and non-scientists constitutes an ethical imperative and a vital tool to promote accountability and promote justice, equity, and solidarity.[9] Meaningful and legitimate engagement contributes to the co-creation of knowledge and enhances the quality and robustness of science as well as good stewardship of resources.[10] It advances policy development and promotes gover-

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nance, transparency, and trustworthiness.[11] A principled approach to broad engagement is based on respect for persons and communities, and is grounded on the principles of equity and inclusion.[12] By giving interested parties a voice and bringing to bear collective expertise, broad engagement can contribute to research that is societally impactful, and that minimizes community and group harms while maximizing benefits by delivering societal value.[13] Broad engagement also serves as an important tool to identify and respond to interested groups' views and priorities, address socio-ethical concerns as well as competing interests, and facilitate social uptake in research, medicine, and biotechnological advances.[14] Broad engagement should seek to be iterative and foster collaboration and inclusion, power sharing (attentive to power imbalances and dynamics), and democratic decision-making.[15] It requires both cultural competence and cultural humility, with long-term commitment to self-evaluation and actionability.[16]

A good case of successful engagement around an emerging technology comes from 1976 when Harvard University announced plans to use federal funds to build the first recombinant DNA laboratories in the US.[17] Public concerns had led to an open hearing at the Cambridge City Council where citizens and scientists could debate and deliberate over the risks and benefits of this emerging branch of research. What resulted from this bi-directional engagement between scientists and interested parties was the nation's first set of municipal guidelines for academia and industry to promote the responsible conduct of recombinant DNA research, helping Cambridge's rise as an early leader and national hub for bioscience.

As this example suggests, broad engagement can be especially useful when a technology is not morally neutral. Rather than relying solely on the scientific elite to set the terms for policymaking, broad engagement enables more inclusive approaches. Consider interested parties' discussions about the allocation of scarce resources. Initially, the availability of preserved organs, tissues, and environmental organisms may be limited. As a result, the interested parties may have to choose between relying on preserved materials such as organs for transplantation that have yet to be fully researched and have been stored for a long time or organs that are scarce but not preserved. We anticipate very important ethical and legal questions emerging that will demand policy responses. To draw on an illustrative example, one US state facilitated broad engagement discussions to formulate allocation policies concerning life-saving ventilators.[18] Its rationale for broad engagement is relevant here: ultimately, the affected parties will have to endure the consequences of these decisions. Diverse community values can thus inform how to choose or rank different approaches. Successful uptake of biopreservation technologies will require broad trust and support. Meanwhile, scientists and policy makers can better design policies, communication strategies, and educational initiatives based on others' input.

Interested parties' engagement with science also provides opportunities for mutual learning between scientists and affected groups. In the context of biopreservation, clinicians may be wary of their patients' participation in biopreservation trials. Organ transplant patients may hesitate to accept preserved organs, or they may have concerns about the fair allocation of limited conventional organs. Communities may object to environmental interference without adequate assurance of the benefits, or an opportunity to define benefit. Engagement with interested groups may help scientists develop and communicate socially relevant biopreservation interventions aligned with communities' values and scientific expertise,[19] including communities of medical providers and patients.

Through deliberation and active participation, scientists and the interested parties can aim for constructive dialogue about the benefits and risks of biopreservation, clarify uncertainties, and delineate real and perceived concerns. Significantly, involving diverse interested parties can help policy makers ascertain perspectives across vested groups and scientists conducting the biopreservation research context at hand. Such mapping of ethical concerns across different biopreservation areas (e.g., medicine, basic science, food production, and species conservation) can help scientists identify the ethical priorities that unite scientists and non-scientists.

Successful engagement, however, requires understanding and addressing its limitations.[20] Engaging potentially affected groups can be an expensive undertaking and there may be barriers to progress on the issues raised during discussion. Since many issues related to emerging technologies may be controversial, politicized, and difficult to resolve, a clear and achievable goal may be needed to justify investment in broad engagement. Some have critiqued the ability of non-experts to meaningfully weigh in on complex bioethics issues and have questioned the value of broad engagement, especially when it does not lead to policy change or resolution.[21] Even when the goal of the engagement activity is clear, how questions or topics are framed can lead to misunderstandings that are difficult to correct.[22] Another concern is that participants in the engagement may be a self-selected group with

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discrete concerns.[23] Further non-expert, community, and expert-group representatives must be engaged in order to properly frame the issues and promote trustworthiness.

Despite these concerns and others — for instance, the process could be slow, delay progress, expose and fuel objections to biopreservation technologies, or possibly even mobilize people against it — engagement with interested groups remains an imperative. There may be constraints; for example, experts and commercial parties may need to navigate intellectual property concerns over premature disclosure of proprietary information if engagement and education efforts become too detailed. Another important concern is that when discussing such new technologies, speakers may overstate the risks or harms. Engagement with interested groups should involve expert collaborators who can help manage these concerns.

II. Examples of the Need for Engagement with Interested Groups in Advanced Biopreservation

A brief tour of some research areas in biopreservation reveals why engagement with potentially affected parties will be crucially important. Advanced biopreservation research can be roughly categorized into four major areas: biomedicine, food and sustainability, environmental conservation and biodiversity, and whole organism research (see **Table 1**). Within biomedicine and healthcare, the focus is on cryopreservation for cell therapies, transplantable organs, tissues, and organoids. Examples in cell test beds include red blood cells (RBCs), a range of immune cells, stem cells, and other primary cells. These cells, the biological drugs of tomorrow, might be directly infused into patients to respond to injury, repair their immune system or damaged organs, or treat cancer or other diseases. Transplantable organs and tissues will include life-preserving organs such as kidneys, livers, and hearts in addition to other organs and tissues such as vascular composite allografts, eyes, reproductive organs, heart valves, blood vessels, and skin. Finally, organoids of interest include pancreatic islets for diabetes treatment, cardiac clusters for ischemic heart disease, and neural tissue clusters that may one day help treat brain disorders. In all of these cases, the living biological system will be transplanted or infused directly into a living human being to benefit their

Table 1
Major Biopreservation Research Areas and Potential Engagement Opportunities.

Research Area	Biomedicine	Food and Sustainability	Environmental Conservation and Biodiversity	Whole Organism Research
Sub-areas	• Cell transplant • Organ transplant • Organoids for research and clinical use	• Alternative food sources • Minimizing food loss during storage • Enhancing aquaculture	• Biobanking species as a hedge against extinction	• Establishing whole animal research models of disease
Example applications	• Diabetes • Cancer • Organ failure • Reproductive medicine	• 3D-printed food • Gene-edited fish embryos to maintain wild fisheries • Preserving insects as fish feed	• Enabling research on coral reefs • Biobanking of seeds	• Zebrafish as a model of transplantation • Preserving *Cryptosporidium* for global health research
Potential engagement opportunities	• Two-way communication on use of donor tissues • Educate public on benefits and limitations • Engage policymakers to avoid donor exploitation and ensure equitable distribution of treatments	• Evaluate the risks and benefits of gene editing in these applications with interested parties • Establish two-way communication with communities that will be affected by new technologies	• Consider where the banks should reside • Determine which species should be prioritized for preservation • Develop criteria to determine who gets access	• Engage policymakers and interested parties to avoid risk of bioterrorism with biopreserved infectious organisms

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healthcare. By combining induced pluripotent stem cell (iPSC) technology with biobanked tissues/cells, the potential arises to create patient-specific organoids and microtissues for disease modeling and drug discovery. This presents an opportunity to develop treatment protocols that are more inclusive and consider factors such as gender, ethnicity, age, and race.[24]

However, the future applications of these biobanks and the purpose of cell donation can sometimes lack clarity. A two-way communication is needed to determine how researchers can address cell donors' questions about the use of their donation and to educate the public on the potential benefits and challenges of these technologies. The convergence of iPSC and biobanking technologies is expected to unlock the potential for clinical breakthroughs and commercialization of bioproducts and discoveries. This raises concerns about the exploitation of vulnerable populations as donors to these biobanks. In addition to patients, physicians, and potential donors, active engagement with policymakers will be crucial to address the following types of questions. What measures can be taken to safeguard against donor exploitation? Assuming these biological systems have been regulated and approved for transplantation, to what extent can they be further modified by scientists in the cryopreservation process prior to transplant or infusion into a patient? How will access to these novel treatments be allocated fairly? Minimizing risk to the first human research participants and patients and ensuring access to patients in need independent of social status or ethnicity are pervasive problems. While advanced biopreservation can promote equity by removing geographical barriers, it could also be misused and exacerbate the existing problems.[25]

In food and sustainability applications some technology is of obvious benefit to all: For instance, new 3D cryoprinting technology may be used to provide food that can be more easily chewed and swallowed for dysphagia patients.[26] Advanced biopreservation will also impact the cold chain for food sourcing, packaging, and delivery. Improvements could reduce loss of agricultural products in transportation and storage, which may prove promising for addressing matters of equity, access, and resource inequality. However, these interventions could also exacerbate existing inequities; past experience suggests that new technology favors large companies that can afford transition, and therefore disadvantages small farmers.[27] Preserving insects as fish feed (such as black soldier flies), researchers could replace the use of wild fish as feed to aquaculture species, thereby better protecting wild populations of fish, although such changes could have hard-to-predict long-term impact on the public consuming such genetically edited insects indirectly. Researchers are also interested in cryopreserving CRISPR-modified sterile fish embryos, such as carp, to better maintain wild fisheries. Cryopreserved CRISPR-modified mosquitoes or pest species could be released to reduce malaria in endemic regions, and to protect food crops. These new technologies raise a host of questions. Are we comfortable with CRISPR-modified animals in our terrestrial and aquatic environments? Won't these genetically modified animals become part of the food web and ultimately part of our diet? To what extent are we going to allow ourselves to change the very environment we are trying to save?

Advanced biopreservation of whole organisms, initially considered for biomedical applications and food sustainability purposes as already discussed above, also has synergistic applications in environmental conservation and whole organism research. This starts with a focus on cryopreservation of vertebrate and invertebrate model systems such as *Drosophila* and Zebrafish that are important models of genetic human diseases and transplantation respectively.[28] Having developed successful protocols for preservation of whole organisms for biomedical applications, scientists are now horizontally translating these protocols to apply into other aquatic and terrestrial systems such as plant seeds, coral and fish species, insects, and amphibians.

Biobanking species is a possible hedge against mass extinction. This approach has been discussed for plant seeds and ecosystem of organisms like coral that are endangered by climate change. However, assuming protocols exist for advanced biopreservation to allow preservation and banking, critical questions then arise for persons outside the research community, such as where should the biobanks reside, what species should be prioritized, and who should have access to the banked material? One famous biobank already exists for seeds (Svalbard Norway), and some banks are maintained for agricultural species (USDA, Fort Collins). However, in the event of worldwide climate catastrophe and ecosystem destruction, a terrestrial biobank may not be as safe as one that was placed on the moon, especially if it is permanently at a cryogenic temperature. Since lunar payloads are currently expensive and small, the size will necessarily be small, maybe even only the size of a suitcase. It is not known at this time whether this would be sufficient or what species should be banked.[29]

Similarly, advanced biopreservation can enable research on infectious organisms. Host organisms such as mosquitos can be preserved, which allows research to be conducted throughout the year, which

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is currently not possible allowing, for instance, malaria research only a few months per year. Similarly, infectious organisms such as *Cryptosporidium*, a leading cause of diarrhea morbidity and mortality in younger children, could be preserved for research efficiently, in order to promote global health applications.[30] But preserving these infectious organisms — an enabling tool for research that may lead to eradication of diseases — simultaneously raises the risk of bioterrorism if these organisms can be preserved and shipped, similar to anthrax. It is not clear how the risk will be balanced, and a long list of interested parties should be involved for engagement purposes.

III. Next Steps in Engagement

Thus far, we have advanced four major points. First, advanced biopreservation technologies span many different research domains, each of which implicates different types of interested parties. Second, as an emerging platform technology, advanced biopreservation offers opportunities for early engagement for developers and stakeholders to produce successful research and implementation strategies based on bi-directional learning. Third, engagement during research and development could result in other instrumentally valuable outcomes, especially better awareness and support of biopreservation technologies, and the capacity to address interested parties' ethical concerns proactively. Fourth, in addition to these instrumentally valuable aims, broad engagement is intrinsically justified as a meaningful expression of an ethical commitment to respect persons and their capacity for autonomy as well as communities and their interests.

If early engagement with interested groups is scientifically and ethically desirable for advanced biopreservation, then some important subsequent issues are (1) how engagements should be financially supported and practically realized, and (2) what untapped approaches could be used to enable effective communication between scientists and various interested groups. We conclude with some recommendations on these issues.

Given the speed at which advanced biopreservation technologies are advancing, and the general lack of awareness by persons outside the biopreservation research community, it seems that agencies funding biopreservation research and companies investing in these technologies are best positioned to incentivize meaningful broad engagement and provide financial support. Funders and companies can also make it a condition of financial support that biopreservation researchers devote effort to developing recurrent engagement opportunities with non-scientific collaborators. Funders and companies need to assume responsibility for enabling meaningful engagement because without external support and incentives for researchers to devote their time and energy to these efforts, other university, department, or company priorities will crowd out researchers' well-intentioned desires to engage with interested parties.[31]

Another reason funders and companies are well-positioned to enable engagement is that — due to the diverse range of biopreservation research — engagements can be targeted to relevant interested groups and calibrated to each research domain's funding and development timelines. This would be an effective way to ensure that bi-directional engagement occurs at the time that the research itself is unfolding, without relying on organizers outside the biopreservation field to keep abreast of the state of the science.

On the other hand, solely relying on funders and companies to support broad engagement runs the risk that there may be disincentives to change course or to halt research trajectories altogether if engagement with interested parties yields conclusions that are unfavorable to the aims of the financial supporters. This possible limitation, in addition to the usual strains on resources, space, and staffing that face most research centers, academic institutions, and companies, makes it prudent to find an alternative entity that could play the role of intermediary between engagement sponsors and interested groups.

One intriguing approach would be to urge biopreservation researchers to use some of their funding to partner with local museums of science to co-create engagement opportunities that meet affected parties and their communities "where they are." Science museums are full of experienced educational staff whose purpose and expertise is built on the day-to-day operations of organizing and running a range of science engagement opportunities for diverse science learners on site, in schools, and online, depending on the composition and needs of participants.[32] Museum-led events and programs can range from open forums and community concern-gathering events, to free digital and school or afterschool programs, to community outreach events delivered off site in local libraries. These multiple opportunities for bi-directional science communication can include interested parties from medicine (including patients), education, government, industry, and communities underrepresented in STEM. In short, with adequate funding and content development partnerships with biopreservation researchers, science museums could serve as effective mediators of ongoing engagement and mutual learning with interested parties poten-

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tially affected by developing biopreservation technologies. Museums could offer a wide range of material to capture the imaginations of different audiences because biopreservation spans such a broad range of activities. Whether persons care specifically about healthcare innovations or the environment or food production, there will be a biopreservation technology use case that could affect them directly.

Importantly, such engagement opportunities would help further the missions of science museums. As defined by the International Council of Museums (ICOM), "[a] museum is a non-profit, permanent institution in the service of society and its development, open to the public, which acquires, conserves, researches, communicates and exhibits the tangible and intangible heritage of humanity and its environment for the purposes of education, study and enjoyment."[33] For science museums, their service to society takes the form of helping informal science learners of all ages, backgrounds, and abilities (1) understand and use scientific concepts and facts, (2) participate in scientific activities and learning practices with others, (3) reflect on their own process of learning about science, and (4) think about themselves as science learners and develop an identity as someone who knows about, uses, and contributes to science. Each of these commitments can be realized through meaningful conversations about biopreservation through bi-directional learning.

Because science museums are designed to support dynamic science communication with diverse populations, they have a clear role to play within the context of enabling the socially responsible advancement of biopreservation technologies. However, in addition to their ability to help with the logistical burdens of broad engagement that otherwise fall on universities, medical centers, and companies, science museums can offer another, often overlooked, benefit. According to a 2021 study by the American Alliance of Museums, museums are viewed by the public as nonpartisan and highly trusted, "ranking second only to friends and family, and significantly more trustworthy than researchers and scientists, NGOs generally, various news organizations, the government, corporations and business, and social media."[34] This holds true across all segments of race, ethnicity, and political beliefs. And these survey results remain durable. For example, according to a recent National Awareness, Attitudes, and Usage (NAAU) study, the rate at which museums are viewed as credible sources of information increased by 9.5% as of the end of 2022 when compared to before the COVID-19 pandemic. This is a notable increase in the percentage of people looking to museums as reliable and credible sources.[35] With well over 230,000 survey respondents, the NAAU is the largest ongoing study of perceptions and behaviors related to visitor-serving organizations in the US. What these data suggest is that science museums have the advantage of already being highly trusted sources of scientific information for non-scientific participants. For an area as complex and as potentially controversial as advanced biopreservation, the fact that museums are widely perceived as a trusted source for accurate science information and as a nonpartisan facilitator of social dialogue means they are likely to be effective in facilitating genuine engagement.

[B]efore any science engagement activity or opportunity is made widely available by a science museum, it is best practice to pre-test the program and accompanying educational materials for their effectiveness and ability to meet learning goals on a subset of the intended audience to receive feedback. Through these best practices for program development, concerns about trustworthiness, hidden agendas, and the adequacy of people's understanding can each be addressed. However, developing engagement programs this way takes time, money, and much planning. Enabling much-needed engagement in advanced biopreservation technologies by interested parties, through partnerships with researchers and science museums, will necessitate support by the funding agencies and companies that are investing in this platform technology.

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There may be challenges ahead, but they are surmountable. First, it is crucial for science museums to maintain their social capital of trust. Thus, collaborations between museums and biopreservation experts must guard against the perception — real or imagined — that researchers are feeding non-scientists a one-sided, self-interested view of the benefits of their technologies. This is why fostering conversations about both the benefits and the accompanying pitfalls and hurdles is essential. Second, with a scientific area as complex as this, it may be tempting to doubt whether some non-scientific participants in an engagement activity will be able to adequately understand what biopreservation means. Both this doubt and the previous concern about trustworthiness could be managed by following current standards for program testing and evaluation that are in place in most science museums. That is, before any science engagement activity or opportunity is made widely available by a science museum, it is best practice to pre-test the program and accompanying educational materials for their effectiveness and ability to meet learning goals on a subset of the intended audience to receive feedback. Through these best practices for program development, concerns about trustworthiness, hidden agendas, and the adequacy of people's understanding can each be addressed. However, developing engagement programs this way takes time, money, and much planning. Enabling much-needed engagement in advanced biopreservation technologies by interested parties, through partnerships with researchers and science museums, will necessitate support by the funding agencies and companies that are investing in this platform technology.

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