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SYMPOSIUM

Emerging Technologies to Stop Biological Time: The Ethical, Legal & Policy Challenges of Advanced Biopreservation

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Timothy L. Pruett, and Korkut Uygun

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Jessica Ohlrich, and Julia Dickson-Gomez

Comparing the Clinical Trial Characteristics of Industry-Funded Trials and Non-Industry-Funded Trials Emily Hughes, Tamara Van Bakel, Ashley Raudanskis, Prachi Ray, Benazir Hodzic-Santor, Ushma Purohit, Chana A. Sacks, and Michael Fralick

Advance Directives to Manage Fears and Anxieties of Transgender People via Dementia Planning
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Ghada A. Zakout

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Symposium Articles

**Emerging
Technologies to
Stop Biological
Time:
The Ethical,
Legal & Policy
Challenges
of Advanced
Biopreservation**

Guest Edited by
Susan M. Wolf,
Timothy L. Pruett,
and Korkut Uygun

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*Letter from
the Editor*

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Introduction: The Ethical, Legal & Policy Challenges of Stopping Biological Time

*Susan M. Wolf, Timothy L. Pruett,
and Korkut Uygun*

Section 1:

**Mapping the Challenges of
Advanced Biopreservation**

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**Anticipating Biopreservation
Technologies that Pause Biological
Time: Building Governance &
Coordination Across Applications**

*Susan M. Wolf, Timothy L. Pruett,
Claire Colby McVan, Evelyn Brister,
Shawneequa L. Callier, Alexander M.
Capron, James F. Childress,
Michele Bratcher Goodwin, Insoo Hyun,
Rosario Isasi, Andrew D. Maynard,
Kenneth A. Oye, Paul B. Thompson,
and Terrence R. Tiersch*

Advanced biopreservation technologies using subzero approaches such as supercooling, partial freezing, and vitrification with reanimating techniques including nanoparticle infusion and laser rewarming are rapidly emerging as technologies with potential to radically disrupt biomedicine, research, aquaculture, and conservation. These technologies could pause biological time and facilitate large-scale banking of biomedical products including organs, tissues, and cell therapies.

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**Successfully Bridging Innovation
and Application: Exploring the Utility
of a Risk Innovation Approach in the
NSF Engineering Research Center for
Advanced Biopreservation Technologies
(ATP-Bio)**

*Andrew D. Maynard, Kenneth A. Oye,
Marissa Scragg, Tim Tripp,
and Susan M. Wolf*

This exploratory study set out to pilot use of a Risk Innovation approach to support the development of advanced biopreservation technologies, and the societally beneficial development of advanced technologies more broadly. This is the first study to apply the Risk Innovation approach — which has previously been used to help individual organizations clarify areas of value and threats — to multiple entities involved in developing an emerging technology.

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**Ethical Issues in Emerging
Technologies to Extend the Viability of
Biological Materials Across Time and
Space**

*James F. Childress, Evelyn Brister,
Paul B. Thompson, Susan M. Wolf,
Shawneequa L. Callier, Alexander M.
Capron, Timothy L. Pruett,
and Nikolas Zuchowicz*

This article presents a framework of ethical analysis for anticipatory evaluation of advanced biopreservation technologies and employs the framework illustratively in three domains. The framework features four clusters of general ethical considerations: (1) Producing Benefits, Minimizing Harms, Balancing Benefits, Risk, and Costs; (2) Justice, Fairness, Equity; (3) Respect for Autonomy; and (4) Transparency, Trustworthiness, and Public Trust.

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**The Need for Early Engagement
with Interested Groups on Advanced
Biopreservation**

Insoo Hyun, John Bischof, Shawneequa L. Callier, Alexander M. Capron, Michele Bratcher Goodwin, Ishan Goswami, Rosario Isasi, Andrew D. Maynard, Timothy L. Pruett, Korkut Uygun, and Susan M. Wolf

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.

Section 2:

**Advanced Biopreservation in
Biomedicine**

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**The Big Chill: Opportunities for, and
Challenges to, Advanced Biopreservation of
Organs for Transplantation**

*Alexander M. Capron, Timothy L. Pruett,
and James F. Childress*

The application of advanced biopreservation to organs donated for transplantation may make possible their indefinite storage and thereby improve the utility and equity they provide to patients. The technology is still at a preclinical stage, with many difficult, scientific issues that remain to be answered. At the moment, however, the actual capabilities of the technology are too indefinite to begin formulating the statutes, regulations, and ethical guidance that will be needed to obtain the benefits expected from its use.

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**An ‘Amazon of Living Things’?
The History & Horror of Commodifying
Life**

Michele Bratcher Goodwin

This article argues that beneath the veneer of legitimacy in the organ, tissue, and body part transplantation systems exists a horrifying history of human commodification whose vestiges surprisingly linger in contemporary supply and allocation systems. This history, as the article demonstrates, dates back to the colonial period in the United States, where “grave robbing” became an important feature in the advancement of medicine. This legacy lives on.

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Biopreserving Pathogens: Promise & Peril

*Justyna Jaskiewicz, Susan M. Wolf,
Mehmet Toner, and Rebecca D. Sandlin*

The development of technologies for the biopreservation of infectious organisms requires careful analysis of benefits and risks. This article reviews the regulatory landscape and oversight responsibilities in the United States in respect to pathogen biopreservation. Focused on two globally significant pathogens, *Cryptosporidium* and *Plasmodium*, the article explores advantages and potential risks of biopreservation concerning biosafety, biosecurity and biocontainment.

Section 3:

**Advanced Biopreservation
in Conservation Biology &
the Food Supply**

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**Manipulating Time by Cryopreservation:
Designing an Environmental Future by
Maintaining a Portal to the Past**

*Evelyn Brister, Andrea R. Gammon,
Paul B. Thompson, Terrence R. Tiersch,
and Nikolas Zuchowicz*

This article explores how time-related metaphors frame advanced cryopreservation technologies in environmental conservation. Cryopreservation “stops” or “freezes” biological time and “buys time” desperately needed to preserve species and ecosystems. We advance a framing of these technologies as logistical, highlighting how they create opportunities to shift materials, knowledge, and decision-making power through space and time. As logistical technologies, advanced cryopreservation techniques require active planning in the present rather than deferring responsibility and accountability to the future.

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**Biopreservation Beyond the Biosphere:
Exploring the Ethical, Legal & Social
Implications of Suspended Animation in
Space**

*Roel Feys, Korkut Uygun,
Irina Filz von Reiterdank, Susan M. Wolf,
and Rosario Isasi*

In the evolving field of advanced biopreservation technologies, the development of suspended animation (SA) is inspired by realworld challenges. In the context of space exploration, SA is seen as a solution to enable humans to undertake missions far beyond low Earth orbit, including routine travel to other planets in our solar system and beyond. While work on the socio-ethical and legal implications (ELSI) of space exploration continues to evolve, NASA has committed to make ethics a priority issue, making this a fruitful field for further examination.

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Biopreservation in Agriculture and Food Systems: A Summary of Ethical Issues

Paul B. Thompson, John Bischof, Matthew J. Powell-Palm, Kieran Smith, and Terrence R. Tiersch

Biomedical research on advanced cryopreservation has spill-over effects on innovation in the food and agricultural sector. Advanced biopreservation technology has three key domains of impact in the food system: (1) improving efficiencies in storage and utilization of gametes and organoids for plant and animal breeding; (2) isochoric methods for preservation of fresh food products; and (3) in biorepositories for storage of genetic resources for agriculturally significant plants and livestock species.

Independent Articles

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Out of Bounds: Physician Licensing Board Disciplinary Cases Related to Opioid Prescribing

Carol L. Galletly, Erika A. Christenson, Jessica Ohlrich, and Julia Dickson-Gomez

Physician prescribing practices contributed to the US opioid epidemic, leading to increased regulation of opioid prescribing. In some instances, prescribers are unscrupulous or corrupt. They are criminally investigated and subject to prosecution. Less egregious opioid prescribing infractions are addressed through state medical licensing boards (MLBs). At stake are physicians' licenses to practice medicine.

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COMMENTARY

Can Medical Licensing Boards Swing the Pendulum Towards Judicious Opioid Prescribing Practices?

Lewis S. Nelson and Jeanmarie Perrone

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Comparing the Clinical Trial Characteristics of Industry-Funded Trials and Non-Industry-Funded Trials

Emily Hughes, Tamara Van Bakel, Ashley Raudanskis, Prachi Ray, Benazir Hodzic-Santor, Ushma Purohit, Chana A. Sacks, and Michael Fralick

We compared study characteristics of randomized controlled trials funded by industry (N=697) to those not funded by industry (N=835). RCTs published in high-impact journals are more likely to be blinded, more likely to include a placebo, and more likely to post trial results on ClinicalTrials.gov. Our findings emphasize the importance of evaluating the quality of an RCT based on its methodological rigor, not its funder type.

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COMMENTARY

Industry Funding by itself is Not a Reason for Rating Down Studies for Risk of Bias

João Pedro Lima, Arnav Agarwal, and Gordon H Guyatt

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Advance Directives to Manage Fears and Anxieties of Transgender People via Dementia Planning

Ames Simmons

As increasing proportions of our global population age, transgender people are experiencing higher rates of dementia, and many are afraid to enter long-term care. Structural interventions such as advance directives may help mitigate fears around entering long-term care by managing specific anxieties that transgender people may have about dementia, loss of decision-making capacity, and discrimination in long-term care settings

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Unjustified Partiality or Impartial Bias? Reckoning with Age and Disability Discrimination in Cancer Clinical Trials

Ghada A. Zakout

The exclusion of the elderly and people with disabilities from cancer clinical research without appropriate justification is discriminatory and is at odds with the ethos of EU principles, laws and research regulations. It further limits study generalizability. Several primary EU laws fronted by the European Charter prohibit engaging in disparate impact discrimination on the grounds of age and disability in all of EU tasks.

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COMMENTARY on **“Unjustified Partiality or Impartial Bias? Reckoning with Age and Disability Discrimination in Cancer Clinical Trials”**

Janice B. Schwartz and Kenneth Covinsky

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Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of JLME.

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A Symposium Guest Edited by Francis X. Shen, Susan M. Wolf, and Frances Lawrenz

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Conflicts of Interest in Clinical Practice: Cleveland Clinic Policy and Experience

Kathleen A. Derwin, Cory Anand, Susannah L. Rose, and Raed Dweik

The Cleveland Clinic Innovation Management and Conflict of Interest (“IM&COI”) Program implemented a policy on Conflicts of Interest in Clinical Practice in 2013. The policy requires review of financial interests greater than \$20,000 in a year, or more than 5% equity in a company, when the clinician is prescribing or using products of the company with which they have a relationship. The IM&COI Committee developed definitions for low, medium and high levels of annual compensation and risk and uses a “Matrix” to guide disclosure based on these factors.

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**COMMENTARY:
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