International Space Medicine Clinical Decision-Making Working Group

Synthetic DNA, Biology and Space: (Human) Rights, Wrongs and Future Governance

White Paper

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Declaration of interests

Dr Gabrielle M Caswell and Dr Douglas Hamilton have contributed to the development of artificial-intelligence clinical tools and assistants. Dr Andrew W Kirkpatrick has undertaken consultancy work for Zoll Medical, 3M and Innovative Trauma Care and is principal investigator for the COOL trial. Dr Mark W Biernacki has undertaken contract work for a Canadian telehealth artificial-intelligence company.

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Editorial note

This Version 2 edition uses the 29 May 2026 white paper as its foundation. It corrects scientific terminology, integrates relevant June 2026 review material, and included missing space-systems, safety, rights and governance topics. This white paper is intended for an international and culturally diverse readership; it is not represented as a peer-reviewed publication.

Executive summary

- Synthetic DNA, genome editing, synthetic biology and mirror life are related but distinct fields. This white paper identifies urgent governance problems including the possibility of biological technologies outpacing protections for dignity, consent, equality and intergenerational justice.
- Synthetic DNA generally refers to DNA made by chemical synthesis, or designed and assembled, using engineering methodology and principles.
- Genome editing changes DNA within [living] cells.
- CRISPR Cas9 associated systems represent a family of editing tools, with the ability to cut or snip DNA with the intent of removal, replacement or joining of DNA.
- Synthetic biology is the redesigning of biological components or systems.
- Mirror life is a narrower, hypothetical category; involving self-replicating organisms composed of opposite chirality bio-molecules [most natural molecules are 'right handed, mirror life molecules are 'left handed']. Mirror organisms do not presently exist and should not be confused or presented as another name for CRISPR Cas9 or [ordinary] synthetic DNA (Adamala et al., 2024; Cameron et al., 2014; Rohden et al., 2021; Wang et al., 2018).
- Current human genome editing is defensible when used somatically to treat serious disease under rigorous clinical oversight.
- Heritable editing, enhancement and environmental release create qualitatively different risks, as effects may extend to descendants, communities and ecosystems.
- Complex proposed adaptations to radiation, altered gravity, cognition or metabolism are polygenic, developmentally contingent and environmentally influenced; they cannot responsibly be described as single-gene engineering targets (Jakutis & Stainier, 2021; Kontarakis & Stainier, 2020).
- For space exploration, the nearer-term value of synthetic biology is likely to lie in contained microbes, plants and cell-free systems that produce medicines, nutrients, materials or fuels, recycle waste and support life-support loops. These systems create new failure modes, including, but not limited to: radiation and selection driven mutation, loss or enhancement of engineered function, possible containment breach(es), horizontal gene transfer, ecological interface, digital-sequence misuse

and a dependence on biological production far from resupply (Averesch et al., 2023; Berliner et al., 2022; Menezes et al., 2015; Radde et al., 2024).

- A governing principle proposed, and which requires discussion, is that personhood and rights should not be defined or depend on whether a genome is inherited, edited or contains synthetic sequence.
- It is suggested that governance should instead classify interventions by purpose, inheritability, reversibility, persistence, containment, uncertainty and distribution of risk.
- Governance should protect refusal [of treatments], prohibit genetic discrimination, maintain genomic data security, require transparent evidence and long-term agreed care protocols, and establish responsibility for harms.
- International space industry and government co-operation can convene dialogue, it is suggested that the Artemis Accords may be an appropriate vehicle to convene such dialogue.
- It is should be noted, enforceable protection requires layered national law, research and clinical regulation, mission contracts, independent review and cross-border accountability as well as accepted international governance policies nad laws (Barlevy et al., 2024; Conley et al., 2025; Gibelli et al., 2025).

Contents

Abstract

Synthetic DNA, genome editing and synthetic biology may support medicine treatments and increase patient outcome, food production, materials manufacture, environmental control and resource recovery during future space missions. These biological capabilities may create risks that differ according to whether a synthetic DNA intervention is somatic or inheritable, replicating or non-replicating, contained or released, reversible or persistent. This white paper clarifies terminology; reviews present scientific capabilities and limitations; examines human-rights for individuals with manipulated DNA; reviews safety, bio-security, planetary-protection; and governance implications of using these technologies beyond Earth. The authors conclude that near-term value is most credible in carefully contained microbial, plant and cell-free production systems, and application in evidence-based somatic therapy. Human enhancement for adaptation to space remains speculative; inheritable editing, and [future potential] mirror organisms, create a substantially greater intergenerational or ecological concern. The proposed governance model requires equal personhood regardless of genetic [DNA] status and incorporates the themes of voluntary consent, protection from genetic discrimination, mandatory human authorization, traceable responsibility for technology, independent review of technology and procedures before deployment, longer-term care imperatives, incident reporting and risk-tiered internationally cooperative oversight. This paper takes a multidisciplinary approach, and is not a systematic review, clinical guideline or statement of law. It has been designed to provoke discussion, reflection of the creation, use and potential misuse, of genetic manipulation technology, with a focus on human space exploration.

Keywords: synthetic DNA; genome editing; CRISPR; synthetic biology; mirror life; space medicine; space bio-manufacturing; bio-security; planetary protection; human rights; governance.

Introduction

This white paper examines synthetic DNA and genome editing where human biology, spaceflight and governance intersect. Its objectives are to clarify terminology, assess present capabilities and limitations, identify credible space applications and hazards, protect human rights, and propose a practical international governance architecture. The document serves as a policy analysis grounded in peer-reviewed literature; it does not serve as legal or clinical advice for any particular jurisdiction.

1.1 Purpose, evidence approach and scope

This is a narrative, multidisciplinary white-paper review rather than a systematic review or meta-analysis on the area of science termed broadly as Synthetic DNA, and associated technologies. Literature was identified with targeted searches of PubMed/MEDLINE, PubMed Central, Web of Science-linked journal records, Crossref/DOI records and publisher journal platforms. Priority was given to peer-reviewed systematic reviews, major reviews, clinical studies, engineering analyses and governance scholarship relevant to genome editing, synthetic biology, bio-security, reproduction, and space bio-processing/biopharmaceutical and other biological based manufacturing.

In addition to the peer literature, when relevant, news reports and commercial web pages, were incorporated into the reviewed literature.

ResearchGate records, pre-prints and non-peer-reviewed policy instruments were excluded from the reference list. The literature search was targeted, rather than protocol-driven, it should be noted that the paper should not be interpreted as exhaustive. All Searches and reference verification are current to 11 August 2026.

1.2 Evidence categories

To enable data handling and clarity, the authors used three defined evidence categories. Information gathered from a range of sources, and peer reviewed papers were assigned to one of these categories, which established the current scientific and technological status of the technology:

Established refers to replicated biological principles, approved or clinically demonstrated interventions, or documented engineering capabilities;

Emerging refers to plausible applications, supported by laboratory techniques and findings, demonstrating analogue or early mission evidence.

Speculative refers to concepts that are technically uncertain, far from implementation or dependent on multiple unproven assumptions, with speculative predictive outcomes.

Readers should note these categories describe maturity [of technology and its application], not the moral acceptability [of technology and its applications].

1.3 Scope exclusions

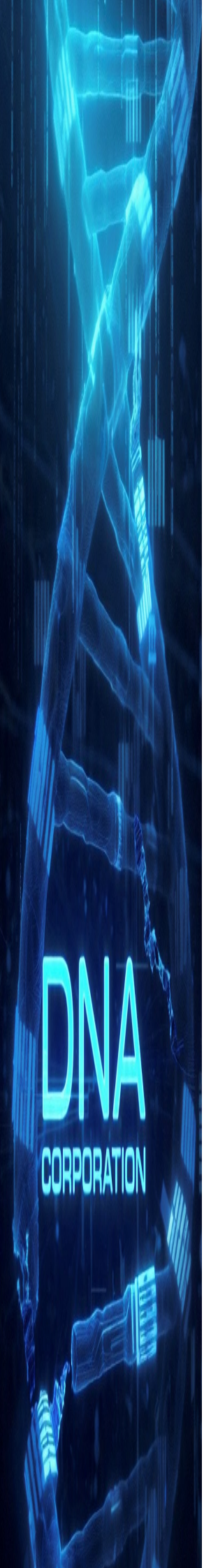
Due to the focus of this report, the paper does not comprehensively evaluate the following:

RNA editing, epigenome editing, gene drives, mitochondrial replacement, cloning, conventional gene therapy without editing, organoids, embryo models, ectogenesis, neural interfaces or whole-microbiome engineering.

The authors acknowledge the techniques or scientific developments listed above may overlap with the governance questions raised here. The authors decided that these techniques and developments require a separate technical and ethical assessment and references to them should not be read as a complete evaluation of these techniques or scientific developments.

Table One: Evidence categories sources

Source	Principle Use	Selection approach
PubMed/MEDLINE and PubMed Central	Clinical genome editing, reproductive health, molecular safety and ethics	Targeted searches; peer-reviewed journal records and full text where available
Publisher journal platforms	Space bio-processing, synthetic biology, AI and mirror-life literature	Primary article pages used to verify authorship, publication details and DOI
Web of Science-linked records	Cross-disciplinary and citation verification	Used to identify and verify relevant peer-reviewed scholarship
Crossref/DOI records	Bibliographic verification	Used to confirm persistent identifiers and publication metadata



2.0 Definitions and conceptual boundaries

It is important that standard definitions and conceptual boundaries are defined, to reduce confusion between different technologies, their uses and potential uses.

Synthetic DNA is an umbrella term for chemically synthesized oligonucleotides, genes, chromosomes or genomes, including sequences designed computationally and assembled for use in cells or cell-free systems. Synthetic genomics extends these methods to genome scale construction and redesign (Gibson et al., 2010; Wang et al., 2018). It is important to note the term does not imply that every cell receiving a synthetic sequence becomes a new category of life.

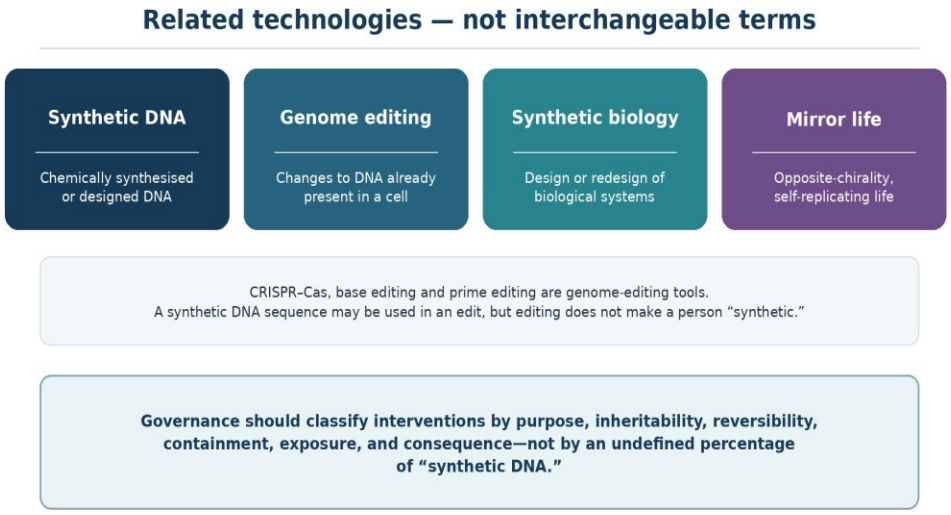
Genome editing alters a genome already present in a cell. CRISPR Cas9 systems use guide RNA and a nuclease or modified enzyme, to target a DNA sequence. Conventional nuclease editing often produces a DNA break, which is repaired by cellular mechanisms utilizing enzymes. CRISPR Cas9 outcomes can include small insertions or deletions, targeted replacement, large rearrangements or unintended variants.

Base editors can convert selected bases without the same double-strand-break mechanism of CRISPR Cas9. Prime editing can write specified DNA changes using a reverse-transcription template (Anzalone et al., 2019; Bak et al., 2018; Komor et al., 2016).

Synthetic biology is a term which can be defined as applying engineering approaches to biological production processes, biological parts (some not all of a thing), circuits, and organisms. It includes engineered microbes, biosensors, metabolic pathways, cell-free systems and synthetic genomes; it is broader descriptive than human genome editing (Cameron et al., 2014).

These terms describe related technologies, but they are not interchangeable terms or technologies. Figure One, demonstrates their functional relationships.

Figure 1. Terminology map for the technologies discussed in this paper



2.1 Mirror Life

Mirror Life means hypothetical *self-replicating organisms* [recursive self replication and functional biological oganization] whose core bio-molecules have a chirality opposite to known 'natural' life. Natural DNA and RNA use D-sugars, while proteins are largely made from L-amino acids; a mirror organism would invert this architecture. Experts have warned that mirror organisms could evade many evolved immune, predatory and degradation processes, creating potentially global and irreversible [disease] risks (Adamala et al., 2024; Rohden et al., 2021). Note: Research on individual mirror peptides or nucleic acids is not equivalent to creating a replicating mirror bacterium. This paper therefore uses ‘mirror life’ only in this precise sense.

2.2 Determination of humanity

The authors suggest that no percentage of ‘synthetic DNA’ provides a scientifically or ethically meaningful threshold for the determination of one’s ‘humanity’.

Humans already differ through inherited variants, *de novo* mutations, somatic mosaicism, transplantation, viral integration and medical interventions.

The authors propose that legal personhood, and any attached 'moral status', must not be made contingent on a 'natural' human molecular tally. A body of international law discussion encapsulating this concept is currently lacking.

3. Scientific foundations and present capabilities

The 2003 Human Genome Project was a landmark catalogue of human DNA, it did not however, deliver the prediction engine for human biology. DNA sequence is interpreted through gene regulation, chromatin, RNA processing, development, cell state, environment, microbiota and stochastic processes. Proteins perform catalytic, structural, transport, and signaling, immune and mechanical roles. A protein variant may be highly penetrative, weakly associated, protective in one context and harmful in another, or compensated through regulatory adaptation (Jakutis & Stainier, 2021; Kontarakis & Stainier, 2020; Salanga & Salanga, 2021).

Clinical genome editing is no longer theoretical, *ex vivo* CRISPR Cas9 editing of haematopoietic stem cells has produced durable fetal-haemoglobin induction in people with sickle cell disease and transfusion-dependent β-thalassaemia. Demonstrating carefully selected somatic target can yield major medical benefit (Frangoul et al., 2021). This success does not establish that all inherited disease is as readily editable. Geneomic expression cooperation brings considerations as to impact of full effect of any editing, both technological and longer-term outcomes: delivery to the required cells, dose, immune response, durability, manufacturing quality, access, and long-term surveillance, remain intervention specific.

The phrase ‘precise genetic scissors’ is useful as an introduction but incomplete. A guide can mis-target similar sequences; intended sites can undergo unexpected insertions, deletions, translocations or complex chromosome damage; edited cell populations can be mosaic; and DNA damage responses can affect cell selection (Haapaniemi et al., 2018; Leibowitz et al., 2021). Base and prime editors avoid some double-strand-break risks but introduce their own bystander edits, off-target activity, delivery constraints and efficiency limits (Anzalone et al., 2019; Komor et al., 2016).

Somatic editing affects non-reproductive cells in the treated person and is not intended to be inherited. Heritable editing alters embryos, gametes or their precursors such that a change may pass to descendants. The latter adds uncertainty about development, mosaicism, reproductive autonomy and multigenerational effects. Future persons cannot consent, and an apparently beneficial edit may interact differently with later environments or genetic backgrounds.

Enhancement is scientifically and normatively distinct from treating a serious condition. Traits such as cognition, stature, strength, radiation response, bone density and tolerance of altered gravity are distributed across many pathways and depend on development and environment.

Even if component mechanisms become editable, changing one pathway may generate trade-offs elsewhere. Claims that a specific edit would reliably create a person adapted to Mars, unable to live on Earth, or superior in a mission role are speculative and should be labeled accordingly.

4. Synthetic biology and genome editing in space

Space missions intensify the value of compact, renewable production. Launch mass, shelf-life, delayed resupply and communication distance make biology attractive as a manufacturing platform. Engineered microbes, plants or cell-free systems could produce pharmaceuticals, vitamins, flavors, polymers, adhesives, fuels and feedstock; recover nutrients from waste; support air and water processing; detect contaminants; and enable local use of mission resources (Averesch et al., 2023; Berliner et al., 2022; Menezes et al., 2015). Near-term applications should be distinguished from proposals to alter astronauts.

A contained bioreactor producing a medicine can be stopped, isolated or replaced more readily than a heritable human edit. Cell-free production may further reduce replication and escape risks, although it still requires validated reagents, secure sequence files and quality control. Plant and microbial systems can contribute to food and life support, but they must be evaluated as integrated ecological and engineering systems rather than as isolated genetic constructs.

Space changes the operating environment. Radiation can damage DNA and equipment; altered gravity changes fluid behavior, mass transfer and cellular physiology; limited volume changes microbial ecology; and long missions provide time for evolution. Engineered functions impose metabolic burden and may be lost when escape mutants gain a growth advantage. A design that performs in a short Earth laboratory test may fail during scale-up or repeated mission cycling (Berliner et al., 2022; Radde et al., 2024).

Manufacture of medicines, enzymes or other clinically important biological products in space remains speculative and application-specific. Producing a molecule is not equivalent to producing a medicine fit for human use. Reduced gravity, radiation, limited analytical equipment, closed-loop contamination risk and constrained crew time may affect upstream production, purification, formulation, packaging, storage and batch testing. Current engineering work demonstrates plausible processing architectures, but not a general capability to release human medicines autonomously in deep space
(Soundararajan et al., 2023).

If future space manufacture involves DNA or RNA manipulation to produce a human-use product, it is recommended that the program pre-define critical quality attributes and release specifications. Release specifications should verify sequence and organism identity; control raw materials and contamination; test identity, purity, potency, sterility or microbial limits, endotoxin where relevant, dose consistency and stability; retain reference and batch samples; validate equipment and software; document deviations; and require qualified human batch-release authorization.

When full Earth-equivalent testing is impossible, the limitations, residual risks, decision authority, restricted indications and contingency supply must be agreed before launch:

- It is strongly suggested that no AI or automated system may independently release a batch for human administration, or without human oversight.

Extremophile biology may inform radiation tolerance, resource processing and bio-signature research, but extremophile traits are not plug-and-play modules. Transferring individual genes may not recreate a network-level phenotype, and an organism robust enough for industrial use may be harder to contain.

- Engineering for persistence therefore creates a safety-performance tension (Kaur et al., 2024).

- Potential human editing for space adaptation requires a much higher evidentiary and ethical threshold.

Environmental countermeasures such as shielding, habitat design, exercise, pharmacology, nutrition, mission duration and operational limits—are generally more reversible and do not transmit risk to descendants.

Genome editing should not become a substitute for safer engineering controls or adequate mission design.

4.1 Technology-readiness orientation

It is important to distinguish between technology that is mature and that which is speculative. The categories below prevent speculative human adaptation from being presented alongside existing clinical or engineering capability as though they were equally mature. Maturity varies by product, target and mission, and must be reassessed for each proposed use

Table Two: Technological readiness of gene editing technology

Application	Present Maturity	Space Relevance	Principal governance concern
Somatic CRISPR therapy	Clinical use exists for narrowly defined indications	Possible future treatment; not a general space countermeasure	Safety, consent, access, delivery and long-term follow-up
Heritable genome editing	Experimental; not accepted for routine reproduction	Speculative	Future persons, mosaicism, multigenerational uncertainty and coercion Evolutionary stability, containment, quality and crew dependence
Microbial bio-manufacturing	Laboratory development and early space-system work	High potential for nutrients, materials, medicines and waste processing	Reagent stability, product quality, sequence security and validation
Cell-free production	Emerging and application-specific		Identity, purity, potency, sterility, dose, stability and qualified human batch release
In-space manufacture involving DNA or RNA manipulation	Theoretical and early engineering development; no general autonomous clinical release capability	Potentially high where replication is undesirable Potential future value for resupply-limited missions	
Human enhancement for space adaptation	Speculative; complex traits are polygenic and environmentally influenced	Uncertain	Weak evidence, trade-offs, hierarchy, discrimination and inheritability
Mirror organisms	No known completed organism; major technical barriers remain	No defensible operational requirement identified	Potentially irreversible human, animal, plant and ecosystem harm

5. Reproduction, development and inheritable change beyond Earth

Knowledge about human conception, gamete function, implantation, pregnancy, fetal development and multigenerational health beyond Earth is limited. Human evidence is sparse, study populations are small, and much of the mechanistic evidence comes from terrestrial analogues, cells or animals. Available reviews identify possible effects of altered gravity, radiation and mission conditions on reproductive hormones, ovarian reserve, sperm function, DNA integrity, implantation biology and development, but do not establish that healthy human reproduction is safe in lunar, Martian or deep-space environments
(Gimunová et al., 2024; Lung et al., 2026).

Genome editing must not be proposed as a remedy for poorly characterized reproductive hazards. Before any reproductive or heritable intervention is considered, programs would need evidence on unedited reproduction under the relevant gravity, radiation, atmospheric, nutritional and psychosocial conditions; multigenerational animal and non-implantation model data where ethically acceptable; independent reproductive and pediatric review; and viable non-genetic alternatives.

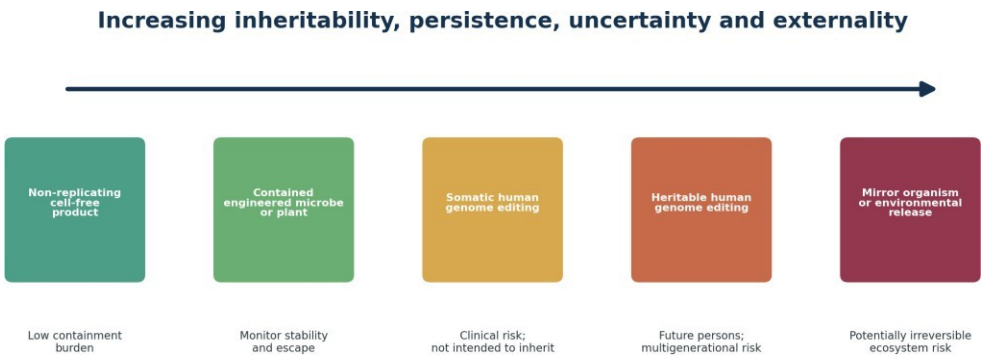
Potential concerns include germ-cell DNA damage; altered gene regulation and epigenetic programming; mosaicism; placental or developmental effects; interaction between an edit and an unfamiliar environment; reduced genetic diversity in small settlements; founder effects; and uncertainty about whether a change that appears advantageous in one habitat may be harmful on Earth or in another habitat. Physiological adaptation acquired during life must also be distinguished from inherited genetic change.

No mission operator, employer, clinic, patent holder or settlement authority should acquire ownership of a child, descendant, reproductive decision or naturally inherited sequence. A patented tool or engineered construct may carry intellectual-property rights under applicable law, but those rights must not create royalties, subscription obligations, reproductive restrictions or claims over descendants. Any future heritable intervention would require protection of the resulting child's independent interests, lifelong care, privacy, nationality, return rights and freedom from genetic discrimination.

6. Safety, reliability and planetary protection

A biological system in space should be governed across its full lifecycle: design, sequence acquisition, synthesis, assembly, verification, transport, operation, monitoring, shutdown, waste treatment and post-mission disposition. It should be appreciated that each stage could fail independently. Minimum controls are suggested and include authenticated sequence provenance, vendor screening, physical and genetic containment, environmental monitoring, retained reference samples, validated kill or shutdown methods where feasible, backup supplies and incident reporting (Berezin et al., 2024).

Figure 2. Conceptual risk continuum; review intensity should rise with persistence, inheritability and irreversibility



6.1 Containment must be layered

Auxotrophy, kill switches, and dependency on non-natural nutrients can reduce risk, but no genetic safeguard should be treated as infallible: mutation, recombination, horizontal gene transfer and operational error can defeat single controls.

6.2 Physical containment

Process isolation, sterilization and monitoring remain necessary. The degree of containment should rise with replication capacity, persistence, host range, pathogenic potential and difficulty of remediation.

6.3 Planetary protection has two directions.

Forward contamination can compromise destination ecosystems or confound life-detection science. Backward contamination concerns return of material capable of harming Earth systems. Engineered organisms introduce additional questions: how to distinguish a released construct from indigenous biology, how long it can persist, whether it can exchange genes, and who bears responsibility for remediation. Terraforming proposals remain speculative and raise exceptionally high ecological and political stakes (Sleator & Smith, 2019).

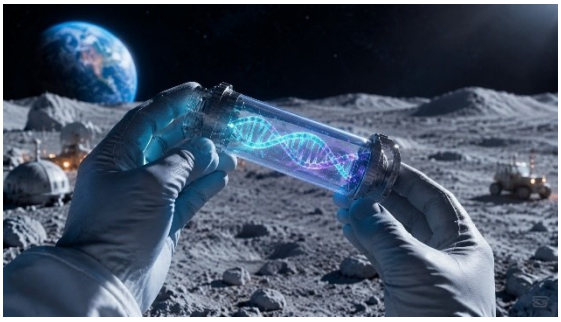
6.4 Mirror organisms

Mirror organisms sit at the extreme end of this risk continuum. Opposite chirality could interfere with immune recognition, predation and biodegradation that normally constrain organisms. Because a self-replicating release could be irreversible at planetary scale, the absence of full certainty is not a reason to proceed. Research on non-replicating mirror molecules should be clearly separated from attempts to create mirror organisms, for which a strong international presumption against creation is warranted (Adamala et al., 2024).

7. Human rights, dignity and equality

Every human retains equal legal and moral status regardless of whether conception involved assisted reproduction, whether cells were edited, or whether a synthetic sequence is present. Sentience, cognitive performance, mission usefulness and genetic origin are unsuitable thresholds for basic rights. Any framework that permits an 'organic' and 'synthetic' caste system would conflict with dignity, equality and disability rights.

Genome editing can support human welfare, but language about 'desirable', 'undesirable' or 'superior' traits can revive eugenic hierarchies and stigmatize disability, neurodiversity, ancestry and ordinary variation. Disease prevention and enhancement are not always separated by a bright line; therefore decisions require transparent justification, disability-informed participation and attention to social context, not only technical feasibility (Gibelli et al., 2025; Villalba et al., 2024).



- Rights requiring explicit protection include bodily integrity; voluntary and continuing consent; privacy and confidentiality; freedom from genetic discrimination; equal access to health care, education, employment, insurance, migration and mission selection; the right to refuse experimental intervention without retaliation; access to counseling; and funded treatment and compensation for adverse effects.

Children and people unable to consent require independent representation and best-interest standards. Future generations create a representation problem, not an ownership opportunity.

Descendants cannot be parties to the original consent or commercial contract. No patent, license or service agreement should create a claim over a person, their descendants or ordinary reproduction.

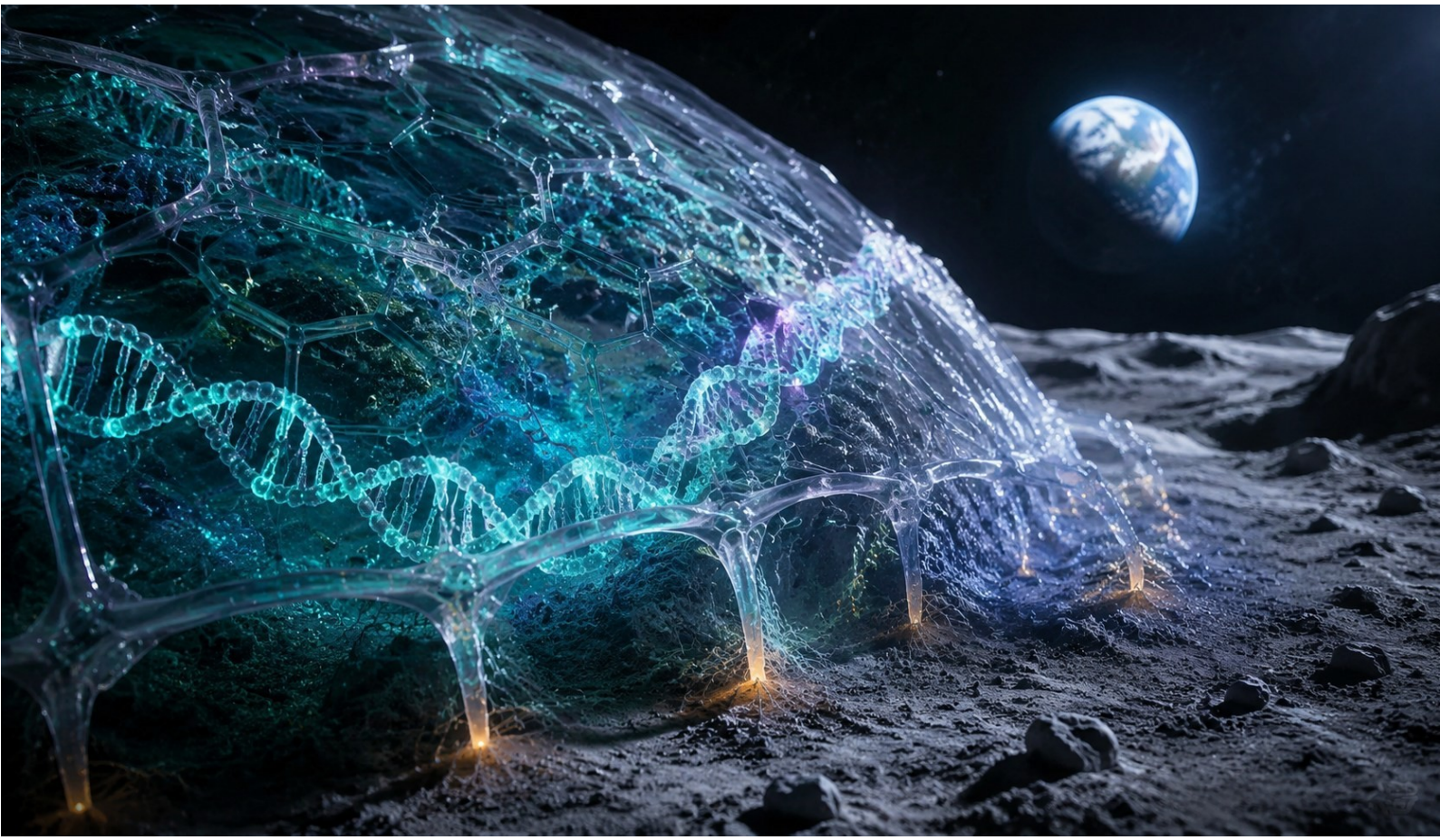
The use of a patented editing tool may generate intellectual-property rights in the tool or process under applicable law, but it must not convert human status into a subscription.

8. Consent, coercion and reproductive governance

Spaceflight is hierarchical and opportunities are scarce. Consent may be formally signed yet practically constrained by employment, command structure, insurance, settlement access, reproductive policy or perceived duty to mission survival. An intervention becomes coercive when refusal, predictably, costs a person ordinary career, residence, family or return rights, without a compelling, proportionate and independently reviewed justification.

A valid consent process must disclose uncertainty, alternatives, reversibility, data uses, reproductive implications, long-term follow-up, who pays for harm and what happens if a participant withdraws. It should occur outside the operational chain of command, allow time for deliberation, provide independent counseling and be revisited as evidence or mission conditions change.

Heritable intervention requires special protection because the subject of the procedure, the resulting child and later descendants are not identical decision-makers. Governance should prohibit implantation following experimental heritable editing unless a legitimate, transparent and internationally informed pathway establishes a narrowly defined permissible use. Even then, independent child advocacy, long-term support, data minimization and protection from publicity or surveillance would remain essential (Barlevy et al., 2024; Cadigan et al., 2022). Space settlements must not use mission necessity to impose genetic reproductive eligibility.



Policies on conception, pregnancy or inherited risk should use the least restrictive means, be evidence-based, time-limited, and appealable and reviewed by bodies independent of employers and mission operators.

9. Ownership, patents, genomic data and digital sequence information

The phrase ‘ownership of DNA’ collapses several different interests: control of a physical sample, privacy in sequence information, patent rights in an engineered construct or method, custody of records, and rights to resulting products.

Governance should separate these interests. No organization should own a person because it supplied an editing platform, nor should an intervention create claims over descendants.

Genomic information is persistent, identifying and shared with relatives. Risks include re-identification, inference about family members, secondary research, commercial sale, model training, law-enforcement access, discrimination and cross-border transfer. Consent cannot be treated as a one-time blanket waiver.
Data stewardship should use purpose limitation, minimization, role-based access, encryption, auditability, retention limits and practicable withdrawal mechanisms, while acknowledging that data already incorporated into analyses may not be fully retractable (Juengst & Meslin, 2019; Oliva et al., 2024; Yu et al., 2025).

Digital sequence information is also an operational and bio-security asset. Mission systems may store designs for medicines, engineered pathways or diagnostics. Compromise can corrupt production, expose sensitive human data or enable harmful synthesis.

Authentication, cryptographic provenance, controlled software updates, separation of safety-critical networks and independent verification of synthesized sequences should therefore be part of both biomedical and spacecraft cyber security (Berezin et al., 2024).

10. Artificial intelligence, automation and dual-use bio-security

The same capabilities that support medicine and manufacturing can enable harmful organisms, altered host range, immune evasion or concealment of provenance. Risk does not arise from sequence information alone; it emerges from the combination of intent, tacit knowledge, automation, materials, delivery and opportunity. Oversight should be proportionate enough to protect legitimate research while identifying experiments with unusually severe or irreversible consequences.

AI-assisted sequence design, predictive models and self-driving laboratories may help distant missions analyze data and operate with limited Earth support. They can also generate erroneous, unstable or hazardous designs at speed and scale. Automation does not hold moral, professional or legal responsibility. Every design, synthesis order, experimental transition, manufactured batch, environmental release and clinical decision must have an identified, appropriately qualified human authorizer who can stop the process and who remains accountable for the decision (Sanders et al., 2023).

The accountability system must be traceable and trackable. It should record the responsible person, role, time, evidence reviewed, software and model version, input and output sequence identifiers, changes made, approval or rejection, downstream recipient, manufacture and batch identifiers, deviations, incidents and final disposition. Records should be tamper-evident, auditable across organizations and preserved for a period proportionate to clinical, hereditary or environmental risk. No automated system should be permitted to self-authorize synthesis, release, reproductive use or administration to a human.

Controls should include synthesis-provider screening, customer verification, secure laboratories, personnel reliability, inventory control, cyber protection, red-team testing, mandatory reporting of loss or anomalous results and channels for protected whistle blowing. Review must be continuous because a project's risk can change when new methods, datasets or automation become available (Barlevy et al., 2024; Berezin et al., 2024). Space adds jurisdictional and operational complexity. A private operator may be headquartered in one country, launch from another, carry a multinational crew and operate beyond real-time terrestrial intervention. Contracts should specify applicable standards, reporting duties, inspection rights, preservation of evidence and responsibility for containment, medical evacuation, long-term monitoring and remediation.

11. Cultural, disability and community perspectives

Cultural and religious diversity is not a barrier to be managed after technical decisions are made; it is part of legitimate decision-making. Views differ on embryos, inheritance, disability, kinship, collective interests, stewardship of biological material and acceptable human intervention. Multinational missions require processes that can hear these differences without assuming that one biomedical culture is neutral.

Engagement must extend beyond scientists, regulators and commercial sponsors to astronauts, prospective settlers, disability advocates, Indigenous peoples, ethicists, workers, families and communities affected by launch, return or environmental release. Participation should begin while options remain open, not after a preferred technology has been selected. Anticipatory public engagement can identify values, uncertainty and governance needs before harms are locked in (Barlevy et al., 2024).

Cultural respect does not justify discriminatory status or unsafe practice. A rights floor—equal personhood, freedom from coercion, privacy, child protection and remedy for harm—should apply across programs, while implementation can accommodate legitimate cultural difference.

12. Governance architecture for space synthetic biology

The Artemis Accords can provide a diplomatic forum among participating states, but they are not a comprehensive biomedical regulatory system and should not be treated as one. Effective governance needs overlapping layers: international principles; enforceable national law; licensing and research regulation; professional duties; mission and procurement standards; independent ethics, bio-safety, bio-security, data and planetary-protection review; public registries; and accessible remedies.

Classification should precede permission. At minimum, policy should distinguish: non-replicating synthetic products; contained engineered organisms; environmental release; somatic human editing; heritable human editing; enhancement; and mirror organisms. Review intensity should rise with inheritability, persistence, transmissibility, uncertainty, population exposure and inability to reverse harm.

No single committee can adequately review clinical benefit, engineering reliability, bio-security, culture, data and planetary contamination. A coordinated review model should assign clear authority while preventing gaps. Conflicts of interest must be declared; commercial sponsors should not control the only safety assessment; and crew medical officers should not be the sole arbiters of research participation.

Transparency should include prospective registration of human editing and high-consequence space synthetic-biology studies, publication of adverse and null findings, sequence and incident traceability under controlled access, and periodic public reporting. Confidentiality and bio-security may justify withholding some operational detail, but not concealing the existence of a program, its risk class, its oversight or serious harm (Cadigan et al., 2022; Conley et al., 2025).

Responsibility must survive the mission and the company. Sponsors should fund long-term follow-up, clinical care, reproductive counseling where relevant, environmental monitoring and compensation. Insurance and indemnity arrangements should not extinguish affected persons' rights. Governance should also address insolvency, acquisition or programme termination so that data custody and care obligations persist.

Table Three: Government responsibility matrix

The matrix assigns functions rather than assuming that one country or committee controls the entire lifecycle. Exact legal authority must be confirmed for each mission and jurisdiction.

Responsible actor	Minimum responsibilities	Required evidence or record	Accountability pathway
Sponsoring state and relevant national regulators	License applicable research, clinical use, manufacture, export, launch and return; coordinate cross-border oversight	Approvals, conditions, inspection and enforcement record	Public law, regulator review, courts and international cooperation
Launch and return states	Apply applicable payload, environmental, quarantine and return requirements	Payload declaration, risk assessment, containment and return plan	Licensing authority and incident investigation
Mission operator or settlement authority	Integrate controls, maintain contingency stocks, protect refusal and preserve evidence	Risk register, operating procedures, training, incident and decision logs	Contract, license, regulator and independent review
Research institution and principal investigator	Ensure scientific validity, protocol compliance, bio-safety and research integrity	Protocol, registration, approvals, deviations, adverse and null findings	Institutional governance, funder and regulator
Independent ethics, bio-safety, bio-security, data and planetary-protection bodies	Review within defined competence; coordinate without leaving gaps	Reasoned decisions, conflicts, conditions and continuing-review dates	Appeal, audit and external inspection
Mission medical authority	Protect patient welfare, consent, clinical indication and emergency documentation	Clinical record, consent, alternatives, authorization and follow-up	Professional duties, medical review and applicable law
Qualified human design and batch authorizers	Approve sequence progression, synthesis, manufacture, batch release and clinical use; stop unsafe automation	Named electronic sign-off, model/software version, sequence and batch identifiers	Tamper-evident audit trail and personal/professional accountability
Synthesis provider and bio-manufacturer	Verify customer and sequence, operate quality systems, report anomalies and preserve traceability	Screening, chain-of-custody, quality, release and deviation records	License, contract, regulator and audit
Data controller and cyber security lead	Protect genomic and digital-sequence information; control access and recovery	Access logs, provenance, incident records, retention and deletion decisions	Privacy, security and mission governance
Insurer, sponsor and successor entity	Fund long-term care, compensation, monitoring and remediation; preserve duties through insolvency or acquisition	Financial assurance, care plan, data-custody and succession plan	Contract, insurance, compensation scheme and courts
Crew member, participant or patient	Follow agreed containment and reporting procedures without surrendering rights	Training acknowledgement and incident reports	Fair mission process; no retaliation for refusal or whistle blowing

13. Emergency-use governance

A distant crew may face a life-threatening condition for which no standard treatment or timely evacuation is available. Emergency circumstances can justify proportionate flexibility, but they do not erase consent, scientific uncertainty or accountability. An experimental somatic intervention should be considered only when the condition is serious, reasonable alternatives are unavailable, a credible evidence-based rationale exists, anticipated benefit outweighs foreseeable harm and the intervention is no broader than necessary.

Where communication is possible, an independent Earth-based clinical and ethics consultation should be obtained and recorded. Where delay would create unacceptable harm, the designated mission medical authority may act under a pre-authorized emergency protocol, but must document the facts, alternatives, consent process, decision, dose or procedure, authorizing personnel and outcome. The patient's voluntary consent remains required whenever capacity exists; command pressure, employment status or mission value must not substitute for consent.

Emergency authority must not be used to initiate heritable editing, embryo implantation, enhancement unrelated to the immediate condition or environmental release of a replicating organism. Every emergency use requires prompt notification, preservation of samples and records, independent post-event review, adverse-event reporting, continued clinical care and transparent learning proportionate to privacy and bio-security needs.

14. Hypothetical case studies

Hypothetical case studies are provided to stimulate discussion and encourage formation of philosophical viewpoints. They are provided not as a statement of fact or current capabilities, but possibilities, where cooperation between parties, states and nations will be required to reach a consensus for technological management.

1. Case Study 1

Loss of function in a Mars bioreactor.

A contained engineered bacterium produces a vitamin for a surface crew. After repeated cycles, output falls because faster-growing variants have lost the engineered pathway. The crew still has a limited reserve. The correct response is to quarantine the affected batch, confirm identity and contamination status, use retained reference material, activate reserve supplies, notify the responsible Earth team, and investigate evolutionary stability before restarting. The production system must not be restored by an unreviewed AI-generated sequence. Responsibility remains with the named human authorizers and mission operator.

2. Case Study 2

Experimental somatic edit as a flight-selection condition.

A program proposes an investigational edit intended to reduce radiation injury and informs candidates that acceptance will improve selection prospects. Even if a consent form is signed, scarcity of flight opportunities creates practical coercion. The intervention should not be an employment condition without compelling evidence, lawful authority, independent review and proof that less intrusive countermeasures are inadequate. Candidates require independent counseling, a protected refusal pathway, continuing care and freedom from retaliation or genetic discrimination.

3. Case Study 3

A genetically altered person, born in an extraterrestrial settlement.

A child inherits an engineered variant introduced before conception to address a predicted habitat-related physiological risk. Years later, the family seeks relocation to Earth, but the operator argues that monitoring data are commercially confidential and that a license applies to the engineered sequence.

The child remains a full person with independent rights. Commercial claims cannot control the child, reproduction, nationality, health care or movement. The operator and sponsor must disclose clinically necessary information, fund assessment and treatment, protect privacy, facilitate safe return where medically possible, and remain accountable for harm. Uncertainty about Earth adaptation is a clinical problem requiring evidence and support, not a basis for detention, lesser status or corporate ownership.

15. Recommended actions

A list of recommended actions has been provided to facilitate discussion and cultural reflection of acceptable use of technology that can manipulate, remove or change genetic makeup in biological organisms. The working group recommends:

1. Adoption of harmonized definitions that separate synthetic DNA, genome editing, synthetic biology, xenobiology and mirror life to provide clarity in discussions and of technique being discussed.
2. Establish a rights floor for equal personhood, bodily integrity, genetic privacy, non-discrimination, protection of children and future persons, with an enforceable right to refuse research or enhancement.
3. Use a risk-tiered approval pathway based on inheritability, replication, persistence, containment, exposure, reversibility and consequence for any intended genetic intervention or modification.
4. Prioritize reversible environmental and engineering countermeasures over permanent human modification for space hazards.
5. Require independent clinical, ethics, bio-safety, bio-security, data-security and planetary-protection review for all programs, allowing for modification of reviews to incorporate such issues as altered gravity, radiation and other specific known and to be known space hazards.
6. Prohibit creation or release of mirror organisms in the absence of compelling evidence that the unprecedented risks identified by the scientific community can be controlled; consider the preservation of proportionate research on non-replicating mirror molecules within firm safety and risk measured guidelines.
7. Require sequence provenance, synthesis screening, secure digital workflows, physical and genetic containment to be a written and validated protocol of all scientific or other enquiry. These protocols are to include validated shutdown procedures and mission contingencies applicable to both Earth and off-Earth environments.
8. Register high consequence research, publish adverse, negative and null results; protect whistleblowers and create cross-border cooperative investigation channels for impartial investigation and validation of data.
9. Protect individual consent from mission hierarchy through independent counseling, validated refusal pathways, access to appeals and separation from employment and command decisions.
10. Prevent patents or contracts from creating claims over persons, genetic material, descendants or ordinary reproduction; define sample, data and intellectual-property interests separately, and validate individual human ownership of genetic material to and for the individual.

11. Fund lifelong or risk-proportionate monitoring, treatment, compensation and environmental remediation before approval for investigations or experimentation, with arrangements that survive corporate failure and sustain the inalienable rights of the human individual or an individual derived from base human DNA or other genetic material.
12. Create a standing multinational forum for space synthetic biology that encapsulates a interdisciplinary approach including scientific, clinical, legal, cultural, disability, Indigenous, worker and public representatives, which meats a least biannually to periodically revise standards in light of evidence, new discoveries or techniques. The forum shall not be constrained to biannual meetings if a priority matter is to be discussed in relation to the remit of the forum.

16. Research priorities and unresolved questions

Research priorities include validated space-relevant containment; evolutionary stability across long mission cycles; quality assurance for in-space pharmaceuticals; radiation and altered-gravity effects on engineered systems; non-replicating cell-free production; detection of construct escape and horizontal transfer; interoperable incident reporting; and ethical methods for representing children, future persons and affected communities.

Unresolved policy questions include jurisdiction in multinational private settlements; standards for return to Earth after experimental intervention; allocation of liability for inherited or ecological harm; the boundary between occupational protection and enhancement; access and benefit sharing; governance of autonomous design-and-synthesis systems; and conditions under which emergency powers may limit refusal.

These questions require scenario exercises and public deliberation before missions depend on the technology.

The most important uncertainty is not whether biology can be altered, but who decides, who benefits, who bears the risk and who remains responsible when effects cross generations or planetary boundaries.

17. Legal status and limitation of this white paper

This document is an interdisciplinary policy white paper prepared to support discussion and anticipatory governance. It is not legislation, a treaty, a clinical guideline, a regulatory approval, a technical standard or legal advice. It does not create a doctor–patient relationship, authorize research or treatment, determine patent validity, allocate liability, or replace the requirements of any launch, return, research, medicines, privacy, employment, discrimination, reproductive, environmental or criminal law.

Laws and enforceable duties differ between jurisdictions and may change. The legal status of genetic material, engineered sequences, human samples, genomic data, inventions, descendants, environmental releases and activities beyond Earth must be assessed by suitably qualified legal advisers in every relevant jurisdiction. The Artemis Accords may support cooperation and discussion but do not themselves constitute a complete biomedical regulatory system.

Scientific evidence and space capabilities also change. Readers should verify current evidence and applicable requirements before relying on any recommendation. The authors and copyright owners do not warrant that the paper is exhaustive or suitable for a particular mission. Nothing in this disclaimer limits rights or remedies that cannot lawfully be excluded, nor does it reduce duties of care, informed consent, research oversight, product quality, environmental protection or accountability.

18. Conclusion

Synthetic DNA and genome editing do not create a scientifically meaningful divide between ‘natural’ and ‘synthetic’ humans. They create a spectrum of interventions whose ethical significance depends on purpose, evidence, inheritability, reversibility, containment, exposure and power. The strongest current case is carefully governed somatic treatment and contained bio-manufacturing; the weakest is coercive enhancement, irresponsible heritable intervention or self-replicating release with irreversible consequences.

Space exploration magnifies both promise and vulnerability. Biology may reduce dependence on Earth, but it can also create dependence on mutable living systems, extend risk across jurisdictions and weaken consent through hierarchy and scarcity. The appropriate response is neither blanket rejection nor technological inevitability; it is anticipatory, layered and enforceable governance.

Technology may change biological systems; it must not diminish personhood. Every edited or unedited person must retain equal dignity and rights, and no descendant should inherit a commercial obligation because of their genome. Where consequences may be global, ecological or irreversible, as is the potential with the creation of mirror organisms, restraint is itself a scientifically responsible expression of morality.

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