

Human Research in Commercial Spaceflight: Ethically Cleared to Launch?

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It has been more than 50 years since the Outer Space Treaty (OST) designated space the “province for all mankind” (1), and we are finally poised to expand opportunities in space beyond primarily government-sponsored missions. Massive public and private investment in space manufacturing, human exploration, and scientific research will enable the commercial spaceflight industry to expand rapidly. Some estimate thousands of commercial spaceflight participants (cSFPs) will fly in the coming decade (2), a huge increase over the roughly 600 astronauts who have flown in the previous half century. Safe commercial spaceflight requires rigorous research. However, the scale of scientific uncertainties, the unique context surrounding spaceflight, and microgravity-associated health risks currently constrain opportunities to involve private citizens in this research (3).

The regulatory environment of commercial spaceflight is also evolving. For example, the U.S. Federal Aviation Administration (FAA) moratorium on occupant safety regulations aboard commercial space vehicles is set to sunset in October 2023. In preparation, the FAA is working to encourage the development of industry consensus standards, revise the U.S. Government’s *Recommended Practices for Occupant Safety*, and establish an aerospace rulemaking committee to garner industry input on a new safety framework. Meanwhile, the Biden Administration confirmed the U.S. will decommission the International Space Station in 2030, which effectively ends decades of collaboration on the only microgravity research platform shared with other spacefaring nations (4).

Well-established norms, policies, and regulations guide ethical conduct of research involving humans on Earth. However, it is unclear which laws and regulations apply for human research conducted in the commercial space sector, whether international cSFPs within the same crew will be covered by different national laws, and how these laws should treat paying customers versus company and government employees aboard commercial flights (5). The OST, ratified by 112 countries, is likewise silent on whether principles for peaceful human space exploration apply to human research sponsored by commercial firms (1). Moreover, diverse research partners and complex funding and sponsorship relationships can lead to redundancies in the science, as well as oversight.

The commercial spaceflight industry would benefit from specific standards for research with cSFPs. In this paper, we propose an ethical framework that is anchored in four guiding principles—social responsibility, scientific excellence, proportionality, and global stewardship—and discuss the application of these principles to the responsible conduct of

research in commercial spaceflight. We intend for the framework to serve as a guide, which evolves as more evidence accumulates about commercial space travel.

Guiding Principles

Social responsibility

Most commercial flights depend on co-funding from both the government and private sources. Additionally, commercial spaceflight services are only possible now because of substantial public investment in past research. Therefore the public has an important role in helping to shape the legitimate commercial interests of companies, and data that builds on initial public investments in spaceflight research should be treated as community resources. Furthermore, what we learn in the early years of commercial spaceflight will be critical for ensuring the safety of future missions, and research with cSFPs has potential to improve human health not only in space but also on Earth. Thus, early cSFPs arguably have a heightened social responsibility to participate in research and other activities that help to build the evidence base.

Scientific excellence

Poorly designed, duplicative and low-priority studies beget poor quality data. They cloud the evidence base, endanger participants, and waste resources. Bad science is also bad for business. It can misguide strategy, permit inefficiency, and expose organizations to liability. By adhering to standards of excellence, those who sponsor and conduct research in commercial spaceflight show by example how rigorous science drives successful business.

Proportionality

Spaceflight research, like all research involving humans, is only permissible if it maximizes social value and minimizes the likelihood and severity of harms to participants, crew members, and other personnel. Spaceflight is itself a high-risk activity, and research procedures considered minimal risk on earth could pose significant increased risk when performed in space. The add-on risks of research participation should therefore be evaluated against the baseline risks of spaceflight, minimized to the extent possible, and proportionately balanced in relation to the anticipated benefits to the individual participant and society.

Global stewardship

The benefits of human space exploration and its resources should be enjoyed by everyone (1). Spaceflight research should therefore engage, as well as be conducted by, individuals and communities representative of humankind's diversity (6).

Application to the responsible conduct of research

Priority setting

Research investigating the effects of spaceflight on cSFPs is expensive, risky, and difficult to reproduce because opportunities are rare and only a select few cSFPs can be accommodated on space vehicles. Such extreme resource constraints have both practical and ethical consequences for setting research priorities. This places a premium on prioritizing scientifically rigorous studies that add the most social value, address questions about which there is genuine uncertainty, and can only be carried out in space as opposed to an Earth-analog.

Those who conduct commercial spaceflight research should develop a transparent research agenda that meaningfully incorporates input from diverse stakeholders, including the public, scientists, regulators, funding agencies, and other industry partners. The experience of prioritizing candidate trials early in the Covid-19 pandemic, when there was a shared public health goal, scarce resources and viable commercial interests at stake, will be instructive. To avoid redundancy and increase scientific impact, research sponsors should consolidate studies that ask similar scientific questions or require participation from cSFPs with similar health/demographic profiles whenever possible. This will require collaboration within a competitive space, sharing data for the public good, while protecting trade secrets to stimulate commercial investment.

Informed consent

If we take seriously the principle of social responsibility, we might condition commercial spaceflight on research participation at least in the early years. Indeed, some missions may be entirely research-focused and fly only research-eligible cSFPs. However, to require all cSFPs to participate in research as a condition of spaceflight could undermine the legitimate commercial interests of privately-funded companies. In addition, mandating that employees participate in research involving more than minimal risk as a condition of their job is problematic and something we do not typically tolerate in federally funded research. Prospective cSFPs should thus be fully informed about the social value of research and encouraged to participate. Preference could be given to those willing to participate, but further ethical attention is needed to determine whether cSFPs should remain flight-eligible even if they decline research participation.

Scientific and Ethics Review

The need for independent ethics review of research involving humans is equivalent in space and on Earth. In the U.S., federal regulations for the protection of human subjects (i.e. Common Rule) (9) govern such research, as well as regulations imposed by other departments or agencies, such as NASA or the Department of Defense. This includes a requirement for prior

review and approval by an appropriately constituted institutional review board (IRB) or research ethics committee (REC) before the research begins.

Research that is funded entirely by private organizations, by contrast, may not be legally required to obtain ethics approval. Research involving cSFPs should nevertheless undergo independent ethics review, even if not strictly required by law, as it is a longstanding ethical obligation that predates many legal requirements. cSFP research could also be funded as part of a multinational space agency collaboration that each maintain their own requirements. In these cases, the legal authority for human subjects research is less clear.

Most ethics committees are unlikely to have the necessary expertise to conduct quality, comprehensive reviews of spaceflight research. A specialty body could be named (7), external experts could be consulted, or membership on ethics committees could be expanded to include human spaceflight experts, such as former or current cSFPs and ethicists with experience reviewing spaceflight research.

Minimizing risks to participants, crew, and bystanders

Known physiological effects of spaceflight stem from research principally performed with government astronauts and other highly trained personnel. Risks for cSFPs with pre-existing medical conditions are expected to be elevated. This is particularly true for less experienced cSFPs in managing adverse events involving fellow crew or responding to operational emergencies during flight. Research missions that enable quick and feasible return to Earth could thus be prioritized for crews composed mostly of cSFPs without prior spaceflight experience. Nevertheless, capable adults ought to be able to assume such risks for the advancement of knowledge and betterment of society.

Flight crews are small, ranging from three to ten people. cSFPs may thus participate in multiple studies, each with their own set of risks and safeguards to manage adverse events. Companies, principal investigators, and ethics committees therefore need to consider the portfolio of risks for cSFPs individually, as well as in the aggregate. Different risk thresholds may be justifiable for different crew members. Companies may, for example, limit a flight surgeon or commander from participating in research that poses more than minimal risks because their role is essential to the safety and welfare of the entire crew.

Maximizing benefits to society

The social value of research increases proportionate to the usefulness of new knowledge gained. Well-annotated datasets, including information about the flight protocol, operational endpoints, and adverse events, among other study features, should be of sufficient scientific quality to substantiate social value. Those who conduct research in space should share these

data to ensure findability, accessibility, interoperability, and reusability for the scientific community and society well into the future. Indeed, private companies must commit to openly sharing scientific data if they are operating on behalf of a signatory (8) to the 2020 Artemis Accords, which includes Australia, Canada, Italy, Japan, Luxembourg, the United Arab Emirates, the United Kingdom and the U.S.

Enforcing proportionate data protections and governance

Some instances of data sharing can be in tension with the proprietary interests of commercial companies or those of their customers. The commercial spaceflight industry would benefit from direct engagement with future regulators on effective methods to share data for research purposes without compromising intellectual property. An industry-wide database should also be created to securely store and manage controlled access to relevant study data for future research purposes (see for example (9)). Robust data governance mechanisms should be developed simultaneously with data infrastructures, which reflect the interests of contributors, as well as downstream users of the data.

Typical protections for research participant data privacy and confidentiality rely heavily on de-identification. However, the small sample size per mission and extensive data linkages needed to support robust data analyses means researchers cannot in good faith promise cSFPs privacy and confidentiality. These limitations must be transparently disclosed to cSFPs at the time of consent. Prospective cSFPs should demonstrate they fully comprehend the realistic risks of re-identification and other privacy-related consequences of their participation.

Promoting the diversity of cSFPs and researchers

cSFPs have not so far been representative in terms of gender, age, genetic ancestry, health and socioeconomic status. Where personal attributes are known to have physiological ramifications for spaceflight, findings may not be generalizable. This raises at least two types of justice concerns: inequity in knowledge gained for those living on Earth, and inequity in evidence collected to support safe spaceflight for diverse cSFPs. With proper oversight, commercial spaceflight research presents a historic opportunity to correct prior underrepresentation and redefine who can experience the wonders of spaceflight. Companies who fly their own staff on research missions, as well as prospective customers should therefore invest in the training, recruitment, and retention of researchers and cSFPs from diverse backgrounds to sustain a thriving commercial spaceflight workforce and participant pool.

Conclusion

To demonstrate trustworthiness and reduce their own risk and liability, companies should issue rules and develop best practices so that company and customer-sponsored research is performed in a socially responsible and ethical manner. These rules and best practices should

address research planning, responsible conduct, and effective dissemination, with attention to equitable benefit sharing. The proposed framework provides an initial launch point. To demonstrate their commitment to global cooperation and responsible stewardship of space resources, regulatory agencies will need to strategize how to effectively implement and ensure accountability for ethical research standards across public and private sectors. We believe there is ample opportunity for collaboration on both fronts consistent with the ethical framework proposed, which calls on us all to be responsible “envoys of [human]kind”(1).

Word Count: 2,030

Table 1. Ethical framework for ensuring responsible conduct of research involving spaceflight participants in the commercial sector.

Guiding Principles	Application to the Responsible Conduct of Research
Social responsibility Scientific excellence Proportionality	<i>Priority setting</i> <ul style="list-style-type: none"> ● Develop research agendas with input from diverse stakeholders ● Prioritize research studies that answer pressing yet highly debated scientific questions, are necessary to conduct in space, and generate the most social value ● Conserve scarce resources by consolidating projects with similar end points or cSFPs populations
Global Stewardship	<i>Informed consent</i> <ul style="list-style-type: none"> ● Discuss the social value of research participation ● Transparently disclose the significant scientific uncertainty, as well as the magnitude and likelihood of harms associated with the research protocol ● Explain limitations to privacy and confidentiality of human spaceflight data <i>Scientific and ethics review</i> <ul style="list-style-type: none"> ● Streamline requirements for quality and effective research ethics review ● Ensure ethics committees have members with requisite space science expertise and incorporate voices from current and/or former cSFPs ● Consult with vetted scientific experts to verify protocols are methodologically sound and feasible ● Data submitted to a repository or other database should be quality controlled and meet standards for findability, accessibility,

	<p>interoperability, and reusability</p> <p><i>Minimize risks to participants, crew, and bystanders</i></p> <ul style="list-style-type: none"> ● Consider individual risks to cSFPs as well as group risks to the crew ● Respect the rights of individuals to assume higher risks than might usually be acceptable in terrestrial research for the advancement of new knowledge <p><i>Maximize benefits to society</i></p> <ul style="list-style-type: none"> ● Share relevant study information from commercial spaceflight research in an accessible and timely manner ● Deposit research data in a shared repository or knowledge commons to address the small “n” problem of research in space <p><i>Enforce proportionate data protections and establish robust governance</i></p> <ul style="list-style-type: none"> ● Make clear the realistic risks of privacy-related harms and re-identification ● Develop data governance mechanisms, including data transfer and access agreements <p><i>Promoting diversity among cSFPs and researchers</i></p> <ul style="list-style-type: none"> ● Require diverse inclusion of cSFPs in commercial spaceflight research to enhance equity and generalizability of research findings ● Commit to training the next generation of space scientists and industry professionals from historically underrepresented groups
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