INSIGHTS

POLICY FORUM

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SPACEFLIGHT

Ethically cleared to launch?

Rules are needed for human research in commercial spaceflight

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Massive public and private investment in scientific research has enabled the commercial spaceflight industry to expand opportunities in space beyond primarily government-sponsored missions (*1*). Commercial companies endeavor to fly thousands of commercial spaceflight participants (cSFPs) and workers to space in the decades ahead (*2*). Although the future of safe commercial spaceflight depends on rigorous and inclusive research, the ethical conduct of such research is complicated by scientific uncertainty, high attendant risks (*3*), and poorly defined rules for research ethics oversight within the commercial spaceflight industry. Now is the opportune time to develop clear rules for ethical cSFP

The SpaceX Falcon 9 rocket with the Crew Dragon spacecraft lifts off from the Kennedy Space Center in Cape Canaveral, Florida, on 21 May 2023.

research while space activities are ramping up and the regulatory environment for commercial spaceflight is actively being shaped. We propose an ethical framework based on terrestrial human research that is anchored in four guiding principles—social responsibility, scientific excellence, proportionality, and global stewardship—and is applicable to the responsible conduct of research in commercial spaceflight.

Well-established norms, policies, and national regulations guide the ethical conduct of most traditional research involving humans on Earth. There is also consensus on ethical principles guiding research with government astronauts (*4*). However, there are no clear frameworks that govern privately funded research with civilians on commercial space vehicles. Existing research ethics safeguards may not apply because of gaps in how research regulations govern private industry, and international space research must contend with interjurisdictional issues. Many of the regulatory and ethics challenges we identify for commercial spaceflight research are amplified by the rare opportunity cSFPs have to travel to space and the outsized social value that only they can provide through research participation (see the box).

The emerging commercial spaceflight sector will have global impact, but the United States currently leads the world in overall spending on space programs, including investment in developing the commercial arm of spaceflight. We therefore highlight ethical tensions posed by the regulatory vacuum for responsible research conduct, primarily in the United States. For example, the US Federal Aviation Administration (FAA) moratorium on occupant safety regulations aboard commercial space vehicles is set to sunset in October 2023 (*5*). The FAA is working to encourage the development of industry consensus standards and revise the US government's human spaceflight safety practices (*6*), and has established an aerospace rule-making committee to garner industry input on a new safety framework. Meanwhile, the Biden administration confirmed that the United States will decommission the International Space Station as soon as 2030, which effectively ends decades of collaboration on the only microgravity research platform shared with other spacefaring nations. International agreements, including the Outer Space Treaty (OST)—signed and ratified by 112 countries—are silent on whether principles for peaceful human space exploration apply to human research sponsored by commercial firms (*7*), and diverse research partners and complex funding and sponsorship relationships can lead to redundancies in the science and provide insufficient oversight.

Gaps in policy intended to protect cSFP health and safety in commercial spaceflight research threaten the industry, hamstring scientific collaboration between public and private partners, and limit the translation of research benefits to society. To foster research safety and utility, our primary objectives are twofold: (i) create an expectation that commercial spaceflight companies provide the infrastructure and resources necessary to engage in high-quality human research, and (ii) inform approaches to safe and effective commercial spaceflight research by advocating for robust ethical principles and standards that reflect consensus among diverse stakeholders and account for the distinct research environments to which future cSFPs will be exposed.

GUIDING PRINCIPLES

Social responsibility

Most commercial flights currently depend on cofunding from 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 commercial interests of companies, and data that builds on initial public investments in spaceflight research should be treated as community resources. 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 the potential to improve human health not only in space but also on Earth (*8*). Thus, early cSFPs arguably have a heightened social responsibility to help advance research to build the evidence base.

Appealing to principles of social responsibility differs from preexisting ethical frameworks that give primacy to autonomy because it explicitly calls on those privileged to have the opportunity to travel into space to contribute to research activities that benefit society at large.

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 practice.

Proportionality

Spaceflight research, like all research that involves 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 a high-risk activity, and research procedures that pose minimal risks on Earth could pose substantially 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 cSFP and to society.

Global stewardship

The benefits of human space exploration and its resources should be enjoyed by all (*7*). Spaceflight research should therefore engage, and be conducted by, individuals and communities representative of humankind's diversity. We draw on stewardship principles and concepts advanced in space governance (*9*), the environmental sciences, and natural resource fields to inform how we might fairly distribute the knowledge benefits of commercial spaceflight research. We emphasize responsible use of time, data, and natural resources in ways that take full and balanced account of the interests of society, future generations, and other species, as well as of private interests to advance the science of safe human space exploration (*10*).

NEW APPLICATIONS OF EXISTING POLICIES AND PRACTICES

Free and informed consent

If we take seriously the principle of social responsibility, we might condition commercial spaceflight on informed research participation focused on improving human health or safety, at least in the early years. Although all astronauts are thoroughly briefed on research protocols and voluntarily consent to participate, many view their participation as an occupational responsibility to support longitudinal health surveillance that benefits future crew. Privately funded cSFPs may not be motivated by the same occupational responsibility but rather could be moved to participate in minimally invasive or minimal risk studies under the principle of social responsibility.

To compel cSFP participation in research as a condition of spaceflight in the commercial context could undermine the business interests of privately funded companies, including their ability to attract future customers. It could also violate cSFP autonomy by providing an excessive benefit that challenges voluntariness. Travel to space can present an opportunity so compelling that cSFPs could opt in to risky research not customarily tolerated on Earth without appropriate safeguards. Furthermore, some cSFPs are employees of commercial space companies, and conditioning employment on research participation is generally impermissible.

All prospective cSFPs should be fully informed about the social value of any proposed research protocols and be encouraged to participate. Incentivizing participation may be justified, so long as the incentive is calibrated with the risks and does not create undue inducement (*11*). Commercial companies may give preference to those cSFPs willing to participate in research, but further ethical attention is needed to determine whether cSFPs should remain flight eligible even if they decline research participation.

Ongoing cSFP research related to spaceflight-associated neuro-ocular syndrome (SANS).

SANS is associated with long-duration spaceflight and is thought to be the result of increased intracranial pressure (ICP). Symptoms include optic disc edema, changes in near vision, and possible reductions in cognitive functions that could compromise mission-critical tasks (*15*). Nearly 70% of NASA astronauts develop some degree of SANS, underscoring the need to identify its pathophysiologic mechanisms and find effective countermeasures. Commercial companies have a vested interest in management and prevention of SANS and support cSFP participation in studies of the issue. The most accurate method for measuring ICP—inserting a probe directly into the brain or cerebral ventricles—is too risky for spaceflight. Investigators developed a less risky method: a catheter surgically implanted in the lumbar cerebral spinal fluid space and attached to a subcutaneous telemetric ICP sensor that would enable ICP readings before, during, and after flight. After NASA concluded that the risks of the modified implant on long-duration missions were also too high, this approach was pursued by the Translational Research Institute for Space Health and a competitively selected experienced research team in coordination with a commercial spaceflight company to include a healthy cSFP in this study (https://taskbook.nasaprs.com/tbp/index.cfm?action=public_query_taskbook_content&TASKID=15266).

Maximizing benefits to society

The social value of research increases proportionately to the usefulness of new knowledge gained. Well-annotated datasets—including information about the flight protocol, operational endpoints, and adverse events—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 to the 2020 Artemis Accords (*10*), which includes Australia, Canada, Italy, Japan, Luxembourg, the United Arab Emirates, the United Kingdom, and the United States.

Minimizing risks

Known physiological effects of spaceflight stem from research principally performed with government astronauts and other highly trained personnel who cleared stringent medical tests before flight. Prospective cSFPs may not undergo the same tests, and commercial companies indeed plan to fly cSFPs with preexisting health conditions (such as cancer) and physical disabilities (for example, the European Space Agency parastronaut program). The attendant risks of cSFP research participation are expected to compound as a result. This is particularly true for cSFPs with less experience managing adverse events that affect fellow crew or responding to operational emergencies during spaceflight. Missions that enable quick and safe return to Earth could thus be prioritized for crews composed mostly of cSFPs without prior spaceflight experience. Competent adults ought nevertheless to be able to assume risks for the advancement of knowledge and betterment of society.

cSFPs may participate in multiple studies, each with their own set of risks and safeguards against adverse events. Future planned studies are likely to reflect different types of research (ranging from noninvasive, to minimally invasive, to invasive), with a broad spectrum of risk potential. Companies, principal investigators, and ethics committees therefore need to consider the portfolio of risks for cSFPs individually, as well as in the aggregate (*3*). Different risk thresholds may be justifiable for different crew members. Companies may, for example, limit a crew medical officer or commander from participating in research that could lead to impairment or incapacitation because their role is essential to the safety and welfare of the entire crew.

To further substantiate spaceflight safety and enhance informed consent for prospective cSFPs, a formal system for reporting adverse events should be developed like what is required of pharmaceutical drug companies. Such a system should be focused on adverse events related to research involving cSFPs, separate from adverse events from operational failures or crew error.

Data protections and governance

Some instances of research data sharing can be in tension with the proprietary interests of commercial companies or their customers. The commercial spaceflight industry would benefit from direct engagement with regulators to develop and

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implement methods to share data for research purposes without compromising intellectual property. An industry-wide database should be created to securely store and manage controlled access to relevant study data for research purposes [for example, (*12*)]. Robust data governance mechanisms—including penalties or sanctions to hold users accountable for data misuse—should be developed simultaneously with data infrastructures and should reflect the interests of contributors as well as downstream users of the data.

Similar data types may be collected to monitor cSFPs' health and welfare while in space and later repurposed for space health research (*13*), with appropriate consent. Privacy and confidentiality of these data rely heavily on the ability to deidentify them. However, the small sample size per mission and extensive data linkages needed to support robust data analyses means that cSFP privacy could be compromised even for minimal risk studies (*14*). Limits to data privacy should be disclosed to cSFPs at the time of consent, and prospective cSFPs should demonstrate that they fully comprehend the realistic risks that research data could be attributed to individual cSFPs and other privacy-related consequences of participation.

EXTENSION OF EXISTING POLICIES AND PRACTICES

Setting research priorities

Research investigating the effects of spaceflight on cSFPs can be 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, which 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.

There may also be competing priorities for commercial spaceflight companies and sponsors of research in terms of what scientific questions to ask and where to invest research dollars. 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. To avoid redundancy and increase scientific impact, research sponsors should consolidate studies that ask similar scientific questions or call for participation from cSFPs with similar health and demographic profiles whenever possible. This will require collaboration within a competitive space and sharing data for the public good as gestures of responsible stewardship, while protecting trade secrets to stimulate commercial investment.

Scientific and ethics review

Independent ethics review of research involving humans in space is expected, as it is on Earth. Although federally funded research is legally required to obtain ethics review, research funded entirely by private organizations is not. Legal authorities can also be unclear for research that involves cSFPs funded through multinational space agency collaborations, in which each agency maintains their own requirements. Research that involves cSFPs should nevertheless undergo independent ethics review that is free of any real or perceived investigator conflict of interest even if not strictly required by law because it is a longstanding ethical obligation that predates many legal requirements.

Given the specialized research focus, many research ethics committees will not have the necessary expertise to conduct quality, comprehensive reviews of spaceflight research. A specialty body could be named, external experts could be consulted, or membership on ethics committees could be expanded to include human spaceflight experts.

Promoting diversity of cSFPs and researchers

cSFPs have not so far been representative of society in terms of gender, age, genetic ancestry, health, and socioeconomic status. Where such individual attributes are known or suspected to have physiological ramifications for spaceflight, findings from research with less diverse cSFPs may not be generalizable. This raises at least two justice concerns: inequity in knowledge gained for those living on Earth, and inequity in evidence collected to support safe spaceflight for more diverse cSFPs in the future.

Investigators should be encouraged to consider diversity when designing research protocols, but ultimately, sample diversity will be driven by the specific research questions. With proper oversight, commercial spaceflight research presents a historic opportunity to address prior underrepresentation and redefine who can safely experience the wonders of spaceflight. Companies that fly their own staff as well as prospective customers on research missions should therefore also invest in the training, recruitment, and retention of researchers and cSFPs from diverse backgrounds to sustain a thriving commercial spaceflight workforce (*2*) and participant pool.

CONCLUSION

To demonstrate trustworthiness and reduce their own risk and liability, companies should issue policies and develop best practices to ensure that sponsored research is performed in a socially responsible and ethical manner. 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 that there is ample opportunity for collaboration on both fronts that is consistent with our proposed ethical framework. Future work should focus on identifying specific responsible actors and determining what level of policy is appropriate for ensuring implementation of the framework. ■

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