



Institute of Medicine Report:

“Health Standards for Long Duration and Exploration Spaceflight: Ethics Principles, Responsibilities, and Decision Framework”

and

OCHMO Implementation Plan

Briefing to

NASA Advisory Committee:

Human Exploration and Operations, and Science

Committees

April 7, 2015

IOM Study: Rationale and Statement of Task

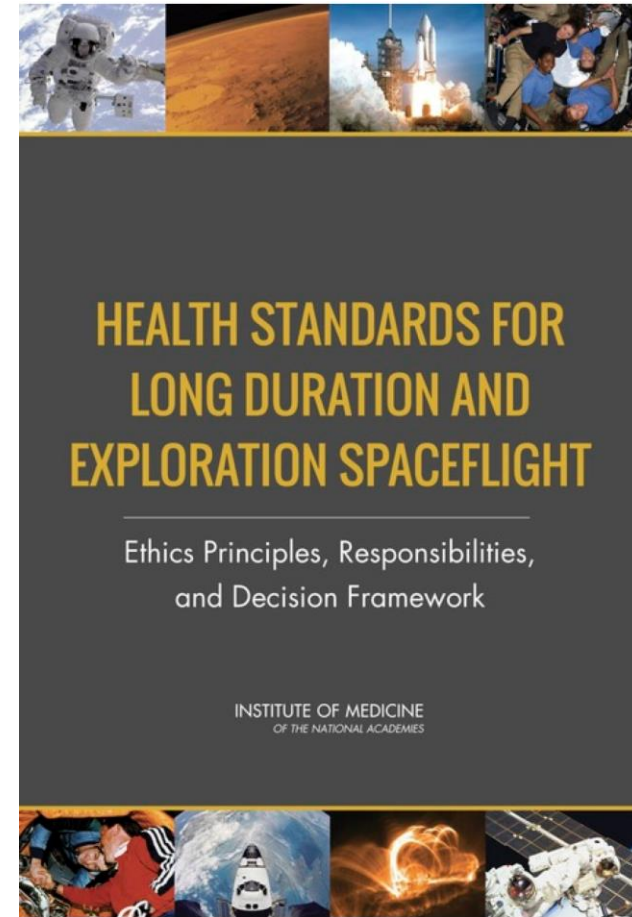


- Long duration and exploration class space missions beyond low Earth orbit may pose hazards that go beyond current risk limits, where current health/medical standards cannot be met or the level of knowledge doesn't permit a standard to be developed.
- OCHMO requested the Institute of Medicine's Committee on Aerospace Medicine and Medicine in Extreme Environments to produce a report on policy and ethical issues and principles relevant to crew health standards for long-duration and exploration space missions. Committee was asked to:
 - Consider the application of existing health standards and the factors that should be considered in implementing them and the potential development of new health standards.
 - Provide a framework of ethical and policy principles that can help guide decision-making associated with implementing health standards for exploration class space missions when existing standards cannot be fully met, or the level of knowledge of a given condition is sufficiently limited that an adequate standard cannot be developed, for the mission.

“Health Standards for Long Duration and Exploration Spaceflight: Ethics Principles, Responsibilities, and Decision Framework” (April, 2014)

The report makes 4 recommendations:

- The first 3 recommendations are directed at how OCHMO develops and implements health and medical standards.
- The fourth recommendation provides a decision-making framework, with 3 levels, based on the ethical principles and responsibilities that can be used when a health/medical standard(s) cannot be met, or when there are health/medical risks that are not fully understood, for a proposed space exploration mission.





Principles

- *avoid harm*
- *beneficence*
- *favorable balance of risk and benefit*
- *respect for autonomy*
- *fairness*
- *fidelity*

Responsibilities

- *informed decision-making process*
- *continuous learning strategy*
- *independent advice*
- *communicate with all relevant stakeholders*
- *equality of opportunity*
- *provide preventive long-term health screening and surveillance of astronauts*
- *protect privacy and confidentiality*

When Health/Medical Standard Can't Be Met – Committee Options



If a human spaceflight mission cannot meet NASA's current health standards, or if inadequate information exists to revise a health standard, the committee identified and examined 3 options:

- Liberalizing existing health standards
 - Current standards based on best available data
 - Modifying outside of established process is arbitrary
- Establishing more permissive health standards for long duration and exploration class missions
 - No clear and compelling justification for why acceptable risks and levels of uncertainty should be greater for long duration/exploration space missions
- **Only ethically acceptable option that could allow for increased risk exposures in the context of long duration and exploration spaceflight is *granting an exception to existing health standards.***
 - Excepting health standards in these situations should be “used under very limited circumstances following the ethics based framework recommended” and that “exceptions increase the responsibilities for NASA and society.”

Process and Criteria for Granting Exceptions



The selection of the process and criteria to grant exceptions to existing health standards should be evidence-based and should reflect policies that encourage independent advice and transparency of process.

Based on the ethics principles identified, criteria for reviewing exception requests could include requirements that the proposed mission:

- be expected to have exceptionally great social value,
- have great time urgency,
- have expected benefits that would be widely shared,
- be justified over alternate approaches to meeting the mission's objectives,
- be committed to minimizing harm and continuous learning,
- have a rigorous process to assure that astronauts are fully informed about risks and unknowns,
- their decisions meet standards of informed decision making, and that they are making a voluntary decision, and
- provide health care and health monitoring for astronauts before, during, and after flight and for the astronaut's lifetime.



Adopt an Ethics-Based Decision Framework

- NASA should apply the relevant ethics principles and fulfill the concomitant responsibilities through a three-level, ethics-based decision framework that examines:
 - Level 1: Decisions about allowing risk to astronaut health and safety in excess of that permitted by health standards,
 - Level 2: Decisions about undertaking specific missions, and
 - Level 3: Decisions concerning individual astronaut participation and crew composition.

Report Implementation



- **OCHMO concurs that excepting health standards (or lack of standards due to limited knowledge) should be “used under very limited circumstances” and would only be excepted at the Agency Level after careful assessment of the risk and benefits with ethical principles guidance.**
 - **Would not represent a standard medical waiver**
- Processes for implementing all 3 levels of decision making developed within the context of the Agency’s overall risk assessment processes:
 - health/medical risk analysis
 - combined with total mission risk analysis – safety, engineering, health/medical
 - individual risk assessment
 - balancing of competing ethical principles
 - operational justification for standard excepting
- **Operational exception is under the authority of the Administrator**