FLIGHT CREW MEDICAL STANDARDS AND SPACEFLIGHT PARTICIPANT MEDICAL ACCEPTANCE GUIDELINES FOR COMMERCIAL HUMAN SPACE FLIGHT

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Introduction

- Viability of the commercial human spaceflight industry is dependent upon safe participation of laypersons.
- Medical standards exist for crewmembers but not for commercial Spaceflight Participant (SFP) passengers.
- Various guidelines have been proposed for SFPs.
- Medical acceptance for research studies has provided initial validation of the use of existing guidelines.
- Actual spaceflight experience is necessary to fully validate the crewmember standards and SFP medical acceptance process.
History of Standards and Guidelines

• Aerospace Medical Association Space Passenger Task Force published two reports in ASEM
  • October 2001
    • Considered both sub-orbital and orbital SFPs
    • Long list of disqualifying conditions
  • November 2002
    • Considered only sub-orbital flights
    • Broad guidelines based on flight profile assumptions

“In summary, the 2nd Task Force on Space Travel offers only broad guidelines, rather than specifics, for short-duration flights. The application of these guidelines should be left to the discretion of the companies, physicians, and passengers. In cases of passengers with significant illness, sound medical judgment will be essential.”
Vehicles and Flight Profiles Differ
FAA Guidelines

• March 2003 – Guidance for Medical Screening of Commercial Aerospace Passengers

• February 2005 – Draft Guidelines for Commercial Suborbital Reusable Launch Vehicle Operations with Space Flight Participants

FAA Guidelines (continued)

• December 2005 – NPRM: Human Space Flight Requirements for Crew and Space Flight Participants; Proposed Rule

• January 2006 – Guidance for Medical Screening of Commercial Aerospace Passengers (DOT/FAA/AM-06/1)

• December 2006 – Human Space Flight Requirements for Crew and Space Flight Participants; Final Rule
Categorizes passengers into suborbital and orbital, but the G force definitions associated with each will put some operators’ passengers into the orbital category for suborbital flights

Assumptions:

- Cabin pressure $\leq 8,000$ feet
- G level limits: $+4 \, G_z$, $-2 \, G_z$, $+/- \, 4 \, G_x$, $+/- \, 1 \, G_y$

Recommendations for medical history and pre-flight physical exam
Crew Members:

- Those with a safety-critical role must possess and carry an FAA Second-class airman medical certificate

Space Flight Participants must:

- Sign informed consent after education about the risks
- Sign waiver of claims against the U.S. Government
- Have training for emergency situations – smoke, fire, depressurization, emergency exit
- Meet security requirement – the SFP may not carry on board any explosives, firearms, knives, or other weapons
Recommendations from COE CST Research Task – 2012

- Differentiated by Suborbital versus Orbital and Spaceflight Participants versus Pilots.
- Take into account the flight profile.
- Medical screening questionnaires and pre-flight medical exams.
- Evaluations by physicians trained in aerospace medicine.
- Employ risk mitigation strategies.
- Provide appropriate pre-flight training.
6.0 Notable Omissions

Some notable omissions from the recommended practices include the following topics:

6.1 Medical Limits for Space Flight Participants

This document does not include any medical criteria that would limit who should fly in space as a space flight participant. Medical consultation for space flight participants is recommended to inform them of risks and to ensure they will not be a danger to other occupants. However, space flight participants should be free to make decisions about their own individual risk.

We do understand that flying members of the public outside the relatively healthy government astronaut population is new, and that commercial operators will be challenged to control hazards to space flight participants from other space flight participants with medical conditions. However, we have not included any performance standards in this document to address this issue.
Summary: Published Medical Standards as of 2018

• Crew Members: those with a safety-critical role must possess and carry an FAA Second-class airman medical certificate

• Space Flight Participants: None
  • Several “guidance” documents
Validation of Medical Screening Process

Recommendation:

1. Medical screening questionnaires and pre-flight medical exams.

2. Evaluations by physicians trained in aerospace medicine.
Three Study Groups: 2007 - 2016

1. Initial data collected 2007-2008 during Virgin Galactic Founders training centrifuge runs at NASTAR centrifuge, Southampton, PA
   - 77 participants, voluntarily offered data for analysis

2. Disease cohort study in 2011 - 2012 by UTMB conducted at NASTAR under FAA COE-CST
   - 86 participants in 5 disease categories plus control group

3. Training and anxiety study in 2015 - 2016 by UTMB conducted at NASTAR under FAA COE-CST
   - 148 participants in 4 cohorts

Total of 311 test participants across 3 studies
Guidelines: Medical Questionnaire

1. Questionnaire – SFPs should complete a medical questionnaire indicating a history of any of the following conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otitis, sinusitis, bronchitis, asthma, or other respiratory disorders</td>
<td>Mental disorders, anxiety, or history of</td>
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<td></td>
<td>hyperventilation</td>
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<tr>
<td>Dizziness or vertigo</td>
<td>Claustrophobia</td>
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<tr>
<td>Fainting spells or any other loss of consciousness</td>
<td>Attempted suicide</td>
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<tr>
<td>Seizures</td>
<td>Use of medications</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Alcohol or drug dependence or abuse</td>
</tr>
<tr>
<td>Surgery and/or other hospital admissions</td>
<td>Current pregnancy, recent post-partum (less</td>
</tr>
<tr>
<td></td>
<td>than 6 weeks), or recent spontaneous or</td>
</tr>
<tr>
<td></td>
<td>voluntary termination of pregnancy</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
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<tr>
<td>Visits to a health care provider in the last 3 years</td>
<td>Recent significant trauma</td>
</tr>
<tr>
<td>History of decompression sickness (DCS) or the “bends”</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Anemia or other blood disorders</td>
<td>Cancer</td>
</tr>
<tr>
<td>Heart or circulatory disorders, including implanted pacemaker or defibrillator</td>
<td>Rejection for life or health insurance</td>
</tr>
<tr>
<td>Disability or deformity requiring accommodation</td>
<td>Given the specific flight parameters, are there any known medical conditions that may require possible accommodation</td>
</tr>
</tbody>
</table>
Online Medical Questionnaire

Instructions:
The purpose of this Medical Questionnaire is to gather information regarding your current and past medical status. The initial section asks for general information about yourself.

- Personal Information
- General Questions
- Current & Past Medical History
- Family History
- Females Only
- Exercise & Activities
- Other Remarks
2. Physical Examination – A physician trained or experienced in aerospace medicine should perform a physical examination with the following components:

<table>
<thead>
<tr>
<th>Vital signs (heart rate, blood pressure, respiratory rate, and temperature)</th>
<th>Upper extremities</th>
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</thead>
<tbody>
<tr>
<td>Head, face, neck, scalp exam</td>
<td>Lower extremities</td>
</tr>
<tr>
<td>Nose, sinuses, mouth, throat, and ears (including eardrum integrity &amp; function and Eustachian tube function)</td>
<td>Spine</td>
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<tr>
<td>Ophthalmologic evaluation (including pupil function and ocular motility)</td>
<td>Lymphatics</td>
</tr>
<tr>
<td>Lungs and chest</td>
<td>Rectal, pelvic, and breast exams will be performed only if indicated by medical history</td>
</tr>
</tbody>
</table>
Guidelines: Physical Exam (continued)

<table>
<thead>
<tr>
<th>Heart (including precordial activity, rhythm &amp; rate, sounds, and murmurs)</th>
<th>General neurological evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peripheral vascular system</strong></td>
<td><strong>General psychiatric evaluation</strong> (appearance, behavior, mood, communication, and memory)</td>
</tr>
<tr>
<td><strong>Abdomen and viscera (including hernia)</strong></td>
<td><strong>Genitourinary system</strong></td>
</tr>
</tbody>
</table>
Your patient, the person named above, is applying to take part in a research protocol evaluating response of individuals with known medical conditions to the acceleration forces experienced in a centrifuge. This study is being conducted by the University of Texas Medical Branch under a grant from the Federal Aviation Administration. Please conduct a physical examination of your patient, then complete and sign this form. The original of this form should be returned to UTMB at the address below. Your patient should have signed and delivered to you an Authorization for Use and Disclosure of Protected Health Information which we believe complies with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and is sufficient to authorize you to provide your patient's medical information to UTMB.

General information: Please provide the following general information on the basis of your physical examination:

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight</th>
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<table>
<thead>
<tr>
<th>Resting Pulse Rate</th>
<th>Resting Pulse Rhythm</th>
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</table>

<table>
<thead>
<tr>
<th>Blood Sugar</th>
<th>Cholesterol</th>
<th>Systolic Blood Pressure</th>
<th>Diastolic Blood Pressure</th>
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<td></td>
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<thead>
<tr>
<th>Distant Vision</th>
<th>Blurred Vision</th>
<th>Near Vision</th>
<th>Near Vision</th>
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<tr>
<td>(Right)</td>
<td>(Left)</td>
<td>(Right)</td>
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</table>

<table>
<thead>
<tr>
<th>Hearing</th>
<th>Hearing</th>
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<tr>
<td>(Right ear)</td>
<td>(Left ear)</td>
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</table>

Clinical Evaluation: Please provide the following clinical evaluation of your patient on the basis of your physical examination:

- **Check each item as indicated:** Normal Abnormal
- **Skin:**
  - Hair and scalp
  - Nails
  - Skin and integument
- **Head and neck (incl. thyroid):**
- **Eye:**
- **Ear:**
- **Lymph nodes:**
- **Lungs and chest:**
- **Heart:**
- **Vascular system:**
- **Abdomen:**
- **G-U system:**
- **Extremities, upper and lower:**
- **Spine, other musculoskeletal:**
- **Neurologic system:**
- **Psychiatric:**
- **General systemic:**
  - Identifying marks, scars, tattoos:

**NOTES:** Describe every abnormality in detail. (Continue on a separate sheet of paper if necessary.)

The following are recommended only if clinically indicated and/or if they are advisable based on the patient’s age. PLEASE ATTACH COPIES OF RESULTS IF PERFORMED and complete the tables below with the relevant information.

**Audiogram results (if performed):**

<table>
<thead>
<tr>
<th></th>
<th>500</th>
<th>1000</th>
<th>2000</th>
<th>3000</th>
<th>4000</th>
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</thead>
<tbody>
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<td>Right</td>
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</table>

**Laboratory results (if performed).** **NOTE:** the EKG is mandatory

- **CBC**
- **Urine Analysis**
- **Chemistry Profile**
- **Pulmonary Function Test**
- **Chest X-Ray**
- **Other (describe)**

**Electrocardiogram:** this is mandatory

<table>
<thead>
<tr>
<th>Check as indicated</th>
<th>Normal</th>
<th>Abnormal</th>
<th>Notes about ECG</th>
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**ECG (include tracing):**

**Physician’s impression:**

Please provide additional remarks in the space below. Please include such things as your general remarks on your patient’s health and fitness, any concerns you may have regarding your patient’s fitness for centrifuge training and areas of your patient’s current or past medical history and family medical history that you feel should be taken into consideration in connection with the patient’s proposed centrifuge ride.

**Remarks:**

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**Additional Notes (if needed):**

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3. Medical Testing – Additional medical testing may be recommended by the examining physician and should be obtained if clinically indicated.

4. Timing of Medical Screening – The SFP’s age and medical complexity should be considered in determining the timing for medical screening. Generally initial screening should be performed within 6 months prior to the SFP’s sub-orbital flight. Follow-up medical screening, including updating the medical history and physical exam, may be advisable prior to initiation of training activities and/or spaceflight.

5. Self-Certification – SFPs should indicate to the examining physician and operator if they know or have reason to know of a medical condition that would impair their ability to 1) safely perform a sub-orbital flight without compromising the safety of other occupants and 2) safely perform an emergency egress without assistance.

6. Post-Flight Medical Debriefing – Given the novel flight environment experienced by sub-orbital SFPs, a post-flight medical debrief is recommended to collect post-flight medical data, inquire about health effects of the flight, and provide for follow-up, if necessary.
Results

• 311 individuals selected for research participation in centrifuge-simulated suborbital acceleration profiles using recommended medical questionnaire and examination

• Several instances of non-disclosed medical conditions causing issues during centrifuge exposures

• No instances of disclosed medical conditions causing issues
Lessons Learned

1. Medical screening process takes time – start early
2. Use of personal physician is not ideal
3. Best results using AMEs for physical exam
4. Many medical conditions can be safely spun (or flown) with prior knowledge and appropriate preparation
5. Implementation of the existing medical guidelines has been effective for screening and acceptance for research studies
Thank You