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

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ECAM 2018 Prague, Czech Republic



#### 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 <u>flight profile assumptions</u>

"In summary, the 2<sup>nd</sup> 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
- February 2005 Draft Guidelines for Commercial Suborbital Reusable Launch Vehicle Operations with Flight Crew



# 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



#### FAA Medical Guidance – Jan. 2006

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 <= 8,000 feet</li>
- G level limits:  $+4 G_z$ ,  $-2 G_z$ ,  $+/- 4 G_x$ ,  $+/- 1 G_y$

Recommendations for medical history and pre-flight physical exam



#### FAA Final Rule – Dec. 2006

#### **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



Flight Crew Medical Standards and Spaceflight Participant Medical Acceptance Guidelines for Commercial Space Flight

June 30, 2012

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



### FAA Recommended Practices - 2014



#### Recommended Practices for Human Space Flight Occupant Safety

Version 1.0

August 27, 2014

Federal Aviation Administration Office of Commercial Space Transportation 800 Independence Avenue, Room 331 Washington, DC 20591

#### 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 posses 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
- 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

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

Otitis, sinusitis, bronchitis, asthma, or other respiratory disorders	Mental disorders, anxiety, or history of hyperventilation
Dizziness or vertigo	Claustrophobia
Fainting spells or any other loss of consciousness	Attempted suicide
Seizures	Use of medications
Tuberculosis	Alcohol or drug dependence or abuse
Surgery and/or other hospital admissions	Current pregnancy, recent post-partum (less than 6 weeks), or recent spontaneous or voluntary termination of pregnancy

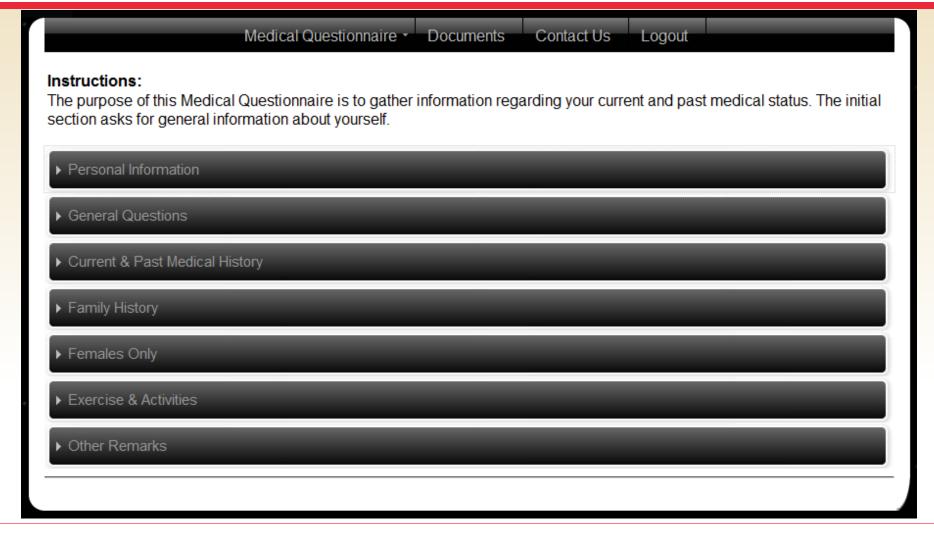


# Guidelines: Medical Questionnaire (continued)

Visits to a health care provider in the last 3 years	Recent significant trauma
History of decompression sickness (DCS) or the "bends"	Diabetes
Anemia or other blood disorders	Cancer
Heart or circulatory disorders, including implanted pacemaker or defibrillator	Rejection for life or health insurance
Disability or deformity requiring accommodation	Given the specific flight parameters, are there any known medical conditions that may require possible accommodation



## Online Medical Questionnaire





# Guidelines: Physical Exam

2. Physical Examination – A physician trained or experienced in aerospace medicine should perform a physical examination with the following components:

Vital signs (heart rate, blood pressure, respiratory rate, and temperature)	Upper extremities
Head, face, neck, scalp exam	Lower extremities
Nose, sinuses, mouth, throat, and ears (including eardrum integrity & function and Eustachian tube function)	Spine
Ophthalmologic evaluation (including pupil function and ocular motility)	Lymphatics
Lungs and chest	Rectal, pelvic, and breast exams will be performed only if indicated by medical history



# Guidelines: Physical Exam (continued)

Heart (including precordial activity, rhythm & rate, sounds, and murmurs)	General neurological evaluation
Peripheral vascular system	General psychiatric evaluation (appearance, behavior, mood, communication, and memory)
Abdomen and viscera (including hernia)	Genitourinary system



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#### University of Texas Medical Branch Physician Examination Form

utmb	Health
	Aerospace Medie

Name of Patient:	
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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 experience 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					
Height		Weight		Resting Pulse Rate	Resting Pulse Rhythm
				_	
Blood Sugar		Cholesterol		Systolic Blood Pressure	Diastolic Blood Pressure
Distant Vision		Distant Vision		Near Vision	Near Vision
	(Right)		(Left)	(Right)	(Left)
Hearing				Hearing	
			(Right ear)		(Left ear)

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

Check each item as indicated:	Normal	Abnormal	NOTES: Describe every abnormality in detail.
Skin			(Continue on a separate sheet of paper if necessary.)
Head and neck (incl. thyroid)			
Nose and sinuses			
Mouth and throat			
Ears			
Eyes			
Lymph nodes			
Lungs and chest			
Breasts			
Heart			
Vascular system			
Abdomen			
G-U system			
Extremities, upper and lower			
Spine, other musculoskeletal			
Neurologic system			
Psychiatric			
General systemic			
Identifying marks, scars, tattoos			

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#### Guidelines: Additional Data

- 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 suborbital 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.
- 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.
- 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 <u>non-disclosed</u> medical conditions causing issues during centrifuge exposures
- No instances of disclosed medical conditions causing issues

#### NASTAR Centrifuge





#### **Lessons Learned**



- 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

