



# Integrated 1 Year Mission Investigator's Face-to-Face

**January 31, 2020**

# Welcome

Jennifer Fogarty, Ph.D./Steven Platts, Ph.D.



## Deep Space Stressors to Human Health & Performance



### Primary Hazards of Human System Risks

Risk can be grouped by common factors contributing to their potential occurrence.

- **Altered gravity** (hyper, hypo, transition)  
*bone, muscle, cardiovascular, sensorimotor, nutrition, behavior/performance, immunology, human factors, clinical medicine*
- **Radiation** (lower earth orbit, deep space)  
*immunology, carcinogenesis, behavior/performance, tissue degeneration, pharmaceutical stability ...*
- **Distance from Earth** (medical care impacts)  
*behavior/performance, autonomy, food systems, clinical medicine*
- **Isolation** (psychological)  
*behavior/performance*
- **Hostile/closed environment** (spacecraft design)  
*behavior/performance, nutrition, immunology, toxicology, microbiology*

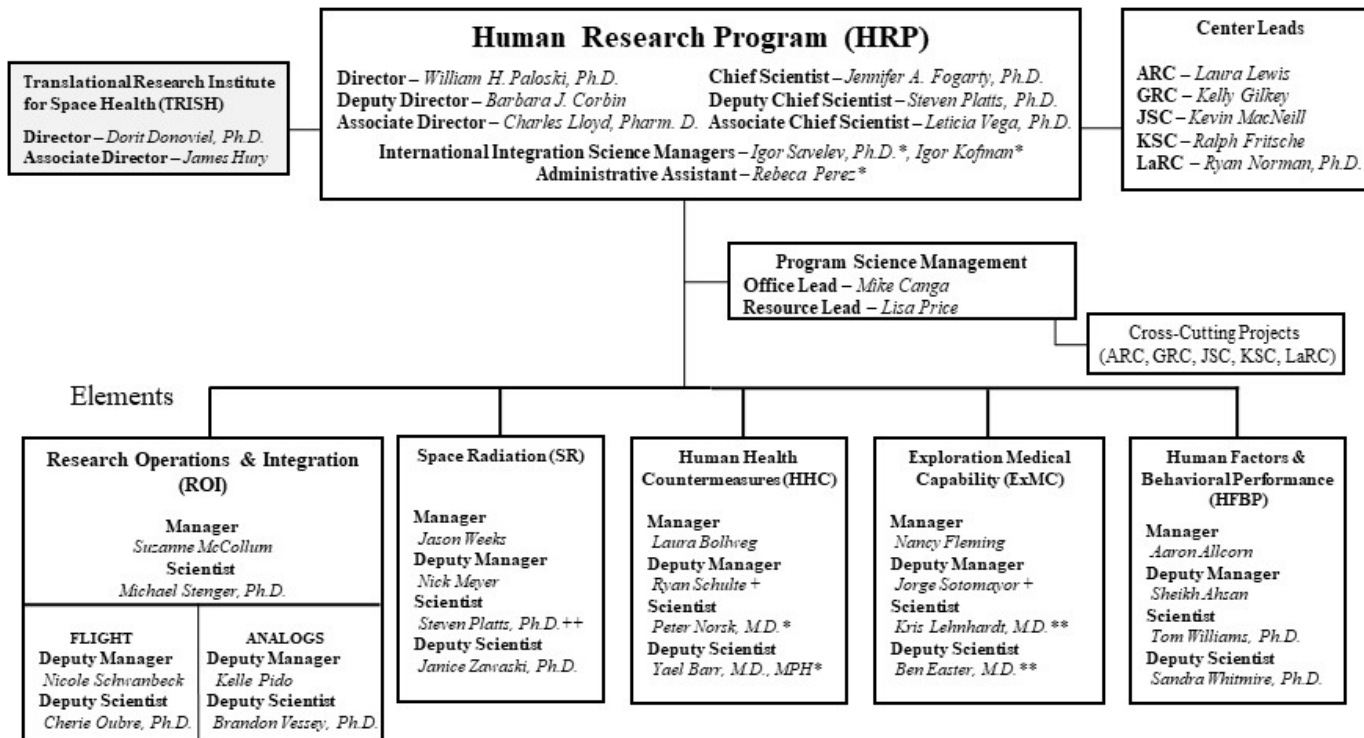
← Earth

*Note that severity generally increases with mission duration.*

# Introductions

Cherie Oubre, Ph.D.

## HRP ORGANIZATION



++ Acting  
 + Rotation  
 \*\* IPA  
 \* Contractor

original signature on file

12/16/2019

William H. Paloski, Ph.D.  
 Program Director

Date

# Introductions

Cherie Oubre, Ph.D.

- What is ROI-Research Operations and Integration Element (formerly ISSMP)?
  - ROI has been developed to maximize the utilization of ISS to obtain solutions to the human health and performance problems and the associated mission risks of exploration class missions.
  - ROI is uniquely focused on the implementation of human research tasks in flight as well as in flight analog environments.
  - Differs from the other HRP elements which develop and manage science content.
  - ROI directly supports the other HRP Elements in the execution of their flight experiments
  - ROI also provides some integration and coordination functions for the USOS international partners.

# Meeting Overview

Cherie Oubre, Ph.D.

## Agenda – Friday, January 31, 2020

8:00 – 8:30	Arrive at ISS Conference Facility for Check-In Light Breakfast/Meet and Greet	
8:30 – 8:45	Welcome	Jennifer Fogarty, Ph.D. / Steven Platts, Ph.D.
8:45 – 9:00	Introductions and Meeting Overview	Cherie Oubre, Ph.D.
9:00 – 9:30	Progress To-Date	Cherie Oubre, Ph.D.
9:30 – 9:45	Break	
9:45 – 10:15	New Cardio Proposal Overview	Mike Bungo, M.D.
10:15 – 11:15	Overview of Final i1YM Complement	Cherie Oubre, Ph.D.
11:15 – 11:45	Data Integration Overview	Mark Shelhamer, Ph.D.
11:45 – 12:45	Lunch	
12:45 – 1:15	Implementation Overview	Nichole Schwanbeck
1:15 – 1:45	Institutional Review Board Discussion	Cherie Oubre, Ph.D.
1:45 – 2:00	Blood and Urine Sample Overview	Scott Smith, Ph.D.
2:00 – 2:15	Break	
2:15 – 3:30	Discussions and Forward Plan	



# Integrated 1 Year Mission Progress To-Date

Cherie Oubre, Ph.D.

# i1YM Implementation Status

- Discussion at several NASA boards for implementation
- First mission launch No Earlier Than July 2021, likely later due to mission schedules and hardware development activities
- Anticipate first subject to return on commercial crew
- ROI has worked with the PIs for flexibilities and collaboration
  - This information was taken to the Elements and HRP for final priority decisions in finalizing the i1YM complement



# Collaborations

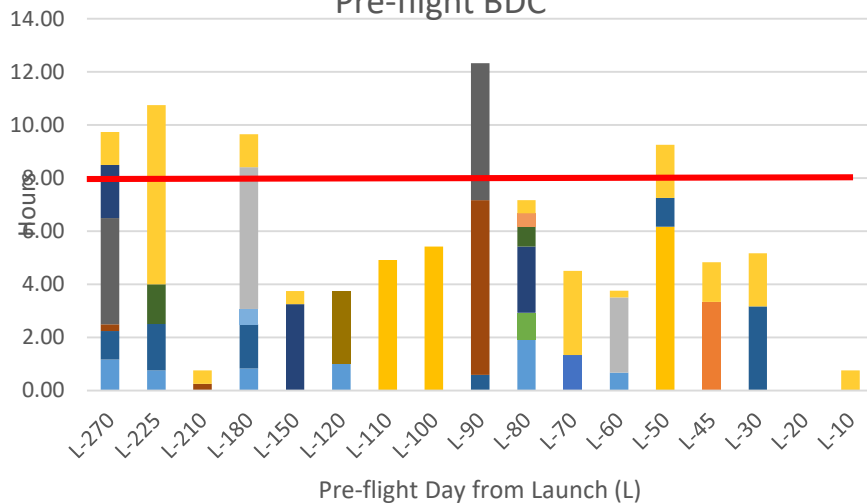
- Thank you to all the PI teams for your flexibility and your collaborations
  - Almost all blood draws have been combined reducing overall blood volume and the crew time associated with these collections
  - Efficiencies with other investigations and Med Ops identified to reduce crew time



# Pre-Flight Overview

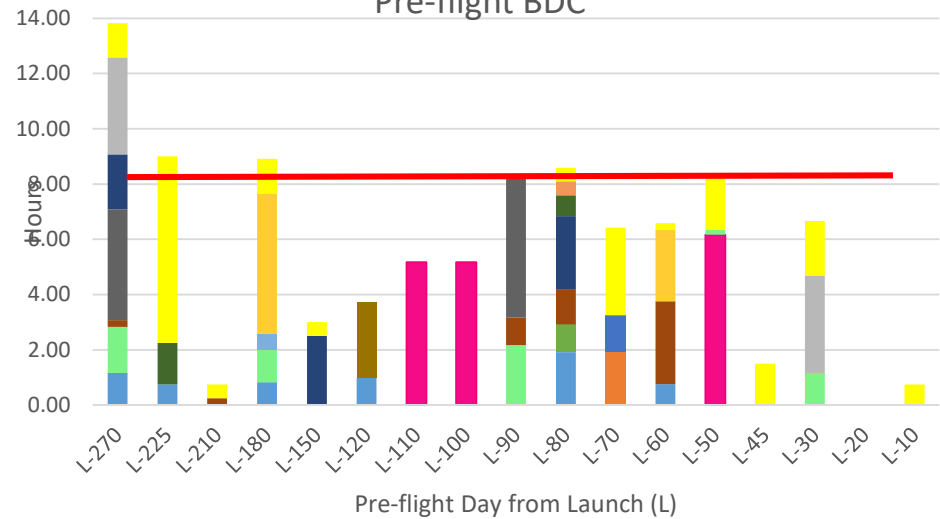
Beginning:

Pre-flight BDC



Current:

Pre-flight BDC



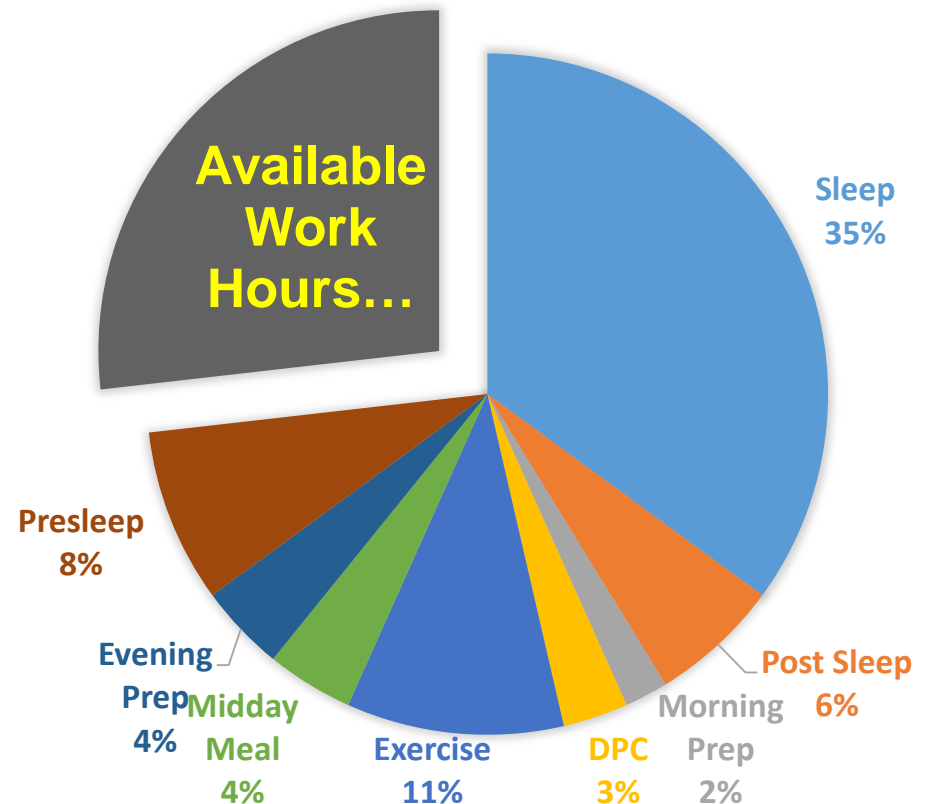
- Red line: Duty day is about 8 hours, but we have the windows to stretch in the timeframe
- Hoping to work with windows in this time with current requirements (assuming more crew time available for USCV crews because of fewer Russia trips)
  - Last 6 months before flight is dedicated to flight specific so more competition for this time period (large amount of BDC in that timeframe may need to be adjusted)

# In-Flight Constraints

- As a reminder, in-flight crew time is extremely limited

## “Available Work Hours” include:

- Traffic Operations
- Medical Operations
- Onboard Training
- Routine Operations (including stowage management)
- Public Affairs Office (PAO)
- Maintenance, Resupply/ Outfitting
- Extravehicular Activities (EVA)
- **Utilization Operations = RESEARCH**



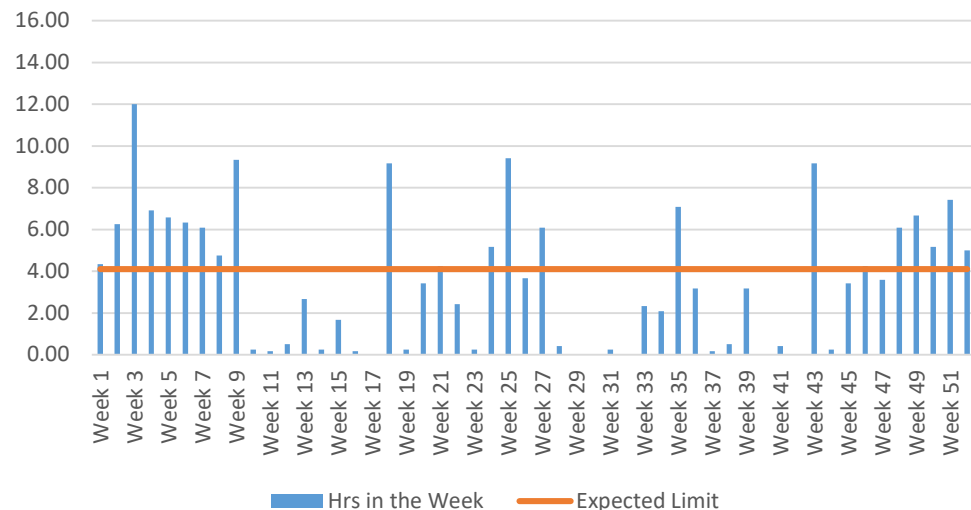
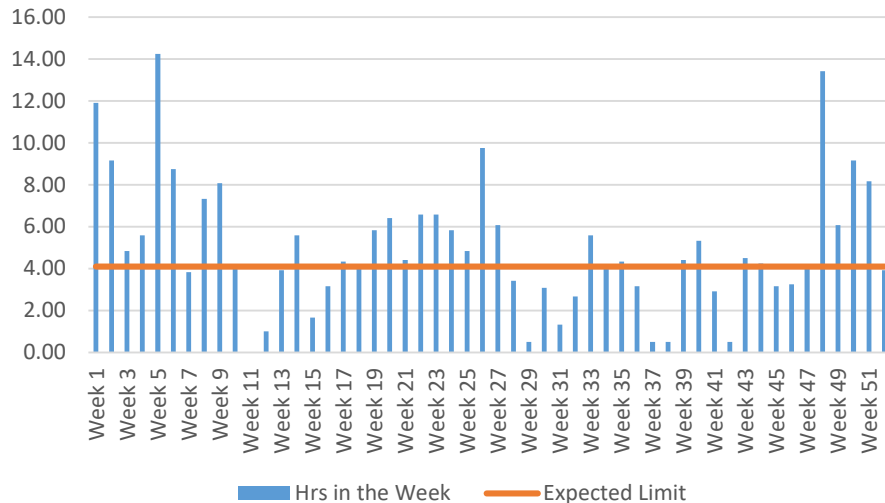
# In-Flight Overview

## Beginning:

## Current:

1YM Subject: Inflight Hrs Each Week vs. Expected Limit

1YM Subject: Inflight Hrs Each Week vs. Expected Limit



Extended Duration	
Total Hours:	255.25
Hours Per Week:	4.91

Extended Duration	
Total Hours:	182.92
Hours Per Week:	3.52

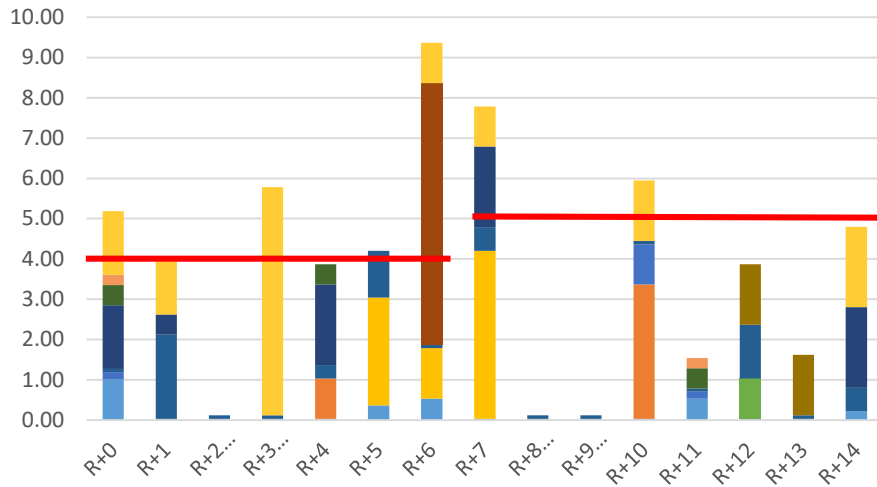
- Estimating ~4 hrs/**week** of crew time available for **one** crewmember to do i1YM studies (after accounting for other users)

# Post-Flight Overview

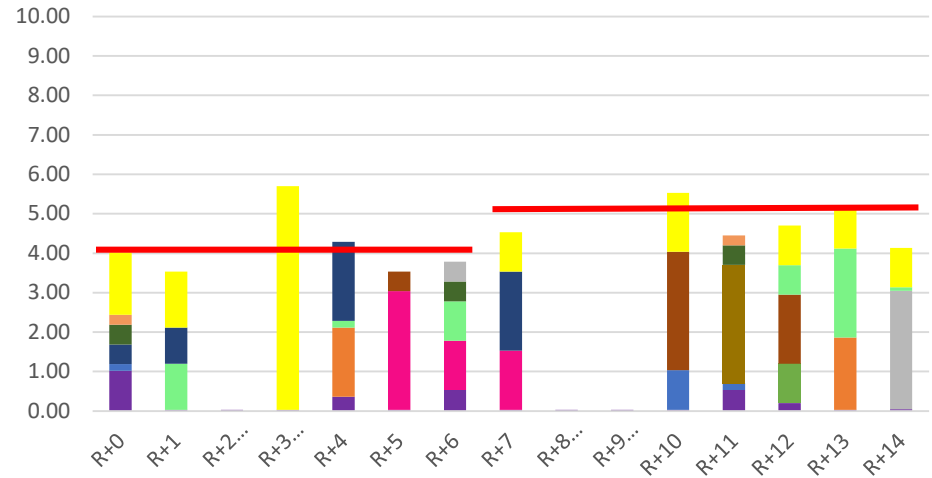
Beginning:

Current:

First Two Weeks Post-flight Crew Time in Hours



First Two Weeks Post-flight Crew Time in Hours



- Red line: Duty day limit is 4 hours/day thru R+6 for ALL testing (including MedOps); increases to 5 hours/day at R+7 thru R+13 is 5 hrs
  - Waivers may be required for time over limit and have to give back the time on another day
  - R+2, 8, and 9 are crew off duty days
- R+14 thru 45 is 6 hrs; after that it's 8 hrs.



# Break

15 minutes



# Coronary Anatomy and Physiology During 1 Year in Space

Mike Bungo, M.D.



# Integrated 1 Year Mission Final Complement

Cherie Oubre, Ph.D.

# Measurements

<b>Routine USND (Arbeille)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. ECHO General Ultrasound	L-90 to L-30 @ 95 min	FD45 ( $\pm 15$ ), FD150 ( $\pm 30$ ), R-45 (+30/-15) @ 160 min each	R+4 ( $\pm 1$ ) - 90 min, R+14 ( $\pm 2$ )- 90 min, R+45 to 60 - 95 min, R+ 180 ( $\pm 15d$ ) - 95 min, R+1 yr ( $\pm 1$ mo) - 95 min
2. Myoton	L-90 to L-30 @ 20 min	FD45 ( $\pm 15$ ), FD150 ( $\pm 30$ ), R-45 (+30/-15) @ 65 min each	R+4 (15 min)-as close to Med Ops MRI as possible, R+14 ( $\pm 2$ ), R+45 to 60, R+1 yr ( $\pm 1$ mo) @20 min each

<b>Telomeres 2 (Bailey)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Blood Collection	L-180, L-90, L-45 (+7/-7) @ 15 min each	2 mid-mission vehicle returns, R-1 vehicle return @ 0 min (time covered by Standard Measures	R+1-7, R+30, R+60, R+180 (+7/-7) @15 min each

<b>Spatial Cognition (Basner)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Cognition Fam	~L-120* (*Shared with Standard Measures)	N/A	N/A
2. Cognition	L-99, L-80*, L-60 @30 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )* @ 30 min each; Reserve sessions @ FD90, FD150, FD210, FD270, and FD330	R+6*, R+30*, R+90, R+180, R+360 @ 30 min each
3. fMRI with Cognition	L-100 @160 min	N/A	R+1 (+6/-0) @ 180 min (some Spatial Cognition MRI tests may be included)
4. Spatial Cognition Fam	L-100 @90 min	N/A	N/A
5. Spatial Cognition Battery 1	L-99, L-60 @ 60 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )* @ 60 min each	R+6, R+30, R+180, R+360 @ 60 min each
6. Spatial Cognition Battery 2	L-98, L-59 @ 90 min each	N/A	R+6, R+31, R+181, R+361 @ 90 min each
7. MRI Spatial Cognition	L-98, L-59 @ 160 min each	N/A	R+31, R+181, R+361 @ 160 min each
8. Blood Draw	L-99, L-60 @15 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )*	R+5, R+30, R+180, R+360 @ 15 min each, within 3 days of Cognition/Spatial Cognition1, same day preferred
9. Cognition Debrief	N/A	N/A	R+95 @ 30 min



# Measurements

<b>Musculoskeletal Adaptations (Bouxsein)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. QCT	L-90 to launch, @60 min (@Methodist, time includes travel)	N/A	R+7/10 and R+1 yr @ 60 min each (@Methodist, time includes travel)
2. EIM	L-3 to 1 month @ 20 min	N/A	R+0/1 (medical tent preferred) @ 10 min, R+7 to 14 @ 20 min, R+1 year @ 20 min

<b>TBone2 (Boyd)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. HR-pQCT with questionnaire	L-80 ( $\pm$ 20 days); scan 55 min, questionnaire 5 min	N/A	R+12 (+/-9); may add R+1 yr; scan 55 min, questionnaire 5 min
DXA Data Share	Data Share with Med Ops	N/A	Data Share with Med Ops
Blood/Urine Data share	Data Share with Bone Health	Data Share with Bone Health	Data Share with Bone Health

<b>Space Phys (Downs)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Muscle Performance with Strength Assessment	L-90 ( $\pm$ 20), L-30 to launch @60 min each	FD14 ( $\pm$ 2), FD45 ( $\pm$ 2), FD75 ( $\pm$ 2), FD105 ( $\pm$ 2), FD135 ( $\pm$ 2), FD165 ( $\pm$ 2), FD195 ( $\pm$ 2), FD225 ( $\pm$ 2), FD255 ( $\pm$ 2), FD285 ( $\pm$ 2), FD315 ( $\pm$ 2), FD345 ( $\pm$ 2), R-7 ( $\pm$ 2) @ 10 min each, integrated into exercise	R+1 ( $\pm$ 1), R+5 ( $\pm$ 1), R+30 ( $\pm$ 3) @60 min each
2. MRI	L-60 to launch @100 min (10 min scan if combined with another MRI that also meets 30 min supine rest rqmt)	N/A	R+1/2; 10 min MRI after 30 min supine rest (100 min including travel time if performed stand-alone)
3. Muscle Ultrasound	Measurements obtained during training	FD14 ( $\pm$ 2), FD45 ( $\pm$ 2), FD90 ( $\pm$ 2), FD180 ( $\pm$ 2), FD270 ( $\pm$ 2), R-7 ( $\pm$ 2) @ 160 min each	N/A
4. Max CEVIS	Shared with Med Ops testing—10 min added for NIRS/Cardiac Function	Shared with Med Ops	Shared with Med Ops testing—10 min added for NIRS/cardiac function
5. Aerobic Performance Eval	Explanation & preflight practice session during daily training w/ASCRs	FD45 ( $\pm$ 7), FD180 ( $\pm$ 7), FD270 ( $\pm$ 7) @30 min each	N/A
6. Isokinetic (Data share)	Shared with Med Ops testing	N/A	Shared with Med Ops testing
7. Sleep, nutrition, exercise data	L-12, 6, & 3 months for 2 weeks each (@5 min/d + 30 min fam with 1st session)	Shared with Med Ops and/or other studies	Shared with Med Ops and/or other studies

# Measurements

<b>Vascular Calcium (Hughson)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Meal Choice	L-270 to L-210 @ 15 min	N/A	N/A
2. Body Measurements	L-210 to L-190 @ 15 min	N/A	N/A
3. CT - Coronary Calcium	L-90 to L-60 @ 60 min	N/A	R+6 to 21, R+1yr, R+2 yr @ 60 min each
4. HR-pQCT- Vascular and Bone	L-90 to L-60 @ 45 min	N/A	R+6 to 21, R+180, R+1yr, R+2 yr @ 45 min each
5. DEXA	L-90 to L-60 @ 45 min; no extra time reqd if MedOps DEXA performed in same timeframe	N/A	R+6 to 21, R+1yr, R+2 yr @45 min each; no extra time reqd if MedOps DEXA performed in same timeframe
6. ECHO Ultrasound (w/BP)	L-90 to L-60 @ 90 min; no additional time required when performed in conjunction with Arbeille's Ultrasound	FD45 ( $\pm 15$ ), FD150 ( $\pm 30$ ), R-45 to R-1 @ 190 min each stand-alone, but only 30 minutes additional when combined with Arbeille ECHO	R+4 ( $\pm 1$ ), R+180, R+1yr, R+2yr @90 min each; no additional time required when performed in conjunction with Arbeille's Ultrasound
7. 13-hr Blood Pressure	L-90 to L-60 @ 20 min (does not include ambulatory time); performed w/ Physical Activity Monitor	FD30 ( $\pm 10$ ), FD150 ( $\pm 30$ ), R-45 to R-1 @ 70 min each	R+6 ( $\pm 2$ ), R+180, R+1yr, R+2yr @20 min (does not include ambulatory time); w/in 2 days of OGTT & USND
8. 48-hr Physical Activity Monitor	L-90 to L-60 @ 10 min; performed w/13-hr BP	FD30 ( $\pm 10$ ), FD150 ( $\pm 30$ ), R-45 to R-1 @ 75 min each	R+6 ( $\pm 2$ ) , R+180, R+1yr, R+2 yr @ 10 min each
9. Oral Glucose Tolerance Test	L-90 to L-60 @ 180 min	FD150 ( $\pm 30$ ), R-45 to R-1 @ 215 min each	R+9-11, R+180 ( $\pm 10$ ) @ 180 min each
10. Blood	L-180 to L-90 @ 15 min/each	FD150* ( $\pm 30$ ), R-30 to R-1* @ 215 min each (FD30 is solely data share w/Standard Measures)	R+30 ( $\pm 5$ ), R+180 ( $\pm 10$ ), R+1 yr ( $\pm 10$ ) @ 15 min each
11. Urine	L-180 to L-90 @ 20 min; schedule with blood draw	FD150 ( $\pm 30$ ), R-30 to R-1* @165 min each	R+30 ( $\pm 5$ ), R+180 ( $\pm 10$ ), R+1 yr ( $\pm 10$ ) @ 20 min each

# Measurements

<b>Cartilage Health (Liphardt)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Blood & Urine	L-270 ( $\pm 14$ ) and L-90 ( $\pm 14$ ) @ 110 min/ea (2 consecutive days of resting blood draws @35 min/ea + 48-hr urine@40 min); one blood draw is on day of MRI)	FD15 ( $\pm 7$ )*, FD60 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, R-14 ( $\pm 14$ )* @0 min each - all shared with Bone Health	R+28 ( $\pm 14$ ), R+365 ( $\pm 14$ ) @110 min/ea (2 consecutive days of resting blood draws @35 min/ea + 48-hr urine @40 min); one blood draw is on day of MRI)
2. MRI + Questionnaire	L-270 ( $\pm 14$ ) and L-90 ( $\pm 14$ ) @ 130 min each (questionnaire performed during rest period of MRI)	Questionnaire only inflight: FD15 ( $\pm 7$ ), FD60 ( $\pm 14$ ), FD180 ( $\pm 14$ ), R-14 ( $\pm 14$ ) @10 min each	R+28 ( $\pm 14$ ), R+365 ( $\pm 14$ ) @ 130 min each (questionnaire performed during rest period of MRI)
3. Loading Experiment	L-90 ( $\pm 14$ ) @105 min (reduced by 35 min if combined with one of the blood draws associated with the MRI)	N/A	R+28 ( $\pm 14$ ) @105 min each (reduced by 35 min if combined with one of the blood draws associated with the MRI)

<b>ISAFE (Macias)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. MRI	L-21/18 months (shared w/Med Ops);	N/A	R+1-3 (shared w/MedOps); R+30; R+180 @ 140 min each
2. Eye Exam/Testing	L-21/18 months, L-9/6 months (both shared with med ops)	N/A	N/A
3. ISAFE Vision & Vascular tests	ISafe Vision & Vascular tests (USND, ERG, OCT, OCT-A w/ dilation, IOP, BP, sublingual nitro): L-90 ( $\pm 14$ d) @ 165 min	FD 10 ( $\pm 7$ ), FD45 ( $\pm 7$ ), FD180 ( $\pm 7$ ), R-30 ( $\pm 7$ ) @365 min each	ISafe Vision & Vascular tests (USND, ERG, OCT, OCT-A w/ dilation, IOP, BP, sublingual nitro): R+30 ( $\pm 7$ ), R+180 ( $\pm 30$ ), R+1 yr ( $\pm 30$ d), R+2 yr ( $\pm 30$ d) @ 165 min each
4. IVFA plus ISAFE tests	N/A	N/A	IVFA and ISafe Vision & Vascular tests (USND, ERG, OCT, OCT-A w/ dilation, IOP, BP, sublingual nitro, IVFA): R+8 (+/-7d) @ 180 min (can be divided into 2 days within window)

# Measurements

<b>Egress Fitness (Norcross)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Suit Fitting	Any time prior to L-180 @120 min	N/A	N/A
2. Full Planetary EVA Circuit + Fam	L-180 ± 60 (150 min), L-60 ± 30 (120 min)	N/A	R+4 (±1), R+7 (±1)@ 120 min; min 2 days between sessions
3. Mock-up Capsule Egress + Fam	L-60 ± 30 (40 min)	N/A	R+0 at landing site @ 30 min (add 5 min if LEA suit re-don needed [for contingency landing site or Port Canaveral])
4. Partial Planetary EVA	N/A	N/A	Early R+1 (R+<24 hrs)@ JSC @ 55 min

<b>Vestibular Health (Reschke)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Neurovestibular Evaluation	L-270 to L-135 @ 90 min	N/A	N/A
2. Vestibular Fam and Exam	L-90 (±30) @ 45 min	FD1 (+1/-0), FD30 (±15), FD150 (±30), FD250 (±30), R-30 (±30) @195 min first, rest at 165 min each; align within 3 days of Cognition, if performed in that timeframe	Vestibular exam: R+0 @ landing site, R+4 (±2d), R+9 (+4/-2), R+30 (±7) @ 30 min
3. Ghost S Camera Battery Change	N/A	FD1 (+1/-0), FD30 (±15), FD150 (±30), FD250 (±30), R-30 ±30) @10 min each	N/A

<b>Bone Health (Romaneillo)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Blood Collection	L-180 (±60) and L-75 (±14) @15 min each; L-180 incl. survey	FD15 (±7), FD30 (±14)*, FD60 (±14), FD120 (±14), FD180 (±14)*, FD240 (±14), FD300 (±14), R-14 (±14)* @85 min each	R+30 (±14), R+180 (±60) @ 15 min each; R+30 incl. survey
2. Urine Collection	L-180 (±60) and L-75 (±14) @20 min each	FD15 (±7), FD30 (±14), FD60 (±14), FD120 (±14), FD180 (±14), FD240 (±14), FD300 (±14), R-14 (±14) @165 min each	R+30 (±14), R+180 (±60) @ 20 min each

# Measurements

<u>Ocular Alignment (Shelhamer)</u>	<u>Pre-flight</u>	<u>In-flight</u>	<u>Post-flight</u>
1. Ocular Alignment Test	L-90 ( $\pm 30$ ) @30 min (performed within 2 days of Standard Measures Sensorimotor Function)	Performed as part of Vestibular Health protocol	R+0 (+1), R+9 ( $\pm 2$ ) & w/in 2d of StdMeas SM, R+30 ( $\pm 7$ ) & w/in 3d of Std Meas. Cognition

<u>NINscan (Zhang)</u>	<u>Pre-flight</u>	<u>In-flight</u>	<u>Post-flight</u>
1. Cognition and ROBoT-r Fam	L-180 (Cog covered by Standard Measures)	N/A	N/A
2. Actigraphy	L-180, L-65 @14 min each	Subset of Standard Measures data	R+18, R+66 @ 14 min each
3. NINscan Sleep	L-180, L-65 @ 40 min each		R+18, R+66 @ 40 min each
4. Blood draw and 3 day saliva	L-180, L-65 @30 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )*;	R+18, R+66 @ 15 min each
5. NINscan + Cognition + ROBoT-r	L-180, L-65* (*Cog covered by Standard Measures) @115 min each	Reserve sessions @ FD90, FD150, FD210, FD270, and FD330	R+18, R+66 @115 min each
6. 3 day sleep and exercise	Part of actigraphy		N/A
7. Tonometry	Data share with ISAFE	Data share with ISAFE	Data share with ISAFE

<u>Cardio (Levine)</u>	<u>Pre-flight</u>	<u>In-flight</u>	<u>Post-flight</u>
1. Coronary Computed Tomography Angiography (cCTA)	L-365, L-30 @ 180 min each (3 hrs including transportation to Baylor St. Luke's)	N/A	R+7 (+7), R+365 @ 180 min each (3 hrs including transportation to Baylor St. Luke's)
2. Myocardial Contrast Echocardiography (MCE)	L-365, L-30 @ 30 min each	FD15 (+10/-5), R-15 ( $\pm 10$ ) @ 240 min each	R+7, R+365 @ 30 min each
3. Blood Draw	L-365, L-30 @ 15 min each	FD15 ( $\pm 7$ )*, FD60 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, R-14 ( $\pm 14$ )* @ 85 min each	R+7, R+365 @ 15 min each



# Integrated 1 Year Mission Data Integration Overview

Mark Shelhamer, Ph.D.



# Lunch

15 min break



# Integrated 1 Year Mission Implementation Overview

Nichole Schwanbeck



# Implementation

- Nominally, once an experiment has completed its Feasibility Assessment and received Select for Flight (SFF), it is added to the suite of complements that will be pitched to upcoming crews
- For the i1YM, the 15 experiments will likely be combined and grouped to maximize efficiencies for the crew, PI teams, and data
- We propose to have the i1YM measures grouped by discipline and functionality
  - This means some investigator measurements may be split across multiple groups
  - Points of contact for the groups will need to be established
  - Measurement priorities will need to be established
- Each group will have its own ROI team and POCs
- There will still be an overarching i1YM integration team to ensure measurements across the groups are implemented correctly

# Implementation (cont.)

- Crew will be pitched all experiments/groups of measures as an integrated package
  - Willingness to participate will be part of the crew selection process for extended-duration crews
  - Ideally, standard-duration crewmembers who are not interested in participating in the entire package will participate in other experiments planned by HRP and IP agencies (a crewmember doing the i1YM complement will have little to no time for other experiments, so not all standard-duration crewmembers can be recruited)
  - Short-duration crewmembers may elect to perform subsets of the complement
- Another meeting will be arranged to discuss the more specific implementation details after more discussions with HRP regarding priorities



# Integrated 1 Year Mission IRB Discussion

Cherie Oubre, Ph.D.

# IRB Expectations

- Each study will receive individual IRB approval through both their home institution and NASA IRB.
- The PI is responsible for making updates to the IRB protocol to capture any changes as a result of the integration process
  - More on subsequent slides
- The protocols will also be submitted to the JAXA IRB, ESA IRB and the Human Research Multinational Review Board (HRMRB) prior to crew consent.
- Details on the plans for an integrated IRB complement are pending further discussions with FOD and the crew office

# Common IRB Updates

- Updated measurement time points
  - For any measurements that changed as a result of the integration
- Data Sharing words
  - Consent Form
  - Protocol
- i1YM complement words
  - Consent Form
  - Protocol
- Your ROI teams will provide the information and boiler plate text needed for these updates



# Integrated 1 Year Mission Blood and Urine Sample Overview

Scott Smith, Ph.D.



# Blood

- Experiments with Blood for coordination
  - Telomeres 2 (Bailey)
  - Spatial Cognition (Basner)
  - TBone2 (Boyd)
  - Vascular Calcium (Hughson)
  - Cartilage Health (Liphardt)
  - Bone Health (Romaniello)
  - NINscan (Zhang)
  - Cardio (Levine)



# Urine

- Experiments with urine for coordination
  - TBone2 (Boyd)
  - Vascular Calcium (Hughson)
  - Cartilage Health (Liphardt)
  - Bone Health (Romaniello)





# Break

15 minutes



# Integrated 1 Year Mission Discussion/Forward Work

Cherie Oubre, Ph.D.



# Discussion

- Questions?

# Forward Work/Next Steps

- There are still risks to work through
  - Hardware readiness
  - Blood limits
  - Radiation exposure
  - Etc.
- Grouping of experiment measures
- Select for Flight
  - Targeted for TBD
- First Informed Consent Briefing
  - Targeted for TBD (NET July 2020)
- BDC
  - Targeted to begin TBD



Back-up

# Measurements

<b>Routine USND (Arbeille)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. ECHO General Ultrasound	L-90 to L-30 @ 95 min	FD45 ( $\pm 15$ ), FD150 ( $\pm 30$ ), R-45 (+30/-15) @ 160 min each	R+4 ( $\pm 1$ ) - 90 min, R+14 ( $\pm 2$ )- 90 min, R+45 to 60 - 95 min, R+ 180 ( $\pm 15d$ ) - 95 min, R+1 yr ( $\pm 1$ mo) - 95 min
2. Myoton	L-90 to L-30 @ 20 min	FD45 ( $\pm 15$ ), FD150 ( $\pm 30$ ), R-45 (+30/-15) @ 65 min each	R+4 (15 min)-as close to Med Ops MRI as possible, R+14 ( $\pm 2$ ), R+45 to 60, R+1 yr ( $\pm 1$ mo) @20 min each

<b>Telomeres 2 (Bailey)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Blood Collection	L-180, L-90, L-45 (+7/-7) @ 15 min each	2 mid-mission vehicle returns, R-1 vehicle return @ 0 min (time covered by Standard Measures	R+1-7, R+30, R+60, R+180 (+7/-7) @15 min each

<b>Spatial Cognition (Basner)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Cognition Fam	~L-120* (*Shared with Standard Measures)	N/A	N/A
2. Cognition	L-99, L-80*, L-60 @30 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )* @ 30 min each; Reserve sessions @ FD90, FD150, FD210, FD270, and FD330	R+6*, R+30*, R+90, R+180, R+360 @ 30 min each
3. fMRI with Cognition	L-100 @160 min	N/A	R+1 (+6/-0) @ 180 min (some Spatial Cognition MRI tests may be included)
4. Spatial Cognition Fam	L-100 @90 min	N/A	N/A
5. Spatial Cognition Battery 1	L-99, L-60 @ 60 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )* @ 60 min each	R+6, R+30, R+180, R+360 @ 60 min each
6. Spatial Cognition Battery 2	L-98, L-59 @ 90 min each	N/A	R+6, R+31, R+181, R+361 @ 90 min each
7. MRI Spatial Cognition	L-98, L-59 @ 160 min each	N/A	R+31, R+181, R+361 @ 160 min each
8. Blood Draw	L-99, L-60 @15 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )*	R+5, R+30, R+180, R+360 @ 15 min each
9. Cognition Debrief	N/A	N/A	R+95 @ 30 min

# Measurements

<b>Musculoskeletal Adaptations (Bouxsein)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. QCT	L-90 to launch, @60 min (@Methodist, time includes travel)	N/A	R+7/10 and R+1 yr @ 60 min each (@Methodist, time includes travel)
2. EIM	L-3 to 1 month @ 20 min	N/A	R+0/1 (medical tent preferred) @ 10 min, R+7 to 14 @ 20 min, R+1 year @ 20 min

<b>TBone2 (Boyd)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. HR-pQCT with questionnaire	L-80 ( $\pm$ 20 days); scan 55 min, questionnaire 5 min	N/A	R+12 (+/-9); may add R+1 yr; scan 55 min, questionnaire 5 min
DXA Data Share	Data Share with Med Ops	N/A	Data Share with Med Ops
Blood/Urine Data share	Data Share with Bone Health	Data Share with Bone Health	Data Share with Bone Health

<b>Space Phys (Downs)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Muscle Performance with Strength Assessment	L-90 ( $\pm$ 20), L-30 to launch @60 min each	FD14 ( $\pm$ 2), FD45 ( $\pm$ 2), FD75 ( $\pm$ 2), FD105 ( $\pm$ 2), FD135 ( $\pm$ 2), FD165 ( $\pm$ 2), FD195 ( $\pm$ 2), FD225 ( $\pm$ 2), FD255 ( $\pm$ 2), FD285 ( $\pm$ 2), FD315 ( $\pm$ 2), FD345 ( $\pm$ 2), R-7 ( $\pm$ 2) @ 10 min each, integrated into exercise	R+1 ( $\pm$ 1), R+5 ( $\pm$ 1), R+30 ( $\pm$ 3) @60 min each
2. MRI	L-60 to launch @100 min (10 min scan if combined with another MRI that also meets 30 min supine rest rqmt)	N/A	R+1/2; 10 min MRI after 30 min supine rest (100 min including travel time if performed stand-alone)
3. Muscle Ultrasound	Measurements obtained during training	FD14 ( $\pm$ 2), FD45 ( $\pm$ 2), FD90 ( $\pm$ 2), FD180 ( $\pm$ 2), FD270 ( $\pm$ 2), R-7 ( $\pm$ 2) @ 160 min each	N/A
4. Max CEVIS	Shared with Med Ops testing—10 min added for NIRS/Cardiac Function	Shared with Med Ops	Shared with Med Ops testing—10 min added for NIRS/cardiac function
5. Aerobic Performance Eval	Explanation & preflight practice session during daily training w/ASCRs	FD45 ( $\pm$ 7), FD180 ( $\pm$ 7), FD270 ( $\pm$ 7) @30 min each	N/A
6. Isokinetic (Data share)	Shared with Med Ops testing	N/A	Shared with Med Ops testing
7. Sleep, nutrition, exercise data	L-12, 6, & 3 months for 2 weeks each (@5 min/d + 30 min fam with 1st session)	Shared with Med Ops and/or other studies	Shared with Med Ops and/or other studies

# Measurements

<b>Vascular Calcium (Hughson)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Meal Choice	L-270 to L-210 @ 15 min	N/A	N/A
2. Body Measurements	L-210 to L-190 @ 15 min	N/A	N/A
3. CT - Coronary Calcium	L-90 to L-60 @ 60 min	N/A	R+6 to 21, R+1yr, R+2 yr @ 60 min each
4. HR-pQCT- Vascular and Bone	L-90 to L-60 @ 45 min	N/A	R+6 to 21, R+180, R+1yr, R+2 yr @ 45 min each
5. DEXA	L-90 to L-60 @ 45 min; no extra time reqd if MedOps DEXA performed in same timeframe	N/A	R+6 to 21, R+1yr, R+2 yr @45 min each; no extra time reqd if MedOps DEXA performed in same timeframe
6. ECHO Ultrasound (w/BP)	L-90 to L-60 @ 90 min; no additional time required when performed in conjunction with Arbeille's Ultrasound	FD45 ( $\pm 15$ ), FD150 ( $\pm 30$ ), R-45 to R-1 @ 190 min each stand-alone, but only 30 minutes additional when combined with Arbeille ECHO	R+4 ( $\pm 1$ ), R+180, R+1yr, R+2yr @90 min each; no additional time required when performed in conjunction with Arbeille's Ultrasound
7. 13-hr Blood Pressure	L-90 to L-60 @ 20 min (does not include ambulatory time); performed w/ Physical Activity Monitor	FD30 ( $\pm 10$ ), FD150 ( $\pm 30$ ), R-45 to R-1 @ 70 min each	R+6 ( $\pm 2$ ), R+180, R+1yr, R+2yr @20 min (does not include ambulatory time); w/in 2 days of OGTT & USND
8. 48-hr Physical Activity Monitor	L-90 to L-60 @ 10 min; performed w/13-hr BP	FD30 ( $\pm 10$ ), FD150 ( $\pm 30$ ), R-45 to R-1 @ 75 min each	R+6 ( $\pm 2$ ) , R+180, R+1yr, R+2 yr @ 10 min each
9. Oral Glucose Tolerance Test	L-90 to L-60 @ 180 min	FD150 ( $\pm 30$ ), R-45 to R-1 @ 215 min each	R+9-11, R+180 ( $\pm 10$ ) @ 180 min each
10. Blood	L-180 to L-90 @ 15 min/each	FD150* ( $\pm 30$ ), R-30 to R-1* @ 215 min each (FD30 is solely data share w/Standard Measures)	R+30 ( $\pm 5$ ), R+180 ( $\pm 10$ ), R+1 yr ( $\pm 10$ ) @ 15 min each
11. Urine	L-180 to L-90 @ 20 min; schedule with blood draw	FD150 ( $\pm 30$ ), R-30 to R-1* @165 min each	R+30 ( $\pm 5$ ), R+180 ( $\pm 10$ ), R+1 yr ( $\pm 10$ ) @ 20 min each



# Measurements

<b>Cartilage Health (Liphardt)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Blood & Urine	L-270 ( $\pm 14$ ) and L-90 ( $\pm 14$ ) @ 110 min/ea (2 consecutive days of resting blood draws @35 min/ea + 48-hr urine@40 min); one blood draw is on day of MRI)	FD15 ( $\pm 7$ )*, FD60 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, R-14 ( $\pm 14$ )* @0 min each - all shared with Bone Health	R+28 ( $\pm 14$ ), R+365 ( $\pm 14$ ) @110 min/ea (2 consecutive days of resting blood draws @35 min/ea + 48-hr urine @40 min); one blood draw is on day of MRI)
2. MRI + Questionnaire	L-270 ( $\pm 14$ ) and L-90 ( $\pm 14$ ) @ 130 min each (questionnaire performed during rest period of MRI)	Questionnaire only inflight: FD15 ( $\pm 7$ ), FD60 ( $\pm 14$ ), FD180 ( $\pm 14$ ), R-14 ( $\pm 14$ ) @10 min each	R+28 ( $\pm 14$ ), R+365 ( $\pm 14$ ) @ 130 min each (questionnaire performed during rest period of MRI)
3. Loading Experiment	L-90 ( $\pm 14$ ) @105 min (reduced by 35 min if combined with one of the blood draws associated with the MRI)	N/A	R+28 ( $\pm 14$ ) @105 min each (reduced by 35 min if combined with one of the blood draws associated with the MRI)

<b>ISAFE (Macias)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. MRI	L-21/18 months (shared w/Med Ops);	N/A	R+1-3 (shared w/MedOps); R+30; R+180 @ 140 min each
2. Eye Exam/Testing	L-21/18 months, L-9/6 months (both shared with med ops)	N/A	N/A
3. ISAFE Vision & Vascular tests	ISafe Vision & Vascular tests (USND, ERG, OCT, OCT-A w/ dilation, IOP, BP, sublingual nitro): L-90 ( $\pm 14$ d) @ 165 min	FD 10 ( $\pm 7$ ), FD45 ( $\pm 7$ ), FD180 ( $\pm 7$ ), R-30 ( $\pm 7$ ) @365 min each	ISafe Vision & Vascular tests (USND, ERG, OCT, OCT-A w/ dilation, IOP, BP, sublingual nitro): R+30 ( $\pm 7$ ), R+180 ( $\pm 30$ ), R+1 yr ( $\pm 30$ d), R+2 yr ( $\pm 30$ d) @ 165 min each
4. IVFA plus ISAFE tests	N/A	N/A	IVFA and ISafe Vision & Vascular tests (USND, ERG, OCT, OCT-A w/ dilation, IOP, BP, sublingual nitro, IVFA): R+8 (+/-7d) @ 180 min (can be divided into 2 days within window)

# Measurements

<b>Egress Fitness (Norcross)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Suit Fitting	Any time prior to L-180 @120 min	N/A	N/A
2. Full Planetary EVA Circuit + Fam	L-180 ± 60 (150 min), L-60 ± 30 (120 min)	N/A	R+4 (±1), R+7 (±1)@ 120 min; min 2 days between sessions
3. Mock-up Capsule Egress + Fam	L-60 ± 30 (40 min)	N/A	R+0 at landing site @ 30 min (add 5 min if LEA suit re-don needed [for contingency landing site or Port Canaveral])
4. Partial Planetary EVA	N/A	N/A	Early R+1 (R+<24 hrs)@ JSC @ 55 min

<b>Vestibular Health (Reschke)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Neurovestibular Evaluation	L-270 to L-135 @ 90 min	N/A	N/A
2. Vestibular Fam and Exam	L-90 (±30) @ 45 min	FD1 (+1/-0), FD30 (±15), FD150 (±30), FD250 (±30), R-30 (±30) @195 min first, rest at 165 min each; align within 3 days of Cognition, if performed in that timeframe	Vestibular exam: R+0 @ landing site, R+4 (±2d), R+9 (+4/-2), R+30 (±7) @ 30 min
3. Ghost S Camera Battery Change	N/A	FD1 (+1/-0), FD30 (±15), FD150 (±30), FD250 (±30), R-30 ±30) @10 min each	N/A

<b>Bone Health (Romaneillo)</b>	<b>Pre-flight</b>	<b>In-flight</b>	<b>Post-flight</b>
1. Blood Collection	L-180 (±60) and L-75 (±14) @15 min each; L-180 incl. survey	FD15 (±7), FD30 (±14)*, FD60 (±14), FD120 (±14), FD180 (±14)*, FD240 (±14), FD300 (±14), R-14 (±14)* @85 min each	R+30 (±14), R+180 (±60) @ 15 min each; R+30 incl. survey
2. Urine Collection	L-180 (±60) and L-75 (±14) @20 min each	FD15 (±7), FD30 (±14), FD60 (±14), FD120 (±14), FD180 (±14), FD240 (±14), FD300 (±14), R-14 (±14) @165 min each	R+30 (±14), R+180 (±60) @ 20 min each

# Measurements

<u>Ocular Alignment (Shelhamer)</u>	<u>Pre-flight</u>	<u>In-flight</u>	<u>Post-flight</u>
1. Ocular Alignment Test	L-90 ( $\pm 30$ ) @30 min (performed within 2 days of Standard Measures Sensorimotor Function)	Performed as part of Vestibular Health protocol	R+0 (+1), R+9 ( $\pm 2$ ) & w/in 2d of StdMeas SM, R+30 ( $\pm 7$ ) & w/in 3d of Std Meas. Cognition

<u>NINscan (Zhang)</u>	<u>Pre-flight</u>	<u>In-flight</u>	<u>Post-flight</u>
1. Cognition and ROBoT-r Fam	L-180 (Cog covered by Standard Measures)	N/A	N/A
2. Actigraphy	L-180, L-65 @14 min each	Subset of Standard Measures data	R+18, R+66 @ 14 min each
3. NINscan Sleep	L-180, L-65 @ 40 min each		R+18, R+66 @ 40 min each
4. Blood draw and 3 day saliva	L-180, L-65 @30 min each	FD15 (+7)*, FD60 ( $\pm 14$ )*, FD120 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, FD240 ( $\pm 14$ )*, FD300 ( $\pm 14$ )*, R 14 ( $\pm 14$ )*;	R+18, R+66 @ 15 min each
5. NINscan + Cognition + ROBoT-r	L-180, L-65* (*Cog covered by Standard Measures) @115 min each	Reserve sessions @ FD90, FD150, FD210, FD270, and FD330	R+18, R+66 @115 min each
6. 3 day sleep and exercise	Part of actigraphy		N/A
7. Tonometry	Data share with ISAFE	Data share with ISAFE	Data share with ISAFE

<u>Cardio (Levine)</u>	<u>Pre-flight</u>	<u>In-flight</u>	<u>Post-flight</u>
1. Coronary Computed Tomography Angiography (cCTA)	L-365, L-30 @ 180 min each (3 hrs including transportation to Baylor St. Luke's)	N/A	R+7 (+7), R+365 @ 180 min each (3 hrs including transportation to Baylor St. Luke's)
2. Myocardial Contrast Echocardiography (MCE)	L-365, L-30 @ 30 min each	FD15 (+10/-5), R-15 ( $\pm 10$ ) @ 240 min each	R+7, R+365 @ 30 min each
3. Blood Draw	L-365, L-30 @ 15 min each	FD15 ( $\pm 7$ )*, FD60 ( $\pm 14$ )*, FD180 ( $\pm 14$ )*, R-14 ( $\pm 14$ )* @ 85 min each	R+7, R+365 @ 15 min each