Human Research On-Orbit Consent Process

International Human Research Complement Working Group (IHRCWG)

POIWG #52 April 2023

Overview

- Role of HRP's Research Operations and Integration (ROI) Element
- Role of NASA's Institutional Review Board (IRB)
- On-orbit informed consent
  - Types of studies requiring consent
  - On-orbit informed consent process
- Backup Charts
  - Nominal informed consent process
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    - Timeline
    - Informed Consent Briefing (ICB)
    - Crew complement development

Role of HRP/ROI

- HRP's Research Operations and Integration (ROI) Element
  - Tasked by ISS to lead the International Human Research Complement Working Group (IHRCWG) which is chartered by the OZ Research Integration Control Board (RICB).
    - The IHRCWG is responsible for the development of Increment-specific human research complement scenarios as part of the MRPWG Increment research planning process .
    - The IHRCWG is also responsible for developing recommendations for the complement scenario that best fits each individual crewmember after the Informed Consent Briefing. Recommendations will take into account the crewmember's willingness to participate in the various experiments offered, International Partner priorities, and any particular interests that the crewmember has expressed (if any).
    - The IHRCWG will also discuss issues related to the status of Mini Experiment Documents (Mini EDs), Test Readiness Reviews, Institutional Review Boards, as well as Informed Consent Briefings. Also, new investigations that each agency anticipates implementing on future increments will be discussed in order to determine if the testing proposed will result in a conflict with another investigation and to identify opportunities for agency investigation collaboration, data and resource sharing.
  - ROI's Science Integration team's Increment Science Coordinators (ISCs) are the team that manage the IHRCWG.

Role of IRB

- Institutional Review Board (IRB)
  - In the US, IRBs are ***federally mandated*** for all institutions that conduct human research to ensure:
    - Voluntary participation, without coercion in any form and indicated by free and informed consent;
    - Freedom for a subject to withdraw from an experiment at any time, for any reason, without penalty;
    - An appropriate balance between potential benefits of the research to the subject or to society and the risks assumed by the subject;
    - Fair procedures and outcomes in the selection of the research subjects.
  - The NASA IRB is responsible for review, approval, and monitoring of research protocols involving NASA astronauts and/or protocols that have BDC performed at JSC (other human subjects participating in NASA-sponsored research are also within their purview). The IRB assures that research is conducted in an ethical and safe manner.
  - IP agencies also have their own ethics boards which follow laws similar to IRBs in the US.
  - Human use research conducted by those agencies must initially be reviewed and approved by that agency's IRB/Ethic boards before being sent to other agencies for their approval.
    - Approval of another agency ethics board is not required if that agency’s crew members will not be targeted as subjects; however, NASA IRB approval is always required for crew studies.
    - Additionally, the approved protocol must be forwarded to the Human Research Multilateral Review Board (HRMRB) for their review.

On-orbit Consent

There are several reasons that could necessitate an On-Orbit Human Research Consent:

- New Study that was not ready in time to be pitched in the initial or delta Informed Consent Briefings
  - **THIS CASE IS VERY RARE:** This refers to a new study that was not ready to be pitched preflight, but is IRB approved and has ***adequate*** justification to warrant an on-orbit consent
- Opportunity for additional research previously thought not possible (i.e. due to additional crew time availability)
  - This is for a study that the crewmember has not signed a consent form, but it is an ***existing*** study that now has an opportunity to support additional subjects versus when it wasn't possible at the time complements were assigned.
- Change to an existing research protocol requiring additional in-flight data collection.
  - This is for changes that require additional in-flight or post-flight data collection ***AND*** one in which the crewmember has already signed a consent form and is a current subject.
- Re-instating a consented study previously removed from the complement.
  - This is for a study that the crewmember ***previously consented***. However, it was removed from complement due to resource availability reasons and NOT by crewmember request AND one in which the crewmember has already signed a consent form.
- Crewmember Mission Extension after launch
  - This is for a significant mission extension (i.e., from 6 months to 1 year) and not for a few week extension due to shifting launch/landing dates. (i.e. Vande Hei)

On-Orbit Consent, first steps…

- For all cases, before an on-orbit consent can be pursued, there are several steps that must be completed:
  - Does the study have all required IRB approvals?
  - Has the crew indicated they agreed to be contacted on orbit for additional research studies?
    - There is a place for them to indicate YES or NO on their initial Informed Consent Interest forms they fill our on the ground.
  - The IHRCWG investigates if the study can fit into the crew members' existing complement without violating constraints of the other studies, blood limit volumes, crew time limits, etc.
- If not, then no further actions should be taken.
- If all the above is accomplished, then the process can continue.

CASE 1

New Study:
Proposing Agency IHRCWG Representative submits Mini-ED and verification of IRB/MB approval to IHRCWG Coordinator (ROI)

THIS CASE IS VERY RARE: This refers to a new study that was not ready to be pitched preflight, but is IRB approved and has **adequate** justification to warrant an on-orbit consent

IHRCWG Coordinator (ROI) leads the investigation into determining* if study can fit within the crew member's existing complement without violating constraints of other studies, blood limit volumes, crew time limits, etc.

*This includes verifying the crew indicated they agreed to be contacted on orbit for additional research studies on their ICB interest form.
**for coordination purposes only

Can the study fit?
- No → STOP: No further actions should be taken.
- Yes →

Is it a NASA Study or requesting NASA Crew member participation?
- Yes → Submit Justification Statement for on orbit consent to IHRCWG Coordinator (ROI)**, HRP Chief Scientist and NASA IRB before proceeding
- No → Submit Justification statement to IHRCWG Coordinator (ROI)**, IP Agency Increment Scientist, and Agency & then NASA IRB/MB before proceeding

Verify approvals from Agency Scientists and IRB/MBs have been given to allow for an on-orbit consent?
- No → STOP: No further actions should be taken if approvals are not obtained.
- Yes →

PI develops on-orbit consent presentation (objectives, risks/benefits, requirements) and provides to the IHRCWG Coordinator (ROI)

IHRCWG Coordinator (ROI) coordinates review of presentation with the IRB/MB, crewmember's management and Flight Surgeon for concurrence. For ESA Crew, the Increment Manager is also involved in review of the presentation.

Do IRB/MB, crewmember management and Flight Surgeon concur with on orbit consent?
- No → STOP: No further actions should be taken after request is denied.
- Yes →

IHRCWG Coordinator (ROI) notifies NASA ISS Chief Scientist/IP Science Office and crew's agency Increment Manager of request & coordinates delivery of request to crewmember

Request for crew to review the consent presentation is delivered from the NASA IHRCWG representative to POIC POM (NASA) to provide privately to the crew. Time is provided on timeline as "Payload Review" and is allocated out of the proposing Agency's crew time for the crewmember to review. PI can be available to respond to any questions the crew may have, privately.

Crew member can respond or ask questions privately. Crew member either agrees or declines to participate.
END

Coercion, or appearance of coercion, is mitigated by keeping communication with the crewmember as private as possible.

CASE 2

This is for a study that the crewmember has not signed a consent form, but it is an existing study that now has an opportunity to support additional subjects versus when it wasn't possible at the time complements were assigned.

Opportunity for additional research previously thought not possible (i.e., due to additional crew time availability)

IHRCWG Coordinator (ROI) determines* if the study changes can fit within the crew member's existing complement without violating constraints of other studies, blood limit volumes, crew time limits, etc.

*This includes verifying the crew indicated they agreed to be contacted on orbit for additional research studies on their ICB interest form.

Can the study fit?

No → STOP — No further actions should be taken

Yes

IHRCWG Coordinator (ROI) coordinates with all IHRCWG representatives to review addition of the study to the complement and verifies with all members that addition of study is ok and that that the study and addition to crew complement are approved through the appropriate agency boards.

Was crew member previously briefed on this study and indicated interest on the Informed Consent form?

No → Use ***CASE 1*** Flow

Yes

PI develops on-orbit re-consent presentation detailing any differences from original informed consent briefing (includes impacts of additional sessions, additional risks/benefits, and additional requirements)

IHRCWG Coordinator (ROI) verifies that all IRB/MB approvals are obtained and coordinates review of presentation with the IRB/MB, crewmember's management and Flight Surgeon for concurrence. For ESA Crew, the Increment Manager is also involved in review of the presentation.

IHRCWG Coordinator (ROI) notifies NASA ISS Chief Scientist/IP Science Office and crew's agency Increment Manager of request & coordinates delivery of request to crewmember

Request for crew to review the consent presentation is delivered from the NASA IHRCWG representative to POIC POM (NASA) to provide privately to the crew. Time is provided on timeline as "Payload Review" and is allocated out of the proposing Agency's crew time for the crewmember to review. PI can be available to respond to any questions the crew may have, privately.

Crew member can respond or ask questions privately. Can also opt to withdraw from study vs. agree to more measures.
END

Coercion, or appearance of coercion, is mitigated by keeping communication with the crewmember as private as possible.

CASE 3

This is for changes that require additional in-flight or post-flight data collection ***AND*** one in which the crewmember has already signed a consent form and is a current subject.

Change in an EXISTING protocol
Proposing Agency IHRCWG Representative submits updated Mini-ED and verification of updated IRB/MB approval to IHRCWG Coordinator (ROI)

This is for a study that the crewmember previously consented. However, it was removed from complement due to resource availability reasons and NOT by crewmember request AND one in which the crewmember has already signed a consent form.

Re-instating a consented study previously removed from complement
Proposing Agency IHRCWG Representative submits updated Mini-ED and verification of updated IRB/MB approval to IHRCWG Coordinator (ROI)

IHRCWG Coordinator (ROI) determines* if the study changes can fit within the crew member's existing complement without violating constraints of other studies, blood limit volumes, crew time limits, etc.

*This includes verifying the crew indicated they agreed to be contacted on orbit for additional research studies on their ICB interest form.

Do the updated measures or reinstated study fit?

No → STOP → Either perform the study without the changes or remove the study from the crewmember's complement.

Yes → IHRCWG Coordinator (ROI) coordinates with all IHRCWG representatives to review additional measures/reinstated study, verify with all members that additions are ok and verify that all additions are approved through the appropriate agency boards.

PI develops on-orbit re-consent presentation detailing any differences from original informed consent briefing (includes impacts of additional sessions, additional risks/benefits, and additional requirements)

IHRCWG Coordinator (ROI) verifies that all IRB/MB approvals are obtained and coordinates review of presentation with the IRB/MB, crewmember's management and Flight Surgeon for concurrence. For ESA Crew, the Increment Manager is also involved in review of the presentation.

IHRCWG Coordinator (ROI) notifies NASA ISS Chief Scientist/IP Science Office and crew's agency Increment Manager of request & coordinates delivery of request to crewmember

Request for crew to review the consent presentation is delivered from the NASA IHRCWG representative to POIC POM (NASA) to provide privately to the crew. Time is provided on timeline as "Payload Review" and is allocated out of the proposing Agency's crew time for the crewmember to review. PI can be available to respond to any questions the crew may have, privately.

Crew member can respond or ask questions privately. Can also opt to withdraw from study vs. agree to more measures.
END

Coercion, or appearance of coercion, is mitigated by keeping communication with the crewmember as private as possible.

CASE 4

This is for a significant mission extension (i.e., from 6 months to 1 year) and not for a few week extension due to shifting launch/landing dates.

Crew member **Mission Extension** after launch:

Proposing Agency IHRCWG Representative submits Mini-ED and verification of IRB/MB approval to IHRCWG Coordinator (NASA)

IHRCWG Coordinator (ROI) coordinates with all IHRCWG representatives to review additional measures that need to be added to the research complement due to the crewmember mission extension.

PIs update IRB Protocols, as needed, to include any data collection changes and submit to applicable IRB/MB for approval.

IHRCWG Coordinator (ROI) develops an overview presentation to provide details on how the extension will impact data/sample collection during flight including additional or moved sessions. Presentation is sent out to IRHCWG members for review and approval.

IHRCWG Coordinator (ROI) verifies that all IRB/MB approvals are obtained and coordinates review of presentation with the IRB/MB, crewmember's management and Flight Surgeon for concurrence. For ESA Crew, the Increment Manager is also involved in review of the presentation.

IHRCWG Coordinator (ROI) verifies that all IRB/MB approvals are obtained and coordinates review of presentation with the IRB/MB, crewmember's management and Flight Surgeon for concurrence. For ESA Crew, the Increment Manager is also involved in review of the presentation.

IHRCWG Coordinator (ROI) notifies NASA ISS Chief Scientist/IP Science Office and crew's agency Increment Manager of request & coordinates delivery of request to crewmember

Request for crew to review the consent presentation is delivered from the NASA IHRCWG representative to POIC POM (NASA) to provide privately to the crew. Time is provided on timeline as "Payload Review" and is allocated out of the proposing Agency's crew time for the crewmember to review. PI can be available to respond to any questions the crew may have, privately.

Crew member can respond or ask questions privately. Can also opt to withdraw from study vs. agree to more measures.

END

Coercion, or appearance of coercion, is mitigated by keeping communication with the crewmember as private as possible.

In Summary…

- This process has been followed for several years, this is just the official documentation of the process.
- Concurrence on process documentation obtained from CSA, ESA, JAXA and NASA (all IHRCWG members) as well as CB and OZ.
- It will be documented in OIP #XXXXX.
- It is VERY important for everyone to follow the policies for crew consent because they are set up to ensure that the code of US federal regulations for the protection of human research subjects are followed (14 CFR1230), as well as International protection laws as approved by the ESA Medical Board, CSA IRB and JAXA IRBs as well.
  - If the policies are not followed and situations like this continue to happen, the MB/IRBs will review the non-compliance of protocols. Depending on the situation the MB/IRBs could potentially suspend or terminate the study.
  - In addition, the MB/IRBs will be forced to report non-compliance to the appropriate US Federal/International offices of human research protections and the steps that were taken to ensure the protections of the human subjects (can approve as is, request changes, or request an investigation done).

Back-up

- Nominal Human Research Integration Timeline & Process Charts

Nominal Human Research Integration Timeline

Target Date	Schedule	Deliverable from PI Team
I-14 to 16 months	Draft Mini-ED for new experiments submitted to ROI to aid in conflict discussions at IHRCWG	Draft Mini Experiment document
I-14 months	Development of Experiment Complement Scenarios	
NLT two weeks before the Informed Consent Briefing (ICB)	**Individual experiment** approvals at JSC IRB, JAXA IRB, ESA Medical Board (MB), and Human Research Multilateral Review Board (HRMRB).	IRB board approvals; at a minimum, a crewmember's home agency must approve prior to the ICB for that crewmember
I-14 months	Finalized Mini-ED (i.e., signed by all parties)	Final Mini Experiment (if edits made)
I-12 to 13 months	Discussion of Complement Scenarios at IHRCWG and subsequent presentation to MRPWG	
I-12 to 13 months	**Informed Consent Briefings (presentations) for crewmembers launching in this increment**	**Presentation and Consent forms. PI will support crew briefing in person or via teleconference**
I-11 months	Discussion of Individual Complements at IHRCWG; subsequently forwarded to IRT or MRPWG. Once approved, ISC provides overview to individual crewmembers and obtains consent form signatures.	
NLT 3 weeks prior to BDC session	Test Readiness Review (TRR) approval (must be obtained prior to Baseline Data Collection [BDC], Instrumented Training, or Testing)	TRR package. ROI Increment Science Coordinator assists in scheduling TRR
I-9 months	Start of BDC	
I-6 months	Delta Consent Briefings as needed and as possible	IRB Approved Protocol
I-5months	Complement package and Data Sharing Plan (DSP) submitted to JSC IRB, JAXA IRB, ESA MB and HRMRB for approval	

Background

- Human research on ISS is constrained primarily by the following limited resources:
  - Crew Consent
  - Crew time: Preflight, Inflight, Postflight
  - Blood Volume Limits
  - Postflight crew time & crew interest/consent are the two most limiting resources affecting integrated human research missions.
- An international working group was developed in 2009 to collectively plan human research mission within these limited resources.
- There are more active human experiments than can be performed by any given crewmember.

History

- During ISS assembly phase – there were relatively few active human research experiments among all ISS Partners.
- A single crewmember could participate in all available experiments without violating blood limits or scheduling constraints.
- Starting with 6-person crew, the number of active human research experiments exceeded the limits of available postflight crew time between R+0 and R+11.
- Soon after, blood volume limits also became an issue
- The Research Operations and Integration Element (ROI) at JSC (via its Increment Science Coordinators) organized the first meetings of what would become the International Human Research Complement Working Group (IHRCWG) in 2009.
- After developing its current processes, the IHRCWG was formally chartered by the ISS Program via the Payloads Control Board (now Research Integration Control Board) in 2012.
  - ROI was tasked with running the IHRCWG on behalf of the ISSP.

IHRCWG Membership

- The ROI Charter assigns a JSC/ROI Increment Science Coordinator as the Chair of the working group, but membership is broadly open to the ISS International partner community of human research teams and allows for ad hoc additions as needed.
- Customarily each agency has assigned one or two representatives to the IHRCWG to represent two types of concerns:
  - Human Research Project Scientists or Managers
  - Mission Science representatives
- Including these two types of representatives ensures that agencies can simultaneously advocate for individual experiment needs as well as integrated agency priorities.

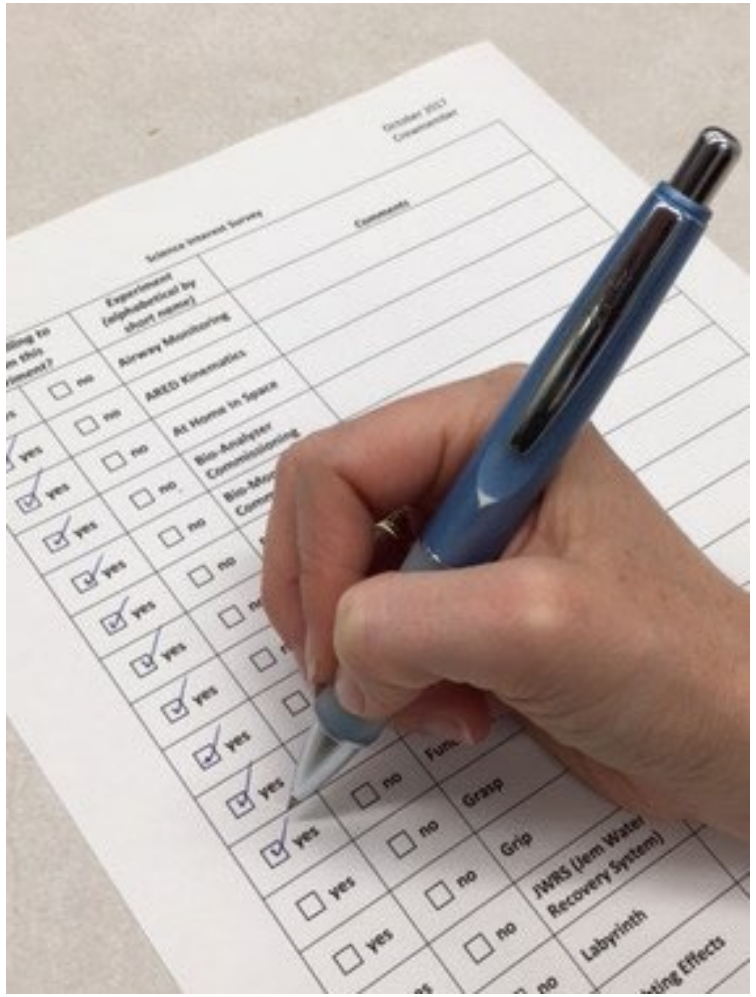
Complement Development Process Overview

- At the start of planning for each ISS Increment pair, a call is made at the IHRCWG to each agency for candidate experiments and a target matrix is created for each crewmember.
- Crewmembers are briefed on each Institutional Review Board (IRB)-approved experiment for which their participation has been requested by the sponsoring agency.
- Individual agencies alone are responsible for the number of experiments presented to a crewmember at an Informed Consent Briefing (ICB). Some agencies only target specific crewmembers due to crew time, budget, or other agency constraints.
- Any experiments not included in the initial target matrix are not included in the ICB.

The Informed Consent Briefing

- Each individual candidate investigation is presented to the crew by the study principal investigator
- Crewmembers are asked to consider each experiment on its own merits, without considering how an integrated set of experiments would affect his or her schedule
- Crewmembers are asked for their willingness to participate in the individual investigations by filling out an interest survey
- ROI integrates the preference to develop a feasible, customized complement
- Unless they ask, crewmembers are not informed of relative priorities to avoid the ethical dilemma of implied coercion

An Example Slide from the Crew Overview Briefing



Science Survey

- Check experiments you'd be willing to participate in
- Feel free to take notes on the survey or add any comments you want us to consider, e.g., "can't wait to do this ..."
- If you check "no," we'll consider your decision final & will remove it from future consideration
- Checking a box is NOT a commitment on your part

Complement Development Process Overview

- Following the ICB and the collection of crew interest surveys, the IHRCWG reconvenes and develops recommended research complements for each crewmember.
- Each crewmember is asked to return the survey within a week, although some crewmembers have indicated that they do not return their surveys until they confer with their management.
- All IHRCWG members review the list of experiments each crewmember is willing or unwilling to perform and agree to recommend a “best fit” experiment complement scenario for each individual.
- Each agency is invited to prioritize some of their experiments over others to ensure that each agency secures as much high priority science as possible (within the limits of crew consent).
- After IHRCWG approves the individual crew complements, they are taken to the Increment Research Team (IRT) or Multilateral Research Planning Working Group (MRPWG) for concurrence.
- The IHRCWG creates a discrete set of experiment complement scenarios, a set of experiments that can be conducted on a single crewmember without violating resource limits or science constraints, into which crewmembers may be assigned.
  - Each scenario includes a fully planned R+0-R+11 schedule, which is designed to optimize all available crew time for science and medical activities.
  - Scenarios also included integrated preflight schedules and blood volume analyses.

Example Target Matrix

- Each IHRCWG member indicates candidate experiments for each crewmember.
- It is highly recommended to pitch all experiments to all crewmembers to maximize flexibility when complements are selected.

	155/56			Participant Limit?
	Feustel	Gerst	Epps	
NASA HRP				
1-Carbon Poly (NEW)	X	X	X	
Biochem Profile	X	X*	X	
Dose Tracker	X	X	X	
Field Test	X	X	X	
Functional Immune	X	X	X	
Lighting Effects	X	X	X	
NeuroMapping	X	X	X	
Repository	X	X*	X	
Rx Metabolism	X	X	X	
Sprint	X	X	X	
NASA Research Office (ASI barter, SLPS, TDO, etc)				
SLPS - Microbial Tracking-2	X	X	X	Contingency subjects
CSA				
At Home in Space	X	X	X	
Marrow	X	X	X	
Vascular Echo	X	X	X	2
ESA				
Airway Monitoring		X	X	2 subj rqd
ARED Kinematics	X	X	X	
Circadian Rhythms	X	*	X	Gerst already performed exp
Energy	X	*		Contingency subject
ESA Active Dosimeter		X		Contingency subject
Grasp		X	X	
Grip		X	X	
Interact	X	X	X	To be included when ICB possible
Muscle Biopsy	X	X	X	
SARCOLAB-3		X		
Space Headaches	X	*	X	Gerst already performed exp
Straight Ahead	X	X	X	
Time Perception	X	X	X	-
JAXA				
Cerebral Autoregulation	X	X	X	
Cell-Free Epigenome (formerly Liquid Biopsy)	X	X	X	
IPVI	X	X	X	Contingency subjects
JEM Water Recovery System	X	X	X	Contingency subjects
Labyrinth	X	X	X	
Medical Proteomics (NEW - TBD)	X	X	X	
Multi-Omics	X	X	X	
Probiotics	X	X	X	

The Reason Scenarios Are Required

Experiment	Preflight BDC (hrs)	Postflight BDC (hrs)	Inflight (hrs)	R+0	R+1	R+2 Day off	R+3	R+4	R+5	R+6	R+7	R+8	R+9	R+10	R+11
Cerebral Autoregulation	2.00	1.50	6.00	<--	0.75	-->	-->								
Field Test	5.00	3.92	0	2.67							<--	<--	<--	1.25	-->
Grasp	12.00	8.00	>8.00								<--	<--	<--	2.00	2.00
Grip	7.25	7.50	17.75		0.50			0.58	0.58	0.58					
IPVI	2.25	1.50	0.75	0.75	-->	-->	-->								
Labyrinth	1.00	3.00	0	1.00	-->	-->									
Marrow	2.17	7.00	7.67	0.00	0.00	-->	0.25	-->	-->	-->	-->				
Microbial Tracking-2	1.50	2.25	14.25	0.50		0.08		0.08		0.08					
Multi-Omics	2.75	3.33	5.33	0.58	-->	-->	-->	-->							
Muscle Biopsy	1.00	1.00	0	1.00	-->										
NeuroMapping	8.33	14.67	2.67		-->	-->	-->	-->	3.67						
Probiotics	2.08	2.50	12.00	<--	0.25	-->	0.33								
Sarcolab -3 (w/ biopsy)	12.42	18.83	6.75	0.00	1.25		<--	1.42	2.75	<--	3.00	-->	-->	-->	
Sprint	17.17	13.92	34.00	1.75	0.67			0.33		0.67	0.00	<--	<--	1.00	
Straight Ahead	2.50	2.25	0	0.75	-->		<--	0.75	-->	<--	<--	0.75	-->	-->	
Time Perception	2.25	2.25	4.50	<--	0.75	<--	<--	0.75	-->	-->	<--	0.75	-->	-->	
Vascular Echo	4.38	12.78	12.75				0.00	1.42	1.22	0.25					
Circadian Rhythms	1.83	1.50	4.67	0.00							<--	<--	<--	0.25	0.42
Dose Tracker	4.58	0.17	4.00							<--	0.17	-->			
Functional Immune	2.33	3.50	9.00	0.13	0.17	0.04		0.04		0.21					
Repository	0.67	1.33	20.83				0.00								
Medical															
1.1	Clinical Asses			-->	1.00		1.00				-->	-->	-->	-->	-->
MR025L	Health Status Check					0.25		0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
1.6	Resting ECG			-->	-->	-->	0.25								
1.8	Hearing						0.33								
1.10	Opthalmology exam				-->	-->	2.50								
1.10	Opthalmology MRI				-->	-->		1.42							
1.10	Opthalmology Ultrasound				-->	-->	0.25								
2.1	Lab			0.00			0.25								
7.5	Psych eval						1.00							1.00	
8.1	Nutrition			0.25											
Total Time				9.38	5.33	0.38	6.16	7.04	8.72	2.04	3.42	1.75	0.25	6.25	2.67

Example Experiment Complement Scenarios

All Experiments	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring
ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics
At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space
Behavioral Core Measures	Behavioral Core Measures	Behavioral Core Measures	Behavioral Core Measures	Behavioral Core Measures
Bio-**Analyzer** Commissioning	Bio-**Analyzer** Commissioning	Bio-**Analyzer** Commissioning	Bio-**Analyzer** Commissioning	Bio-**Analyzer** Commissioning
Bio-**Monitor** Commissioning	Bio-**Monitor** Commissioning	Bio-**Monitor** Commissioning	Bio-**Monitor** Commissioning	Bio-**Monitor** Commissioning
Cell-Free Epigenome	Cell-Free Epigenome	Cell-Free Epigenome	Cell-Free Epigenome	Cell-Free Epigenome
Cerebral Autoregulation	Cerebral Autoregulation	Cerebral Autoregulation	Cerebral Autoregulation	Cerebral Autoregulation
Functional Immune	Functional Immune	Functional Immune	Functional Immune	Functional Immune
Grasp	Grasp	Grasp	Grasp	Grasp
Grip			Grip	Grip
JEM Water Recovery System	JEM Water Recovery System	JEM Water Recovery System	JEM Water Recovery System	JEM Water Recovery System
Labyrinth	Labyrinth	Labyrinth	Labyrinth	
Lighting Effects	Lighting Effects	Lighting Effects	Lighting Effects	Lighting Effects
Marrow	Marrow	Marrow	Marrow	Marrow
Medical Proteomics	Medical Proteomics	Medical Proteomics	Medical Proteomics	Medical Proteomics
Microbial Tracking-2	Microbial Tracking-2	Microbial Tracking-2		
Multi-Omics or Probiotics	Multi-Omics or Probiotics	Multi-Omics or Probiotics	Multi-Omics or Probiotics	Multi-Omics or Probiotics
Muscle Biopsy	Muscle Biopsy	Muscle Biopsy	Muscle Biopsy	Muscle Biopsy
NeuroMapping	NeuroMapping	NeuroMapping	NeuroMapping	NeuroMapping
One-Carbon Expansion	One-Carbon Expansion	One-Carbon Expansion	One-Carbon Expansion	One-Carbon Expansion
Patterns	Patterns		Patterns	Patterns
Repository	Repository	Repository	Repository	Repository
Soyuz Occupant Risk	Soyuz Occupant Risk	Soyuz Occupant Risk	Soyuz Occupant Risk	Soyuz Occupant Risk
Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches
Standard Measures	Standard Measures	Standard Measures	Standard Measures	Standard Measures
Straight Ahead	Straight Ahead			Straight Ahead
TBone	TBone	TBone	TBone	TBone
Team Task Switching	Team Task Switching	Team Task Switching	Team Task Switching	Team Task Switching
Time		Time	Time	
Vascular Echo		Vascular Echo		Vascular Echo
Veg-04	Veg-04	Veg-04	Veg-04	Veg-04
Vertebral Strength	Vertebral Strength	Vertebral Strength	Vertebral Strength	Vertebral Strength
Wayfinding	Wayfinding	Wayfinding	Wayfinding	Wayfinding

Complement Development Finalization

- After IRT or MRPWG concurrence, an Increment Science Coordinator from ROI delivers the crewmember an integrated summary presentation that offers a preview of all preflight, inflight, and postflight time commitments for the complement selected for him or her.
  - It is at this briefing that the crewmembers is then asked to formally sign consent forms.
- Because all these experiments had previously received positive interest from the crew, they typically sign up for all experiments during this overview presentation.
- After consent forms are collected, BDC and training can begin.

Exceptions to IHRCWG Processes

- The research complements developed by ROI and concurred upon by all IHRCWG members do not account for postflight crew time requirements not included in ISS Program documentation.
- E.g., additional postflight PAO/Media requirements at EAC that may exceed those stipulated in the ISS Program Postflight Mission Handbook are not accounted for.
- Some medical tests require differing implementation times at different centers. To the extent that the information is not known, those numbers may not be reflected in the experiment complement scenarios.
- The result of these exceptions may result in postflight duty days that exceed established limits when implemented outside JSC.
- In some cases the late addition of experiments may be facilitated on a case by case basis, but they are subject to procedural and legal limitations beyond the control of the IHRCWG.

Summary

- Crew science complements are constrained heavily by resource limitations like postflight time requirements.
- The complexity of the human research complement development process is entirely dependent on the number of active experiments and their corresponding resource demands.
- Because of ethical constraints applied by the JSC Institutional Review Board and other international Bioethics boards, there are limits as to how the research community may communicate its concerns to the crew.
- When in doubt – consult ROI at JSC.
- The mission of the IHRCWG is to balance the goals of multilateral human research portfolios with the most fundamentally limited resource – crew consent.