Human Research Program: ISS Medical Projects

Increment Planning for Experiments Using Human Subjects

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ISSMP Deputy Project Manager

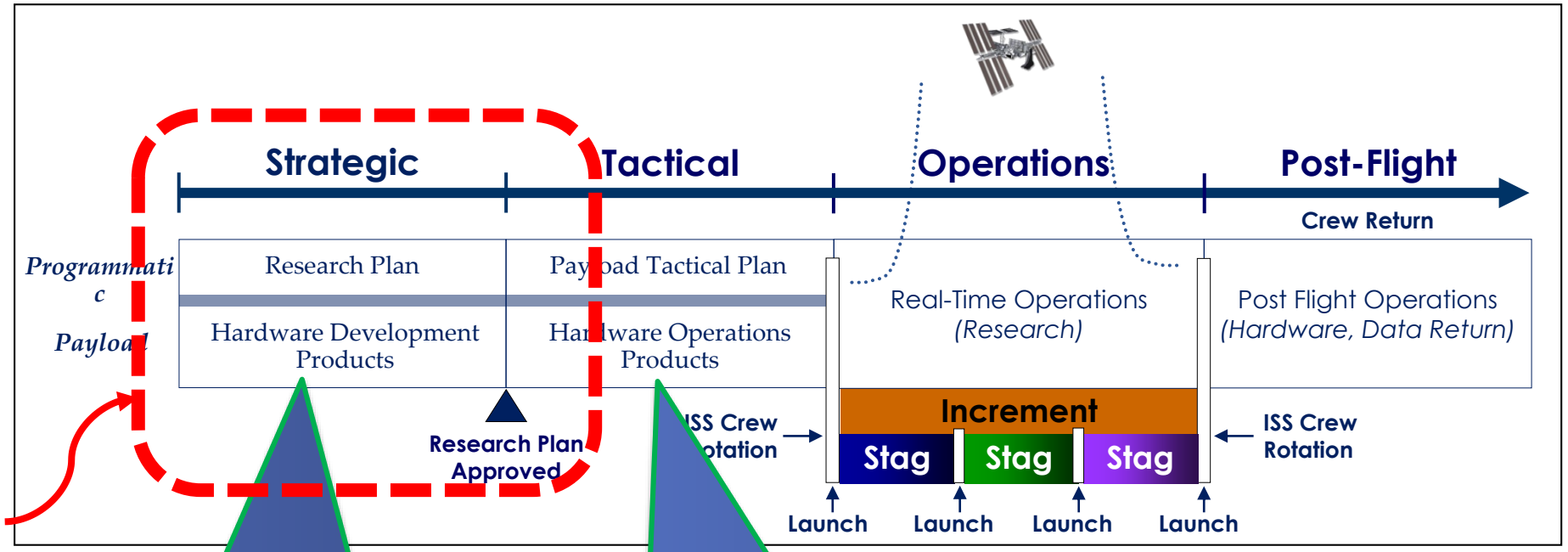
Purpose

- To explain the USOS (CSA, ESA, JAXA, NASA) process for coordinating USOS Human Research experiments for subsequent increment planning.

Agenda

- ISS Research Phases
- Increment Research Planning Timeline
- International Human Research Complement Working Group (IHRCWG)
- IHRCWG Responsibilities
- IHRCWG Human Research Planning Process
- Increment Research Planning Timeline Review
- Inc 53/54 Specific Planning Milestones for USOS Human Research
- Target Incr. 53 (52S) and 54 (53S) IRB Approval Schedule for Individual Experiments

ISS Research Phases



Focus of Discussion Today

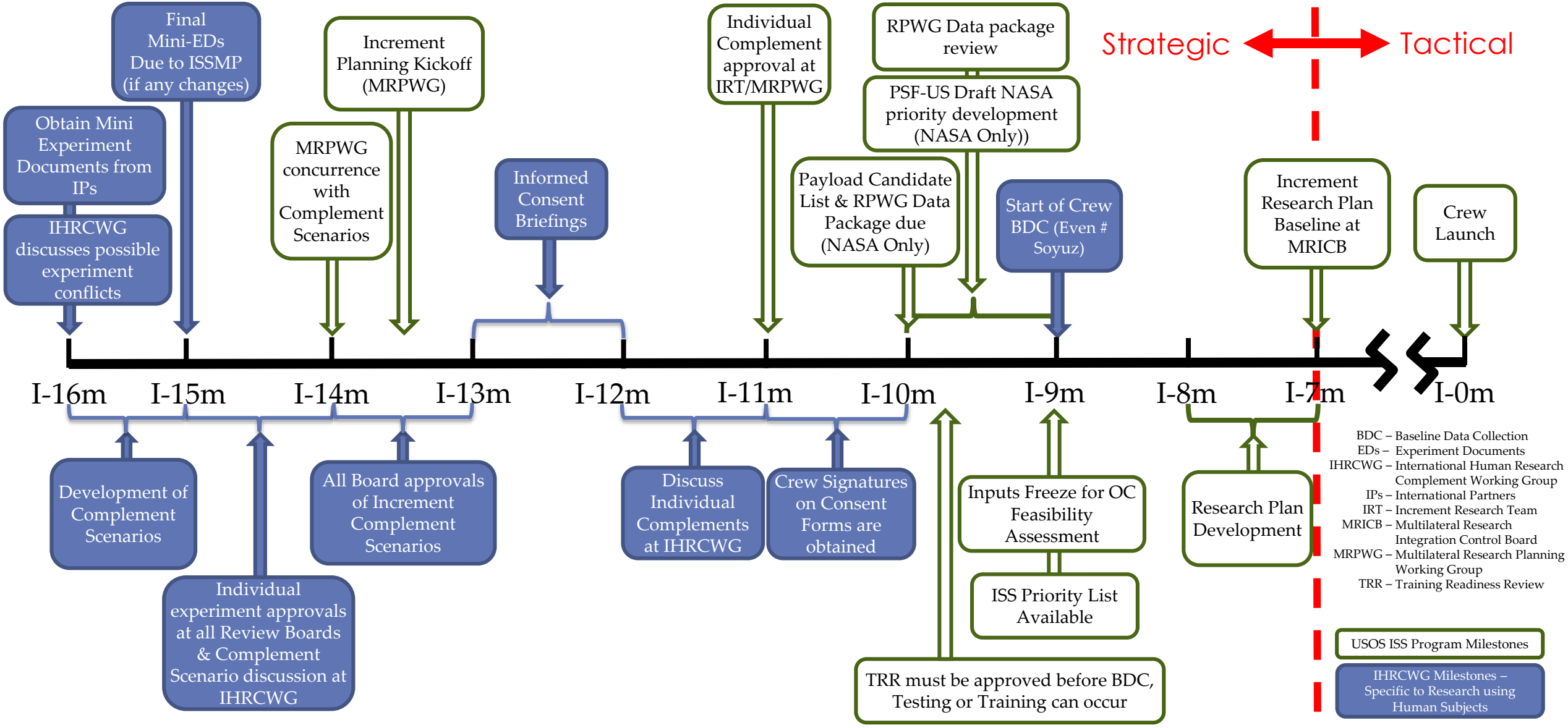
Payload Developer Inputs

WHO: Points of Contact
WHAT: Requirements Definition
WHEN: Operations Plan
WHERE: Launch & On-Orbit Requirements
WHY: Investigation Objectives

Payload Developer Inputs

- Changes to Baselined Research Plan
- Training Products and Procedures
- Safety Review Packages
- Hardware Verification Data
- Software Verification Data

USOS Increment Research Planning Timeline



IHRCWG

The International Human Research Complement Working Group (IHRCWG) was chartered by the Research Integration Control Board (RICB) to multilaterally coordinate ISS USOS human research plans for an increment in support of the Increment Research Plan produced by the Multilateral Research Planning Working Group (MRPWG). All reporting is done through the MRPWG.

IHRCWG Responsibilities

- Responsibilities of IHRCWG:
  - Develop Increment-specific, multilaterally integrated complement scenarios as part of the MRPWG increment research planning process.
  - Serve as a forum to identify science, scheduling and resource conflicts between human research investigations for all pre-, in- and post-flight human research sessions.
  - Provide recommendations for the complement scenario that best fits each individual crewmember after the Informed Consent Briefing (ICB) is presented and crewmember Interest Questionnaires are received.
  - Discuss new investigations that each agency anticipates implementing on future increments 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.
- The IHRCWG holds monthly teleconferences (usually 2nd Thursday of the Month)
- It is coordinated by the ISS Medical Projects (ISSMP) at Johnson Space Center (JSC), an organization within NASA's Human Research Program (HRP).
- Its membership is comprised of representatives of ISS partners:
  - NASA Increment Science Coordinators (ISCs)
  - Agency Increment Scientists or Mission Managers and Human Research Coordinators for CSA, ESA, JAXA and NASA.
  - Other ad-hoc members, as required (i.e. ASI with Inc 41/42 planning)

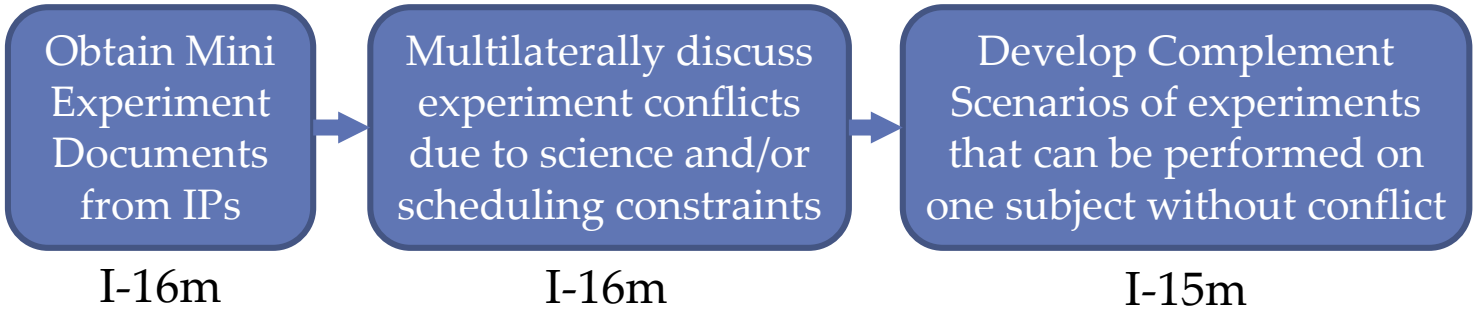
IHRCWG Human Research Planning Process

Obtain Mini Experiment Documents from IPs

I-16m

- Experiment Summary
- Operational Summary
- Pre-/Post-flight BDC Session Information
- Samples & Measurements Information
- BDC Hardware and Software required, only if BDC sessions will be scheduled at JSC
- Training required in addition to BDC that may be needed for the study

IHRCWG Human Research Planning Process

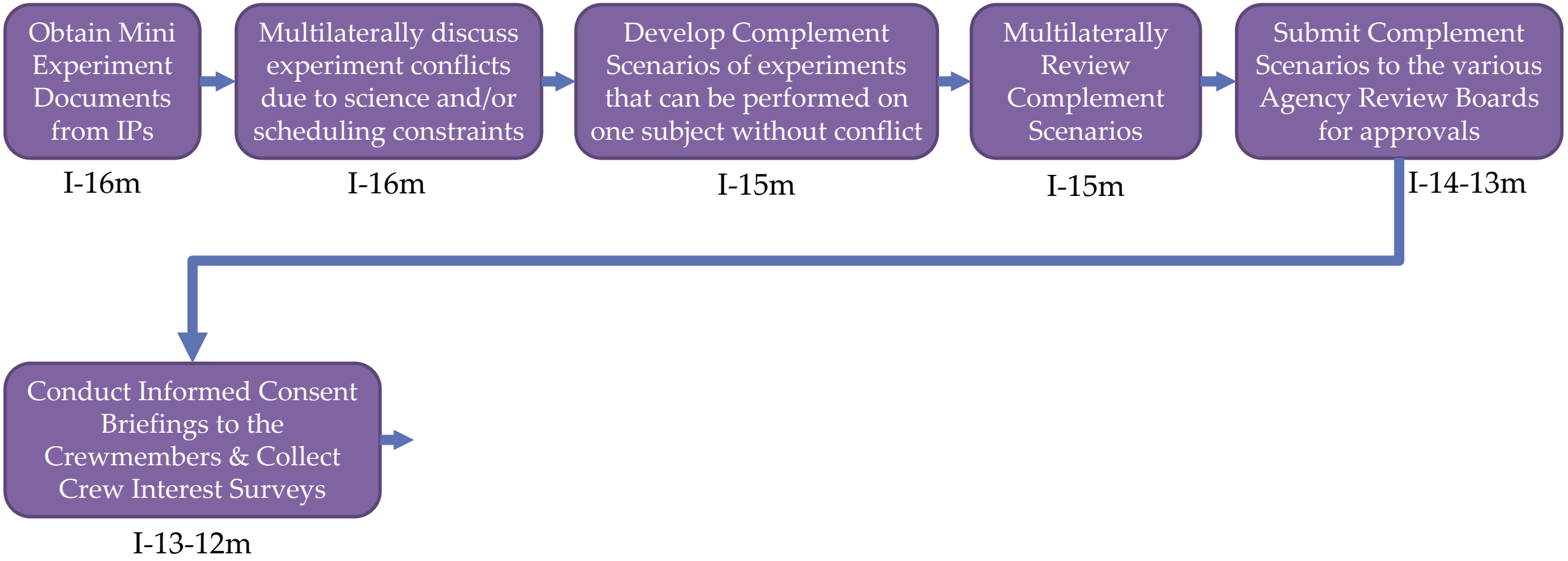


Complement Scenarios Example

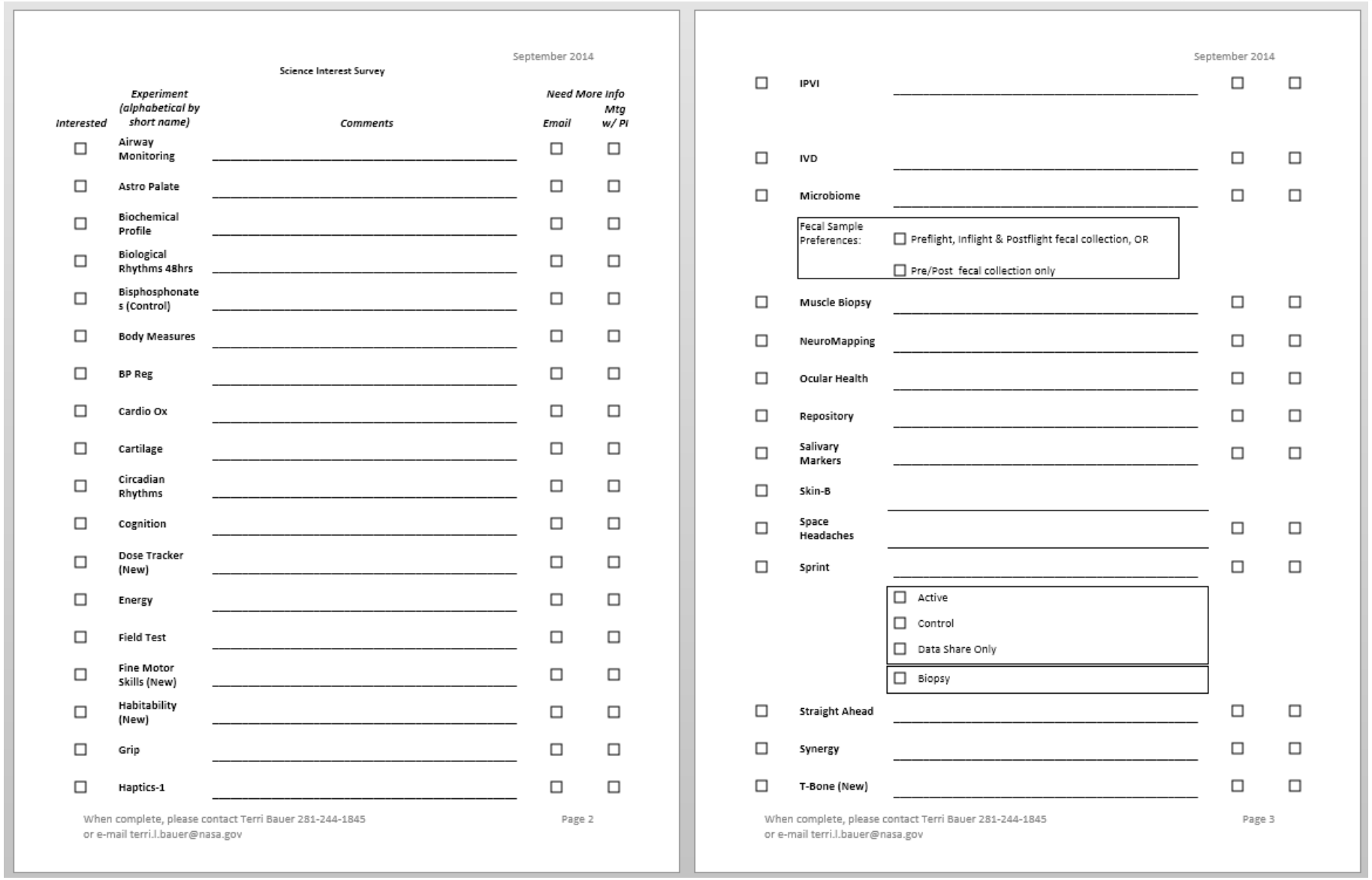
IXX/YY Complement Scenarios

ALL EXPERIMENTS	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6	Scenario 7	Scenario 8	Scenario 9
Cardio Ox		Cardio Ox	Cardio Ox	Cardio Ox	Cardio Ox	Cardio Ox	Cardio Ox	Cardio Ox	Cardio Ox
Cartilage	Cartilage	Cartilage	Cartilage			Cartilage	Cartilage		Cartilage
Cephalad Fluid		Cephalad Fluid						Cephalad Fluid	
Field Test								Field Test	Field Test
Fine Motor Skills		Fine Motor Skills		Fine Motor Skills	Fine Motor Skills		Fine Motor Skills		
Fluid Shifts		Fluid Shifts	Fluid Shifts	Fluid Shifts	Fluid Shifts	Fluid Shifts			Fluid Shifts
Grip			Grip						
IPVI	IPVI	IPVI	IPVI		IPVI	IPVI	IPVI	IPVI	IPVI
IVD	IVD				IVD				
Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow
Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics
Muscle Biopsy		Muscle Biopsy	Muscle Biopsy		Muscle Biopsy				
NeuroMapping				NeuroMapping	NeuroMapping		-		NeuroMapping
Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B
Sprint (no biopsy)	Sprint (no biopsy)								
Sprint				Sprint		Sprint	Sprint		
Straight Ahead	Straight Ahead	Straight Ahead		Straight Ahead		Straight Ahead	Straight Ahead	Straight Ahead	
Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy
Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance		Vascular Compliance	Vascular Compliance
Vascular Echo			Vascular Echo			Vascular Echo	Vascular Echo		
Minor Postflight Experiments									
ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics
Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring
Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate
At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space	At Home in Space
Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs	Bio Rhythms-48hrs
Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile
Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures
Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm
Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker
Energy	Energy	Energy	Energy	Energy	Energy	Energy	Energy	Energy	Energy
Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)
Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability
Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics
In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ
Repository	Repository	Repository	Repository	Repository	Repository	Repository	Repository	Repository	Repository
Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches
TBone	TBone	TBone	TBone	TBone	TBone	TBone	TBone	TBone	TBone
Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres
Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention

IHRCWG Human Research Planning Process



Example of Crew Interest Survey



September 2014

Science Interest Survey

Interested	Experiment (alphabetical by short name)	Comments	Need More Info: Email	Need More Info: Mtg w/ PI
☐	Airway Monitoring		☐	☐
☐	Astro Palate		☐	☐
☐	Biochemical Profile		☐	☐
☐	Biological Rhythms 48hrs		☐	☐
☐	Bisphosphonates (Control)		☐	☐
☐	Body Measures		☐	☐
☐	BP Reg		☐	☐
☐	Cardio Ox		☐	☐
☐	Cartilage		☐	☐
☐	Circadian Rhythms		☐	☐
☐	Cognition		☐	☐
☐	Dose Tracker (New)		☐	☐
☐	Energy		☐	☐
☐	Field Test		☐	☐
☐	Fine Motor Skills (New)		☐	☐
☐	Habitability (New)		☐	☐
☐	Grip		☐	☐
☐	Haptics-1		☐	☐

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or e-mail terri.l.bauer@nasa.gov

Page 2

September 2014

☐	IPVI		☐	☐
☐	IVD		☐	☐
☐	Microbiome		☐	☐
	Fecal Sample Preferences: ☐ Preflight, Inflight & Postflight fecal collection, OR ☐ Pre/Post fecal collection only			
☐	Muscle Biopsy		☐	☐
☐	NeuroMapping		☐	☐
☐	Ocular Health		☐	☐
☐	Repository		☐	☐
☐	Salivary Markers		☐	☐
☐	Skin-B			
☐	Space Headaches		☐	☐
☐	Sprint		☐	☐
	☐ Active ☐ Control ☐ Data Share Only			
	☐ Biopsy			
☐	Straight Ahead		☐	☐
☐	Synergy		☐	☐
☐	T-Bone (New)		☐	☐

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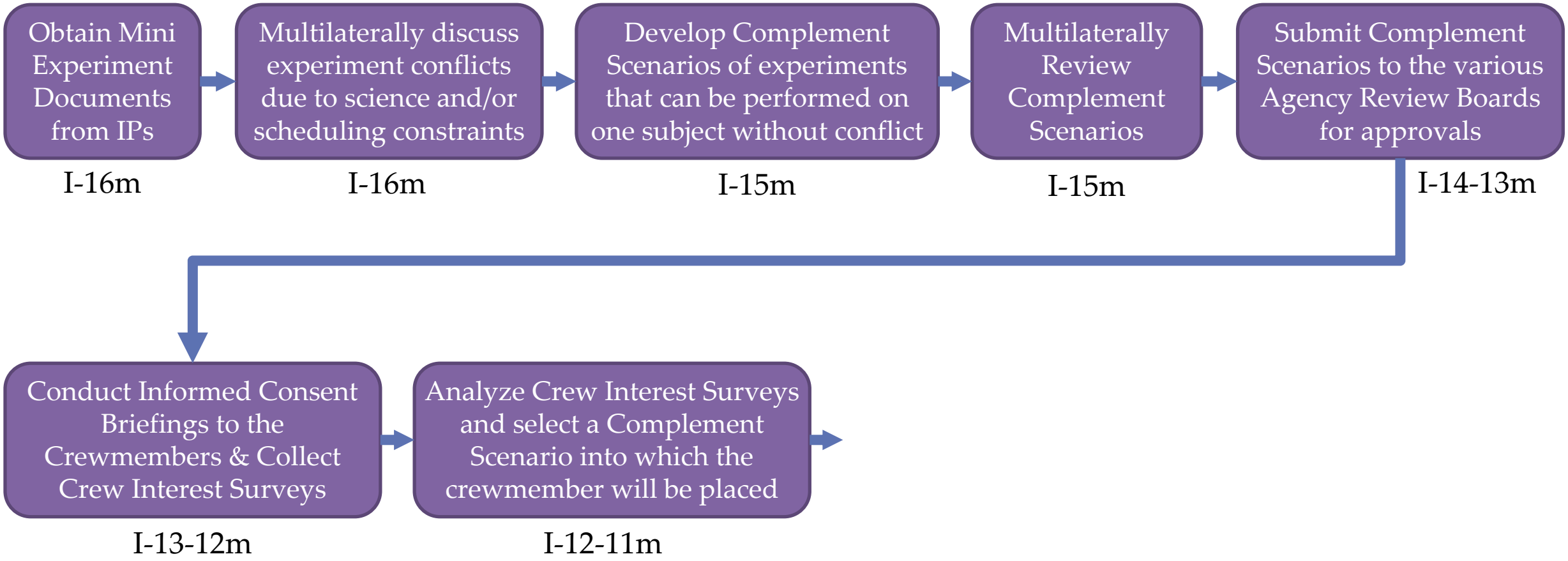
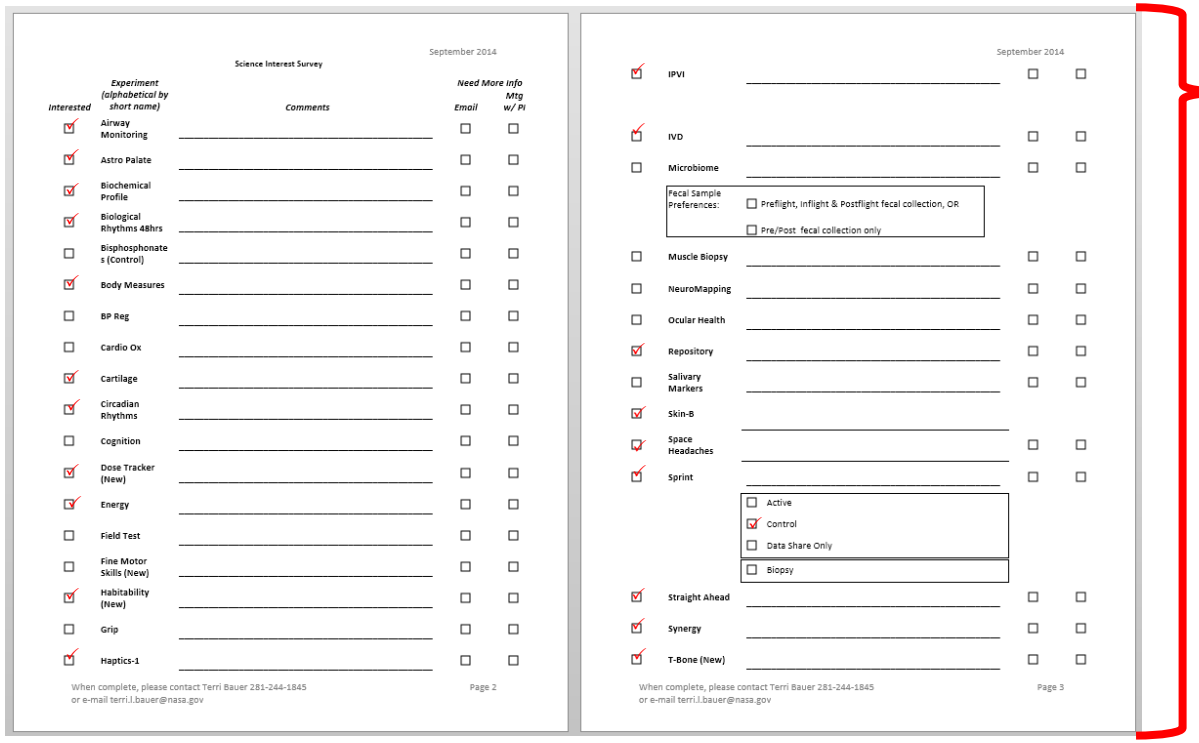
Page 3

IHRCWG Human Research Planning Process



Example of Crew Interest Survey



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Page 2

September 2014

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☑	Skin-B		
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Page 3

IXX/YY Complement Scenarios

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Cephalad Fluid		Cephalad Fluid						Cephalad Fluid	
Field Test								Field Test	Field Test
Fine Motor Skills		Fine Motor Skills		Fine Motor Skills	Fine Motor Skills		Fine Motor Skills		
Fluid Shifts		Fluid Shifts	Fluid Shifts	Fluid Shifts	Fluid Shifts	Fluid Shifts			Fluid Shifts
Grip			Grip						
IPVI	IPVI	IPVI	IPVI		IPVI	IPVI	IPVI	IPVI	IPVI
IVD	IVD				IVD				
Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow	Marrow
Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics	Multi-Omics
Muscle Biopsy		Muscle Biopsy	Muscle Biopsy		Muscle Biopsy				
NeuroMapping				NeuroMapping	NeuroMapping				NeuroMapping
Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B	Skin B
Sprint (no biopsy)	Sprint (no biopsy)								
Sprint				Sprint		Sprint	Sprint		
Straight Ahead	Straight Ahead	Straight Ahead		Straight Ahead		Straight Ahead	Straight Ahead	Straight Ahead	
Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy	Synergy
Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance	Vascular Compliance		Vascular Compliance	Vascular Compliance
Vascular Echo			Vascular Echo			Vascular Echo	Vascular Echo		
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ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics	ARED Kinematics
Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring	Airway Monitoring
Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate	Astro Palate
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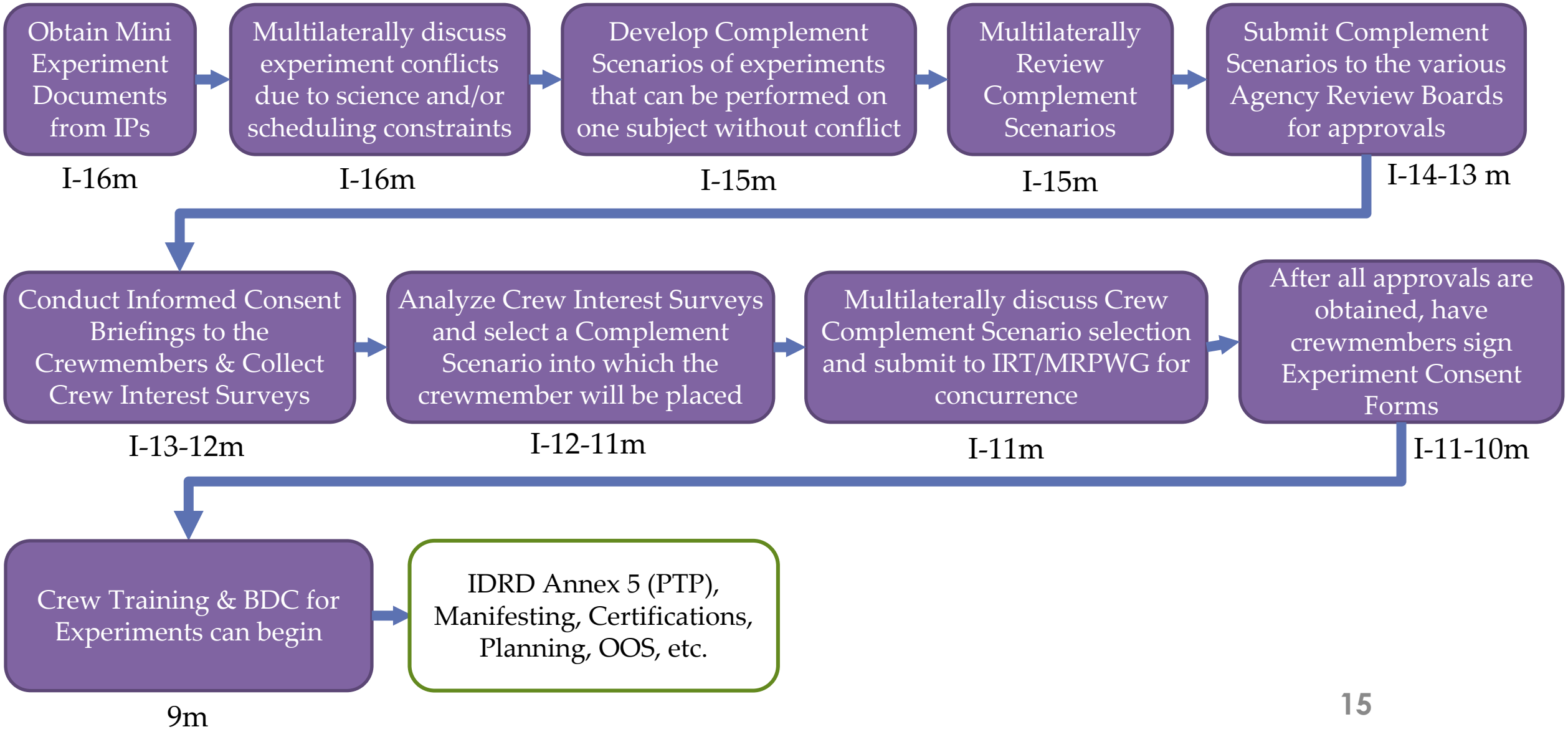
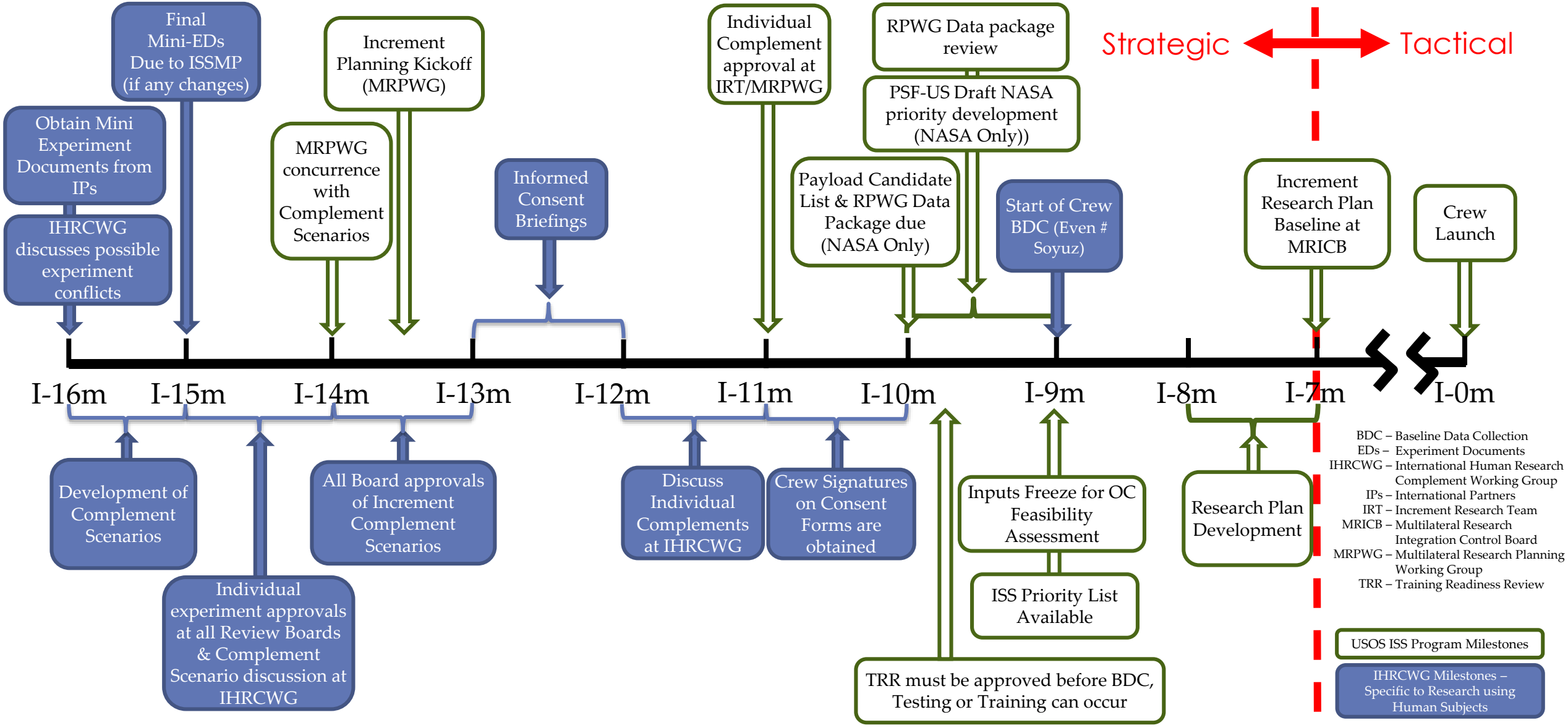
Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile	Biochem Profile
Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures	Body Measures
Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm	Circadian Rthm
Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker	Dose Tracker
Energy	Energy	Energy	Energy	Energy	Energy	Energy	Energy	Energy	Energy
Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)	Energy (control)
Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability	Habitability
Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics	Haptics
In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ	In-Situ
Repository	Repository	Repository	Repository	Repository	Repository	Repository	Repository	Repository	Repository
Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches	Space Headaches
TBone	TBone	TBone	TBone	TBone	TBone	TBone	TBone	TBone	TBone
Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres	Telomeres
Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention	Training Retention

IHRCWG Human Research Planning Process



USOS Increment Research Planning Timeline



USOS Human Research Inc 52/53 Specific Planning Milestones

Target Date	Deliverable	Submittal Due
19 May 2016	Draft Mini-ED for new experiments and updates for existing experiments to HRP	
June - October 2016 meetings	**Individual experiment** approvals at NASA IRB, JAXA IRB, ESA MB and HRMRB for 52S and 53S (unless on periodic renewal). Includes approval of page changes to existing protocols. **See slide 2 for IRB schedules**.	
16 June 2016	Finalized Mini-ED	
01 August 2016	MRPWG Concurrence with 52S and 53S Complement Scenarios	
September/October 2016	NASA IRB, JAXA IRB, ESA MB and HRMRB approval of **52S and 53S Complements** • NASA IRB: Meeting Date – 15 September 2016 • ESA MB: Meeting Date – 15 September 2016 • JAXA IRB: Meeting Date – 11 October 2016 • HRMRB: Meeting Date – 26 October 2016	18 August 2016 (ESA MB)
Mid-September 2016	52S and 53S Informed Consent Briefings (presentation)	4 weeks before
25 October or 01 November 2016	IRT Approval of Individual Crewmember Complements	
NLT 3 weeks prior to session	TRR approval (must be obtained prior to BDC, Instrumented Training, or Testing)	
29 December 2016	Start of BDC with 52S Crew (~L-9 months)	
27 February 2017	Start of BDC with 53S Crew (~L-9 months)	
~29 September 2017	Launch of 52S Crew	
~29 November 2017	Launch of 53S Crew	

Assumptions: • 52S Crew: 1 US and 2 FSA crewmember • 53S Crew: 1 US, 1 JAXA, and 1 FSA crewmember

No FSA crewmember participation planned at this time.

Target Incr. 53 (52S) and 54 (53S) IRB Approval Schedule for Individual Experiments

- The following table provides "No Later Than" deadlines for individual experiment approvals at all IRBs in order to be included in the Incr. 53/54 complement package.
- It is highly recommended that sponsoring agency IRB review be targeted at least one month prior to submitting to other agency IRBs since action items from the home IRB need to be closed prior to submittal to other agency IRBs.
- Sponsoring agency IRB approval is needed at least six weeks prior to the ICB (01 Aug 2016) since CB review of ICB presentations will not be requested for protocols without sponsoring agency IRB approval.

Sponsoring Agency	Meeting Dates	Submittal Due
NASA/CSA	• NASA IRB: Meeting Date – 16 June (19 May highly recommended) • ESA MB: Meeting Date – 18 August 2016* • JAXA IRB: Meeting Date – 30 August 2016 • HRMRB: Meeting Date – 26 October 2016	NASA IRB: 30 May 2016 (02 May recommended) ESA MB: 21 July 2016 JAXA IRB: 19 July 2016 HRMRB: 26 September 2016
ESA	• ESA MB: Meeting Date – 16 June (19 May highly recommended) • NASA IRB: Meeting Date – 18 August 2016 • JAXA IRB: Meeting Date – 30 August 2016 • HRMRB: Meeting Date – 26 October 2016	ESA MB: 19 May 2016 (21 April recommended) NASA IRB: 01 August 2016 JAXA IRB: 19 July 2016 HRMRB: 26 September 2016
JAXA	• JAXA IRB: Meeting Date – 12 July 2016 (01 June highly recommended) • NASA IRB: Meeting Date – 18 August 2016 • ESA MB: Meeting Date – 18 August 2016* • HRMRB: Meeting Date – 26 October 2016	JAXA IRB: 31 May 2016 (20 April recommended) NASA IRB: 01 August 2016 ESA MB: 21 July 2016 HRMRB: 26 September 2016

* No ESA crewmember in I53/54; however, ESA MB review will help to avoid issues at HRMRB

Backup Charts

Increment Planning Milestones

Target Date	Deliverable
I-16 months	Obtain Mini-EDs for new experiments and updates for existing experiment's Mini-EDs from IPs to ISSMP; ISSMP leads IHRCWG discussion on possible experiment conflicts
I-15-16 months	Development of Experiment Complement Scenarios
I-15 months	Finalized Mini-ED (i.e., signed by all parties)
NLT I-14 to 15 months	**Individual experiment** approvals at JSC IRB, JAXA IRB, ESA Medical Board (MB), and Human Research Multilateral Review Board (HRMRB) unless on periodic renewal. Includes approval of page changes to existing protocols. Complement Scenario discussion at IHRCWG.
I-14 months	MRPWG concurrence with Complement Scenarios
I-13 to 14 months	JSC IRB, JAXA IRB, ESA MB and HRMRB approval of **Increment Complement Scenarios**
I-13.5 months	Kick off of increment planning at MRPWG
I-12 to 13 months	Informed Consent Briefings (presentation) for crewmembers launching in this increment (both primes and backup) and receipt of the crewmembers interest forms.
I-12 months	Initial Data Packages due to MRPWG (PTP, 1-pagers, initial SRTD) & Candidates due to OD
I-11 months	Individual Complement approval at IRT.
I-10-11 months	Obtain Crew signatures on Experiment Consent Forms, make changes to baselined Increment Research Plan at MRICB if required due to crew consents that are different from assumptions made in research planning.
I-10 months	Payload Candidate List & RPWG Data Package Due (NASA Only)
I-10-11 months	Research Plan Development
I-9 to 10 months	RPWG Data Package Review
I-9 to 10 months	PSF-US Draft NASA Priority Development (NASA only)
NLT 3 weeks prior to 1st BDC	TRR approval (must be obtained prior to BDC, Instrumented Training, or Testing)
~I-9 months	Start of BDC with even-numbered Soyuz Crew
I-9 months	Inputs Freeze for OC Feasibility Assessment
I-9 months	ISS Priority List Available
I-7 to 8 Months	Research Plan Development
I-7 months	Increment Research Plan Baseline at MRICB

Shaded rows indicate IHRCWG Planning Milestones

Acronym List

- BDC – Baseline Data Collection
- ESA MB – European Space Agency Medical Board
- HRMRB – Human Research Multilateral Review Board
- HRP – Human Research Program
- I- - Increment Minus
- ICB – Informed Consent Briefing
- IHRCWG – International Human Research Complement Working Group
- IP – International Partner
- IRB – Institutional Review Board
- IRT – Increment Research Team
- ISC – Increment Science Coordinator
- ISSMP – International Space Station Medical Project
- (M)RPWG – (Multilateral) Research Planning Working Group
- PI – Principal Investigator
- TRR – Test Readiness Review