Human-in-the-Loop:

IRB Approval & Informed Consent for Human in the Loop Testing/Tech Demos/ Engineering Evaluations

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What is ISSMP?

- ISSMP represents the Human Research Program (HRP) to the International Space Station (ISS) Program.
- Our PRIMARY role is to provide end-to-end support to HRP-funded research that requires flight subjects.
- Our SECONDARY role is to provide some integration and coordination functions for the USOS International Partners (IPs) and other research or operational organizations that require a human-in-the-loop for research, tech demos and engineering evaluations.
  - We coordinate crew consent for all human-in-the-loop activities – with the exception of Rodent Research studies.

What is an IRB?

- An Institutional Review Board (IRB) is a committee operating under Federal regulations (Code of Federal Regulations Title 21), that reviews research involving human subjects to ensure the ethical, safe, and equitable treatment of the subjects.
- IRBs are a direct result of several research abuses of the 20th century, the most notorious of these being the experiments carried out by Nazi physicians.
  - The result of these abuses was the National Research Act of 1974 and the development of the Federal Policy for the Protection of Human Subjects in the United States. Most other developed countries also have their version of IRB laws.
  - These laws require that subjects give their voluntary, uncoerced "informed consent" PRIOR to performing tests/procedures that the IRB has approved.

What requires Informed Consent?

- Informed Consent is required for any payload that involves human-in-the-loop activities. Other activities that may (or may not) require consent include studies that collect/require information that could be considered private. Recent examples of the latter include:
  - Questionnaires with queries about a crewmember's thoughts or feelings
  - Recording of keystrokes during an activity for error analysis
  - Requests for the crewmember to provide information that is considered private, such as height, weight, age, blood pressure, etc.
- WHEN IN DOUBT, the JSC IRB should be contacted (https://irb.nasa.gov/?p=irbContactInfo) with a description of the activity so that they can provide a determination as to whether or not consent is required.

IRB & Informed Consent for ISS

- For human use payloads that require IRB approval and Informed Consent of the crew, approval from the following boards is required:
  - JSC IRB – all NASA studies, all studies seeking NASA crewmember participation and all studies performing pre- or post-flight BDC at JSC.
  - ESA Medical Board - if seeking ESA crewmember participation
  - JAXA IRB - if seeking JAXA crewmember participation
  - Human Research Multilateral Review Board HRMRB) – all studies regardless of crewmember-subject's agency affiliation

What is Human-in-the-Loop?

- Human-in-the-loop testing is often a component of human research studies; however, it also refers to hardware tests and evaluations conducted by other studies where a human (subject) is required to interface in some manner with the hardware being tested.
  - These hardware tests/evaluations do not involve human research of the type normally reviewed by the IRB, but have the potential of exposing test subjects to some amount of risk to their safety and well-being and thus must be reviewed.
  - More information on specific guidelines of the IRB for Human-in-the-Loop hardware tests and evaluations can be found here: http://irb.nasa.gov/?p=crStudyGuidance#tocGroundBasedStudyHumanInTheLoop
  - As mentioned, WHEN IN DOUBT….contact the IRB (http://irb.nasa.gov/?p=irbContactInfo)

What can ISSMP do for you?

- With the exception of rodent research, ISSMP organizes the USOS crew Informed Consent Briefings (ICBs) for experiments that the IRB has determined require informed consent. The ISS Program has delegated responsibility to ISSMP for:
  - Integrating your study/demonstration into the crew's overall complement during the ISS Strategic Planning phase.
  - Including your study/demonstration in the crew's ICB package (briefing opportunities are very limited).
  - Collecting crew signatures on your study/demonstration's consent form and provide the documentation back to you.
- Individual Payloads are not allowed to approach the crew for consent; they must be integrated into the process by ISSMP.

IHRCWG

- The International Human Research Complement Working Group (IHRCWG) is coordinated by ISSMP (SD2) and is chartered by the Payloads Control Board (now RICB) to coordinate all human use research activities for an increment in support of MRPWG.
  - IHRCWG is chaired by ISSMP.
  - Membership includes Increment Scientists or Mission Managers and the human research coordinators for CSA, ESA, JAXA, and NASA.
  - E-mail distribution also includes the RPWG Chair, LISs, ASI representatives, and RPMs/RIMs/PIMs for experiments known to require humans-in-the-loop.
    - Although no confidential/private information is distributed for or discussed at meetings, much of the material is considered “need to know” so distribution is limited.
    - If you feel that you have a need to know and should be included on distribution, contact information is on the last slide.

IHRCWG (continued)

- IHRCWG monthly telecon is used to:
  - 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 or limited human resource (e.g., blood volume, early post-flight crew time)
  - Develop research complement scenarios (sets of experiments that can be conducted on a single individual within constraints/allowable limits) and select a scenario for each crewmember based on that individual's interests and each agency's priorities
  - Discuss target milestone schedule for each increment to ensure readiness of individual studies for crew briefing

IHRCWG Target Milestone Schedule

Presented at RPWG around I-18 months

Target Date	Schedule	Deliverable from PI Team
I-16 months	Draft Mini-ED for new experiments submitted to ISSMP to aid in conflict discussions at IHRCWG	Draft Mini Experiment document
I-15 months	Development of Experiment Complement Scenarios	
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).	IRB board approvals
I-14 to 15 months	Discussion of Complement Scenarios at IHRCWG and subsequent presentation to MRPWG	
I-14 months	Finalized Mini-ED (i.e., signed by all parties)	Final Mini Experiment (if edits made)
I-13 to 14 months	JSC IRB, JAXA IRB, ESA MB and HRMRB approval of **Increment Complement Scenarios**	
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 telecon**
I-11 months	Discussion of Individual Complements at IHRCWG and subsequent presentation to MRPWG. Once approved, crew signs research consent forms.	
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. ISSMP Increment Science Coordinator assists in scheduling TRR
I-9 months	Start of BDC	

IHRCWG Target Milestone Schedule
Delta Informed Consent Briefing

To be presented at RPWG around I-12 months

Target Date	Schedule	Deliverable from PI Team
NLT I-9 to 10 months	**Individual experiment** approvals at JSC IRB, JAXA IRB, ESA MB, and HRMRB.	IRB approvals secured
I-9 months	Finalized Mini-ED due and IHRCWG discussion of studies on Delta list	Mini-ED provided
I-7 to 8 months	JSC IRB, JAXA IRB, ESA MB and HRMRB approval of **Delta Complement Package**	
I-6 to 7 months	**Delta Informed Consent Briefings for crewmembers launching in this increment**	**Presentation and Consent forms. PI will support crew briefing in person or via telecon**
I-6 months	Discussion of briefing results at IHRCWG and crewmembers sign consent forms	

- The initial ICB is recommended as the targeted timeline to ensure an opportunity to brief the crew; however, a Delta ICB is typically scheduled with the crewmembers at ~L-6 months
- Experiments targeting the Delta ICB will be assessed to ensure they can be accommodated (BDC crew time, blood volumes, etc.) with a crewmember's existing science complement. If it doesn't fit into the crewmember's existing complement, it will not be pitched.
- Good candidates for the Delta ICB are protocols with little to no pre/post-flight BDC and no unworkable conflicts with any of the studies in which the crewmember is already participating (from the initial ICB).

Informed Consent Briefing Process

- Crewmembers are given informed consent briefings on all experiments and human-in-the-loop hardware demonstrations per a target participation matrix. They are NOT shown the complement scenarios or asked to choose one.
- Crewmembers complete an interest survey to indicate level of interest in participation for each study they are pitched. These surveys are used to determine the “best fit” complement scenario for each crewmember.
- Proposed crew complements are reviewed at IHRCWG and concurred upon by MRPWG prior to obtaining signed consent forms from crewmembers. Actual crew participation can be any subset of a complement scenario (each represents a maximum number of studies that will fit together).

Informed Consent Briefing Process (continued)

- Crewmembers are approached only 1-2 times before they fly to request their participation in studies so the process does not feel coercive and they do not feel obligated to participate when they do not want to.
- For this same reason, an inflight ICB is HIGHLY discouraged and only allowable under very special circumstances that must be vetted and approved by the various IRBs involved.
- It is imperative to have a coordinated, vetted effort going into the ICB so that any science or operational conflicts are identified early and can be easily mitigated before implementation to prevent loss of science or loss of evaluation opportunity on orbit.

Crew Consent

- If your study/demonstration is included in the complement approved for a given crewmember, ISSMP will provide the crew with your Consent Form and collect their signature.
- Once signatures are collected, a copy will be provided back to you.

What to take away from this presentation…

- If you are using humans as test subjects or “in the loop” for tech demos or engineering evaluations, CONTACT THE JSC IRB EARLY to see if your project requires crew consent.
  - If you are unsure if your payload is “human-in-the-loop”, ASK THE JSC IRB.
- Be aware of the TARGET MILESTONES FOR INFORMED CONSENT for human-in-the-loop studies, tech demos or engineering evaluations.
  - Milestones are updated for every increment pair and distributed around I-18 months!
- LET ISSMP HELP GUIDE YOU. We have been tasked by the ISS program to provide this service, so please take advantage of our expertise.

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