Human Research Program Flight Experiment Information Package

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Introduction

This Flight Experiment Information Package (FEIP) will provide some basic information for investigators proposing human life sciences studies for the International Space Station (ISS). Top level information is provided regarding restrictions on performing flight research, and reference information is provided on research hardware that is available for investigator use.

1.0 Guidelines for Human Life Sciences Flight Investigations

Implementation of human life sciences research during space flight is limited by various resource constraints such as crew time (before, during, and after flight), up and down mass, and cold stowage. Thus, experiments that require fewer of these resources will be more feasible to implement. Investigators should carefully consider the constraints outlined in this document when developing their protocol requirements, keeping in mind that technical feasibility will be considered in the selection process. Technical feasibility will be primarily determined based on the data provided in the Flight Experiment Resource Worksheet, and care should be taken to ensure this is accurately and thoroughly filled out in its entirety.

Flight experiment proposals must represent mature studies strongly anchored in previous or current ground-based or flight research. For a flight experiment proposal, ground-based research should be limited to activities that are essential for the final development of an experiment for flight, such as definition of flight procedures and control activities for the flight experiment. In this case, only one (flight) proposal needs to be submitted.

1.1 Flight Resource Requirements

This section will provide investigators with additional information about the most constrained flight resources and provide an indication of how much of a given resource is likely to be perceived as “too much” and would therefore be difficult to implement. This information should assist investigators in determining the flight resource requirements for the investigation that must be documented in the Flight Experiment Resource Worksheet. In each case below, the values given for what is difficult to implement are provided as a guideline only; each investigation will be assessed for technical feasibility in its entirety.

1.1.1 Flight Hardware and Software

Background: There are many research tools available to investigators who wish to conduct human physiological research on ISS. The Human Research Facility (HRF) is a suite of hardware that provides core capabilities to enable research on human subjects. HRF consists of items mounted on two racks located in the Columbus module, as well as separate equipment kept in stowage and brought out as needed. HRF Racks 1 and 2 are currently on orbit and are regularly used for data collection and downlink of experiment data. More information on the currently available HRF flight hardware can be found in the ISSMP On-Orbit Hardware.pdf provided with this package. Additional information on all available facilities on ISS can be found at:
http://www.nasa.gov/mission_pages/station/research/facilities_category/index.html

Hardware is available on board ISS for investigations that require conditioned storage of samples. Information about these facilities can be found at: http://www.nasa.gov/mission_pages/station/research/facilities_category/index.html under Multipurpose: Refrigerator or Freezer section.

Some investigators may wish to develop their own special experiment hardware to work in conjunction with the facilities and functional capabilities of existing hardware. Development of experiment-unique equipment will require additional funding, which may negatively impact the overall assessment of the experiment feasibility. Design, construction, and flight of major experiment-unique equipment hardware items or facilities usually require the commitment of large quantities of resources (power, crew time, volume). In the event that such items are proposed, they should be clearly identified, including a detailed description and indication of overall size, power required, how data is obtained, and interfaces to the crew. If commercially available hardware is required, the make and model of the hardware should be identified and a description provided of how it will be used in-flight.

Commercially available hardware is often more feasible to prepare for flight than custom made hardware, but it will still require additional funding in order to meet the requirements levied on all hardware flying to the ISS. It should not be assumed that any device can fly “as is” off the shelf. Proposals for major hardware items or facilities to be developed by the investigator will not be considered. With the retirement of the Space Shuttle, all hardware will be launched to ISS using an International Partner resupply vehicle or a US commercial vehicle. At this time, return of hardware and samples from the ISS will only be possible using US commercial vehicles, with a very limited capability on the Soyuz.

Investigators proposing to fly unique software will need to be prepared to comply with NASA standards and requirements. Unique software will require additional funding in order to meet the requirements levied on all software flying to the ISS. The requirements will be explained in detail during the definition phase upon selection, but overall guidelines and information regarding available platforms are provided below:

- Compatible with Windows 10 (64-bit) for laptop applications
- Software shall not require communication with a system outside the NASA domain while in use on the ground or outside the ISS while on orbit.
- The use of iPad apps is discouraged.
    - In the event an iPad app is required, PIs must provide a server side solution for data retrieval to be installed on the Station Support Computer server.
    - iPad apps must be compatible with multiple versions of iOS starting with iOS version 8.1.
    - No assumptions should be made regarding iPad hardware versions.
- File based data is preferred rather than real-time

Investigators should also make provision for maintenance of the software during the life of the experiment, including any capabilities required for post-experiment data processing upon return of the data to ground.

Investigators planning to reuse software need to include funding for any updates required due to change in available platforms and interfaces. If the software being reused was part of another experiment, the new investigator must arrange permissions to use the software from the previous experiment and provide funding for any updates required due to changes in requirements, platforms and interfaces.

Difficult to Implement:

- Any new flight hardware required. The extent of how difficult this development will be is dependent on how much design and development is required for custom made equipment and how extensive off the shelf equipment will have to be modified.
- Return of hardware for refurbishment or data retrieval. Down mass resources will be protected for critical science samples; data should be planned to be down linked and hardware will likely be discarded.
- Requirements for cold stowage that exceed the capabilities of the equipment identified on the cold stowage web site. Experiment unique refrigerators or freezers will not be developed.
- Software that requires a dedicated computer or operating system other than specified above.
- Software that uses a “Click Once” installation model

1.1.2 Subject Requirements

Background: Currently, the maximum number of crewmembers on board ISS at any given time is six; this includes 3 Russian crewmembers and 3 United States Operation Segment (USOS) crewmembers (includes participants from International Partner agencies: Europe, Canada, and Japan). On-orbit durations are approximately 6 months, and the crew rotations are staggered; there are periods when only three crewmembers are onboard ISS. At this time, NASA sponsored investigations generally only seek participation from USOS crewmembers, due to the limited availability of Russian crewmembers in the US for pre and post flight Baseline Data Collection (BDC). Therefore, the maximum number of subjects per year for any one experiment is six. For planning purposes, four subjects per year is the average that should be assumed since other constraints and crew consent may limit participation. All crewmembers will be given an informed consent briefing on all proposed human research for their Expedition at approximately one year prior to launch. There are a large enough number of human life sciences investigations being performed that it is not possible for one crewmember to participate in all of them, even if they were willing. This is due to resource limitations described in this document as well as science conflicts between investigations. Based on crewmembers' interest or lack thereof, a specific complement of research is developed for them that can be performed within the flight resource constraints.

With a small subject pool and a large number of investigations requiring human subjects, the number of subjects required becomes an important aspect of technical feasibility for flight proposals. In addition to taking a long time to complete, studies that require large subject numbers limit the throughput for overall human spaceflight research. An investigation that has multiple constraints that will effectively reduce the number of other investigations a subject can participate in will also not be technically feasible to implement. Investigators should note that one crewmember can participate in up to twenty human life sciences investigations.

Difficult to Implement:

- Studies requiring more than 12 subjects.
- Studies requiring overly invasive or complicated procedures that may hinder crew consent.

1.1.3 Pre-Flight Baseline Data Collection (BDC) and Training

Background: The availability of ISS crewmembers prior to launch for training and BDC is extremely limited due to a heavy training schedule requiring a great deal of international travel (Russia, Europe, Japan). All US training and BDC (including vehicle and ISS system training as well as all NASA payloads) must be scheduled during the three periods of time pre-flight when crewmembers are at JSC (referred to as "trips"). Each trip is approximately one month long, and they occur at around nine, five and three months prior to launch. The JSC trips at nine and three months before launch are extremely busy. Crewmembers depart for Russia approximately two months before launch (L-60 days). Between L-60 and L-30, it is possible to perform some simple testing in Russia (i.e. minimal sampling, simple ambulatory monitoring, questionnaires), but there must be strong justification for why this cannot be done prior to crew departure from JSC. There are no unique facilities available for performing BDC in Russia, and the only resources available are a freezer and centrifuge. In the L-30 to L-15 time frame, crewmembers' schedules are very busy with required simulations, tests, and commissioning activities as well as time with their families and scheduling testing of any kind is usually not possible. The crew travels to the launch site at around L-15 days, where there are no BDC facilities available for investigator use. The only feasible activities during this time are those that require passive monitoring (i.e. Actigraphy), or simple computer or pen/paper entries. There is no freezer or any other equipment available at the launch site and retrieval of data and equipment must be arranged with crew surgeons (no PI travel to launch site), who are extremely busy during this timeframe.

Due to facility constraints and the cost associated with arranging for BDC to be performed in Russia, unless there is a strong scientific justification, all pre-flight BDC should be planned to be completed prior to L-60. Since crew time is very constrained during their trips at JSC, the number and length of BDC sessions should be minimized as much as possible, and timing of sessions should be as flexible as possible.

Pre-flight time for crew training is also very restricted, and sessions are limited to skills-based sessions as opposed to lecture style overview sessions. A team of experts at JSC will work with investigators to develop an appropriate training plan for each investigation that is selected for flight.

Difficult to Implement:

- Total pre-flight BDC requirements of more than 10 hours.
- Single BDC sessions requiring more than 2 hours.
- More than 2 hours of BDC required within 3 months of launch.
- BDC testing requirements within two months of launch.
- In-flight procedures that require a high degree of proficiency and training prior to crewmember launch (e.g. requires more than three, 2 hour sessions for one unique procedure/skill; requires refresher session within 60 days of launch).

1.1.4 Post-Flight Baseline Data Collection

<u>Background:</u> All crewmembers are currently returned from ISS via the Soyuz spacecraft, landing in Kazakstan. USOS crewmembers are returned directly to JSC within approximately 24 hours after landing using a NASA plane.. However, there are instances where European crewmembers will be returned directly to Cologne, Germany for immediate post-flight BDC processing. Due to logistical limitations, it is extremely difficult for Investigators to gain access to crewmembers until they have returned to JSC, and only limited testing is possible during their return flight (i.e. Actigraphy, urine and saliva sampling). There is some opportunity for limited, passive testing upon crew return to JSC (blood draws, Ultrasound scans), but extensive or lengthy testing is not possible. The time period from crew landing to crew sleep after return to JSC is considered landing day, or "R+0". The start of R+1 begins after crew wake up the day after their return to JSC.

The total amount of time available for science BDC in the first week post-flight (R+0-R+7) is only 11.5 hours, and this scarce resource must be shared with multiple investigators. Therefore, investigators should only request BDC during this timeframe if it is required. In addition, scheduling flexibilities should be noted so that the post-flight schedule can be optimized for science return. If testing requires use of a facility not located at JSC, travel time to and from the facility must be included in the session time. The figure below provides a graphical representation of crew time availability in the first week post-flight to further illustrate how constrained this resource is. This is a general representation only; there is flexibility in the scheduling of some of the medical operations times, and an individual schedule is developed for each crewmember.

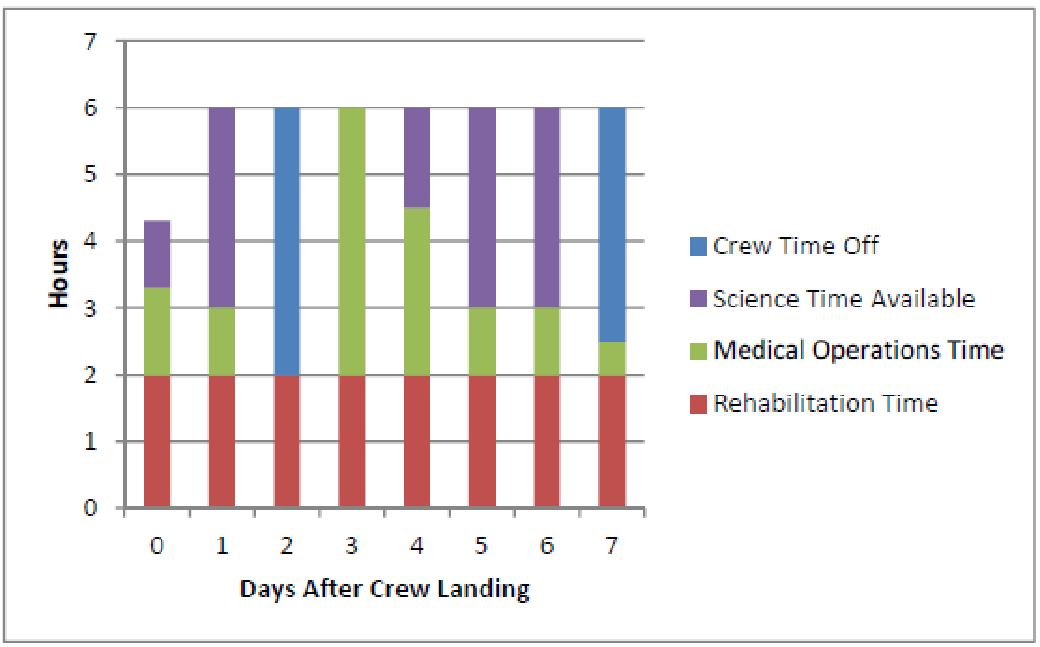

Figure 1: General representation of crew time availability post-flight

<u>Difficult to Implement:</u>

- Two or more hours of testing required within the first three days of landing.
- More than three hours of total testing in the first week post-flight.
- Strenuous or provocative sessions on R+0 or R+1. Any activity that could be considered strenuous or provocative for a healthy normal subject may not be feasible for crewmembers in this time frame.

1.1.5 In-Flight Crew Time

Background: All ISS crewmembers will be launching via the Russian Soyuz spacecraft until a US crew vehicle is available. Depending on the launch profile, it can be up to two days before the Soyuz docks with the ISS. The Soyuz is very space constrained and it is not feasible to perform any in-flight operations prior to docking with ISS. After docking with ISS, crewmembers are typically busy with handover activities, and crew time for science is extremely limited for the first two weeks. Crew time is also limited during periods when other vehicles dock or undock due to required preparation activities, as well as around Extra Vehicular Activities (EVA's). Weekends are protected as time off for crewmembers, and science is only performed if it is crew preference or as part of voluntary science.

In-flight crew time constraints require investigators to build in flexibility in their scheduling requirements. In addition to the constraints mentioned above, many investigations often have similar in-flight timing requirements, and they all cannot be scheduled during the same week. Investigators should clearly state the reasoning for specific timing requirements and explain how flexible the timing is (+/- number of days).

Difficult to Implement:

- Complicated in-flight sessions before the second week in-flight (e.g. requires set-up of multiple pieces of equipment, followed by testing session of more than an hour; sessions that require privatized voice or video)
- More than five complicated in-flight sessions involving multiple pieces of equipment. (e.g., requires set-up of multiple pieces of equipment, followed by testing of more than 2-3 hours, requires extensive privatized resources).
- A single session with one crewmember requiring 4 hours in one day.
- Crew activity that must be performed daily or more than once a week.
- Very precise/inflexible timing requirements for sessions (e.g., +/- window for testing of less than one week, multiple timed blood draws, sessions that are linked to other crew activities like meals, EVA's, etc.) Note that occasional fasting data collections upon crew wake up are not difficult to implement.
- Extended, continuous activities over multiple days that could interfere with other operations.

1.2 Flight Experiment Implementation

Investigators should be aware that if they are selected for definition, they will be assigned an experiment team experienced in conducting human life sciences investigations on ISS to assist them in further defining their experiment hardware, software, and operational requirements. If selected for flight, the experiment team will remain with the investigator to provide assistance in preparing the experiment for flight.