A PI's Guide to Analog Research

Human Research Program
Research Operations & Integration

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Spaceflight Research in Analogs

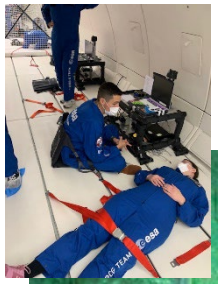
- Analog missions prepare us for near-future exploration to asteroids, Mars, and the moon.
- Not all experiments can be done in space – there is not enough time, money, equipment, and crew time.
- Measures, countermeasures, procedures, and equipment can be tested in analogs to address issues prior to flying them in space.
- Ground-based analog studies are completed more quickly and less expensively.
- Analogs provide conditions similar to some (but not all) conditions encountered in space flight.
- Analogs provide a more "controlled" environment, often more repeatable scenarios, and higher "n" than available in space

Research in an Analog

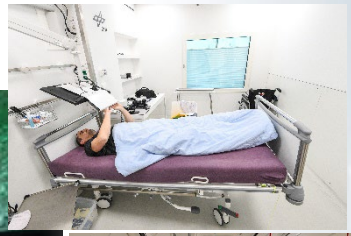
Documentation

Requirements

IRB Approval



Integrated Testing

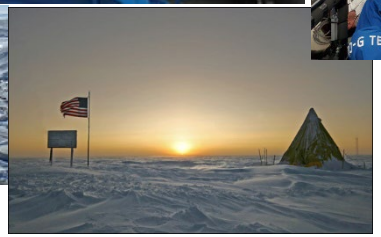


Subject Recruitment

Software

Campaign Integration

Hardware



Subject Screening

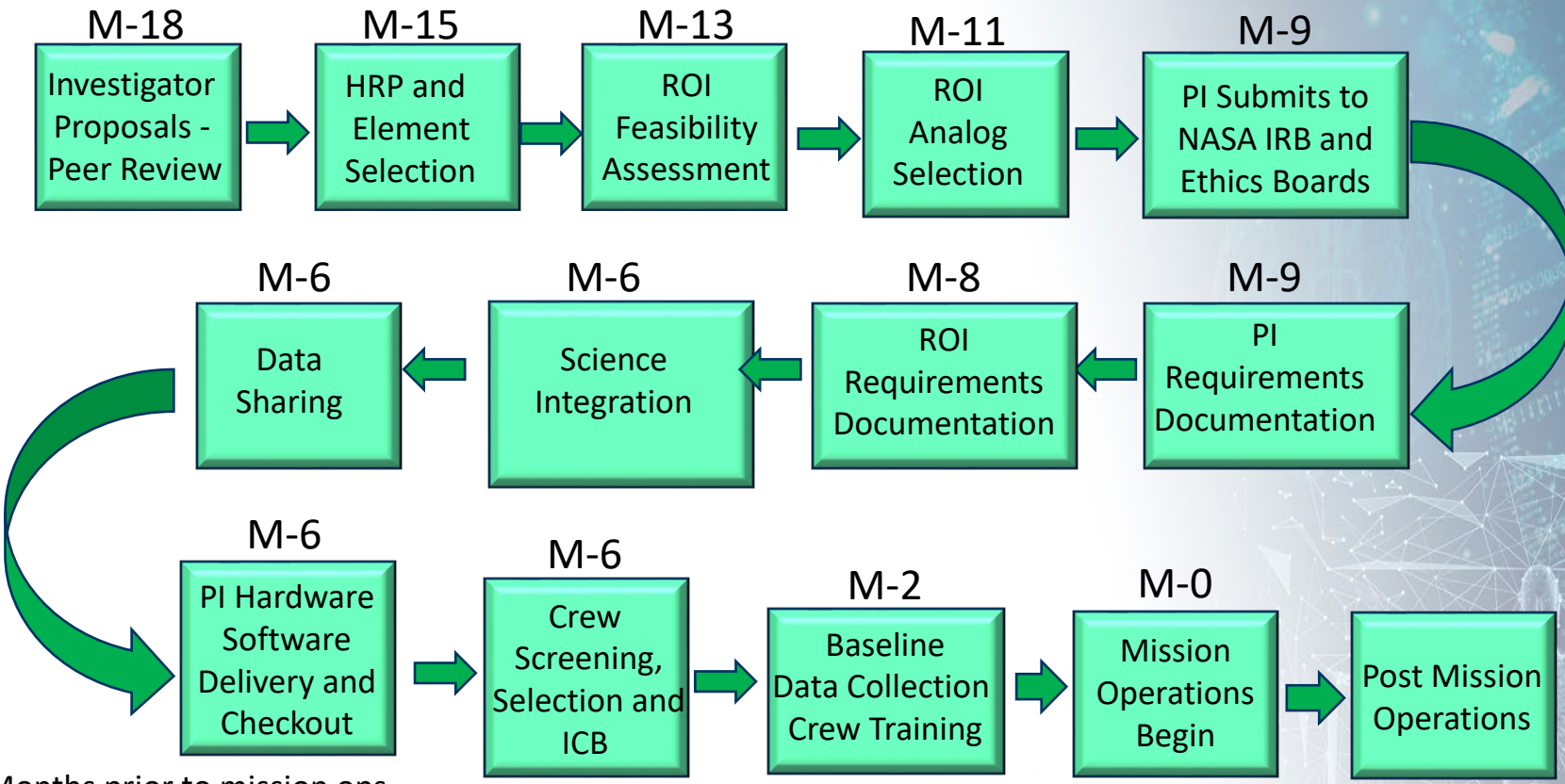
Training

ICB - Consent

Procedures

GENERAL INVESTIGATION PROCESS FLOW FOR ANALOG MISSIONS

Flow is descriptive only and each analog has a unique process



M –: Months prior to mission ops

ROI: Research, Operations and Integration

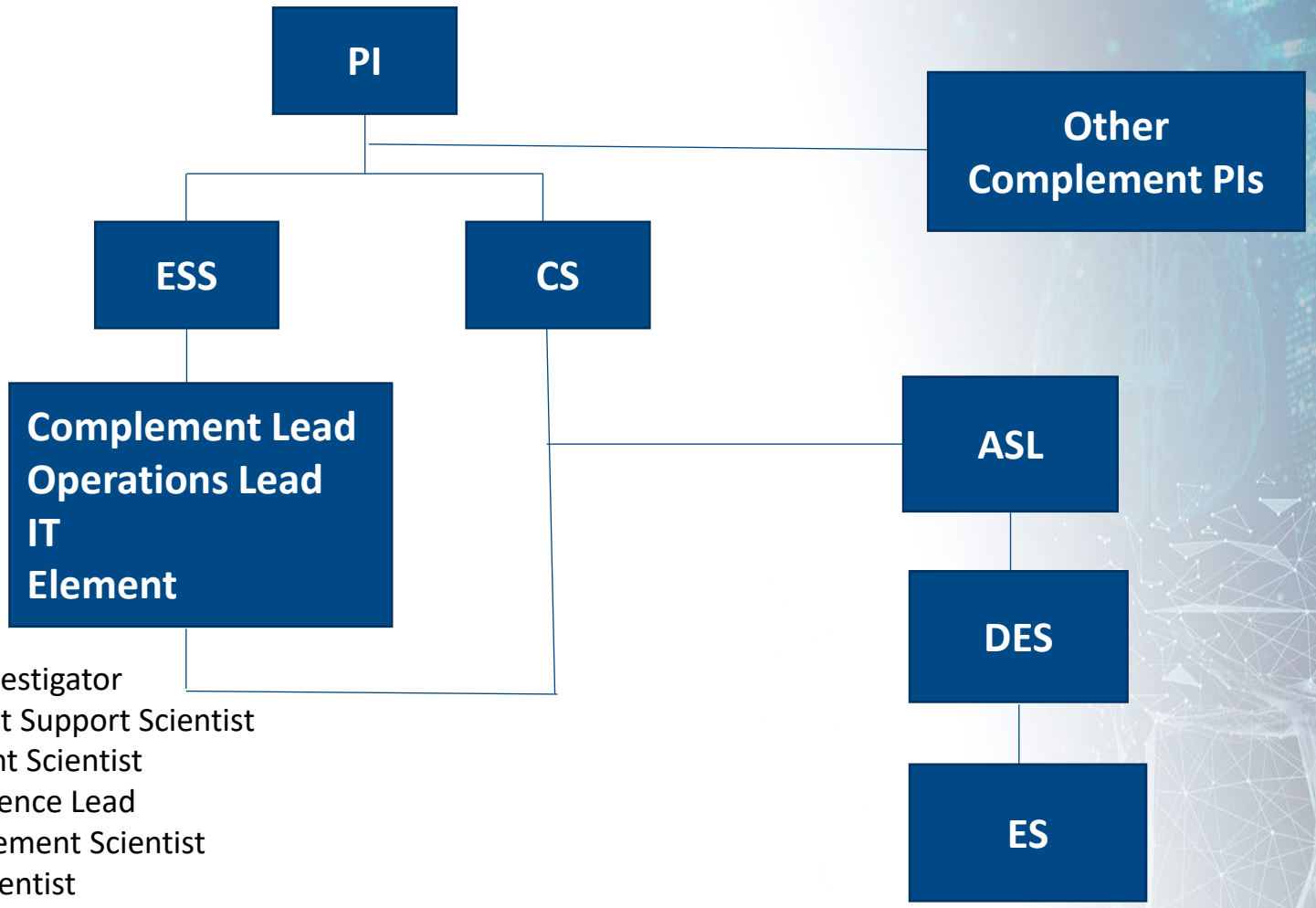
Mission Documentation includes Science Requirements Document, Science Application Form, Integrated Research Document

Structure of an Analog Study

For the most part, Analog Studies are performed as a single Complement

- A complement is comprised of a group of studies requiring a common platform and/or scenario that are able to be integrated on a non-interference basis for implementation in an analog platform (bedrest, ICC, ICE, etc.)
- Full integration of an individual study has three phases:
  - Integration
  - Preparation
  - Implementation
- These phases occur in order with some overlap in the integration and preparation phase
- The Research Operations and Integration (ROI) team assists in adapting a PI's study to the assigned analog and then integrates, plans and implements analog study complement

Who do I work with from ROI?



PI: Principle Investigator
ESS: Experiment Support Scientist
CS: Complement Scientist
ASL: Analog Science Lead
DES: Deputy Element Scientist
ES: Element Scientist
flow may differ depending on platform

Phase 1: Integration

Roles and Responsibilities

ROI	PI
➢ Lead the integration of multiple investigator protocols for each analog science return ➢ Assign a designated Experiment Support Scientist to each PI team (depending on platform) ➢ Provide guidance on NASA Institutional Review Board (IRB) package development ➢ Work with the PI team to define and document study requirements	➢ Required to obtain their respective IRB approval followed by submission and approval by the NASA JSC IRB ➢ Work with your ESS/Campaign Lead to identify your study requirements ➢ Work with ROI ESS/Campaign Lead to fully define PI science requirements and flexibilities to develop the Science Requirement Documents (SRD) for each study ➢ Support campaign integration and elimination of conflicting requirements by providing timely input and feedback to ROI Integrated Requirements Document (IRD)

Phase 1: Integration
Individual Requirement Definition & Integration

- Individual requirements integration is the first step in ensuring that the research fits into an available analog platform or the ROI team may provide information on structural study changes needed for participation in an analog platform.

- Investigators need to understand exactly what their requirements are to produce scientifically relevant data and convey their “must have” needs to the Flight Analog team.

NOTE: Unclear or changing requirements make integration difficult and have negative direct effects on implementation of each study.

- Participation in analog research requires flexibility from the investigator to ensure implementation of their research into a flight like analog platform.

How do I Integrate?

The key to efficient and effective integration is well defined requirements. Early understanding the requirements in detail ensures that the science is not compromised by outside influences. This step is vital to the integration, preparation, and implementation phases

- The ROI Analog team works with the Principal Investigators (PI) to identify and document individual study details and requirements through the PI's specific science requirements document (SRD).
  - Note- it is important to inform ROI of BOTH the ideal and minimum requirements….bad science is worse than no science
- Once SRDs are complete, ROI combines all PI, Operational, and Platform requirements into a Complement Integrated Requirements Document (IRD).
- The IRD outlines and documents all individual and complement research requirements for planning and implementation.

Phase 1: Integration
Keys to writing good requirements

- What do you "need" vs what would be "nice to have"
- Be as specific as possible and include any constraints associated with your testing
- Include a reasonable "window"
- Balance mission fidelity with science purity
- Screening inclusion/exclusion criteria
- Be aware of other science going on (attend IWGs)
- Make sure you know about other "constraints" of platform
- What hardware, software or consumables do you need?
  - Who will provide?
  - Who will collect (test subjects do not act as laboratory technicians)?
    - Do you have a local Co-I?

Phase 1: Integration

Common requirements/constraints that may impact science

- Sleep schedule
- Biological collections (especially fasting)
- Meal schedule
- Exercise
- Noise levels/distractions
- MRIs
- Ingestible devices
- Wearable technologies
- Personal hygiene activities
- Conflicting requirements within the study complement

Phase 1: Integration
Final Integration

- Additional restrictions, limitations and constraints may be required by the analog in order to make all of the science work.
- Many studies need to be combined into each complement and there are a limited number of hours available for data collection.
- Through data/sample sharing, we can reduce the burden on the test subject, while usually avoiding significant science impacts.
- Restrictions on food, exercise, medications and sleep cycle are important to consider for your research.

Phase 2: Preparation
Roles and Responsibilities

ROI	PI
➢ Provide updates on the Campaign Planning Schedule and applicable milestones as needed ➢ Ensure communication of key campaign information (status, decision, risks, etc.) ➢ Hosts IWG meetings to focus on resolution of issues ➢ Track delivery of all hardware, software and procedures ➢ Conduct tests on all hardware, software and procedures received from PI teams to ensure the perform as expected ▪ Standalone testing for each PI's suite ▪ Integrated testing with all PI HW/SW (including wearables) to ensure compatibility w analog facility and resolve interference issues between systems	➢ Provide deliverables per campaign schedule, and identify/communicate any issues as early as possible ➢ Provide all hardware, software, and expendable supplies required for your study ➢ Maintain all hardware, software, etc. within certification, licensing, or other required compliance to ensure continuity of operations ➢ Provide all training materials and procedures required for crew and mission operations ➢ Work with other PIs to negotiate data sharing (e.g. publication rights, etc.) ➢ Maintain NASA IRB approval throughout campaign

Phase 2: Preparation
Roles and Responsibilities cont.

ROI	PI
➢ Ensure appropriate PI access to analog data systems ➢ Build all timelines and schedules (pre-, in-, post-) and distribute to PI teams ➢ Develop mission scenario, crew tasks, stressor plans, etc. to meet Element and/or PI requirements ➢ Recruit, screen, select subjects according to approved Inclusion/Exclusion criteria ➢ Conduct all safety reviews as required by analog facility	

Phase 2: Preparation
Subject Recruitment, Screening, Selection

- In most cases, subjects will be recruited, screened and selected by the platform sponsor.
- Subjects will be recruited by the specified platform and PI inclusion/exclusion (I/E) criteria. It is important this is well defined in your SRD.
- Any deviation from specified and approved I/E criteria will be discussed with the PI(s) prior to subject selection.
- When appropriate and requested, back-up subjects will be identified in the event of subject withdrawal.

Phase 2: Preparation
Hardware, Software & Procedures

- It is the PIs responsibility to provide all hardware, software, procedures and consumables required for their protocol, including wearables, per the study/campaign schedule.
- In some instances, there may be platform/facility resources available, but this is heavily dependent on the facility and availability. Your ESS will be able to help you determine availability.
- Please verify all licenses are update and any updates are completed prior to shipping.
- Keep in mind, some analogs have back-up subjects that will participate in baseline data collection (BDC) and consumables/hardware/etc. will need to be provided for them as well.

Phase 2: Preparation
Standalone & Integrated Testing

- Once all PI hardware is received, the ROI team will perform testing to assure functionality and compatibility with the platform.
- ESSes will work with the PI teams to test all hardware, software and wearables on a standalone basis to address and troubleshoot any issues with the hardware in the platform environment.
- The ESSes will then perform integrated testing to assure there are no issues with functionality in the integrated environment.
- Any issues identified during standalone and/or integrated testing will be worked with by ROI with the PI team and Element as required.

Phase 2: Preparation
Schedules

- The Campaign Lead will develop and maintain a Campaign schedule and will distribute to the PIs for awareness of milestones and delivery dates.
- An integrated daily test schedule (IDTS) will also be developed and provided by the platform scheduler/lead that will reflect when activities will be performed. This will include pre-, in- and post- testing phases.
- All IDTS's will be distributed to the PIs for their review.

Phase 2: Preparation
Data Sharing

Data Sharing:

- Data exchange documented in the DSP shall occur directly between investigators, following test subject consent.
- Data distribution shall adhere to NASA security standards regarding subject privacy requirements
- ROI will develop an initial DSP and distribute to the PI team for input and/or concurrence

Sample Sharing:

- Sample sharing (physiological samples, venipuncture) will be encouraged to minimize blood volumes and inconvenience to subjects.
- Sample exchange will be documented in the DSP and shall occur directly between investigators.
- Sample distribution shall adhere to NASA security standards regarding subject privacy requirements.

Phase 2: Preparation
Data Sharing Process

- A Campaign-specific Data Sharing Plan (DSP) will be developed by ROI
- The DSP will define *what* requested data are to be shared between PIs
  - The DSP enables all PIs to view the data to be collected during the HERA mission
- Once agreed upon, all PIs and ROI will sign the DSP
- No data sharing specifics or amendments to your standalone IRB will be required; however, you must have included the requirement for the data collection in your IRB submitted protocol
- Sharing of data between investigations in no way abrogates the individual investigator's first right to publication of the data derived from their own investigation.
  - Data shared from other investigations must be referenced in publications of recipient investigators to maximally safeguard this right.

Phase 2: Preparation
Data Sharing Plan Purpose

- The purpose of a complement Data Sharing Plan (DSP) is to:
  - Document mission efficiencies as determined during the integration process
  - Document supplemental data sharing as a secondary objective
- A comprehensive data sharing plan allows ROI Campaign team to:
  - Facilitate research planning
  - Develop metrics to measure mission success in terms of data delivery
  - Allocate resources related to data management and file storage (e.g., large video files)

Phase 2: Preparation
Data Sharing Agreements

- It is up to the PIs to coordinate and outline how the data will be shared, when the data will be shared and to negotiate publishing rights, etc.
- Supplemental inter-experiment data sharing should also be documented in a Data Sharing Agreement (DSA)
  - A DSA captures the data details, use, and protection of experiment data between investigators and sponsors, where applicable
  - DSA's are developed by the PI teams and may need to coordinate with their institution for any guidelines and/or documenting agreements.
  - ROI can provide a DSA template upon request

Phase 2: Preparation
Consent and Data Exchange

- Subject consent to data sharing is obtained via the Campaign consent form
- Subjects will be provided a copy of the DSP
- Inter-experiment data exchange may happen directly between investigators using a secure transfer mechanism
  - Your ESS can help you identify a secure transfer mechanism if needed

Phase 3: Implementation
Roles and Responsibilities

ROI	PI
➢ Mission/Campaign execution includes: ▪ Staffing to support subjects ▪ Subject care and support ▪ IDTS maintenance and updates as required ▪ Mission summaries (frequency dependent on platform) ▪ Off-nominal support ▪ Oversight of the implementation of all PI science ▪ Direct communication with PIs to maximize data collection/science return ➢ Distribution of data and samples ➢ Post-Mission/Campaign reporting	➢ Provide all crew briefings, training, BDC and mission/campaign support as needed ➢ Mission/campaign support includes after hour support to address any off-nominal situations that may occur ➢ Work with other PIs on data transfer for all data sharing ➢ Confirm timely receipt of data sets post-mission/campaign

Phase 3: Implementation
Mission/Campaign Support

- ROI, or platform personnel, will provide support for all subjects during campaign implementation such as medical and psychological monitoring, dietary, subject compliance, etc.
- IDTS's will be maintained and updates communicated to PI teams as needed.
- Daily/weekly/end of campaign status will be provided to summarize all data and activities completed.
- All off-nominal situations impacting PI science will be communicated to the PI team(s) as appropriate. NASA IRB notification may be required.

Phase 3: Implementation
Receipt of Data

- ROI, or platform personnel, will provide a mechanism for PI data delivery as required per the approved SRD and/or IRD.
- Data sharing between PIs will be handled PI to PI or may be accommodated by the platform depending on data storage and transfer protocols.
- PIs should check their data as early and as frequently as possible—once a mission/campaign ends and a new one start, fixing missing data issues may become difficult or impossible.

Phase 3: Implementation
Post-Mission/Campaign Reports

- ROI will provide to PIs a post-mission/campaign report outlining final subject N, data collected and a summary of any off-nominal situations as required by the platform or campaign requirements.
- Any additional data requests received from PI teams for additional and/or ancillary data will be handled on a per case basis.

Closing

Don't worry – the ROI Analog Team will be there to support you along the way and together we will help you effectively and efficiently reach your scientific goals!

Questions?