Human Research Program

Unique Processes, Criteria, and Guidelines (UPCG)

July 28, 2011

Revision C

National Aeronautics and Space Administration

Lyndon B. Johnson Space Center

Houston, Texas 77058

Human Research Program
Unique Processes, Criteria, and Guidelines (UPCG)

July 28, 2011

Concurrence

Prepared By:

Duane Chin Book Manager Human Research Program	Date

Concurred By:

Katherine R. Daues Manager, Program Integration Office Human Research Program	Date

Approved By:

Dennis Grounds Program Manager Human Research Program	Date

REVISION AND HISTORY PAGE

REV.	DESCRIPTION	PUB. DATE
Baseline	Baseline approved by HRPCB per SLSDCR-HRPCB-07-033	01-24-08
A	Revised by HRPCB per SLSDCR-HRPCB-08-009	07-10-08
B	Revised by HRPCB per SLSDCR-HRPCB-09-005	07-23-09
PC#1	Page Change B-1 Revised per SLSDCR-HRPCB-09-PCN1	12-10-09
PC#2	Page Change B-2 Revised per SLSDCR-HRPCB-10-PCN2	04-29-10
PC#3	Page Change B-3 Revised per SLSDCR-HRPCB-10-PCN3	09-23-10
PCN#4	Page Change B-4 Revised per SLSDCR-HRPCB-11-PCN4	03-23-11
C	Revised by HRPCB per SLSDCR-HRPCB-11-016	07-28-11

TABLE OF CONTENTS

Table of Figures

Table of Tables

Human Research Program
Unique Processes, Criteria, and Guidelines (UPCG)

1.0 INTRODUCTION

1.1 PURPOSE

This document defines the processes, criteria, and guidelines exclusive to managing the Human Research Program (HRP).

1.2 SCOPE

This document is applicable to all distinctive functions, tasks, and deliverables required for accomplishing the goals of the HRP. These requirements are not contained within other program documentation.

1.3 AUTHORITY

This document is under Configuration Management (CM) control of the Human Research Program Control Board (HRPCB). Changes to this document will result in issuance of change pages or a full re-issue of the document. Regular review of this document and subsequent changes are necessary to maintain consistency with the evolving Exploration Systems Mission Directorate (ESMD) strategies, goals, and objectives.

1.4 INTENT

The intent of this document is to provide instruction to the reader in the form of processes, criteria, and guidelines. Of the three instructional categories, processes contain the most detail because of the need for a systematic series of actions directed to some end. In contrast, criteria have lesser detail than processes with the idea of creating a rule or principle structure for evaluating or testing something. Guidelines are a higher level indication of a course of action typically with the least amount of detail. The lack of detail in guidelines allows the reader flexibility when performing an action or actions.

2.0 PROCESSES

2.1 FLIGHT SELECTION AND APPROVAL PROCESS

2.1.1 Process Introduction

Access to flight resources is controlled at the Program Office to ensure maximum coordination and utilization of limited flight resources. Therefore, experiments requiring flight resources must be fully vetted and reviewed for scientific, operational, and technical merit as well as operational feasibility before access to flight resources is considered through a Science Management Panel (SMP) Change Request (CR). This process is designed to communicate the expectations and appropriate pathway for gaining access to flight resources, through either payload or operational routes.

NOTE: This process does not include deselecting an experiment. When a review of an already selected experiment yields a decision to deselect, then follow the process in Section 2.3, Process for Deselecting Investigations.

2.1.2 Element Endorsement

The Principal Investigator (PI) submits a study plan and a completed Flight Experiment Resource Worksheet (HRP-F01-FERW.R2; http://hrp.jsc.nasa.gov/?viewFile=program/forms) that are reviewed within the element or organization. If an experiment requires the use of Medical Operations (Med Ops) time, or equipment that is not under the control of HRP, the element must arrange for appropriate review, concurrence, and approval of the study plan to ensure operational relevance and availability of the required non-HRP resources. Non-HRP resources could include the use of Health Maintenance System (HMS) hardware, Med Ops time, either pre-, in-, or post-flight, or other mission operations resources. The sponsoring element is responsible for arranging presentations to all appropriate stakeholder organizations or boards before proceeding to the feasibility assessment. The requestor follows the "Space Life Sciences Directorate DTO/SDTO Joint" process.

Once all appropriate stakeholders have concurred with the plan and approved use of their resources, the PI is asked to prepare a full proposal for scientific or technical merit review.

NOTE: If the investigation is a DTO/SDTO and it has completed the "SA DTO/SDTO Joint" process, this paragraph is not applicable, as these tasks are performed as part of the other process and therefore do not need to be duplicated here.

The sponsoring Element utilizes the guidelines established in Section 2.5.3, Writing a Task Proposal, to determine the appropriate proposal format and level of merit review required. The Element Scientist (ES) submits the proposal to the Program Scientist and recommends a level of review. The Program Scientist must concur on the level of merit review required.

If the merit review requires any modifications, the PI will work with the sponsoring element/project to complete them. The sponsoring element initiates coordination with International Space Station Medical Project (ISSMP) for informal assessment of implementation feasibility. The PI may be asked by the sponsoring element to rework the proposal as recommended by the ISSMP. The Program Scientist approves or disapproves proceeding with the selection/approval process based on the outcome of the scientific merit review.

After successful completion of the scientific or technical merit review, the PI prepares a Committee for the Protection of Human Subjects (CPHS) protocol and flight resource worksheet (available from the ISSMP to facilitate data collection) and submits it to the sponsoring element. If the protocol is not endorsed initially, the protocol is revised until endorsement is gained. The sponsoring element reviews the protocol and accompanying flight resource worksheet and formally submits the endorsed protocol to the CPHS and the protocol plus worksheet to the ISSMP.

Once the protocol is endorsed, it enters a subsequent process of having its feasibility formally assessed by the ISSMP while obtaining CPHS approval.

2.1.3 Feasibility Assessment

The ISSMP will utilize the complete protocol and the flight worksheet (HRP-F01-FERW.R2; http://hrp.jsc.nasa.gov/?viewFile=program/forms) to understand the full extent of required flight resources, determine the complexity of the investigation, and determine whether it can be added to the ISSMP flight queue without significant cost impacts. The flight resource worksheet is required for proposals submitted in response to a National Aeronautics and Space Administration (NASA) Research Announcement (NRA) and is included as part of the solicitation. For studies not submitted in response to an NRA, the flight resource worksheet (or equivalent data content) is included with the proposal to assist ISSMP in performing the feasibility assessment. This initial feasibility study is targeting significant obstacles or mismatches in required and available resources, and may require discussions with the PI and/or the sponsoring organization to clarify requirements. The feasibility assessment will include the following:

1) Recommendation on implementation strategy, including estimated first flight opportunity and time to complete requested subject count,
2) Impact to current staffing levels,
3) Recommendation regarding formal reviews (if any),
4) Summary of resources required,
5) List of assumptions made in performing the assessment, and
6) A risk assessment and the proposed mitigation plan.

If recommended in the feasibility assessment, a more detailed feasibility is performed during the experiment definition phase immediately following selection for flight. Required resources include in-flight resources, flight hardware requirements and availability, as well as pre- and post-flight baseline data collection (BDC). If the ISSMP determines the protocol is not feasible to perform, the protocol is reworked in conjunction with the PI and sponsoring element. The sponsoring element approves the revisions.

If the feasibility assessment states that the protocol is within the scope of available ISSMP resources, the ISSMP endorses the protocol and supports the sponsoring project's initiation of an SMP "Select for Flight" CR. If the protocol is not within the scope of available ISSMP resources, the ISSMP and project must attempt to resolve the issue prior to initiation of the SMP CR.

If the ISSMP and project cannot resolve the resource issue, it must be taken first to the SMP for resolution without additional resources, then to the HRPCB if the SMP cannot resolve the issue or conflicts without additional resources.

2.1.4 CPHS Approval

After the protocol is endorsed by the sponsoring element, and while the ISSMP is formally assessing the feasibility of the protocol as described above, it goes through the process of obtaining CPHS approval. The sponsoring project or organization representative takes the protocol to the CPHS.

If the CPHS either disapproves the protocol or approves it with modifications, the PI works with the sponsor and ISSMP to address those concerns and revise the protocol. In this case, the revised protocol must be re-endorsed by the sponsoring organization and then it re-enters the parallel processes of having its feasibility formally assessed by ISSMP and being re-submitted to CPHS. If for any reason concerns about the protocol cannot be adequately addressed, the protocol is removed from the selection process.

Once the CPHS approves the protocol without changes and the ISSMP feasibility assessment is complete with all issues resolved (except potentially resources) the sponsoring project and ISSMP prepare the SMP select for flight CR.

NOTE: The CPHS approval follows the scientific or technical review because that review established the "benefit" of the proposal. Only then can the CPHS determine whether the risk to the human subject is justified by the benefit.

2.1.5 Program Office Approval

Once the ISSMP feasibility assessment and the CPHS approval are complete, the experiment is ready to go to the Program Office for approval and a Select for Flight Directive (SFD). The sponsoring Element or Project submits an SMP Select for Flight CR. The CR must follow the SMP-approved template (using the following template https://sa.jsc.nasa.gov/cm/?viewFile=formsAndPresentationTemplates), which includes a presentation summarizing the investigation, the merit review status, the CPHS recommendation, and the results of the ISSMP feasibility assessment. The CR must also include a detailed description of any changes to the investigation made by the ISSMP and/or CPHS reviews. The sponsoring project schedules the presentation with the SMP Executive Secretary. Once the information has been presented to the SMP, the CR is released for review allowing a minimum of two weeks for the identified reviewers to evaluate the CR and formulate questions or concerns. Any comments or questions that were received during evaluation must be fully addressed, and all issues are clearly identified for resolution by the SMP.

If there are no issues, or the issues are resolved without the need for additional resources, the SMP will approve the CR and recommend that it proceed to the HRPCB. If the SMP does not approve selection of the protocol, the protocol is revised as described above and re-enters the process at the step of being endorsed by the supporting element or organization.

Once the SMP approves the CR, the sponsoring Element or Project submits a HRPCB CR for Outside-of-Board (OSB) disposition; the HRPCB CR serves as a SFD. This CR will clearly indicate the SMP approval date, how many subjects are approved, flight duration of the experiment, and any actions or changes levied by the SMP. The ISSMP then updates LS-73005, ISSMP Flight Queue Master List, and proceeds with implementation. The sponsoring organization is responsible for notifying the PI of the decision.

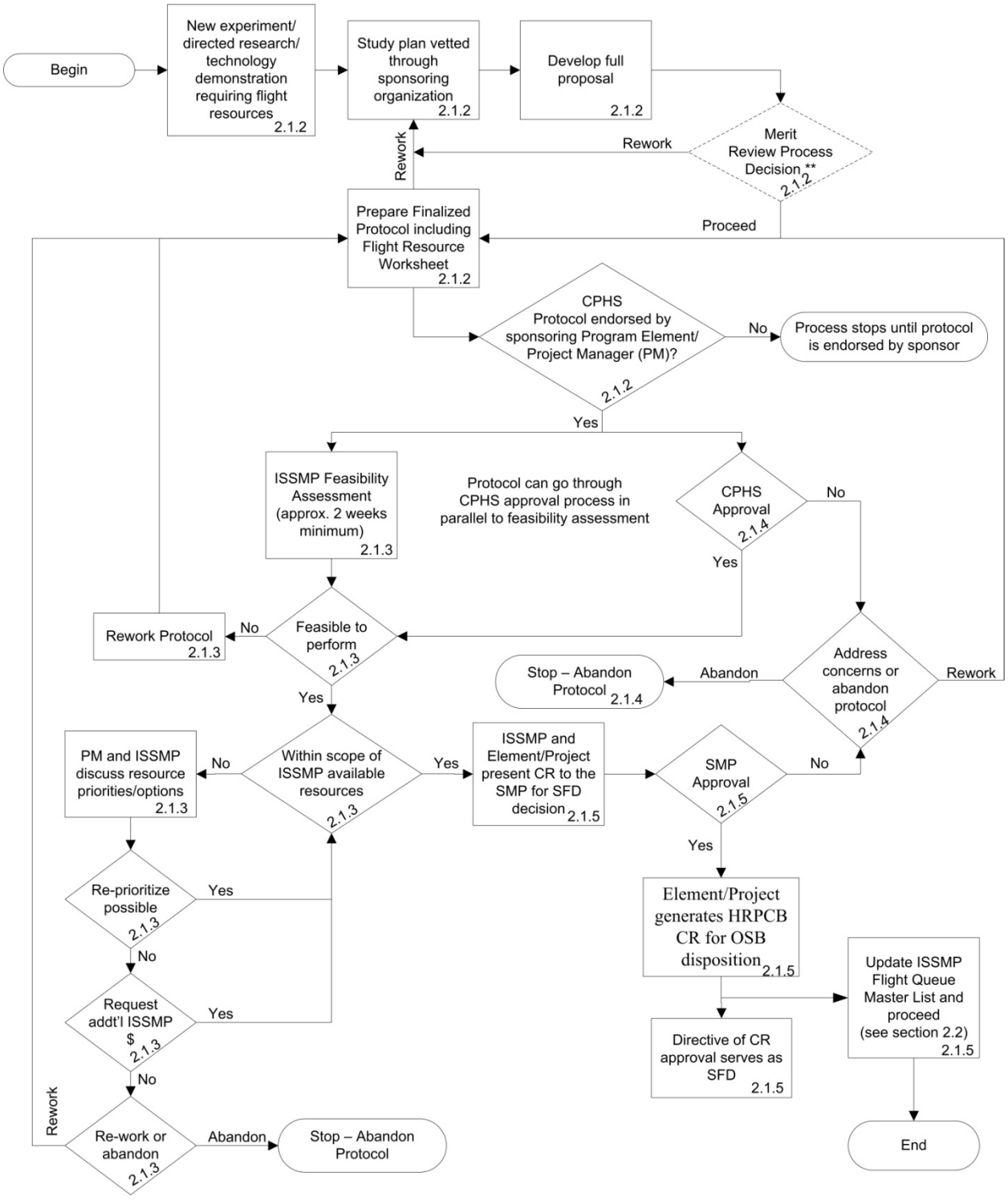
If the SMP cannot resolve a resource issue, the decision package is forwarded to the HRPCB for resolution. If the HRPCB resolves the issue, it approves the decision package CR. That approval serves as an SFD, enabling resources to be transferred to the appropriate Element. ISSMP updates the Flight Queue Master List and proceeds with implementation. If the HRPCB

does not find a satisfactory resolution of the resource issue, the protocol is removed from the selection process.

NOTE: The SFD confirms the HRP plans to expend flight resources to conduct the experiment. However, once an experiment is added to the Flight Queue Master List, multiple factors determine when it is actually conducted on-orbit, such as date for results, available up and down mass, on-orbit crew time, and BDC time, and other experiments in the flight queue. The ISSMP works with the PI and sponsoring Element to determine the earliest time for on-orbit operations and then incorporates the experiment into the associated complement planning and approval process. The final approved complement is a balance of all competing resources and the result of Program-level review, including the ISSMP Configuration Control Board (CCB) and SMP forums to discuss the relative priority of flight queue experiments. Any conflicts are elevated to the SMP and HRPCB, as needed. See Section 2.2, Complement Approval Process, for further details of processing an experiment after it is added to the Flight Queue Master List.

2.1.6 Figure

See Figure 1 for a pictorial representation of the Flight Selection and Approval Process.



** Refer to UPCG Sections 2.4 and 3.2 for the details of the process decision.

Figure 1 - Flight Selection and Approval Process

2.2 COMPLEMENT APPROVAL PROCESS

2.2.1 Process Introduction

The ISSMP Flight Queue Master List (LS-73005) is an ISSMP CCB-controlled document listing all active flight experiments. An SFD from the SMP and HRPCB is required for an experiment to be considered in the "flight stage" in this document (see Section 2.1). This also includes the recommended Increment/Flight start date. All flight complements are developed from experiments that are in the ISSMP Flight Queue Master List.

The timing of this process is driven by due dates to the Research and Planning Working Group (RPWG) for the Increment planning process. ISSMP CCB approval occurs prior to submittal of resource data to the RPWG. Plans developed for six-month periods include all shuttle flights within those six months. Since only flight experiments previously selected for flight by the SMP and HRPCB are considered, the complement is approved at the ISSMP CCB and an informational presentation is brought to the SMP for concurrence.

2.2.2 Initial Preparation of Complement

The ISSMP strategic planning team prepares a presentation of the proposed complement of research/activities based on readiness per the ISSMP Flight Queue Master List. All active flight experiments/activities known, or targeted to be ready, are considered. The presentation will assess potential conflicts between protocols, data distribution, pre/in/post flight crew time and schedules, ascent/descent manifest requirements, and blood volume requirements. Also, projected available resources, operational constraints, and known priorities will be taken into consideration when developing the proposed options.

2.2.3 ISSMP and HRP Program Element Managers/Scientists and Project Managers/Scientists Review

The ISSMP strategic planner prepares a walk-on CR to update LS-73004, ISSMP Launch and Experiment Manifest, to reflect the complement proposed for the Increment. A presentation is made at the ISSMP CCB to review the plan in detail, and an email notifying all HRP Element Managers and Scientists, as well as Project Managers and Scientists, is sent at least two weeks ahead of time to notify them of the meeting.

The presentation at the ISSMP CCB is the opportunity for HRP Element and Project Scientists and Managers to review in detail the proposed complement, as well as the potential issues and conflicts that have been identified and to engage in discussion. All SMP members who are stakeholders in flight complements are included in the ISSMP CCB discussion; they are also included as mandatory reviewers on all updates to the Flight Queue Master List and ISSMP Launch and Experiment Manifest.

The result of the meeting is a consensus opinion on the composition of the complement, which is then carried forward to the ISS Program. The decisions and agreements made at this meeting are then used to develop the official inputs made by the ISSMP to the ISS Payloads Office as part of the Increment planning process.

An informational presentation of the complement is brought to the SMP. This presentation also includes prioritization information that the ISSMP provides to the ISS Program Scientist. If a consensus has not been reached at the ISSMP CCB, the dispositions will be resolved by the SMP.

2.2.4 Science Management Panel (SMP) Review

The complement approved at the ISSMP CCB is brought to the SMP as an informational presentation. A CR is not required since the ISSMP CCB controls manifests and Increment/Flight complements and all HRP Element Managers and Scientists are included in the review of the plan. The SMP presentation will consist of the following:

- Manifest snapshot showing ascent/descent target flights for each experiment (included for information only; detailed manifests are controlled by the ISSMP.)
- Status update on prior Increment plans
- Complement for the specified Increment long duration crewmembers as well as all short duration missions launching within the Increment
  - List of experiments
  - Number of subjects targeted per flight
  - Background information regarding how the complement was prepared
  - Additional data such as potential issues and risks
  - Prioritization information
  - Forward work and schedule

Dispositions that could not be resolved at the ISSMP CCB are resolved by the SMP. If the SMP disagrees with the ISSMP CCB-approved complement, the ISSMP is given an action to make the directed changes to the complement submitted to the RPWG. In the event that dispositions to comments pertaining to the complement cannot be resolved at the ISSMP CCB, these will be taken forward to the SMP for resolution. Additionally, if the SMP does not concur with the proposed ISSMP CCB approved complement, direction will be given to ISSMP regarding requested changes to the complement. These will be incorporated as directed and subsequently provided to the RPWG to update affected documentation.

2.2.5 Figure

See Figure 2 for a pictorial representation of the Complement Approval Process.

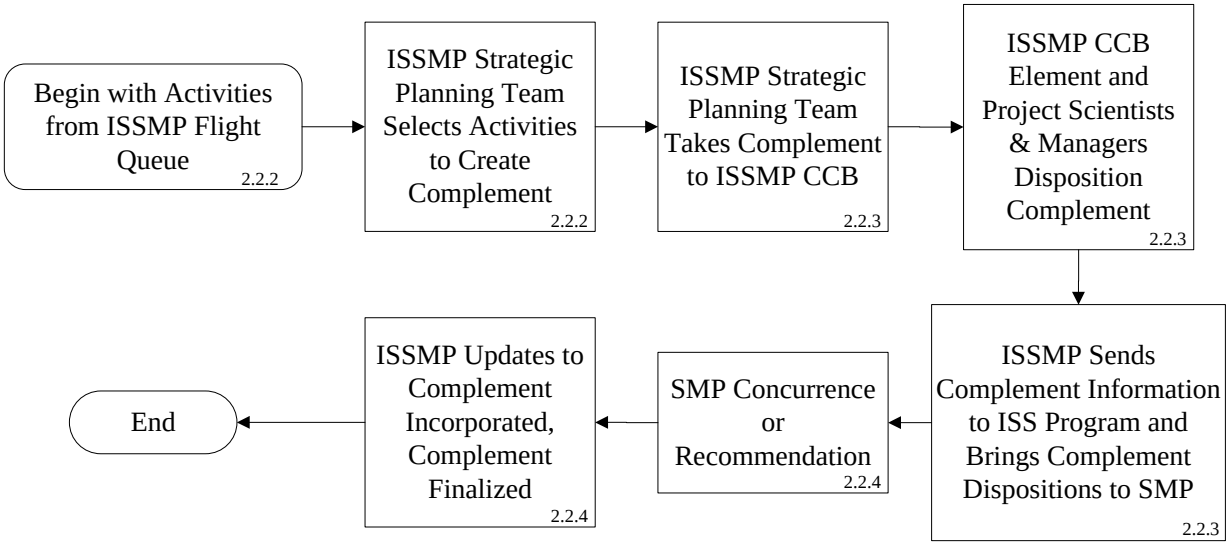


Figure 2 - Complement Approval Process

2.3 PROCESS TO DESELECT INVESTIGATIONS

2.3.1 Process Introduction

On occasion, there is a need to deselect an investigation. The decision to deselect an investigation can result from the Program's annual Project review revealing data that would warrant a recommendation to deselect the investigation. HRP-47051, HRP Program Plan, Section 3.15, Termination Review Criteria, details the Program Manager's criteria for terminating a project.

The programmatic decision to deselect an investigation could also be the result of a recommendation from within the program. When requesting a programmatic deselect decision based on a recommendation from within the program, follow the criteria detailed in Section 3.1 Criteria for Raising Decision to Program Level Decision Authority. If the program concurs with the recommendation to deselect an investigation a CR is generated documenting the recommendation. Upon approval of the CR, the Program Manager issues a directive deselecting the investigation.

The process in this section of the UPCG documents the flow of a deselect recommendation from within the program to the directive to deselect the investigation (flight or ground). The process for selecting a flight investigation is in UPCG, Section 2.1, Flight Selection and Approval Process. The process for selecting a ground investigation is under development and planned for incorporation into this document.

2.3.2 Deselecting Investigations Based On a Recommendation within the Program

Step 1

The recommendation to deselect an investigation has been agreed to by the following:

- Project Scientist
- Project Manager
- Element Scientist
- Element Manager

Step 2

The Project Manager or designee will create an SMP CR in the Bioastronautics Planning System (BPS) to document and record the decision.

Within the CR, the Project Manager must attach all correspondence with the stakeholder(s) regarding the deselection decision, as well as a CR presentation using the template provided by the SMP (https://sa.jsc.nasa.gov/cm/?viewFile=formsAndPresentationTemplates), which contains the following information:

- Title of the investigation
- Flight assignment or ground analog/mission complement (if applicable)
- Background
  - Goals of the study
  - Progress-to-date – including subjects, data collection, flight hardware status
  - Results
  - Publications
- Stakeholder statements
  - If there is a dissenting opinion among the stakeholder(s) [e.g., PI, ISSMP, Exploration Programs, Flight Analogs Project (FAP), Med Ops], additional information should be requested by the Project/Element and included in the CR.
- Recommendations

The following are listed as required reviewers:

- All SMP Panel Members
- Project Scientist
- Project Manager
- ISSMP Manager (flight studies only)
- FAP Manager (ground analog studies only)
- Element Manager
- Principal Investigator (if internal to NASA)

Elements not directly affected by a decision to deselect can record their input as “no comment/recommendation.”

Step 3

Upon concurring with the review of the recommendations, the SMP will forward the CR to the HRPCB. Refer to Step 3a "Project Manager or Designee Creates a HRPCB CR "Based On" the SMP CR" of this process. If the SMP review results in non-concurrence with the recommendations, then the SMP will inform the project that a corrective action is needed. Refer to Step 3b "SMP Informs the Project of the Need for Corrective Action" section of this process.

NOTE: This process covers the decision to deselect an investigation. It is the responsibility of the Project Manager or designee to follow any other process or best practice supporting post decision activities.

Step 3a

Project Manager or Designee Creates a HRPCB CR "Based On" the SMP CR

The HRPCB, outside of board, approves the recommendation and issues a directive to the Project Manager to create a formal deselection letter for the HRP Program Manager to sign. A copy of the signed deselection letter should be sent to the following as a matter of record:

- Program Manager
- Program Scientist
- Element Manager
- Element Scientist
- Principal Investigator
- Contracting Officer
- JSC Legal (for external investigations only)

If the HRPCB disapproves the recommendation for deselection then:

- The HRPCB issues action(s) to the Project.
- The Project develops a response to the action(s).
- After receiving notice from the HRPCB, the Project develops a recommendation for corrective action.

Upon completion of the corrective action, the Project Manager receives approval via a directive from the HRPCB and a formal deselection letter (as detailed above) is required.

Step 3b

SMP Informs the Project of the Need for Corrective Action

After receiving notice from the SMP, the Project develops a recommendation for corrective action. Upon completion of the recommendation for corrective action, the Project Manager receives approval from the SMP. Proceed to HRPCB as indicated in Step 3a.

2.3.3 Figure

See Figure 3 for a graphical representation of the Process to Deselect Investigations.

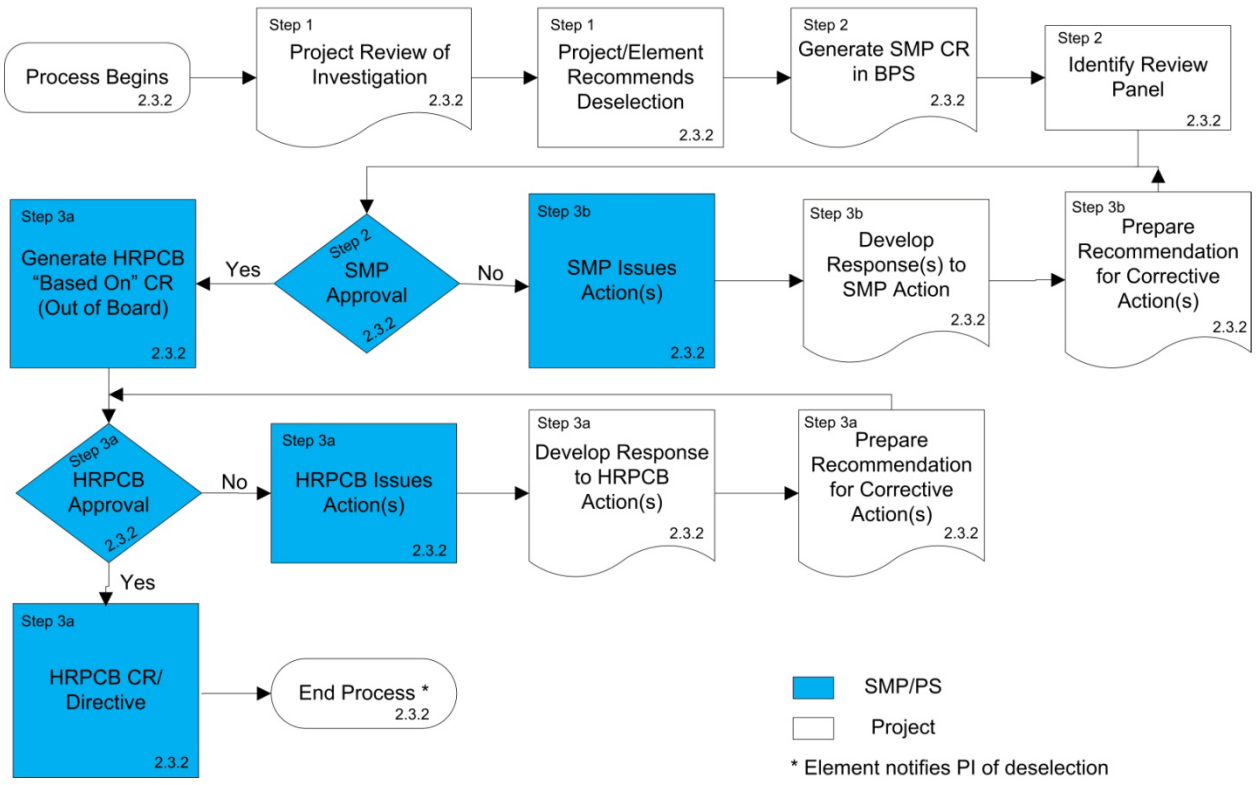


Figure 3 - Process to Deselect Investigations

2.4 PROCESS FOR DIRECTED RESEARCH TASK REVIEW - OVERVIEW

Prior to initiation of a directed task review process, the Element and Project are encouraged to determine that the proposed task meets one of the two criteria that HRP accepts as justification for classification of a task as a directed research task. This determination is made through a review of the rationale provided in the Task Synopsis Form.

- **Insufficient time for solicitation.** In certain cases, NASA must define complete scientific activities in a short time (e.g., because of the emergence of new opportunities to carry out activities in space). When this is the case, use of a directed task may be the only practical way to respond.

- **Highly constrained research.** In this case, the project requires focused and constrained data gathering and analysis that is more appropriately obtained through a non-competitive proposal. For example, the research activity involves operational practices and the associated flight personnel or research very specific to NASA.

If at least one of the two justifications above is met, the task can be classified as a directed task, and can move forward in the directed task review process. If neither of these criteria is met, the task cannot be funded as a directed task and the Element and Project should seek an alternate funding source, such as solicitation.

It is the goal of the HRP to utilize competitive means of solicitation for HRP research tasks when appropriate. However, given the applied nature of HRP and highly specialized nature of spaceflight research, competition of research tasks is not suitable in all cases. Research tasks that are initiated without being competed are referred to as directed research tasks and are awarded directly to PIs with the requisite skill to accomplish the work.

The responsibility and authority for establishing policies and guidelines for all types of merit reviews rests with the Program Scientist. The Program Scientist stipulates the following review categories for directed research tasks, and derives the authority to do so from NASA Program Requirement document NPR 7120.8, NASA Research Technology Program and Project Management Requirements.

A **formulation review** is initiated and completed prior to starting a directed research task. The formulation review is analogous to the non-advocate peer review processes that a solicited proposal would undergo when seeking funding by an external funding agency, such as the National Institutes of Health (NIH), National Science Foundation (NSF), U.S. Department of Defense (DoD), etc. Once the task completes the formulation review process and is given Authority to Proceed (ATP) by the Program Scientist, the research team will submit **annual reports** as part of a continual review process. These annual reports will be evaluated by the Program Scientist for progress against the stated goals of the research task. In addition to annual reporting, the Program Scientist may require a **status review** on a directed research task. A status review is initiated at a key point in the execution of a research task, such as once a pre-defined number of subjects have completed a research protocol or a certain subset of the work is completed. The Program Scientist will communicate the assignment of a status review as part of ATP in the formulation review process, or may do so in response to concerns raised against a task that is in work. If the products of the research are intended for an entity outside of HRP, the Program Scientist may require a **pre-delivery review**, to assess the research products prior to their delivery to the external customer. In addition, the customer may request a **customer acceptance review**, which occurs during the transition of a research product from HRP to its customer. This review is conducted by the product customer and the Program Scientist receives notification that the customer of the research product is satisfied with the delivered products. Once a research task is completed, a **final report** is submitted, summarizing the results and products of the study and the conclusions reached.

Each of the review mechanisms introduced above is described in detail below. The sections that follow constitute a detailed description (PI guide) to the directed task review process from task formulation to product delivery.

NOTE: After completing formulation review: 1) proposals requiring the use of human subjects must receive approval of the Committee for Protection of Human Subjects, 2) proposals requiring spaceflight resources must also be evaluated for flight feasibility by the ISSMP, and 3) proposals requiring ground analog resources must also be evaluated for ground analog feasibility by the FAP.

2.5 PROCESS FOR FORMULATION REVIEW OF A DIRECTED RESEARCH TASK

The initial review of a task—prior to task initiation—is the formulation review. This prospective review is analogous to the review of a proposal that would occur to secure research funding from an external agency (NIH, NSF, DoD, DoE, etc).

2.5.1 The Task Synopsis Form

Having established that the task meets the classification criteria above for a directed task, the Element then communicates its desire to conduct a directed research task to the Program Scientist. This is accomplished through the submission of a Directed Task Synopsis and Justification Form (Task Synopsis form or, more commonly, a Task Synopsis). The Task Synopsis form can be found electronically at the following address: http://hrp.jsc.nasa.gov/?viewFile=program/forms

The Task Synopsis form is broken into three sections:

1. General information: Information on the name of the task, PI, Co-I(s) and MTL number (the MTL number is an HRP reference number that is assigned after the Task Synopsis is submitted for review).
2. Type of review requested by the element: There are four types of review for directed research tasks. These are none, Project, Element and Program-led reviews. Details about each type of review are provided below. Table 1 below provides the default type of review that the Program Scientist has assigned to specific types of research.

3. Task synopsis: This section provides fields that are used to describe the planned work to the Program Scientist. The purpose of this brief description is to provide sufficient detail regarding the proposed task so that the Program Scientist can evaluate the element's assertion that the task is justifiably directed (insufficient time for solicitation or highly constrained) and to determine the level of review required.

Once fully completed, the Task Synopsis form can be submitted to the Program Scientist for evaluation at the following email address: JSC-HRP-Directed-Tasks@mail.NASA.gov.

Table 1 - Merit Review Types and Their Characteristics

GUIDELINES FOR ASSIGNMENT OF FORMULATION REVIEW				
	Task Type	**Task Characteristics**	**Reviewers**	**Review Criteria**
Evaluation of Task Synopsis Only	• Data Mining	• Evaluates existing data • Peer-reviewed publication not typically a product of the work.	• Program Scientist/SMO	• Does this meet the criteria for a data mining task?
	• Technology Watch	• Non-hypothesis driven • Initial data gathering for future tech development • Examples: Market surveys, TRL assessments, identification of innovation opportunities • Peer-reviewed publication not typically a product of the work.	• Program Scientist/SMO	• Does this meet the criteria for a technology watch task?
Project-led Reviews	• Pilot Testing to gather data needed to design a full research study or to evaluate a research technique)	• Non-hypothesis driven • Data to substantiate or refine future research protocol that undergoes an Element or Program-led • Examples: Test/Retest, end-end simulations • Non-competed • Peer-reviewed publication not expected	• Funding Project Scientist & Manager	• Relevance • Appropriate resources
Element-led Reviews	• Requirements Definition • Characterization Activities	• Non-hypothesis driven • Goal to capture physiologic or human factors needs to support requirements • Non-competed • Peer-reviewed publication may result	• 1-3 non-advocate scientists, including a flight medicine representative or flight surgeon (when appropriate)	• Technical Merit • Operational feasibility • Appropriate resources
	• Hardware tests • Engineering Evaluations (flight, ground or analog)	• Non-hypothesis driven • Non-competed • Feasibility assessment		
	• Analog validation studies	• Non-hypothesis driven • Non-competed • Intramural • Low-level complexity • Intent is to characterize and validate analog environment with flight	• 1-2 non-advocate scientists	
Program-led reviews	• Full research or technology development activity (flight, ground or analog)	• Hypothesis driven • Non-competed • Contributes to space normal database • Requires flight or highly visible resources • Involves astronauts as test subjects. • Medium to high level of complexity • Peer-reviewed publication is a likely outcome or planned deliverable of the task. • Intramural or extramural • Is a highly visible research study	• Program Scientist, independently as a subject matter expert • Small ad hoc group (e.g., mail review) • Mail review • Full non-advocate review panel	• Technical merit • Appropriate intra-extramural approach • Appropriate resources
	• Medical Requirements Implementation Document (MRID) enhancement activity	• Non-hypothesis driven • Non-competed • Contributes to space normal database • Descriptive enhancements of medical requirements • Is a highly visible research study • Peer-reviewed publication expected	• Program Scientist independently • Small ad-hoc group (mail review)	• Medical Requirements Implementation Document (MRID) enhancement activities

The Program Scientist may assign a Program-led review to any task if it is deemed highly visible to the program. Highly visible can mean it involves the astronaut corps, involves flight resources, is likely to draw specific attention and interest from NASA Headquarters or for any other reason deemed valid by the Program Scientist.

For studies that involve the participation of human subjects, the defaults assume that non-astronauts are being recruited for participation (except where indicated). Research tasks that involve crewmembers will undergo the most rigorous review at the Program Scientist's disposal: a Program-led Review. Since research tasks involving crewmembers as subjects utilizes limited resources, a compelling rationale is required, these research tasks will be evaluated within the overall priorities of the HRP.

Note that initiation of the Program-led review does not always initiate a Non-Advocate Review (NAR) established by a third party review vendor. As indicated above, the Program-led review spans the spectrum from the Program Scientist acting as a subject matter expert, to the full NAR panel.

2.5.2 Program Scientist's Evaluation of a Task Synopsis and Assigning a Formulation Review

Upon receipt of the Task Synopsis, the Program Scientist will evaluate the document to decide…

1. Whether the task meets the criteria of a directed task, and if so…

2. What HRP organizational level should conduct the review?

In addition, the evaluation may be used to assess whether the scope of the proposed work falls within the scope of a task that was previously granted authority to proceed, and therefore does not need to complete the merit assessment process.

After rendering a decision on the two points listed above, the Program Scientist notifies the Element Scientist, in writing, of the decision. This notification specifies the next steps for the task, which can include:

1. Rejection of the Task Synopsis on the grounds it does not meet one of the directed task criteria.

2. Authorization to undergo a review other than the type recommended by the Element.

3. Authorization to undergo a type of review other than the type of review suggested by the Element.

4. Authorization to proceed without further review under the umbrella of a previously approved task.

5. Authority to proceed without further review due to classification as a data mining or technology watch task. If the task is presented by the submitting element as a data mining task or technology watch task, and during review of the Task Synopsis the

Program Scientist concurs that the task is a data mining or technology watch task, the Program Scientist will communicate to the submitting element that no further review action is required.

For steps 2 and 3, the process proceeds to development of a task proposal. The proposal outlines the work associated with the proposed task.

2.5.3 Writing a Task Proposal

All HRP research and technology development tasks require a proposal be submitted to the managing project to describe activities, resources required and approximate schedule for completion.

As discussed below, the Program Scientist provides guidelines for the content of a directed task proposal. These guidelines are intended to serve as a helpful model of the contents and structure of a non-competed, directed task proposal. The proposal should be prepared in 12-point font Times with 1-inch margins, header and footer. The proposal should be single spaced.

1. Proposal Title Page: The proposal title page should provide the:
    - Task Title
    - Short Title (<20 characters or 4 words)
    - HRP Master Task List ID# (if already assigned)
    - Originating Project
    - PI and Co-I with Affiliation and Contact Information

2. Abstract: The abstract should be a short, succinct description of the directed task being proposed. It should be no longer than two pages. For experiments that utilize analogs or the spaceflight environment, the experiment may be highly constrained and may differ from a similar 'optimal' experiment that might take place in a laboratory setting. For instance, if an exercise experiment is desired on ISS, the experiment will be constrained by the number of subjects available, crew composition, crew schedules, exercise equipment available on Station, etc. The investigators should use the abstract to briefly describe the optimal experiment in a terrestrial setting, and how the flight or analog environment limits the ability of the investigators to conduct that experiment. Providing this information is critical for the review process, as it will convey to the reviewer (potentially an individual from outside the spaceflight community) the rationale for the constrained methodology or scope presented in the body of the proposal.

3. Table of Contents: The Table of Contents should reference all sections of the proposal and provide page numbers.

4. Directed Task Description: The directed task description is the body of the proposal, and will provide all the information necessary to understand and evaluate the scientific or technological aspects of the proposed study. Usually, this part of the proposal should not exceed 5 pages for a project-led review, 20 pages for an Element-led review, and 20 pages

for a program-led review. **The proposal should be no longer than is necessary to fully describe the proposed work.**

I. Specific Aims: A concise list of the specific aims of the proposed task, either as hypotheses (if hypotheses are being tested) or as expected outcomes, or both.

II. Relevance of the Task to the Originating Project: Provide an explanation of why this task is important to the originating project. Relevance to HRP Risks and Gaps should also be included.

III. Background and Significance: Provide a summary of important previous work relevant to the proposed task and a discussion of the significance of the proposed study to the research area or to clinical and operational needs.

IV. Research Design and Methods: Provide a detailed description of the research to be undertaken, including a discussion of the research protocol, subject issues, data collection and analysis, and statistical design.

V. Deliverables and Schedule: Provide a description of the research products and that will result from this task along with the estimated schedule for delivery and associated customer. Please also indicate the CSA status for the deliverables.

VI. References: A list of the key references cited in the text.

5. Management Plan: This section should specify how this study will be managed. In particular, if there are several members of the investigator team, the management plan should provide a clear description of the authority and responsibility of each individual.

6. Biographical Sketches: A biographical sketch, not to exceed two pages, should be provided for each named principal and co-investigator participating in the study.

7. Required Service Components: If spaceflight or special ground analogs provided through one of the HRP Core Service Projects are needed to carry out all or part of the study, these requirements should be clearly specified in this section.

8. Use of Human or Animal Subjects: This section should provide a brief, high-level description of the investigators plan to obtain human subject Institutional Review Board (IRB) certification or animal subject Institutional Animal Care and Use Committee (IACUC) certification. Note that at Johnson Space Center, the IRB is designated the Committee for the Protection of Human Subjects (http://irb.nasa.gov).

   Policies for the protection of human subjects in NASA sponsored research projects are described in NASA Policy Directive (NPD) 7100.8E *Protection of Human Research Subjects* available at: http://nodis.hq.nasa.gov/displayDir.cfm?Internal_ID =N_PD_7100_008E_ &page name=main.

Animal care and use requirements are described in the NASA Code of Federal Regulations (CFR) 1232 available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title14/14cfr1232_main_02.tpl.

9. Budget Justification: Full cost budget detail provided in this section must be sufficient for evaluation of costs for realism, reasonableness and allocation. This justification must include the following two components:
    1. Budget narrative: summary of personnel and work effort; facilities and equipment.
    2. Budget details: expenses in major budget categories, and detailed subcontract budgets.
10. Current and Pending Support: Grant awards or program funding that support tasks within the study to include current support and any pending awards.
11. Other Supporting Information: This section should be used for any appendices that provide additional information supporting the proposed study.

2.5.4 Reviewer Conflict of Interest

The following is wording describing conflict of interest. Similar language is utilized in the NASA Research Announcement process.

1. In the performance of peer review of proposals submitted to NASA, a reviewer may have access to or be furnished with information that contains unpublished research results, unpublished research ideas, and/or proprietary plans, information, and budgetary data. All NASA supervisory and management personnel and reviewers, and all non-NASA participants, are bound by Federal regulations to maintain the confidentiality of such information and to avoid conflicts of interest in the review process. [Note that Federal law prohibits Federal employees from making unauthorized disclosure of confidential information (18 U.S.C. 1905)]. Therefore, with respect to any proposals that may be furnished to or discussed in the presence of the reviewer, or that the reviewer may have access to or learn about, the reviewer agrees to use such data and information only for the purpose of carrying out the requested proposal review;
2. Refrain from disclosing or discussing such data and information with submitters of proposals, other reviewers, non-NASA support personnel, or NASA personnel outside the meetings of any designated peer review sessions;
3. Refrain from copying in part or all of any proposals that may be provided;
4. Return to NASA all proposals that may be provided along with all review sheets and other forms that have been generated in the course of the review process, or to make other disposition of such materials as directed by NASA;
5. Exercise due care to avoid any real or apparent conflict of interest in carrying out any reviews. Specifically, a person identified in a proposal (e.g., principal investigator, co-investigator, consultant or collaborator) is not permitted to participate in the review of

competing proposals unless specifically authorized by NASA to do so. A person may also be excluded from participating as a reviewer of any proposals, unless authorized by NASA, if a close professional associate from his/her own organization is identified in a proposal. In addition, a reviewer is not permitted to take part in the review of a particular proposal (a) that originates from his/her own organization; or (b) if any of the personnel identifies in the proposal are closely related to the reviewer (e.g., household family members, partners, or professional associates); or (c) if the reviewer has a financial interest in a proposing organization (e.g., ownership of stock or securities, employment, or arrangements for prospective employment); or (d) if the one or more of the investigators are individuals the potential reviewer has worked with, published with or been jointly funded with in the past 3 years.

6. Advise the HRP Program Scientist of the disclosure of any information obtained from NASA that is disclosed, used, or handled in a manner inconsistent with this agreement.

2.5.5 Executing a Formulation Review

Three types of formulation reviews (Project-led, Element-led and Program-led) are described in the following sections. The different levels of Program-led reviews are described in further detail in Section 2.5.5.3.

2.5.5.1 Project-led Review

The assignment of the project-led review will be conveyed to the Element Scientist in an email communication from the Program Scientist. The project-led review is the review with the lowest amount of programmatic involvement, and is simply a communication from the sponsoring Project or Element to the Program Scientist detailing the relevance of the task to the project's gap-closing work and noting that they have the necessary resources to complete the task.

The project-led review requires, at a minimum, the submission of the following to the Program Scientist:

1. a task proposal, as described in Section 2.5.3.
2. a resources and relevance statement.

The resources and relevance statement provides documentation to the Program Scientist that 1) the project has the funding, materials, equipment, time and personnel to complete the task and that 2) the task is relevant to the gap-closing measures of the project. This is an important document, as the Program Scientist is delegating the review to the project, and is relying on this statement to make decisions regarding ATP. The resource and relevance statement is to be developed jointly by the Project Scientist (PS) and Project Manager (PM). If an Element is not subdivided into projects, the resource and relevance statement will be developed by the Element Scientist and Element Manager. The Program Scientist allows the project wide latitude in the form of the resource and relevance statement, as long as it meets the intent and conveys the information that the Program Scientist needs to make a proper assessment of resources and relevance.

Upon submission of the resource and relevance statement, the Program Scientist will examine it and the accompanying proposal. At this time, the Program Scientist will convey any additional needs regarding the project-led review or will issue ATP.

Upon completion of the review, the Program Scientist will archive, at a minimum, the following documents to demonstrate that the task has completed the project-led review process.

- The Task Synopsis
- A communication from the Program Scientist to the element including feedback on the Task Synopsis and stating that a project-led review is assigned to the task.
- A copy of the proposal
- A copy of the resource and relevance statement
- A communication from the Program Scientist to the element issuing ATP.

Additional documents may be necessary, depending on the manner in which the review proceeds. For instance, if the Program Scientist requests an amended Task Synopsis, both the communication between the Program Scientist and the element and the amended Task Synopsis must be archived.

The Science Management Office encourages the use the following email address in order to ensure timely delivery of directed task review documents and requests – JSC-HRP-Directed-Tasks@mail.nasa.gov.

2.5.5.2 Element-led Review

The assignment of the Element-led review will be conveyed to the Element Scientist in an email communication from the Program Scientist. The Element-led review requires that the Element establish a review panel of non-advocate subject matter experts (number to be specified by the Program Scientist) to evaluate the proposal and provide the Element and Program Scientist with expert opinion on the proposed task.

Review by the panel will be guided by a review charge document, which is provided by the Program Scientist. This document provides a framework for the review, asking the reviewers to answer specific questions regarding the proposal, to identify strengths and weaknesses of the proposal and to rank the proposal relative to other proposals given the reviewer's experience. The content of the Element-led review charge is standardized, but the Program Scientist may insert additional requests for information into the charge, based on the review of the Task Synopsis. (For instance, if a specific modeling methodology is described, the Program Scientist may explicitly request that the reviewers identify any other appropriate modeling methods).

The element-led review performed by a reviewer consists of a narrative evaluation (where the reviewer is asked to provide impressions of the proposal in a narrative form), an evaluation of the specific aims (where reviewer is asked to identify strengths and weaknesses), a section on recommendations on methods to alter the proposal and an overall score. The reviewer will be provided detailed instructions describing what is required to complete the review.

The Element-led review is to be managed by the Element, on behalf of the Program Scientist. Once the review is complete, the products of the review are submitted to the Program Scientist for evaluation and a decision on ATP. The following steps should be utilized by the Element Scientist to conduct the review:

1. Identify qualified reviewers (see Section 2.5.4, Reviewer Conflict of Interest).
2. Provide reviewers with proposal and charge.
3. Collect the initial reviews from the reviewers (including a numerical score).
4. Instruct the PI to make changes to the proposal based on reviewer feedback (where appropriate).
5. Ask the reviewers to inspect and approve changes made to the proposal.
6. Have the reviewers assign a final score to the proposal.
7. Provide the review documentation to the Program Scientist for evaluation.

Once the reviewers have completed their evaluation, the review material is submitted to the Program Scientist. At minimum, completion of an Element-led review requires submission of the following:

- The Task Synopsis
- A communication from the Program Scientist to the element commenting on the Task Synopsis and stating that an Element-led review is assigned to the task
- The charge document used to guide the reviewers
- A copy of the original proposal as reviewed
- The names and CVs (or bio sketches) for the reviewers
- The comments of the reviewers to the proposal
- The amended, finals proposal, based on the comments of the reviewers (with tracked changes)
- The final proposal with all changes accepted.
- Indication from each reviewer that they are satisfied with the revisions to the proposal
- A final score for each reviewer on the proposal
- A communication from the Program Scientist to the element issuing ATP

Additional documents may be necessary, depending on the manner in which the review proceeds. For instance, if the Program Scientist requests an amended proposal, both the communication between the Program Scientist and the element and the amended proposal must be archived. Projects and Elements should use reviewers free of conflict of interest. It is important to note that having another project or element review the task is discouraged by the Program Scientist, as it may result in the appearance of conflict of interest.

The Science Management Office encourages the use the following email address in order to ensure timely delivery of directed task review documents and requests – JSC-HRP-Directed-Tasks@mail.nasa.gov.

2.5.5.3 Program-led Review

In the Program-led review, the Program is responsible for coordinating the review efforts. At the Program Scientists discretion, the Program-led review may take several forms. These include a full NAR, a mail review and a review facilitated by the Program Scientist.

1. Full Program-led NAR: The program utilizes a third party review contractor (which assigns a lead review coordinator) and NASA Advanced Capabilities Division support, to facilitate the review. Below, the individual steps of the full Program-led review are described.

   Step 1: The Program Scientist sends the lead review coordinator a memo that formally initiates the review once the proposal is received from the element. Prior to official submission of the proposal, the Program Scientist may choose to interact with the element to alter the proposal before it is sent for review.

   Step 2: The lead review coordinator develops the charge, identifies and confirms the panel Chair, recruits panel members and schedules panel meetings. The lead review coordinator sends the full proposal and charge to all panel members.

   Step 3: A review panel telecon is arranged by the lead review coordinator for initial review of the proposal to include the lead review coordinator, the Program Scientist and the review panel. The review panel, in accordance with their charge, reviews the proposal and develops a list of questions and recommendations for the PI team to address. The lead review coordinator sends the review panel's questions and recommendations to the Element Scientist (and Program Scientist).

   Step 4: The Element Scientist coordinates with the PI team to develop a response package. The response package is sent to the lead review coordinator and the Program Scientist. The lead review coordinator then sends the response package to the review panel.

   Step 5: The review panel convenes (site visit or telecon) with the PI team to discuss the response package. This meeting includes the review panel, the lead review coordinator and the Program and Element Scientists.

   Step 6: Following discussion with the PI team, the review panel develops a final report. The lead review coordinator sends the final report to the Program Scientist.

   Step 7: After reviewing the final review panel report, the Program Scientist will issue a selection memo decision on ATP. The memo and the final panel report are sent to the Element Scientist.

Table 2 - Full Program-led Review Time Estimate

Step	Description	days (median) Avg. working	days (median) Cumulative working	Range
1	REVIEW Initiated			
2	Recruit Panel/Schedule mtgs.	28	28	15 - 54
3	Panel telecon /Questions to PI team	20	48	10-40
4	PI team develops response pkg.	10	58	5 -21
5	Panel site visit w/ PI team (teleconheld when no site visit)	*26	84	30-65
6	Final Panel Report	15	99	10-31
7	Selection memo issued	16	115	12-28
			23 weeks (5.2 months)	16.2-47.8 weeks (3.7-10.8 months)

2. Program-led Mail Review: Below, the individual steps of the Program-led mail review are described.

   Step 1: The Program Scientist sends the lead review coordinator a memo that formally initiates the review once the final proposal is received from the Element. Prior to finalization of the proposal, the Program Scientist may choose to interact with the Element to alter the proposal before it is sent for review.

   Step 2: The lead review coordinator develops the charge and identifies panel members. The lead review coordinator sends the full proposal and charge to all panel members.

   Step 3: The review panel examines the proposal, and each panelist individually provides their assessment of the proposal. The lead review coordinator sends these reports to the Program Scientist.

   Step 4: After reviewing the input of the panelists and possibly consulting with the Element, the Program Scientist will issue a decision on ATP. The memo and the final panel reports are sent to the Element Scientist. If ATP is granted, the Program Scientist will request that the PI submit a revised proposal for archiving in the Program Scientist files.

3. Program-led Review Facilitated by the Program Scientist: The Program Scientist may choose to utilize his/her expertise as a subject matter expert to review a task in one of the following ways:

   - The Program Scientist uses his/her knowledge, combined with the critique of others he/she identifies in the research community, to assess the scientific merit of a given

proposal. This is less formal than the full Program-led review or Program-led mail reviews.
- The Program Scientist uses his knowledge, combined with that of members of the Science Management Office, to assess the scientific merit of a given proposal.
- The Program Scientist uses his knowledge as a subject matter expert to unilaterally assess the scientific merit of a given proposal.

At a minimum, completion of a Program-led review requires submission of the following to the Program Scientist:

- The Task Synopsis.
- A communication from the Program Scientist to the Element commenting on the Task Synopsis and stating that a Program-led review is assigned to the task (this communication will state the type of program-led to be executed).
- The charge document used to guide the reviewers.
- A copy of the proposal as reviewed.
- The names and CVs (or bio sketches) for the reviewers (including the Program Scientist if the Program Scientist served as a unilateral reviewer).
- The comments of the reviewers to the proposal (including the Program Scientist if the Program Scientist served as a unilateral reviewer).
- The amended proposal, based on the comments of the reviewers.
- Evidence that the reviewers are satisfied with the amended proposal (including a scoring of the proposal).
- A communication from the Program Scientist to the element issuing ATP.

Additional documents may be necessary, depending on the manner in which the review proceeds. For instance, if the Program Scientist initiates a full NAR, official communications between NASA Research and Education Support Services (NRESS) and the Program Scientist will be archived.

The Science Management Office encourages the use the following email address in order to ensure timely delivery of directed task review documents and requests – JSC-HRP-Directed-Tasks@mail.nasa.gov.

2.5.6 Receiving Authority to Proceed from the Program Scientist

Upon successful completion of the formulation review, the Program Scientist will decide whether to issue ATP. The notice of ATP from the Program Scientist is a component of NPR 7120.8 authorizing work to proceed. ATP to the Element Scientist will contain the information found below. Note that not all text below would be in every ATP letter. For instance, if a task is not scheduled to last more than one year, no annual reporting is required. Also, if a task is not required to be included in Task Book, no reference to Task Book will be included.

> Period of Performance: The authorized period of performance for the task is set as [*mm/dd/yyyy*] to [*mm/dd/yyyy*] and ATP is valid over this period of performance. If the task is not complete by the end of the period of performance and the PI/element wishes to

continue the work, the task will re-enter the review process with submission of a re-scoped Task Synopsis.

Issues raised in review: [*issues with review for which the PgS wants to state a formal opinion.*]

Lifecycle Reporting and Review Requirements: As a condition of funding, life cycle reporting and review requirements are assessed for this task.

Entry into Task Book: This directed research task will be entered into The Advanced Capabilities Division Research and Technology Task Book. This is an online database of research projects supported by the Human Research Program (HRP) and Exploration Technology Development and Demonstrations (ETDD). Task Book can be found at: *http://taskbook.nasaprs.com*. The Merit Review Scientist in SMO has provided a completed Task Book entry form ([*task-short-title-here]-taskbookentry.doc*) and will submit this to Task Book by [xx-xx-xxxx]. If changes to this entry are required, they should be provided to the Merit Review Scientist by [xx,xx,xxxx].

Annual Updating Requirements: The PI will receive annual requests to update task information in Task Book. This request will be sent 90 days prior to the anniversary of ATP. These updates must be completed 60 days before the anniversary of ATP. Annual updating of Task Book is a two-step process that includes 1) submission of a Task Book report and 2) submission of an annual report. Information on how to submit task book reports and annual reports can be found within the following document: *guidelines-submitting-taskbookreport.pdf.* If a task is not required to submit a report to Task Book, the Program Scientist may request that the annual report be sent to him directly.

Status Review (if requested): A status review will be conducted on this task on or around [xx-xx-xxxx]. The annual report from year [xx] will serve as the review material for the review panel. Approximately three months before the review is to commence [xx-xx-xxxx], the Program Scientist will provide the Element Scientist with a status review document. This document will contain 1) requirements for the composition of the review panel, 2) the charge to be utilized by the reviewers in completing the review, and 3) the review products that must be submitted to the Program Scientist. If an element conducts a mid-point review, the Program Scientist will attempt to synchronize the status review with the mid-point data review.

Final Update Requirements: You will receive a final request to update task information in Task Book. This request must be completed no later than 90 days after the completion of this task. Final updating of Task Book is a two-step process that includes 1) submission of a Task Book report and 2) submission of a final report. Information on submission of task book reports and final reports can be found within the following document: *guidelines-submitting-taskbookreport.pdf.* A template for use in development of final reports is attached for use, in the absence of element-specific formats. If a task is not required to submit a final report to Task Book, the Program Scientist may request that the annual report be sent to him directly.

2.5.7 Formulation Review and CPHS Evaluation

If a research protocol supported by HRP funds requires review by CPHS, it must have successfully completed the appropriate scientific merit assessment prior to evaluation by CPHS. This HRP position was defined in a joint policy statement (SA-10-247) issued by the HRP Program Scientist and the CPHS Chair on September 7, 2010. The text of the policy statement reads as follows:

> This policy statement is being issued jointly by the Program Scientist of the HRP and the Chair of the NASA CPHS Institutional Review Board (IRB). The intent of this policy statement is to reiterate the proper order of two review steps necessary to initiate a study involving human subjects: 1) scientific merit assessment and 2) CPHS evaluation.

A research protocol supported by HRP funds must have successfully completed the appropriate scientific merit assessment for the utilized funding mechanism prior to evaluation by CPHS.

This ordering of events is established to allow the Program Scientist and CPHS Chair to focus on their respective areas of responsibility. Specifically, the Program Scientist will carry out his responsibility to maintain the scientific integrity of HRP through defined merit assessment mechanisms. Completion of the scientific merit assessment process prior to evaluation by CPHS will allow CPHS to focus their efforts wholly on their responsibility to assess a planned research protocol for subject safety and protection of subject data.

Sections 1.2 (Study Funding Information) and 1.3 (Scientific Merit Assessment) of the new electronic CPHS application, scheduled to come on-line in FY11 Q1, have been designed to assist the investigator in providing evidence that the necessary scientific merit assessment for the funding mechanism has been successfully completed. The PgS and CPHS will use the information in these sections of the CPHS application to assess adherence to the correct order of merit assessment (Program Scientist) and cost-benefit analysis (CPHS).

Concurrent merit review and CPHS review requires the approval of the Program Scientist and concurrence of CPHS Chair and will be considered only in extreme circumstances.

2.5.8 Figure

See Figure 4, Process for Review of Directed Task Proposals, for a graphic presentation of the process.

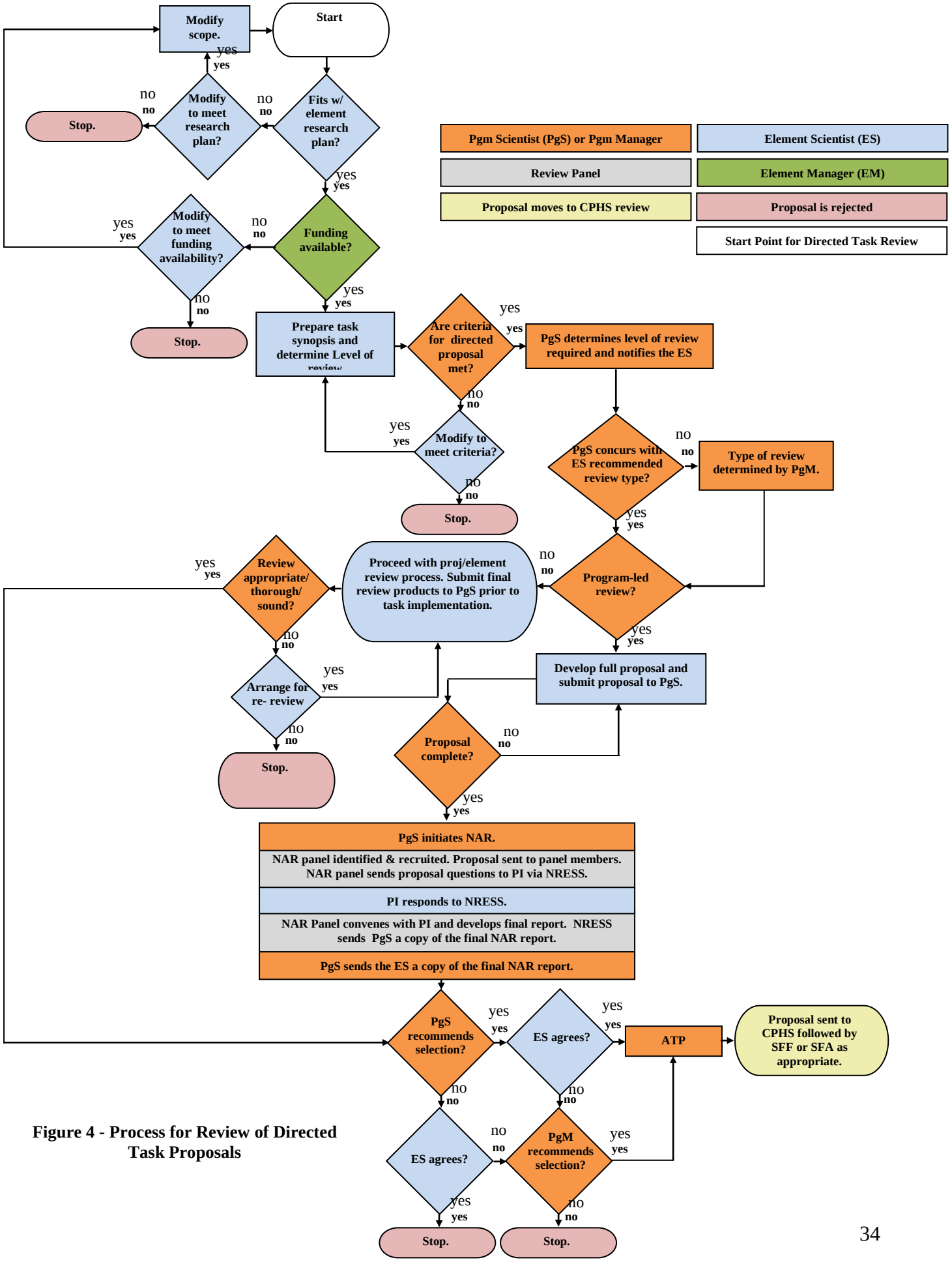


Figure 4 - Process for Review of Directed Task Proposals

2.6 PROCESS FOR ANNUAL AND FINAL REPORTING FOR DIRECTED RESEARCH TASKS

As a condition of issuance of ATP, the Program Scientist requires that annual reports and a final report be submitted. This submission fulfills the Program Scientist's responsibility to maintain review of a task over the lifetime of that task. In an effort to avoid duplication of effort, the Program Scientist utilizes a reporting mechanism that already exists to accomplish this goal.

The NASA Advanced Capabilities Task Book is a public, online database of research tasks, including directed research tasks within HRP.

2.6.1 Entry of a Task into NASA Advanced Capabilities Task Book

The Task Book Initial Input Form is utilized by the Program Scientist to convey the necessary information about an HRP directed research task to Task Book personnel, in order that they may enter the task into the Task Book database. The information listed below is the minimum set needed by Task Book personnel to initiate a Task Book entry. The information is culled from the final products of the review process (final proposal, Task Synopsis, etc.) by the SMO merit review coordinator to complete a Task Book Initial Entry Form for each task. As a component of the issuance of ATP by the Program Scientist, the completed Task Book Initial Entry Form for the task will be provided to the Element Scientist. The Element is given 2 weeks to examine the Initial Entry Form and to provide the merit review coordinator with any necessary corrections to the form. The merit review coordinator then provides the Task Book coordinator with the completed initial entry form, which is used to enter the task into Task Book. The initial Task Book Initial Entry Form fields include:

Initial PI Name, Affiliation, Contact Information**:** (name, address, phone, fax, email, organization for the task PI):

Co-I(s) Name(s), Affiliation, Contact Information: (name, address, phone, fax, email, organization for the task Co-I(s)):

Task Title**:** (consistent with IRP and MTL)**:**

Short Title: (consistent with IRP and MTL)**:**

HRP Master Task List ID#:

Originating HRP Element/ Project:

HRP Integrated Research Plan (IRP) risk(s) and gap(s) addressed by this task:

Task Start Date:

Task End Date:

Executive Summary/Abstract: The abstract should be a short, succinct description of the directed task, including background, aims, methods, preliminary results (if any), future directions and a numbered list (with brief description) of specific aims.

Deliverables: Report deliverables category and subcategory using the same format as in the IRP: Requirements [vehicle/suit design, Flight rule/MRID/practice Guideline], Technology [System solution/prototype hardware, computational models, database, tools/simulations, clinical care/medical informatics]or Tool or Countermeasures [prescription, protocol]

Flight/Ground/Analog and resources: Provide a short paragraph identifying basic information from which estimates of required flight or analog resources for queue analysis can be made. Questions to consider include the following:

- How many subjects are required?
- How many complements are needed?
- When are measurements required (pre/during/post)?
- Frequency of measurement sessions?
- Type of sessions – computer-based questionnaire, Ultrasound scanning, pulmonary testing, sample collection, etc.
- Sample collection required? Types (urine/blood/saliva)? Using existing equipment? Samples frozen, refrigerated, ambient?
- Will it require new hardware/software development? New technology or COTS?
- Estimation of size/weight (can be in comparison to something)?
- If flight, expect to require BDC in the first week? If yes, what kind of testing? About how many hours?

2.6.2 Figure

See Figure 5, Process for Entry of a Task into NASA Advanced Capabilities Task Book, for a depiction of the process.

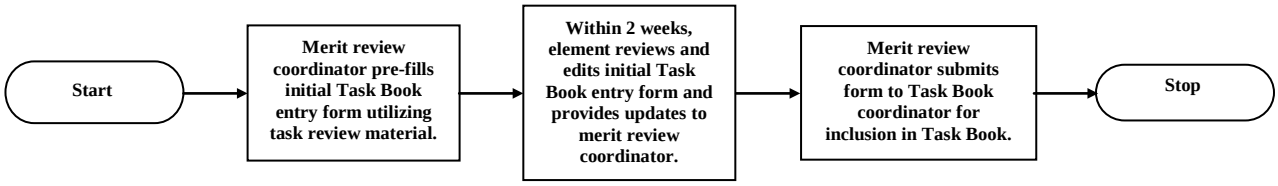


Figure 5 - Process for Entry of a Task into NASA Advanced Capabilities Task Book

2.6.3 Annual Reporting Requirements

Once a task is entered into Task Book, the Task Book database will automatically request that the basic information associated with the task be updated annually. In addition, Task Book will request the submission of an annual report, which is only accessible by NASA management. These annual reports are submitted to Task Book 60 days prior to the anniversary of authority to proceed. Submission of an annual report is utilized by the Program Scientist to assess progress of the task against the stated objectives of the task in the task proposal.

The information below is a general format for annual reports. Formatting required from a sponsoring HRP Element may be utilized in lieu of the formatting below, given that all components of the annual report listed below are present. Questions regarding Annual Reports may be addressed to taskbook@nasaprs.com

1. Date of Report:

2. Task Title: The official task title listed in the HRP Master Task List.

3. Short Title: The official short task title listed in the HRP Master Task List.

4. HRP Master Task List ID#: The Master Task List ID number associated with this task.

5. Originating HRP Element/Project: The HRP Element that conducted/sponsored the work in the report.

6. HRP Integrated Research Plan (IRP) risk(s) and gap(s) addressed by this task: The risks and gaps are found in HRP 47065, IRP. List the risk and gaps addressed by this proposal.

7. Time Interval Covered in This Report: For the annual report, this should be the previous year.

8. PI Name, Affiliation and Contact Information (name, address, phone, fax, email, organization for the task PI):

9. Co-I(s) Name, Affiliation and Contact Information (name, address, phone, fax, email, organization for the task Co/I(s)):

10. Directed Task Description:

    I. Abstract: The abstract should be a succinct description (500 words) of the directed task.

    II. Background/Introduction: Information necessary to understand the specific aims and research methods

    III. Specific Aims: A numbered list of the specific aims (including a description of each aim).

IV. Research Methods: A detailed description of the research methods utilized/planned for this task.

V. Annual Progress: A list of results over the last calendar year (if any) that derive from the task.

VI. Discussion and Planned Work for the Next 12 Months: Description of next year's planned work and any potential updates to the IRP or other programmatic level documentation.

VII. References: A list of references cited in the report.

11. Request Change to Start or Stop Dates (please provide original date, requested new data and rationale. For NRAs, COTR must authorize change in date. For Directed task, Element Manager must authorize change in date):

12. Awards, Publications, Presentations: A list of all presentations, published abstracts, articles or other materials this grant has supported during the last 12 months.

13. Budget or Key Personnel Changes: Any changes to the budget or personnel over the period covered in this report.

2.6.4 Final reporting requirements

Final Reports are submitted no later than one year after receipt of final flight data session (flight studies), data collection (ground studies), or return of samples. Submission of a final report is utilized by the Program Scientist to assess the accomplishments of the task against the stated objectives of the task in the task proposal.

The information below is a general format for Task Book final reports. Formatting required from a sponsoring HRP Element may be utilized in lieu of the formatting below, given that all components of the final report listed below are present. Questions regarding final reports may be addressed to taskbook@nasaprs.com

1. Date of Report:

2. Task Title: The official task title listed in the HRP Master Task List.

3. Short Title: The official short task title listed in the HRP Master Task List.

4. HRP Master Task List ID#: The Master Task List ID number associated with this task.

5. Originating HRP Element/Project: The HRP Element that conducted/sponsored the work in the report.

6. HRP Integrated Research Plan (IRP) risk(s) and gap(s) addressed by this task: The risks and gaps are found in HRP 47065, IRP. List the risk and gaps addressed by this proposal.

7. Time Interval Covered in This Report: For the final report, this should be the entire project duration.

8. PI Name, Affiliation and Contact Information (name, address, phone, fax, email, organization for the task PI):

9. Co-I(s) Name, Affiliation and Contact Information (name, address, phone, fax, email, organization for the task PI):

10. Directed Task Description:

    I. Abstract: The abstract should be a succinct description (500 words) of the directed task.

    II. Background/Introduction: Information necessary to understand the specific aims and research methods

    III. Specific Aims: A numbered list of the specific aims (including a description of each aim).

    IV. Research Methods: A detailed description of the research methods utilized/planned for this task.

    V. Annual Progress: A list of results over the last calendar year (if any) that derive from the task.

    VI. Discussion and Planned Work for the Next 12 Months: Description of next year's planned work and any potential updates to the IRP or other programmatic level documentation.

    VII. References: A list of references cited in the report.

11. Awards, Publications, Presentations: A list of all presentations, published abstracts, articles or other materials this grant has supported over the lifetime of the grant.

12. Life Sciences Data Archive (LSDA)/ Equipment Archive: A significant amount of data from NASA-funded research is archived in NASA's Life Sciences Data Archive (LSDA). Utilize this area to identify data (if any) from this experiment that has been made available in the LSDA data archive and/or a list of any specialized equipment and the location/ contact information for persons who can grant access to that equipment.

2.7 PROCESS FOR STATUS REVIEW OF A DIRECTED RESEARCH TASK

Annual reports are intended to serve the Program Scientist's responsibility to assess the progress of any given research task on an ongoing basis. Specifically, the annual report provides insight into the results to date and planned work over the next annual cycle for the task.

However, it is possible that a specific aspect of a task is identified that is novel, controversial or not well understood. Unlike the annual report, the status review is a defined mid-term review gate, akin to the element and Program-led review processes that must be completed prior to continuation of the task.

A status review is initiated at a key point in the execution of a research task, such as once a pre-defined number of subjects have completed a research protocol. The annual report for the last full year will serve as the review material for the review panel, along with any additional information requested by the Program Scientist. The PI team should tailor the annual report to address the issues under examination in the status review. The issues under examination will be communicated to the PI via a review charge, similar to the review charge for the Element-led review. The charge will be composed of a narrative section, with specific language calling out the specific aspect of the study that resulted in the initiation of a status review.

If an element conducts a mid-point review, the Program Scientist will attempt to synchronize the status review with the mid-point data review.

Approximately two months before the review is to commence, the Program Scientist will provide the Element Scientist with a status review charge. This charge will contain 1) requirements for the composition of the review panel, 2) the charge to be utilized by the reviewers in completing the review, and 3) the review products that must be submitted to the Program Scientist. The manner of execution of the review will be decided by the Program Scientist, in consultation with the Element Scientist at this time.

If the Program Scientist and Element do not concur on the outcome of the status review and an agreement cannot be reached, then the Program Manager will provide input on how the task will proceed.

2.8 PROCESS FOR PRE-DELIVERY REVIEW OF A DIRECTED RESEARCH TASK

- TBD

2.9 PROCESS FOR CUSTOMER ACCEPTANCE REVIEW OF A DIRECTED RESEARCH TASK

Customer-Supplier Agreements (CSA) are established to document the responsibilities of both the customer and supplier of a research product prior to the initiation of a research task. The CSA gives both parties a framework to judge the relative success of a research effort in developing and delivering a specific product. The Program Scientist has responsibility to assure that the products developed within HRP and delivered to entities outside of the program meet the needs of their customers. The customer acceptance review is a process that takes place between the customer and supplier, which assists the Program Scientist in achieving this review responsibility. The Program Scientist allows the element and project wide latitude in the form of evidence that the customer acceptance review is complete. In essence, the evidence needs to document that the goals of the customer supplier agreement were satisfied by both parties and that the agreement is competed in full.

Upon completion of the CSA, the Program Scientist will archive, at a minimum, the following documents to demonstrate that the task has completed the customer/supplier review process.

- The original CSA.
- Any documentation that was delivered by the element to the customer in support of the transition of the research product.
- A joint notification from the customer and supplier that the research product meets the requirements described in the CSA and that the effort is concluded.

If the Program Scientist and element do not concur on the outcome of the customer acceptance review and an agreement cannot be reached, then the Program Manager will provide input on how the task will proceed.

2.10 PROCESS FOR TRACKING REVIEW PROGRESS

Once a task has entered any of the review processes mentioned above, review progress is monitored by the SMO and reported on the HRP Review Summary which is sent to stakeholders as needed. If an individual wishes to be kept up to date on the progress of any individual task, they can contact the SMO for inclusion on the distribution list.

The Merit Review Summary provides the status of the review, the current action of the review, who is responsible to complete that action and when that action is anticipated to be complete.

The SMO encourages the use of the following email address in order to streamline the delivery of directed task review documents and requests – JSC-HRP-Directed-Tasks@mail.nasa.gov.

2.11 PROCESS FOR ARCHIVING DATA RESULTING FROM A DIRECTED RESEARCH TASK

A significant amount of data from NASA-funded research is archived in NASA's Life Sciences Data Archive (LSDA). As not all data is archived using this mechanism, determination of which datasets to archive in LSDA is science-driven. The supporting Element Scientist will work with LSDA to determine whether the data collected in this experiment can be archived in LSDA, no later than one year from the granting of authority to proceed. If data archive is deemed appropriate for this task, specific archiving requirements will be specified in a LSDA Data Submission Agreement, to be entered into by the element and LSDA.

2.12 PROCESS FOR PRINCIPAL INVESTIGATOR (PI) INITIATED REQUEST FOR CHANGE IN FUNDED INVESTIGATION

2.12.1 Process Introduction

This process defines the steps necessary in the review and disposition of PI-initiated requests for changes within an HRP investigation and the roles of each individual involved in the process.

2.12.2 The Principal Investigator Requests for Review and Approval of Changes

The first step in this process is the written notification from the PI to the PS and/or PM and Contracting Officer Technical Representative (COTR) or Technical Officer requesting changes in the following:

- Funded Investigation PI/ Co-I
- Funding Level
- Period of Performance
- Scope of the investigation – A change in scope will follow this process unless the assessment from the PS concludes that the changes are significant enough to warrant a different process to be followed [i.e., Process for Determining Level of Peer Review/NAR for Investigation Change in Scope (TBD)]. If the PS determines that the change in scope does not warrant an additional review, concurrence from the next higher-level scientist (PES or Program Scientist) is required.

Only the formal notification via letter or email to the PS (in the event PS is not the COTR), COTR and/or PM containing written rationale for the request will be considered as a PI-initiated change.

In the event that the COTR is not the PS, then the COTR of record must forward the request to the PS and PM (if not included in the original request) for assessment within one week of receipt. If the PS is the COTR, then the PS must forward a copy of the request to the PM within a week if not included in the original request. This allows the request to be assessed from all aspects. Before proceeding with the next step, the COTR will submit a copy of the PI request to the Grant Administrator for record keeping.

The Grant Administrator is the official HRP repository of all grant information including changes to individual grants and notifies the Task Book Administrator of changes in particular grants. The Grant Administrator serves as the liaison to Procurement, the NASA Support Services Contract (NSSC), and the Defense Contract Management Agency (DCMA) in all matters regarding HRP grants. They are responsible for ensuring all grants have the appropriate documentation prior to submission to NSSC. The Grant Administrator may also serve as the COTR, and in that capacity participates in the approval or disapproval of the PI-initiated request with the assessment team. When serving as the COTR, the Grant Administrator is responsible for notifying the appropriate HRP project management team, coordinating assessment, and officially notifying the PI, Contracting Officer (CO) and DCMA, in writing, of the final disposition of the request(s).

Table 3 - Grant Administration

Function Description	**CO**	**Grant Administrator**	**COTR**
Official repository of Grant proposal		**X**	
Receives and records formal requests for changes to Grant		(receives copy from COTR)	**X** (with a copy to Grant Admin)
Coordinates Assessment of formal change request			**X**
Evaluates paper for consistency with	**X**		

Grants Handbook/ QA paper			
Notifies Procurement (CO) of Change		(receives copy from COTR)	**X** (with a copy to Grant Admin)
Notifies PI (Grantee) of Change	**X** Via 1687 form	(receives copy from COTR)	**X** (with a copy to Grant Admin)
Notifies Taskbook Administrator		**X**	
Issues Grant contract changes	**X**		
Liaison to Procurement/CO		(receives copy from COTR)	**X** (with a copy to Grant Admin)

2.12.3 The Project Manager, Project Scientist, and COTR Assess the Requested Change

The assessment of the changes within this process only pertains to identified projects and not to tasks within those projects. It is the responsibility of the PM and PS to determine impacts between or among tasks, to assess priority within their project, and to deal with them appropriately.

A response regarding the assessment to the PI is provided by the COTR within 30 days of receipt of request. The response may include disposition of the request or identification of when a final disposition can be expected. The steps carried out within the assessment by the Project differ for single project elements and for multiple project elements as follows:

2.12.3.1 Single Project Element Assessment

The assessment for a single project element has three facets. First, the assessment team determines if the change benefits the project and is of high enough priority, compared with other project liens, to proceed. The assessment team is comprised of the PS, the PM, and the COTR, if other than the PS. Next, the assessment team will evaluate the change request and determine approval or disapproval of the request.

The final facet of the assessment is affirming the benefit to the project. The team must make three additional assessments prior to any decision to approve the change: whether the project has resources available, whether it affects another element, and whether the change affects the original plan sufficiently to warrant re-review. If the result of the assessment indicates that there is a benefit to the Project and resources are available within the Project, the Project should implement the decision.

The first step of the project's assessment will hinge on whether the requested change benefits the project directly or indirectly. Considerations regarding the effects of the change on other tasks

within the project are made at this point. If it is found that the change benefits the PI's ability to complete the research study and does not harm the project, it is considered a benefit to the project. If the requested change does not benefit the project directly or indirectly, the requested change will not be approved.

If applicable, the project will evaluate the available resources to implement the change. If there are no resources available or the change affects an HRP-controlled milestone, a project representative will submit the CR to the HRP Manager via the HRPCB.

If it is determined that the change is significant enough to warrant re-review by the peer review panel, a different process is followed [i.e., Process for Determining Level of Peer Review/NAR for Investigation Change in Scope (TBD)]. This review must be completed with positive scientific merit results prior to final resource assessment and recommendation for approval.

2.12.3.2 Multi-Project Element Assessment

The assessment for a multi-project element has three facets to be considered. First, the assessment team must determine if the change benefits the project and is of high enough priority, compared with other project liens, to proceed. The assessment team is comprised of the PS, the PM, and the COTR, if other than the PS. After affirming the benefit to the project, the project must make four additional assessments prior to any decision to approve the change: whether the project has resources available, whether it affects another project/element, or controlled milestone, and whether the change affects the original plan sufficiently to warrant re-review. The final facet of the assessment activity is the decision implementation by the project.

The project's assessment will hinge on whether the requested change benefits the project directly or indirectly. Considerations regarding the effects of the change on other tasks within the project are made at this point. If it is found that the change benefits the PI's ability to complete the research study and does not harm the project, it will be considered a benefit to the project. If the requested change does not benefit the project directly or indirectly, the requested change is not approved.

If applicable, the project will evaluate the available resources to implement the change. If there are no resources available, a project representative will submit the CR to the HRP Manager via the HRPCB.

Additionally, the results of the assessment will determine if the requested change will impact an HRP-controlled milestone or another project within the same Element or another Element within the Program. Any change in implementation of an experiment that has been selected for flight must be coordinated with the ISSMP. When a change affects an HRP milestone, another project within the same Element, or another Element within HRP, it should be understood that elevation to the Element Control Board (CB) and/or to the HRPCB (for changes in HRP-controlled milestones) will follow.

In the event that the requested change affects other project(s) or Element(s), the respective PMs, PSs, and COTRs will attempt to reach a consensus. This step allows the teams to work out the issues and to seek approval for the change without having to take these matters to a higher board.

No issues with any of the projects means that all projects can accommodate the change within current resources, the change does not harm any project, the change does not affect an HRP-controlled milestone, and all management teams agree the change should be implemented. If a consensus is reached, based on the previous criteria and a CR is not written, the PS will document the details of the consensus in the response letter to the PI.

If there is no consensus between or among the affected parties, a project representative will submit the CR containing the unresolved issues to the respective Control Board at the next higher level within the HRP structure.

If it is determined that the change is significant enough to warrant re-review by the peer review panel, a different process is followed [i.e., Process for Determining Level of Peer Review/NAR for Investigation Change in Scope (TBD)]. This review must be completed with positive scientific merit results prior to final resource assessment and recommendation for approval.

2.12.4 A Representative from the Project Receiving the PI Request Submits a CR for Board Review

When a consensus is not reached, a project representative will submit a CR via the BPS, where applicable, to the controlling Board for resolution. There are some Program Elements where BPS is not used as a CM tool; for those Program Elements, their current avenue to process CRs is implemented. In the event that the particular Program Element does not have a Control Board at their level, the CR will be elevated to the HRPCB for final resolution.

If the issues are not resolved at the Program Element CB level, elevation to the HRPCB via CR into BPS is required.

2.12.5 The Controlling Board Assesses the Request

The board will convene and assess impacts for acceptability; if the impacts are accepted, the board will provide or make available the resources necessary to implement the change. Additional resources may indicate additional funding is needed.

In the event that changes in center, Project, or Program Element funding levels are required, the "Process and Criteria for Preparing a Budget Change Directive (BCD)" should be followed; this process references the pertinent documentation needed and provides funding realignment guidance.

If it is concluded at the end of the assessment that the impacts are not acceptable by the board due to lack of available resources, the PI-requested change is disapproved.

2.12.6 The Project Implements the Decision Regarding PI-Initiated Request

If the request is approved, the assessment team comprised of PM, PS, and COTR will determine if a contract change is needed. In the event that updates to the contract are required, the Contract Change Process will be initiated.

If the request is approved and no changes to the contract are needed, the COTR informs the PI and CO via letter under the Technical Officer or COTR's signature, with the PM and PS

concurrence (if PS is not the COTR) and a copy to the Grant Administrator. Subsequently, the Grant Administrator will notify the Taskbook Administrator.

If the request is disapproved, the COTR will inform the PI and CO via letter under the Technical Officer or COTR's signature, with the PM and PS concurrence (if PS is not the COTR) and a copy will be provided to the HRP Program Scientist and the Grant Administrator. Subsequently, the Grant Administrator will notify the Task Book Administrator and the HRP Master Task List point of contact.

2.12.7 The Contract Is Changed

If the approved request warrants a change to the existing contract, the COTR will work with his/her associated Contracting Officer, Resource Analyst, and the Grant Administrator to implement it via the Contract Change process.

2.12.8 Figure

See Figure 6 for a pictorial representation of the Process for PI-Initiated Request for Change in Funded Investigation.

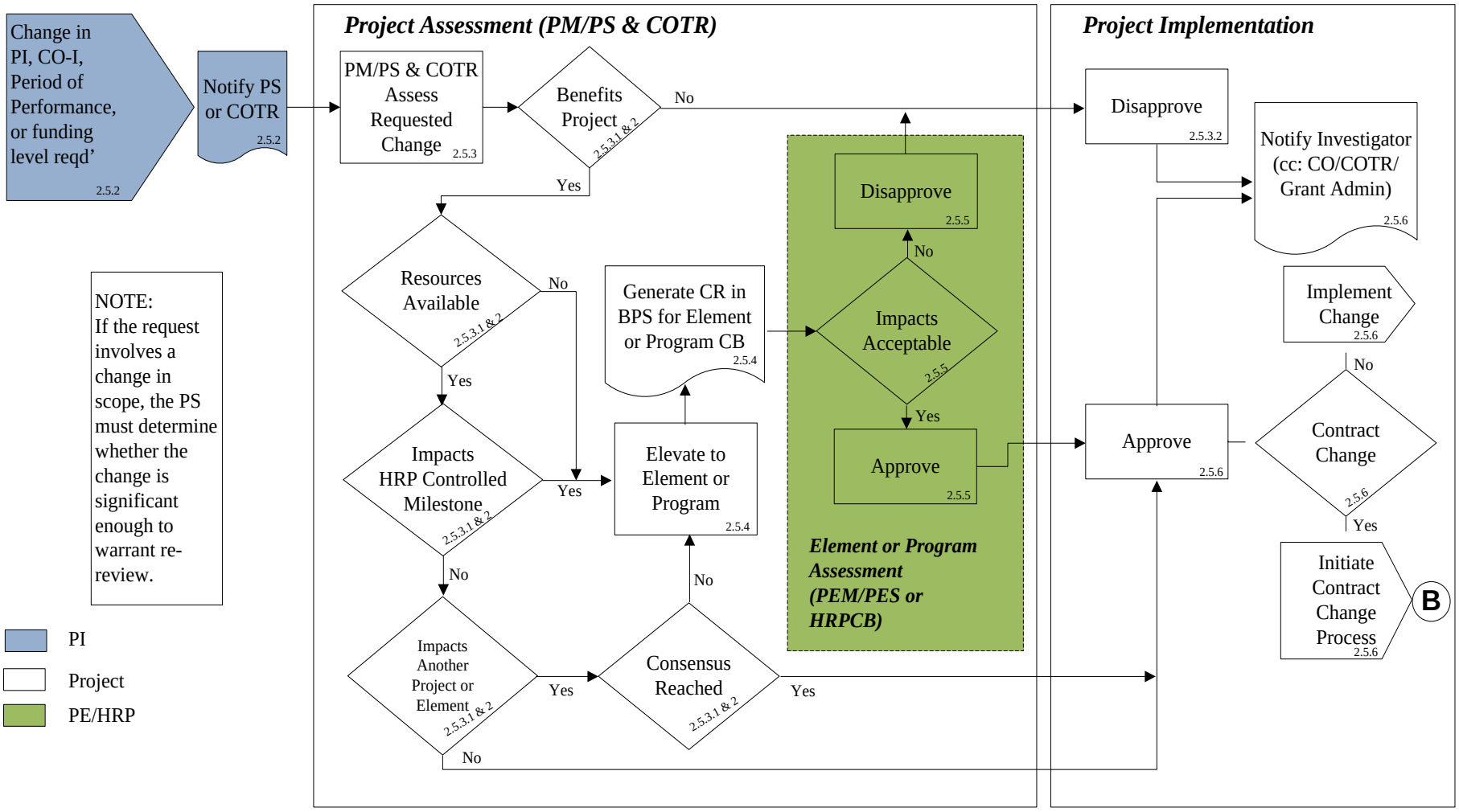


Figure 6 - Process for PI-initiated Request for Change in Funded Investigation

Contract Change Process

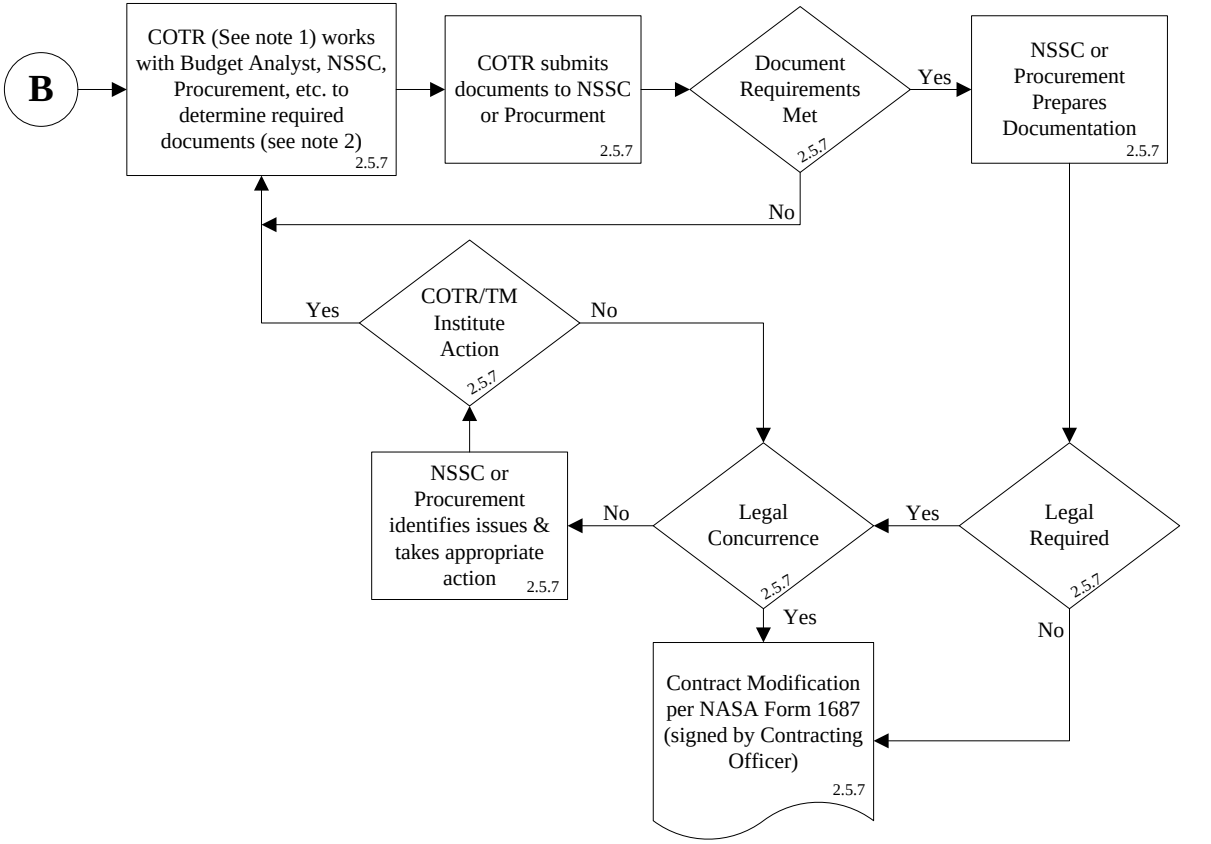


Figure 6 - Process for PI – Initiated Request for Change in Funded Investigation (Continued)

2.13 PREPARING A BUDGET CHANGE DIRECTIVE (BCD) TO MOVE FUNDING

2.13.1 Process Introduction

This process defines the steps and criteria involved in the preparation and approval of a BCD. These changes affect the budget baseline. The budget baseline includes decisions from the Programming, Planning, Budgeting and Execution (PPBE) process along with subsequently approved BCDs.

2.13.2 Initiation of the Budget Change Directive (BCD)

The BCD process starts when a change to the baseline budget is required. The Budget Analyst for the party desiring the change usually initiates the BCD in the BCD system. Budget changes include the following:

- Budget shifts between full cost elements (civil service labor, travel, procurements), even if zero-sum
- Budget shifts between projects within a program element
- Budget shifts between centers within a program element
- Budget shifts between program elements
- Changes in the number of civil service full time equivalents (FTEs)

In addition, two types of budget changes also require approval by HRP management:

- Distributions from or additions to HRP Program reserves
- Areas of management interest

2.13.3 Threshold for BCDs

For changes under $100,000, an approved BCD is not required prior to implementing the budget change. However, these changes need to be reported on a quarterly basis to the HRP budget analyst until a BCD is processed. Multiple changes may be aggregated into one BCD. For example, a $30,000 budget change from labor to travel, and another $20,000 change from labor to procurement can be combined into one $50,000 BCD.

2.13.4 Determine Approval Levels for the BCD

Approval levels for the BCD are determined by the type and impact of budget change requested. The approvals are explained in detail in the following sections:

2.13.4.1 Change within Center, Within the Program Element, and Within the Project – No Change to FTE

This type of change involves a shift between full cost elements without a change to the center, Program Element, or project bottom line budget. This change does not affect previously approved civil service FTE levels. Approvals required for this change are:

- Center Technical Manager (if Project Manager is external to the center)
- Center Budget Analyst (if Project Manager is external to the center)
- Project Manager
- Project Budget Analyst

2.13.4.2 Change within Center, Within the Program Element, and Between Projects – No Change to FTE

This type of change involves a shift between projects within a program element at a center. The projects' bottom line budgets are affected, while the center and program element bottom line budget remain the same. This change does not affect previously approved civil service FTE levels. Approvals required for this change are the following

- Center Technical Manager (if Project Manager is external to the center)
- Center Budget Analyst (if Project Manager is external to the center)
- Supply Project Manager
- Recipient Project Manager
- Project Budget Analyst(s)
- Program Element Manager

2.13.4.3 Change within Center, Between Program Elements – No Change to FTE

This type of change involves a shift between program elements at a center. The program elements' bottom line budgets are affected, while the center bottom line budget remains the same. This change does not affect previously approved civil service FTE levels. Approvals required for this change are:

- Center Technical Manager (if Project Manager is external to the center)
- Center Budget Analyst (if Project Manager is external to the center)
- Supply Project Manager
- Recipient Project Manager
- Project Budget Analyst(s)
- Supply Program Element Manager
- Recipient Program Element Manager
- Program Element Budget Analysts
- HRP Program Management
- HRP Budget Analyst

2.13.4.4 Change between Centers, Within the Program Element, Within the Project –No Change to FTE

This type of change involves a shift of budgets within a project but between centers. The centers' bottom line budgets are affected; however, program element and project bottom line budgets remain the same. This change does not affect previously approved civil service FTE levels. Approvals required for this change are:

- Supply Center Technical Manager
- Recipient Center Technical Manager
- Supply Center Budget Analyst
- Recipient Center Budget Analyst

- Project Manager
- Project Budget Analyst
- Program Element Manager
- Program Element Budget Analyst
- HRP Program Management
- HRP Budget Analyst

2.13.4.5 Change between Centers, Within the Program Element, Between Projects –No Change to FTE

This type of change involves a shift of budgets between centers and between projects. The centers' and projects' bottom line budgets are affected; however, the program element bottom line budget remains the same. This change does not affect previously approved civil service FTE levels. Approvals required for this change are:

- Supply Center Technical Manager
- Recipient Center Technical Manager
- Supply Center Budget Analyst
- Recipient Center Budget Analyst
- Supply Project Manager
- Recipient Project Manager
- Project Budget Analyst(s)
- Program Element Manager
- Program Element Budget Analyst
- HRP Program Management
- HRP Budget Analyst

2.13.4.6 Changes to FTE

This type of change involves any change to the FTE levels. The bottom line budget of the impacted center, program element, or projects may or may not be affected, depending on how the funding associated for the FTE change is handled. For example, if the Ames Research Center (ARC) FTEs in Exploration Medical Capability (ExMC) are decreased, but the associated civil service labor funding is shifted to ARC ExMC procurements, the bottom lines of the center and program element are not impacted. Any change involving FTEs must be approved by the following parties, in addition to the approvals for associated budget changes.

- Center Technical Manager(s)
- Center Budget Analyst
- HRP Program Management
- HRP Budget Analyst

2.13.5 Distribution from or Additions to HRP Program Reserves

Any change involving HRP Program Reserves must be approved by the following parties, in addition to the approvals for associated budget changes:

- HRP Program Management
- HRP Budget Analyst

2.13.6 Budget Changes in Areas of Management Interest

Some budget changes may require HRP program management approval even though it is not required in the other sections. These types of changes will vary over time depending on the programmatic environment. Some current examples of budget changes that will require HRP Program Management approval include:

- Changes impacting international partnerships
- Significant changes to a program element's content
- Changes to any area of interest as determined by HRP Program Management

In these cases, HRP Program Management and an HRP Budget Analyst will need to be included on the BCD for approvals.

2.13.7 BCD Final Approval

Once the final approver has signed the BCD, the HRP budget analyst will document the budget change in the HRP internal databases.

If the change affects program elements and/or centers, the HRP budget analyst will also coordinate the change with NASA Headquarters. This may also involve changes in the Resource Management Reporting System (RMRS) and NASA accounting systems. The budget analyst that initiated the BCD is automatically notified of the final approval by the BCD system. At this point, it is the responsibility of the budget analyst to notify all affected parties of the BCD status.

2.13.8 BCD Disapproved

If a BCD is disapproved, the BCD system will automatically notify the initiating Budget Analyst. At this point, the initiating Budget Analyst can modify the original BCD and re-route it for approval, withdraw the BCD from the BCD system, or withdraw the original BCD and submit a new one.

2.13.9 Figure

See Figure 7 for a pictorial representation of the Preparing a BCD To Move Funding process.

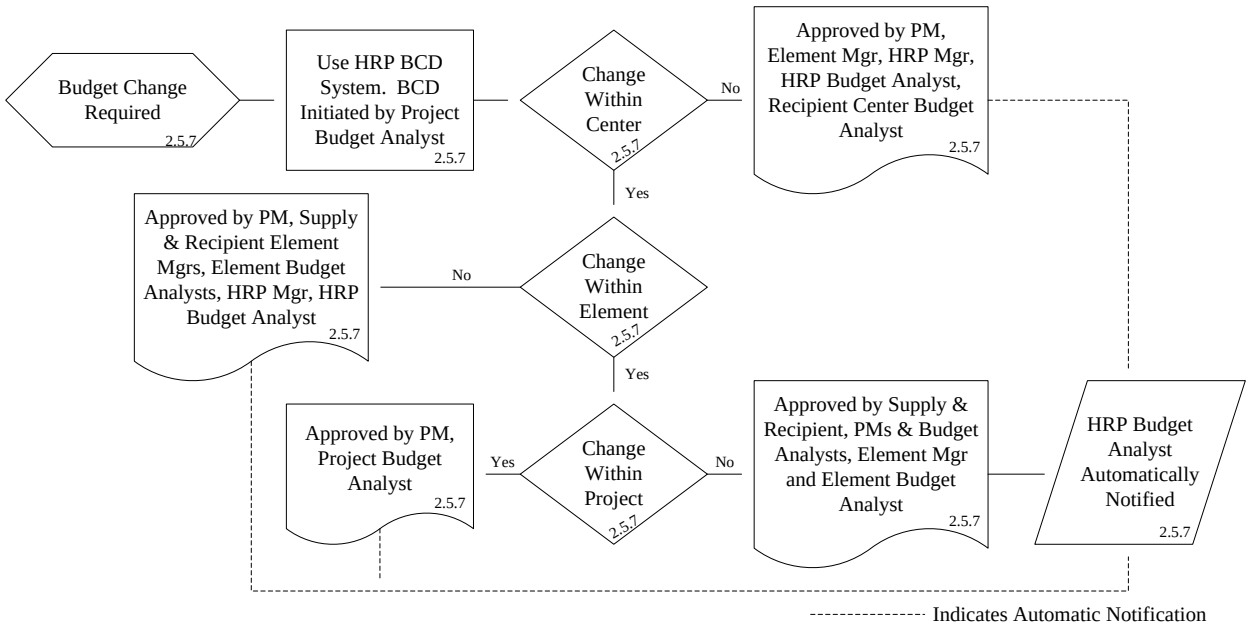


Figure 7 - Preparing a BCD to Move Funding

2.14 PROCESSING CHANGE REQUESTS THROUGH THE HRPCB AND SMP

2.14.1 Process Introduction

A change request is a document used to request a change to the approved version or configuration of an item that requires configuration management. Items requiring configuration management include, but are not limited to, controlled documents, BCD, flight manifests, etc. Processing of CRs is under the purview of JSC-28330, Space Life Sciences Directorate Configuration Control Management Plan, Section 4.0. The process described below defines the change flow through the HRPCB and SMP.

2.14.2 CR Logistics

The initiator drafts a CR in the BPS. The Space Life Sciences Directorate (SLSD) CM support personnel work with the initiator refining the CR content and list of evaluators prior to releasing it for further processing by the HRPCB and SMP.

2.14.3 Initial Processing

The Executive Secretary reviews the CR for submittal readiness to the Chairperson or Deputy. If the Executive Secretary determines the CR is not ready, then the CR initiator has an opportunity to rework the CR. Once the initiator reworks the CR, the Executive Secretary reviews the reworked CR for submittal readiness to the Chairperson or Deputy. If the Executive Secretary determines the CR is ready, then it is forwarded to the Chairperson or Deputy for further processing.

2.14.4 HRPCB or SMP Releases the CR

The Chairperson or Deputy decides whether or not to release the CR for review by the evaluators and whether it will be per normal board processing or out of board processing. It may be decided that it is appropriate to have an informational presentation prior to releasing the CR. The purpose of

the informational presentation is to introduce the change and provide clarification to the board. In addition, the informational briefing provides the opportunity to ensure all necessary evaluators are listed on the CR. Unless decided otherwise, the CR is released.

2.14.5 Normal Board Processing

The CR goes out to the list of evaluators for review and comment. The initiator gathers the comments and dispositions them with the evaluators. This disposition can occur during a Technical Coordination Meeting (TCM) as required. Upon completing the comment disposition, a board meeting is held to determine whether or not to approve the CR. If the CR is approved, a change directive and actions are issued. The actions are then closed and archived. If the CR is not approved, then the initiator has the opportunity to rework or cancel/withdraw the CR as previously described.

2.14.6 Out of Board Processing

The CR goes out to the list of evaluators for review and comment. The initiator gathers the comments and dispositions them with the evaluators. The Chairperson or Deputy reviews the disposition results and determines whether or not to approve the CR. If the CR is approved, a change directive and actions are issued. The actions are then closed and archived. If the CR is not approved, then the initiator has the opportunity to rework or cancel/withdraw the CR as previously described.

2.14.7 Figure

See Figure 8 for Processing CRs through the HRPCB and SMP.

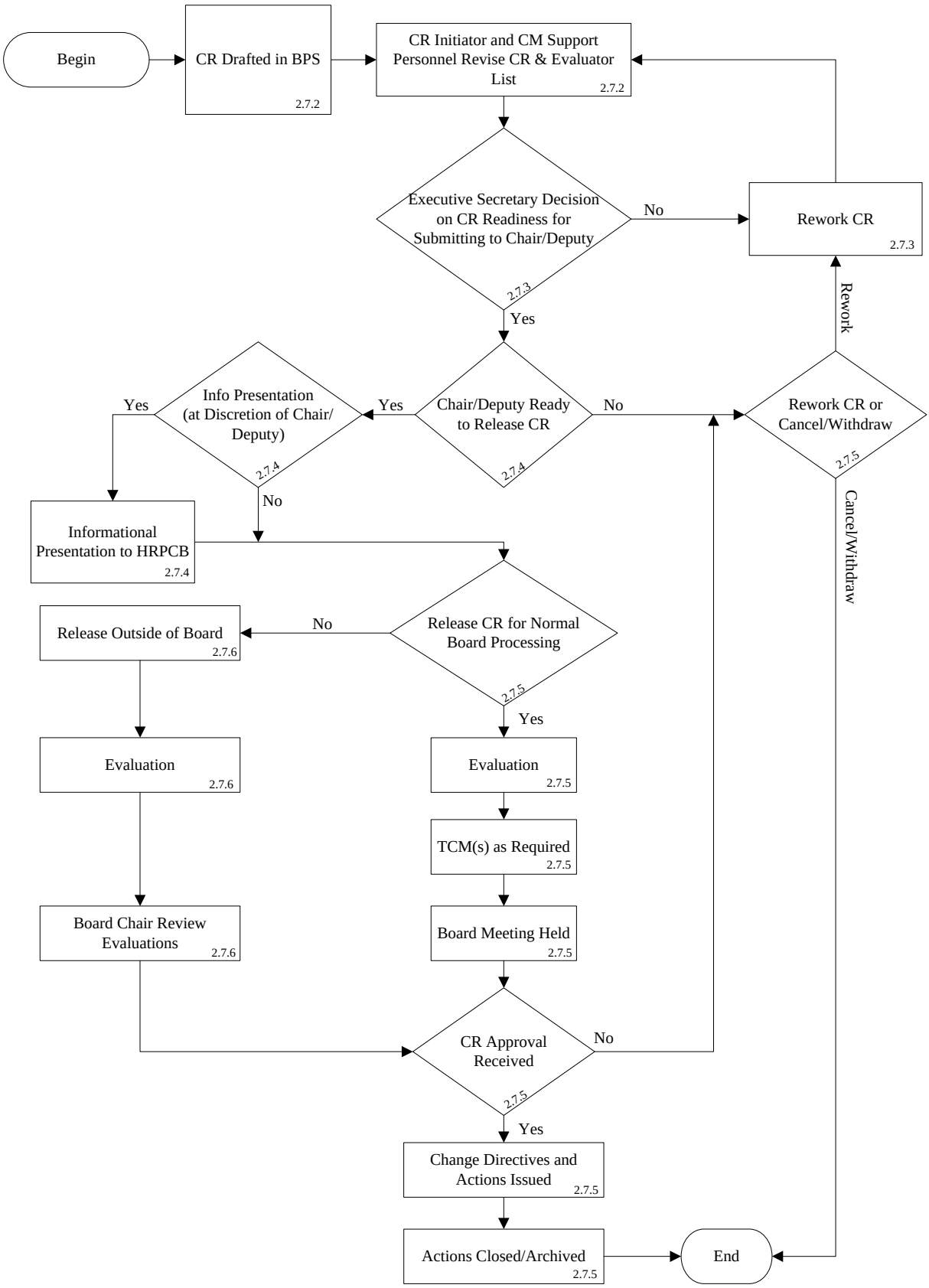


Figure 8 - Processing CRs through the HRPCB and SMP

2.15 PROCESS FOR UPDATING THE RISK MANAGEMENT ANALYSIS TOOL

The HRP is responsible for updating the Risk Management Analysis Tool (RMAT) for risks assigned to the HRP. Updates result from changes to risks, receipt of additional evidence relative to a risk, or the introduction of new contributing factors. The RMAT is formally maintained by the HSRB; however, the HRP has delegated responsibility for updating a subset of the risk information. The HSRB maintains the "quality record" of the RMAT; however, the HRP is responsible for recommending updates.

Each RMAT for a risk owned by the HRP is mapped to a HRP Program Requirements Document (PRD) risk. This mapping is maintained in the HSRB Master Risk List (MRL) comments column. Each Element is responsible for updating the RMATs associated with the PRD risks that are their responsibility.

2.15.1 Identify Change to RMAT Content

Changes in RMAT content can range from changes driven by a new decision to changes in information documented in one of the risk factors to changes in the overall likelihood or consequence of a risk. The following are examples of ways in which a change to RMAT content is identified:

2.15.1.1 An HRP Element encounters new data or evidence that necessitates a change in the RMAT.

2.15.1.2 Once per year, the Science Management Office issues a call for review of the evidence within the HRP. As part of this review, the Elements assess whether there has been new evidence that would necessitate a change to any RMAT.

2.15.1.3 The HSRB identifies a new risk needing research or changes to an existing risk assigned to the HRP.

2.15.2 Review Supporting Data and Proposed RMAT Change

2.15.2.1 The responsible Element works with the Risk owner and subject matter experts to capture the recommended changes in the RMAT and prepare a presentation with supporting evidence.

2.15.2.2 The proposed changes and evidence are reviewed through the appropriate Element-level board.

2.15.2.3 The Element Scientist and/or Risk owner presents the updated research approach to the HRP SMP for concurrence.

2.15.3 The Element Scientist or Risk Owner Presents the Recommended RMAT Risk Update to the HSRB for Approval

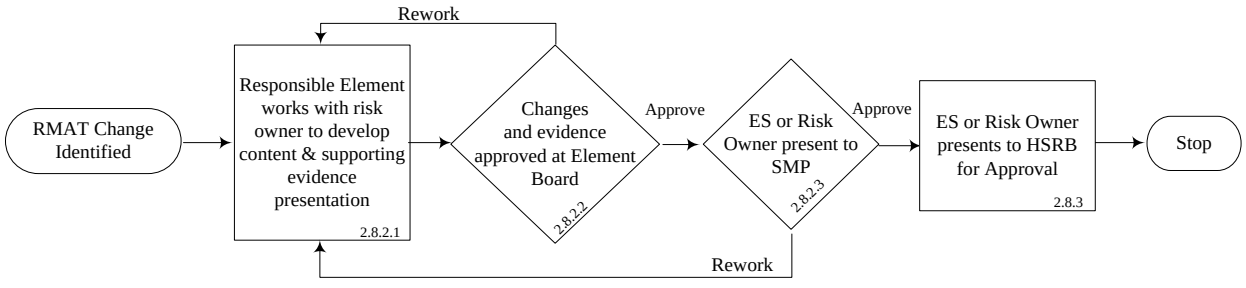


Figure 9 - Process for Updating the Risk Management Analysis Tool

2.16 PROCESS FOR CHANGING A HUMAN HEALTH AND PERFORMANCE RISK IN THE PROGRAM REQUIREMENTS DOCUMENT (PRD)

This process describes how the HRP changes the human health and performance risks identified in the PRD. In the context of this process, change is defined as adding a new risk or modifying or deleting an existing risk. Any change to the HRP PRD must be accompanied by associated changes to the Risk Management Analysis Tool (RMAT) as well as other appropriate documentation. See Section 2.15, Process for Updating the Risk Management Analysis Tool, for details on how to update the RMAT.

2.16.1 Identify Change to a Risk

There are two primary ways in which a change to PRD content is proposed: Human System Risk Board (HSRB) deliberation or from within the HRP.

2.16.1.1.a During deliberation, the HSRB identifies the need for research to better understand or mitigate a risk (as distinct from mitigations that do not require research (e.g., operational workaround, crew selection, design solutions) acceptance, watch, or transfer) and then recommends that the HRP take responsibility for addressing the risk.

2.16.1.1.b The HSRB Executive Secretary notifies the HRP Program Scientist that a new risk has been added or changed in the HSRB Master Risk List (MRL) and allocated to the HRP. The Program Scientist then brings the change to the HRP Science Management Panel (SMP).

2.16.1.2.a An HRP team member identifies the need for a PRD change.

2.16.1.2.b The HRP member will provide the appropriate HRP Element Scientist with the evidence that indicates the need to change the PRD.

2.16.1.2.c If the Element Scientist agrees with the evidence that a change in the PRD is warranted, the Element Scientist will notify the HRP Program Scientist of the required change.

2.16.1.2.d The Element Scientist and/or risk owner then brings the change to the HRP SMP.

2.16.2 The SMP Reviews New Risk Content.

The SMP review of the proposed risk change produces one of three possible outcomes.

- A change to a PRD risk is not necessary and the result is communicated to the initiating entity for further assessment, if needed. Otherwise, the process stops.
- The change falls within scope of an existing risk.
- The change necessitates a new risk.

2.16.3 Develop Risk Content

If the SMP determines the risk change falls within the scope of an existing risk or necessitates a new risk, then the responsible Element Scientist works with the appropriate discipline and SMO representatives to:

- develop new or updated risk wording (title and context)
- identify which table in the PRD (Table 1 or Table 2) the new risk belongs
- develop any necessary changes to the HSRB MRL including updates to the comment field with mapping from the list to new PRD words.

The Element Scientist brings risk content to the HSRB for review and approval. If the HSRB disapproves the content, then the Program Scientist will determine the proper course of action.

2.16.4 Update the RMAT and Research Plan

2.16.4.1 The Element to which the new or updated risk is assigned must assess the new information to complete or update the RMAT and determine whether a change is required to their research plan.

2.16.4.2 The Element Scientist works closely with the appropriate subject matter experts to develop an approach to address the new aspects of the risk.

2.16.4.3 The Element management team evaluates the research approach and identifies the budget required to address any new aspects of the risk.

2.16.4.4 See Section 2.15 for RMAT update process.

2.16.5 Update the PRD

(Once New or Updated Risk Wording is Approved at the HSRB)

2.16.5.1 The Program Scientist brings that result to the SMP and initiates an action to the PRD book manager to revise the document.

2.16.5.2 The PRD book manager will open the CR through the normal configuration management process. The HRPCB will review the CR and proceed through the normal deliberation process.

2.16.5.3 When the PRD is approved by the HRPCB, the PRD book manager notifies the HSRB Executive Secretary that the update was approved. At this point in the process, the HSRB MRL and HRP PRD are synchronized.

2.16.6 Approve New HRP Integrated Research Plan (IRP) Content

2.16.6.1 When a risk is changed in the PRD, the responsible HRP Element flows the new PRD requirement into the lower level documentation (element requirements, research plan, budget, etc.).

2.16.6.2 Once the SMP and HSRB concur on the approach, the Element will submit associated updates to the Element requirements (if there are new gaps) and/or an HRPCB CR to update the IRP. HRPCB approval marks the authority to proceed with implementation of the updated research plan.

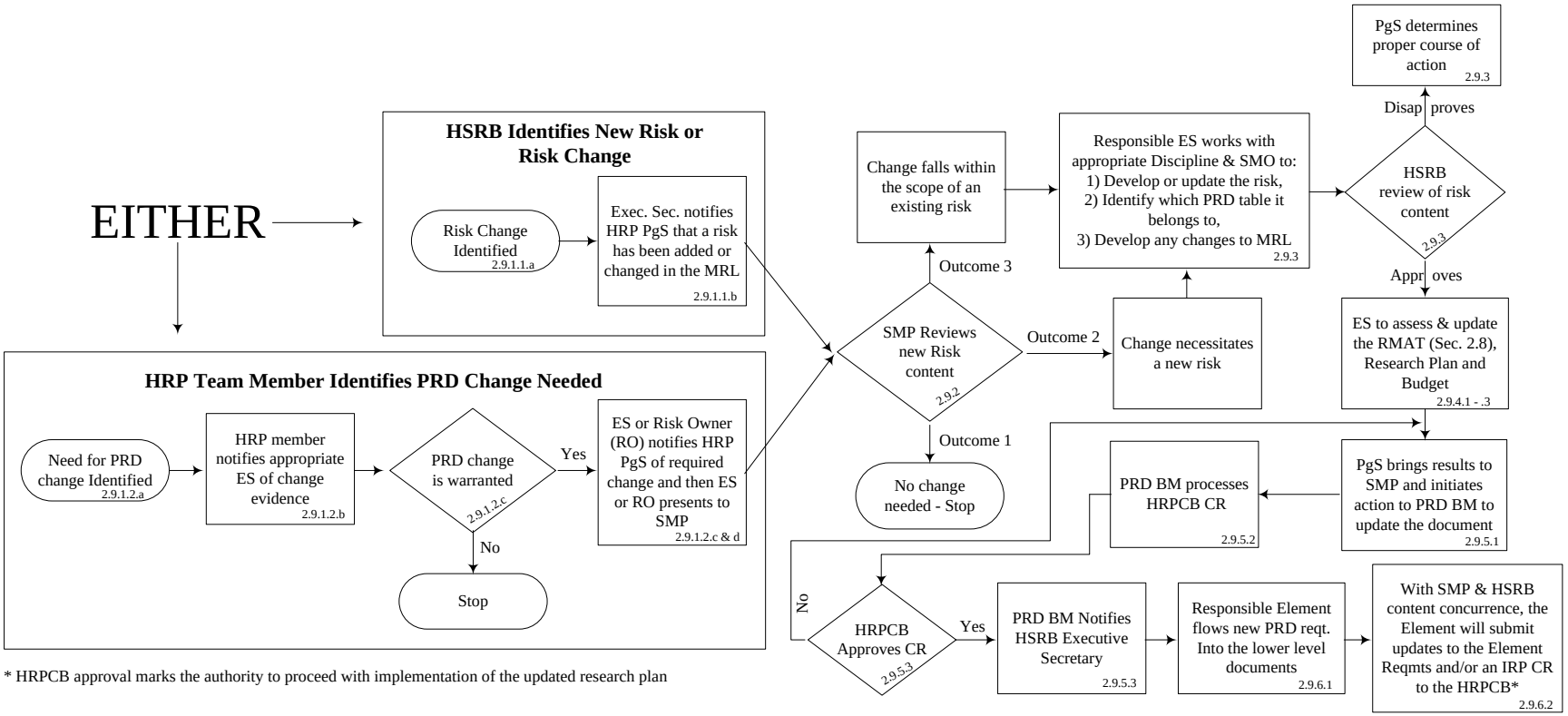


Figure 10 - Process for changing a Human Health and Performance Risk in the PRD

2.16.7 Process for Generating New and Updated Criticality Ratings

The HRP uses a risk criticality metric to assist the HRP Program Manager in making decisions pertaining to allocation of resources and risk prioritization. Criticality ratings (*Unacceptable*, *Acceptable*, and *Controlled*) are assigned to each HRP risk based on the degree to which the current state of knowledge about a risk will prompt the Program manager to recommend a no-go or a go for a mission while considering both the expected value of a risk and the uncertainty in the expected value. These ratings are documented in the HRP Program Requirements Document (PRD). Below is the process for generating new and updating existing criticality ratings preceded by three ways by which such a need is identified.

A. Identifying a need for a new or updated criticality rating:
    1. A new risk is baselined at the Human System Risk Board (HSRB) as 'research required'.
    2. A Risk Custodian believes that new evidence or updates that warrant a review of the current criticality ratings.
    3. The HRP Science Management Office (SMO) recommends an update to criticality ratings based on new evidence or updates, and the Element concurs with the recommendation.

B. Process of generating a new rating or proposing a change:
    1. For a given risk, the Risk Custodian (the HRP point-of-contact assigned to the risk) will work with the responsible Element and Subject Matter Experts (SMEs) to provide criticality ratings for all mission described in the RMAT, based on the definitions stated in the PRD. Each criticality rating has to be justified based on:
        a. The state of knowledge of the effectiveness of current risk mitigations in preventing consequences of the risk; and
        b. The willingness of the Program Manager to accept the associated likelihood of occurrence and consequence of the risk.
    2. The Risk Custodian and the Element Scientist meet with the HRP Program Scientist and presents the recommended criticality ratings and justification.
    3. If the Program Scientist deems the evidence sufficient to support the new rating or the change, and recommends that it be assessed, an HRP Control Board (HRPCB) Change Request (CR) is generated. The set of evaluators will be expanded to include the HRP Science Management Panel and recommended SMEs. A Technical Coordination Meeting (TCM) will be held if it is necessary to resolve significant issues arising from the comments. (TCM in configuration management is meant to be a coordination meeting to allow coordination and resolution of comments.)
    4. If the Program Scientist does not deem the evidence sufficient to support the new rating or change, the change is denied and there is no appeal.
    5. Following the closing of the CR process, the Risk Custodian brings the final recommendation with evidence and comments to the HRPCB for approval.
    6. If approved, the criticality ratings will be included in the PRD in the next document revision or through the Page Change Notice (PCN) process.
    7. The ratings will then be brought forward by the Risk Custodian to the Human System Risk Board for concurrence.

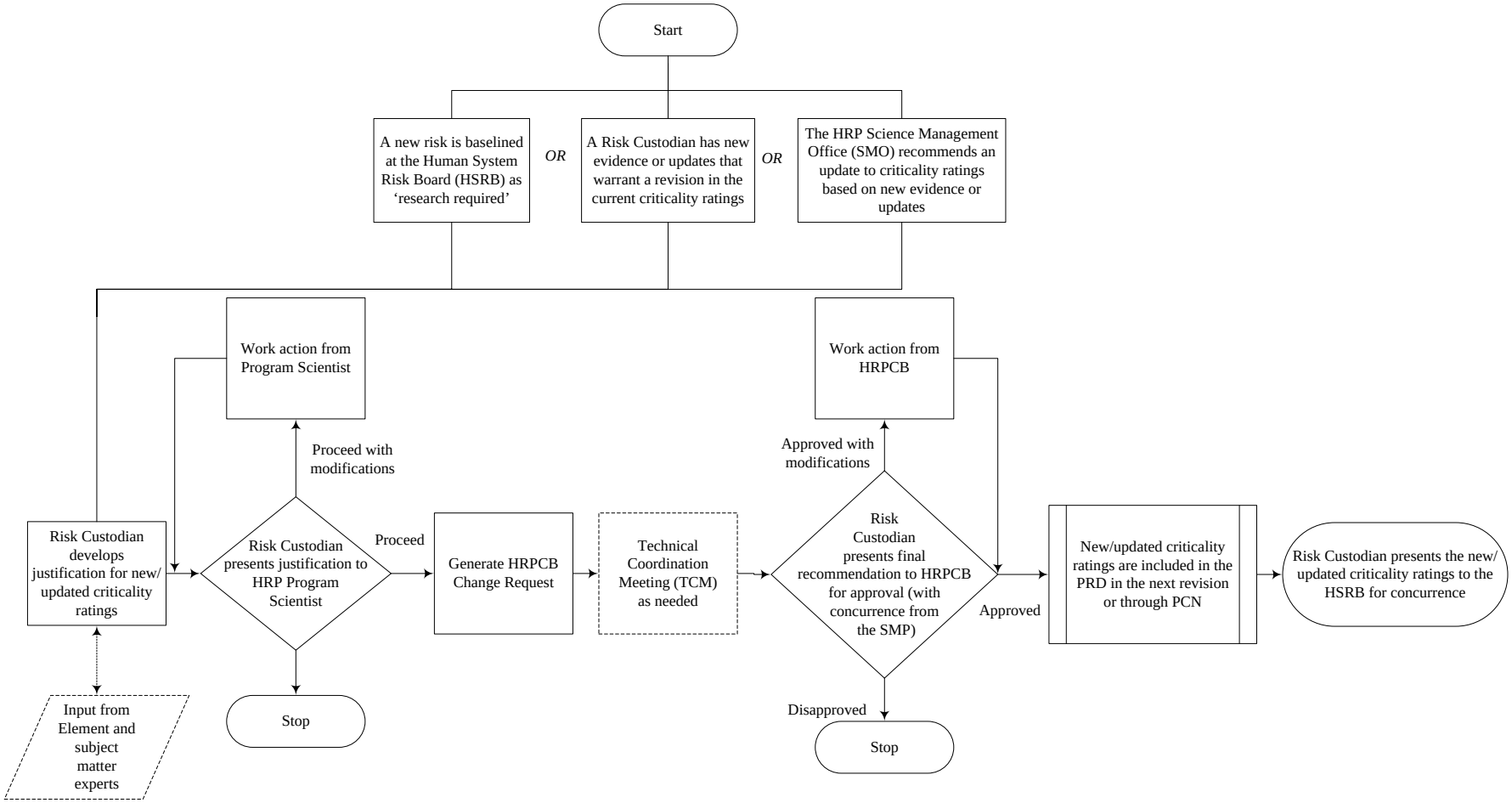


Figure 11 - Criticality Ratings Process

2.17 SELECT FOR ANALOG APPROVAL PROCESS

Access to and utilization of space analog opportunities is controlled at the HRP Program-level for HRP studies to ensure maximum coordination of limited analog resources. HRP tasks requiring the use of analog resources must be vetted and reviewed for scientific, operational, and technical merit as well as operational feasibility before access to space analogs will be considered through a SMP CR. Descriptions of the analogs available are located at the following link: http://humanresearch.jsc.nasa.gov/analogs/analogs.asp.

The Select for Analog (SFA) process is designed to communicate the expectations and pathway for gaining access to ground-base studies which use space analogs and only applies to proposed investigations that are not invitational opportunities for study.

Note: If the research task is an invitational analog opportunity coordinated through another agency (e.g., CHOICE) or from another Program within NASA, then the PI may implement the study after obtaining the appropriate reviews and without the involvement of the FAP, which provided coordination and integration of HRP requirements enabling the use of the appropriate analog.

2.17.1 Element Endorsement

In the case of a directed study, the sponsoring element receives the proposal the PI; the sponsoring element reviews the document(s) and decides whether or not to endorse the study. If the sponsoring element decides not to endorse the study then the PI is notified and works to resolve any issues.

If the element supports the proposal, the element must decide whether approval or concurrence is needed from an element-level CCB prior to the SMP. If a study requires the use of medical operations time, or equipment that is not under the control of HRP, the element must arrange for the appropriate review, concurrence and approval of the study proposal to ensure operational relevance and availability of the required non-HRP resources. The sponsoring element is responsible for arranging presentations to appropriate stakeholder organizations or boards before requesting Program-level approval and a feasibility assessment.

2.17.2 Merit Review

Once all appropriate stakeholders have concurred with the study proposal and approved use of their resources, the PI or project manager is responsible for obtaining the appropriate scientific or technical merit assessment for the task; refer to the HRP Unique Processes, Criteria and Guidelines document Sections 2.4, Process for Review of Directed Task Proposals, and 2.5, Process for Formulation Review of a Directed Research Task, for details on the merit review process.

Once the proposal has completed the merit review process and receives either a selection letter (e.g., NRAs) or the ATP to implementation (directed tasks) from the HRP Program Scientist, then the task enters the Select for Analog process.

2.17.3 Entering the Select for Analog Process

The PI prepares an Analog Resource Worksheet (http://humanresearch.jsc.nasa.gov/analogs/docs/Analog_Study_Resource_Worksheet.docx) and

a NASA Institutional Review Board protocol (http://cphs.nasa.gov/docs/nasaIRB-ProtocolApplication.doc), which details the plan for the use of human subjects and submits it to the project/element for vetting. The project/element in turn submits the documents to FAP.

2.17.4 Committee for the Protection of Human Subjects (CPHS) Approval

The Committee for the Protection of Human Subjects is the JSC IRB that reviews research involving human subjects to ensure the ethical, safe, and equitable treatment of the subjects. All HRP analog studies using human subjects must obtain CPHS approval prior to start. The sponsoring project or element takes the study to the CPHS.

If the CPHS either disapproves the protocol or approves with modifications, the PI or the PM will address those concerns and revise the protocol. In this case, the revised study must be re-endorsed by the sponsoring element and then continue to obtain CPHS approval. (NOTE: External PIs must also adhere to their institution's IRB requirements as well as any facility IRB required in order to utilize an analog.)

2.17.5 Feasibility Assessment

The study protocol must be endorsed by the sponsoring element and receive CPHS approval prior to FAP's initial feasibility assessment. The FAP will utilize the Analog Resource Worksheet and the CPHS approved study protocol to understand the full extent of required analog opportunities, determine the complexity of the investigation, and determine whether it can be added to a FAP analog complement without significant cost impacts. This initial feasibility study will identify potential problems or mismatches in required and available resources, and may require discussions with the sponsoring element in coordination with the PI to clarify requirements. The initial feasibility assessment will include the following: 1) required analog characteristics based on proposed study measurements and 2) evaluation of available analogs for appropriate matching.

If the initial feasibility assessment states that the study is within the scope of available resources, FAP supports the sponsoring project's/element's initiation of an SMP "Select for Analog" CR. If the study is not within the scope of available resources, the FAP, the PI and the sponsoring project/element will work to resolve the issue prior to initiation of an SMP CR.

If the FAP and sponsoring project/element cannot resolve the resource issue without the use of additional resources, it must be taken first to the SMP for resolution and then to the HRPCB if the SMP cannot resolve the issue.

2.17.6 Program Approval

Once the CPHS approves the single study protocol and the FAP analog feasibility assessment is complete, the study is ready to go to the HRP SMP for approval and a Select for Analog Directive (SAD). The sponsoring project/element, in conjunction with the FAP, brings the Select for Analog CR to the SMP. The SMP will approve the release of the CR for two week evaluation period. The CR must include the SFA template (https://sa.jsc.nasa.gov/cm/?viewFile=formsAndPresentationTemplates) which summarizes the investigation, the merit review history, CPHS approval history, and the results of the FAP feasibility assessment. The CR must also include a detailed description of any changes in scope made to the investigation made by FAP or CPHS reviews (e.g., subject number, methods etc).

If there are no issues during the standard two-week evaluation period, or the SMP resolves the issues without the need for additional resources, the CR will be approved out-of-board. If any issues arise during the evaluation period, the sponsoring project must return to the SMP to present the plan for addressing the issues.

After the SMP has approved the "Select for Analog" CR, FAP generates a CR for HRPCB out-of-board disposition, which serves as a SAD. This CR will clearly indicate SMP approval date, how many subjects were approved by CPHS and any actions or changes levied by the SMP. FAP then updates the HRP Master List of Study Assignments to Analogs and proceeds to the Analog Complement Approval process. The sponsoring organization is responsible for notifying the PI of the decision.

If the SMP does not approve selection of the study, the study is revised as described above and re-enters the process at the step of being endorsed by the supporting element.

If the SMP cannot resolve a resource issue, a decision package CR will be forwarded to the HRPCB for resolution. If the HRPCB resolves the issue, then it approves the decision package CR; that approval serves as a SAD. FAP then updates the HRP Master List of Study Assignments to Analogs and proceeds with the Analog Complement Approval process. If the HRPCB does not find satisfactory resolution of the resource issue, the study is removed from the Select for Analog process.

NOTE: The Select for Analog Directive confirms the HRP is willing to expend its resources to conduct the study in an analog platform. However, once a study is added to the HRP Analog Master List of Study Assignments to Analogs, multiple factors determine its implementation. The FAP works with the PI and sponsoring project/element to determine the earliest time for operations and then incorporates the study into the Analog Complement Approval process. The final approved complement is a balance of all competing resources and the result of Program-level review, including FAPCCP and SMP forums to discuss the relative priority of analog complement studies. Any conflicts are elevated to the SMP and HRPCB, as needed. See Section 2.2, Analog Complement Approval Process, for further details.

A secondary feasibility assessment will occur after the study receives Select for Analog approval by the SMP and is ready for the Complement Approval Process. This feasibility assessment is a step FAP uses for building and analog complement and includes but is not limited to the following: 1) recommendation on implementation strategy, including estimated first analog opportunity and time to complete requested subject count, 2) recommendation regarding additional reviews needed (if any), 3) list of assumptions made in performing the assessment, and 4) a risk assessment and proposed mitigation plan. A more detailed secondary feasibility assessment can be required depending on the complexity of the study. Required resources include analog requirements and availability as well as baseline data collection. If FAP determines the study is not feasible to perform, the study is reworked in conjunction with the PI and sponsoring element.

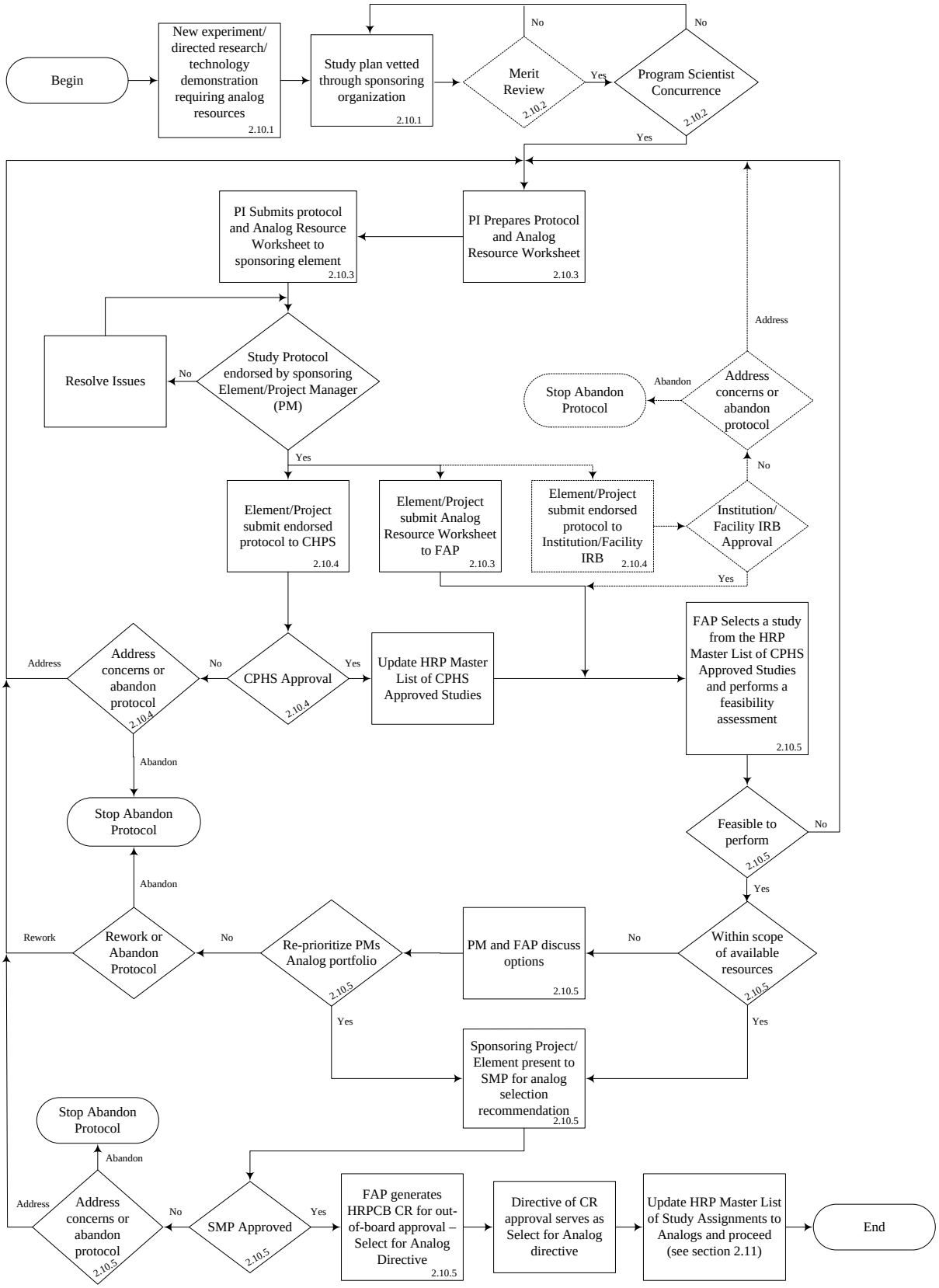


Figure 12 - Select for Analog Approval Process

2.18 ANALOG COMPLEMENT APPROVAL PROCESS

2.18.1 Introduction

The FAP utilizes an Analog Implementation Plan (AIP) (http://sk.jsc.nasa.gov/sk211/analogs.aspx) as the control for documenting strategic and tactical assignments of studies to analog missions and complement development. Once a Select for Analog Directive is received by FAP from the SMP and HRPCB, the AIP will be revised to include the study and will reflect the proposed implementation within an analog mission complement.

2.18.2 Preparation of Complement

Once the Select for Analog directive is incorporated into the AIP and the change is approved at the FAP CCP, the FAP team prepares for implementation of the analog mission complement by creating the Integrated Protocol Document (IPD) for each analog mission in the tactical timeframe. The IPD addresses and documents the specific implementation details of the integrated HRP analog complement for the FAP.

Baselining the IPD at the FAP CCP will allow the opportunity for HRP Element and Project Scientists and Managers to review in detail the proposed integrated complement, as well as the potential issues and conflicts that have been identified in the integration process.

2.18.3 CPHS Approval

FAP PS/HRP Analog Coordinator develops the CPHS submittal for each analog mission, reflecting information baselined in the IPD, as an integrated HRP package for approval. The CPHS is responsible for ensuring the health, safety, and well-being of human research subjects while ensuring the ethical conduct of experiment operations. Research protocols using human test subjects must be approved by the JSC CPHS when research is funded or sponsored by NASA JSC and conducted in a spacecraft, at NASA JSC Facilities, on NASA JSC aircraft, or at other centers or institutions when JSC civil service or contractor personnel are directly involved in the research activities.

2.18.4 Science Management Panel (SMP) Review

The final approved complement is brought to the SMP as an informational presentation at approximately launch minus (L-30) days depending on the analog mission. A CR is not required since the FAP CCP controls analog complements and all HRP Element Managers and Scientists are included in the review of the plan. The SMP presentation will consist of the following:

- Complement snapshot showing the title for each study and the sponsoring Element/Project
- List of experiments
- Number of subjects targeted per complement
- Background information regarding how the complement was prepared
- Additional data such as potential issues and risks
- Prioritization information
- Forward work and schedule

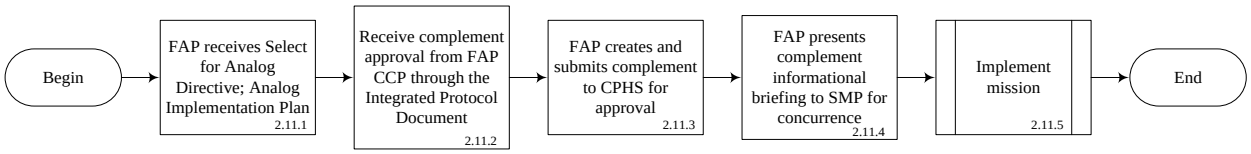


Figure 13 - Analog Complement Approval Process

3.0 CRITERIA/GUIDELINES

3.1 CRITERIA FOR RAISING DECISION TO PROGRAM LEVEL DECISION AUTHORITY

Under certain circumstances, Element and Project decisions require Program level review. Within the purview of Program level authority, the decision may reside either with the HRPCB or the SMP.

Criteria for raising decisions to the HRPCB include:

1. The budgetary impact exceeds ten percent of the annual project budget or $400,000.00 over the life of the project.
2. The investigation changes affect a controlled Integrated Master Schedule (IMS) milestone.
3. The decision impacts the resources of another Program Element.
4. The decision impacts a controlled or visibility milestone of another Program Element.
5. The issue, depending on how it is decided, could result in an external customer or another HRP Element not accepting the deliverable.

Criteria for raising decisions to the SMP include:

1. The decision impacts the technical content of another Program Element.
2. The existing study or technology test increases already approved flight resources by > 10%
3. The decision impacts the flight complement or the ability of ISSMP to implement another Program Element's flight experiment on the originally planned schedule.

The HRP Program Manager and Program Scientist retains discretion to bring issues to the HRPCB and SMP, even if changes do not meet the above criteria. If there is a dispute as to whether the change fits the above criteria, then the issue will be brought before the HRPCB.

3.2 HRP CUSTOMER-SUPPLIER AGREEMENTS

The HRP CSA is a formal document that ensures that the responsibilities and expectations are understood and agreed-to by both Customer and Supplier. A signed CSA should be obtained before the research or effort begins, and is required whenever a deliverable from HRP to an external customer will result. The information contained in the CSA is also used in the development of schedules and other Program-level products.

When creating a CSA, it should be noted that the Customer is typically the non-HRP entity for whom the deliverable is being developed. However, a Customer can also be another Element or Project within HRP. Such Internal CSAs are not required, but may be useful and are left to the discretion of the Element/Project. The Supplier is the HRP Element or Project developing the deliverable. Element/Project-funded researchers may support the development of deliverables but the CSA is still an agreement between the Element/Project and the Customer. If the deliverable is funded by the National Space Biomedical Research Institute (NSBRI), then the NSBRI is the Supplier and the CSA should also include the relevant EM's signature, if appropriate. The Stakeholder is any other entity with a interest in the deliverable. These terms are also defined in the CSA Template which is provided in Appendix D of this document. The template shall be used when creating a CSA by entering the specific information in *place* of the italicized wording in each section. The italicized wording should be deleted. If a section does not apply, then an entry of "N/A" may be substituted. A table providing deliverables categories, with examples, is provided in Appendix E.

Some Customers may require the use of their own CSA templates. If this is the case, the HRP supplier shall ensure that the content addresses all of the sections in this HRP CSA template. A supporting document, using the HRP CSA template cover page and containing the missing required HRP information shall be created by the HRP supplier and be appended to the Customer's CSA template.

3.3 PROCESS FOR APPLICABILITY OF NASA-STD-7009 TO HRP TASKS

This process details the steps to be used by HRP personnel to determine if NASA-STD-7009 is required to characterize the credibility of HRP model and simulation (M&S) deliverables and, if it is determined that the standard is to be applied, it also describes what must be done to ensure and document compliance with the standard. The application of NASA-STD-7009 to an HRP task can be invoked by the HRP Program Manager, HRP Program Scientist, HRP task manager, HRP task scientist or, when one exists, by the external customer. (This statement addresses NASA-STD-7009, Requirement 4.1.2 – identifying which models and simulations are in the scope of NASA-STD-7009.)

NOTE: A task manager corresponds to what NASA would usually call a project manager. Normally, the HRP task manager will assess the applicability of NASA-STD-7009 by developing 1) a *Risk Assessment* (for all M&S deliverables), and 2) a *Credibility Assessment* (where applicable), and submit the results to the HRP SMO for concurrence. The resulting product is also known as a Verification & Validation (V&V) Plan.

Step 1: The task manager (supplier), working with the Element, identifies the customer who will be the end-user of the model or simulation.

Step 2: The task manager (supplier) will meet with the end-user (customer) and ask the following questions regarding the M&S deliverable:

a. What is the product being delivered?
b. When is the product being delivered?
c. Will this model or simulation be used to make decisions?

Step 3: If the M&S deliverable will be used to make decisions, the task manager (supplier) and end-user (customer) will develop a *Risk Assessment* to determine if NASA-STD-7009 should be used.

a. What is the consequence of the decisions being made? (Section 3.3.1.1, UPCG)
b. How much influence does the M&S deliverable have upon those decisions? (Section 3.3.2.2, UPCG)
c. Using the M&S Risk Assessment Matrix (Section 3.3.3, UPCG), those M&S that fall within the green (G) boxes in Table 1 are not in scope; therefore, NASA-STD-7009 does NOT apply to the specified deliverable.
d. M&S that fall within the yellow (Y) boxes may be deemed to be in scope; utilization of NASA-STD-7009 will be at the discretion of program/project management in collaboration with the customer.
e. Those M&S that fall within the red (R) boxes in Table 1 are within scope; therefore, NASA-STD-7009 DOES apply.

Step 4: Once it is determined that NASA-STD-7009 does apply, or is required, the task manager (supplier) and end-user (customer) will develop a *Credibility Assessment* using NASA-STD-7009, Appendix B which must include the following:

a. What are the agreed-to and expected thresholds for the 8 credibility factors, and who is responsible for providing the supporting evidence or technical review for each factor as appropriate?
   1. Verification
   2. Validation
   3. Input pedigree
   4. Results uncertainty
   5. Results robustness
   6. Use history
   7. M&S Management
   8. People Qualifications
b. What mechanism(s) will be used to verify that the thresholds have been met (i.e., compliance matrix per Appendix C - NASA-STD-7009, or other)?

Step 5: The task manager will provide the Risk Assessment (from Step 3, above) and, if applicable, the Credibility Assessment (from Step 4, above), documenting agreement with the customer, to the HRP SMO for concurrence and amend the applicable CSA with the V&V plan once concurrence is received from SMO (see Section 3.2, UPCG).

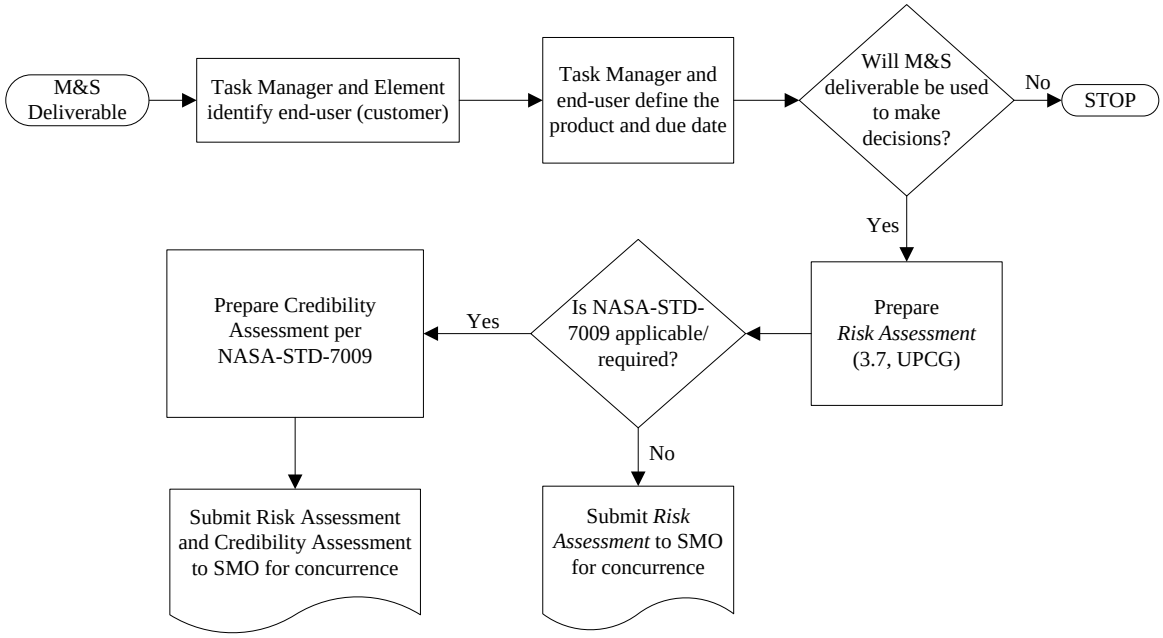


Figure 14 - HRP Process for Implementation of NASA-STD-7009

3.3.1 NASA-STANDARD-7009, APPLICABILITY CRITERIA

The goal of NASA-STD-7009, Standard for Models and Simulations, is to ensure the credibility of the results from M&S is properly conveyed to those making critical decisions. Critical decisions based on M&S results, as defined by this standard, are those technical decisions related to design, development, manufacturing, ground, or flight operations that may impact human safety or program/project-defined mission success criteria. The intent is to reduce the risks associated with critical decisions. This standard covers the development and operation (or execution) of M&S as well as the processes of analysis and presentation of the results from the M&S. The purpose of this standard is to provide uniform engineering and technical requirements for processes, procedures, practices, and methods that have been endorsed as standard for M&S developed and used in NASA programs and projects, including requirements for selection, application, and design criteria of an item.

The purpose of these criteria is to assist HRP personnel with how to apply NASA-STD-7009 and follows language of the evidence-risk-gap-task-deliverable schema used in the HRP. A task manager corresponds to what NASA would usually call a project manager. For example, the Integrated Medical Model (IMM) is considered a task for the purpose of this standard.

3.3.2 Applicability of NASA-STD-7009 to HRP Tasks

The first question is whether or not NASA- STD-7009 should be applied to an HRP M&S task. This question is answered in section 3.3.4 below by first assessing the consequence of the decisions being made (3.3.2.1) and the amount of influence the M&S has upon the decision (3.3.2.2).

The application of NASA-STD-7009 to an HRP task can be invoked by the HRP Program Manager, HRP Program Scientist, HRP task manager, HRP task scientist or, when one exists, by the external customer. (This statement addresses NASA-STD-7009 Requirement 4.1.2- identifying which models and simulations are in the scope of NASA-STD-7009). Normally, the HRP task will assess the applicability of NASA-STD-7009 and submit the assessment to the HRP SMO for concurrence.

3.3.2.1 Decision Consequence

Consequence classifications assess the impact of a decision that proves incorrect. The number of Consequence levels and most of the language is taken from NPR 8000.4. This particular scale is provided in NASA-STD-7009 as a sample and is used as-is by HRP. Aspects particularly applicable to HRP are bolded. The last item in each class description has been added to address impact upon mission success criteria, such as science objectives.

a. Class IV - Negligible. A poor decision may result in the need for **minor first aid treatment but would not adversely affect personal safety or health**; damage to facilities, equipment, or flight hardware more than normal wear and tear level; internal schedule slip that does not impact internal development milestones (e.g., task, Project, Element milestones); cost overrun less than 2 percent of planned cost; all mission success criteria met, with at worst **minor performance degradations**.

b. Class III - Moderate. A poor decision may result in **minor injury or occupational illness**, or minor property damage to facilities, systems, equipment, or flight hardware; internal schedule slip that does not impact launch date; cost overrun between 2 percent and not exceeding 15 percent of planned cost; **a few (up to 25 percent) mission success criteria not met due to performance degradations**.

c. Class II - Critical. A poor decision may result in moderate to severe **injury or occupational illness**, or major property damage to facilities, systems, equipment, or flight hardware; schedule slippage causing launch date to be missed; cost overrun between 15 percent and not exceeding 50 percent of planned; **many (between 25 percent and 75 percent) mission success criteria not met due to substantial performance degradations**.

d. Class I - Catastrophic. A poor decision may result in **death or permanently disabling injury**, facility destruction on the ground, or loss of crew, major systems, or vehicle during the mission; schedule slippage causing launch window to be missed; cost overrun greater than 50 percent of planned cost; **most (more than 75 percent) mission success criteria not met due to severe performance degradations**.

3.3.2.2 M&S Influence

Influence estimates the degree to which M&S results influence program/project engineering decisions or flight-related planning decisions. (Engineering decisions include determination of whether design requirements have been verified.) This particular scale is provided in NASA-STD-7009 as a sample. The only HRP modification to the scale is the text added in italics.

a. Influence 1 - Negligible. Results from the M&S are a negligible factor in engineering or flight-related planning decisions. This includes research on M&S methods, and M&S used in research projects that have no direct bearing on program/project decisions (for NASA missions).

b. Influence 2 - Minor. M&S results are only a minor factor in any program/project decisions. Ample flight or test data for the real system in the real environment are available, and M&S results are used just as supplementary information.

c. Influence 3 - Moderate. M&S results are at most a moderate factor in any program/project decisions. *Subject Matter Experts (SME) are still relied upon to make the final judgment*. Limited flight or test data for the real system in the real environment are available, but ample flight or test data for similar systems in similar environments are available.

d. Influence 4 - Significant. M&S results are a significant factor (*weighted equally or higher than SME opinion*) in some program/project decisions, but not the sole factor for any program/project decisions. While no flight or test data in real environments are available, ample flight or test data for similar systems in similar environments are available.

e. Influence 5 - Controlling. M&S results are the controlling factor in some program/project decisions (*no SME involvement*). Neither flight nor test data are available for essential aspects of the system and/or the environment.

3.3.3 M&S Risk Assessment Matrix and Scope

Those M&S that are judged to fall within the red (R) boxes in Table 4 are within the scope of NASA-STD-7009, and those that fall within the green (G) boxes are not in scope. The M&S that are judged to fall within the yellow (Y) boxes may be deemed in scope at the discretion of the program/project management in collaboration with the Technical Authority. This particular matrix is provided in NASA-STD-7009 as a sample and is used as-is by HRP.

Table 4 - M&S Risk Assessment Matrix

M&S Results Influence	Controlling	G	Y	R	R
	Significant	G	Y	R	R
	Moderate	G	Y	Y	R
	Minor	G	G	Y	Y
	Negligible	G	G	G	G
		Negligible	Marginal	Critical	Catastrophic
		Decision Consequence			

3.3.4 Application of NASA-STD-7009 to HRP Tasks

If NASA-STD-7009 is applied to an HRP task, the applicable version and date of the standard will be identified by program/project management, and the following apply and will be implemented by the PI team:

All NASA-STD-7009 requirements except 4.1.3 and 4.1.5 will be met by a) the HRP task or b) the task will delegate, with documentation, the requirement to an organization outside the task. The customer and HRP Program Scientist are possible delegates.

NOTE: The issue of who meets each requirement becomes complicated very quickly once one makes the distinction between developers, operators and analysts. Some HRP tasks may deliver a tool that the customer operates while other HRP tasks may go so far as

the analysis stage and deliver results to the decision maker. Rather than anticipate all the possible cases, this form of the standard leaves it to the task to articulate who is meeting each requirement.

For the HRP task to meet Requirement 4.1.3 (define the objectives and requirements for the deliverables), the customer must concur with the definitions.

To meet Requirement 4.1.5 (document technical reviews), a) the HRP task will conduct and document the internal technical reviews and b) the customer or the HRP Element Scientist will conduct and document the external reviews. The roles of the customer and Element Scientist in the technical reviews will be defined in the CSA and approved by the Element Scientist. Acceptable types of reviews include…

1. Self assessment by the task
2. Self assessment with an audit by an independent party
3. Vetting of the self assessment as part of a merit review process such as a NAR
4. Independent assessment conducted without knowledge of the self assessment

Confirmation that the requirements of NASA-STD-7009 have been met will be conducted by the customer or the HRP Element Scientist. The roles of the customer and Element Scientist in the confirmation process will be defined in the CSA. The HRP SMO will review the confirmation for concurrence.

In cases where there is no external customer, the HRP Element Scientist will act as the surrogate customer.

In cases where the Element Scientist has a conflict of interest, the HRP Program Scientist will fill his/her roles in the above reviews.

3.4 HRP OVERALL PROCUREMENT STRATEGY

It is the HRP's policy to utilize full and open competition for research and technology investigations sought by both NASA and the NSBRI and to maintain a balance between selected intramural and extramural investigations. Most of these solicitations occur periodically (Figure 1), and HRP Elements may employ a variety of solicitation mechanisms in order to fulfill research and technology objectives. Since HRP is an applied research program, the use of non-competitive, directed studies may be warranted in some cases. Different award mechanisms and solicitation vehicles are listed below, and Elements are encouraged to contact the SMO to determine which mechanism is most appropriate for a particular case.

3.4.1 Award Instruments

The main award instruments used by HRP are grants, cooperative agreements, and contracts. A grant shall be used as the legal instrument to reflect a relationship between NASA and a recipient whenever the principal purpose is the transfer of anything of value to the recipient to accomplish a public purpose of support or stimulation authorized by Federal statute. Grants are distinguished from cooperative agreements in that substantial involvement is not expected between NASA and the grant recipient when carrying out the activity. Grants are distinguished

from contracts in that grants provide financial assistance to the recipient to conduct a fairly autonomous program; contracts entail acquisition.

The decision whether to use a contract, grant or cooperative agreement as an award instrument must be based on the principal purpose of the relationship. When NASA enters into a transaction where the principal purpose is to accomplish a public purpose of support or stimulation authorized by Federal statute, a grant or a cooperative agreement is the appropriate instrument. Conversely, if the principal purpose of a transaction is to accomplish a NASA requirement, i.e., to produce something for NASA's own use, a procurement contract is the appropriate instrument.

Both non-reimbursable and reimbursable Space Act Agreements are alternative award instruments that can be used by HRP. Under a Space Act agreement, NASA can tailor the allocation of intellectual property rights according to the nature of the particular agreement and contributions of the parties.

A non-reimbursable Space Act Agreement is a collaborative R&D effort where NASA and the other parties contribute personnel, use of NASA facilities, expertise, or equipment, technology, etc., but no transfer of funds. NASA participation will require that the other party adequately demonstrate…

(a) the relevance of the proposed activity to a NASA mission or program requirement;
(b) the level of the other party's contribution is adequate compared to NASA's contribution.

No transfer of funds or other financial obligation between NASA and the private entity is permitted. Each party agrees to fund its own participation under this agreement.

The reimbursable Space Act Agreement is an agreement for the reimbursable use of NASA facilities, personnel, expertise or equipment by a public or private entity wishing to advance research and development efforts. The effort involves a transfer of funds or other financial obligation from the private entity to NASA. NASA will not transfer funds to the other entity. The terms, conditions, and schedule are negotiable, but NASA must be paid in advance for each stage of the effort. NASA may not compete with commercially available facilities or services.

Under certain circumstances, NASA may transfer funds to another government agency in order to utilize the unique non-commercial capabilities that can be provided by the non-NASA servicing agency in support of the NASA mission. FAR Subsection 17.503 and 31 U.S.C. 1535 describe the use of Interagency Acquisitions under the Economy Act. In order for an Inter-Agency Agreement (IAA) to be used as a mechanism, generally, the procurement may not conflict with any other agency’s authority or purchasing responsibility and the supplies or services may not be obtained as conveniently or economically by contracting directly with a private source. In general, no solicitation is required to be posted for NASA to use an IAA for acquisition purposes.

3.4.2 Procurement Mechanisms

Details for each solicitation mechanism are provided below. Please see Table 1 for a concise list of the available mechanisms.

3.4.2.1 NASA Research Announcement

Frequency: Typically one Crew Health NRA per year

Preparation Time for Posting: 2 months

Total Time to Award from Inception: Approximately 1 year

Nature of Product Solicited: Complex, multi-year research projects

Targeted Investigator Community: Academic researchers

Resultant Award Type: Grant

Type of Merit or Technical Review Required: External Peer Review

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: Human Research Program Science Management Office, unless Program Scientist delegates authority

Example of Project: Developing, Maintaining, and Restoring Team Cohesion

The NASA Research Announcement (NRA) is used to solicit proposals for complex, multi-year research projects. NASA may issue NRA solicitations jointly with NSBRI to solicit topics for both organizations. Typically, a multidisciplinary NRA is issued by HRP each year with topics contributed by one or more Elements. Since NRA projects last several years, research needs using this mechanism should not be immediate. The duration of an NRA research task is typically three years; flight studies typically require additional time due to flight preparation activities and limited subject availability. NASA awards for the multidisciplinary NRA average $350K per year. An NRA is a type of Broad Agency Announcement.

3.4.2.2 NASA Specialized Center of Research

Frequency: Typically one per year

Preparation Time for Posting: 2 months

Total Time to Award from Inception: Approximately 1 year

Nature of Product Solicited: Complex, multi-year research projects which require a team of investigators

Targeted Investigator Community: Academic researchers

Resultant Award Type: Grant

Type of Merit or Technical Review Required: External Peer Review

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: Human Research Program Science Management Office, unless Program Scientist delegates authority

Example of Project: Space Radiation and Intestinal Tumorigenesis: Risk Assessment and Countermeasure Development

Similar to the NRA, the NASA Specialized Center of Research (NSCOR) is used to solicit proposals for complex, multi-year research projects. An NSCOR consists of a team of investigators who have complementary skills and who work together to solve a closely focused set of research questions and which includes strong undergraduate, graduate, or post-graduate training components. A variation of the NSCOR is the virtual NSCOR (VNSCOR) in which NASA aligns a set of individual awards into an NSCOR like team project. Typically, an NSCOR Award will have an average cost of $1,800,000 per year (total annual cost) for up to 5 years while VNSCOR Awards will have an average cost of $350,000 per year (total annual cost) for up to 3 years. An NSCOR is a type of Broad Agency Announcement.

3.4.2.3 Small Business Innovation Research

Frequency: 1 per year

Preparation Time for Posting: 5 months

Total Time to Award from Inception: Approximately 1 year

Nature of Product Solicited: Technology development

Targeted Investigator Community: Small businesses

Resultant Award Type: Contract

Type of Merit or Technical Review Required: Internal NASA review by subject matter experts

Performance Review Required: No

Availability of Option Period: Yes

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Topic Manager

Issuing Authority: NASA SBIR/STTR Program Management Office

Example of Project: Fast Neutron Dosimeter for the Space Environment

The Small Business Innovation Research (SBIR) program provides the small business researcher with a technology or idea the opportunity to adapt or apply that technology towards a specific subtopic for HRP mission needs. A small business concern is one which, including its affiliates, has a number of employees not exceeding 500.

The SBIR program is divided into three phases. In Phase 1, a $100K award is issued to a small business to conduct a feasibility study. The Phase 1 award is six months in duration. If a project is selected for Phase 2 funding, a two-year award of $600K is issued. NASA has developed a Phase 2 Enhancement policy to further encourage the transition of SBIR research into NASA

acquisition programs as well as the private sector. Under this option, NASA will match with SBIR funds up to $150K of non-SBIR investment from a NASA project, NASA contractor, or third party commercial investor to extend an existing Phase 2 project from 4 months up to 1 year to perform additional research. The total cumulative award for the Phase 2 contract plus the Phase 2-Enhancement match is not expected to exceed $750K of SBIR funding. Finally, projects that produce readily infusible technology can be considered for Phase 3 funding. Phase 3 projects are funded by HRP money as well as private sector dollars. Phase 1 projects can proceed directly to Phase 3 if the technology is ready to be infused into the Program.

3.4.2.4 Request for Proposals

Frequency: as necessary

Preparation Time for Posting: 1 month

Total Time to Award from Inception: 3 months

Nature of Product Solicited: Technology development, protocol/procedure development, technology assessment

Targeted Investigator Community: Companies, academic researchers

Resultant Award Type: Contract

Type of Merit or Technical Review Required: NAR Panel Evaluation

Performance Review Required: Yes

Availability of Option Period: Yes

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR) from issuing Element

Issuing Authority: Element or Program

Example of Project: TBD

In order to fill general research needs, Elements may opt to use the Request for Proposals (RFP). RFP's can be processed in approximately three months, and technology development, protocol and procedure development, and technology assessment are areas where RFP's are well suited. Since respondents to RFP's tend to be businesses rather than universities, it is better to solicit fundamental research through an NRA rather than an RFP.

3.4.2.5 Request for Information

Frequency: as necessary

Preparation Time for Posting: 1 month

Total Time to Award from Inception: N/A

Nature of Product Solicited: Information collected can be used in writing of future solicitations or strategic planning

Targeted Investigator Community: Companies, academic researchers

Resultant Award Type: N/A

Type of Merit or Technical Review Required: N/A

Performance Review Required: N/A

Availability of Option Period: N/A

Potential to Negotiate Scope Prior to Award with Company or PI: N/A

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: Element or Program

Example of Project: Crew Health RFI

Elements can use a Request for Information (RFI) to collect information from private individuals, commercial entities, international organizations, academia, NASA Centers, and other government agencies. This information can be used in the refinement of specific research questions as well as in the development of strategic plans for the Program.

NASA Research and Education Support Services (NRESS) or NASA Procurement can issue RFI's. If NASA Procurement is used, additional time will be required for review. When NRESS issues an RFI, Procurement is not involved in the process.

3.4.2.6 Open Innovation

Frequency: TBD (still in experimental phase)

Preparation Time for Posting: 1 month

Total Time to Award from Inception: 4-6 months

Nature of Product Solicited: Basic research, technology development

Targeted Investigator Community: Professional and amateur solvers, companies

Resultant Award Type: Usually monetary prize

Type of Merit or Technical Review Required: Internal NASA review by subject matter experts

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Varies

NASA supervision: Varies

Issuing Authority: Element or Program

Example of Project: Improved Food Packaging

Open Innovation Service Providers are currently being evaluated to solve HRP problems. Specifically, InnoCentive posts individual challenges or gaps to their established network of

solvers. Solutions are sought and granted a financial award if the solution is found viable by the posting entity. Yet2.com acts as a technology scout by searching their network of companies, development organizations, and experts for potential solutions based on the specific challenges or gaps. They bring together buyers and sellers of technologies who then establish technology development partnerships.

3.4.2.7 Sandpit

Frequency: TBD (still in experimental phase)

Preparation Time for Posting: 2 months

Total Time to Award from Inception: 6-8 months

Nature of Product Solicited: Problems at the intersection of existing disciplines which can be understood by an intelligent non-domain expert

Targeted Investigator Community: Academic researchers

Resultant Award Type: Grant

Type of Merit or Technical Review Required: Science advisory board

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Varies

NASA supervision: Varies

Issuing Authority: Program, unless Program delegates authority

Example of Project: TBD

The sandpit can be used to solve problems at the intersection of existing disciplines which can be understood by an intelligent non-domain expert. The structure of the sandpit is quite different than conventional solicitation mechanisms (e.g. NRA). First, a topic is selected that is reviewed by a science advisory board. Then a call for participants is issued, and the science advisory board selects 20-30 participants. The group will consist of a mixture of new and experienced investigators. Participants then attend a workshop and brainstorm ideas in self-assembled teams. Rough proposals are developed during the workshop, and final proposals are submitted several weeks after the workshop's conclusion. The science advisory board then reviews the proposals and makes the awards. The sandpit mechanism is currently under investigation by NASA.

3.4.2.8 Announcement of Opportunity

Frequency: Typically 1 per year

Preparation Time for Posting: 2 months

Total Time to Award from Inception: Approximately 1 year

Nature of Product Solicited: Complex, multi-year research projects which involve significant hardware construction

Targeted Investigator Community: Academic researchers

Resultant Award Type: Grant

Type of Merit or Technical Review Required: Multiple levels of rigorous peer review

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: Program, unless Program delegates authority

Example of Project: Discovery Program in Science Mission Directorate

The Announcement of Opportunity (AO) is a form of broad agency announcement (BAA). This solicitation does not specify the investigations to be proposed but solicits investigative ideas which contribute to broad objectives. The AO is preferred for significant hardware development by the PI. If the hardware already exists and the PI is just providing insertions to an existing module, there is no need for an AO. If the PI is required to build a facility to fit in a space station rack, an AO may be the best option.

3.4.2.9 Experimental Project to Stimulate Competitive Research (EPSCoR)

Frequency: Typically 1 per year

Preparation Time for Posting: 3 months

Total Time to Award from Inception: Approximately 1 year

Nature of Product Solicited: Complex, multi-year research projects

Targeted Investigator Community: Academic researchers from jurisdictions that have not in the past participated equably in competitive aerospace research activities (e.g. South Dakota, Wyoming)

Resultant Award Type: Grant

Type of Merit or Technical Review Required: External peer review

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: NASA HQ, Office of Education

Example of Project: Molecular Mechanisms of Cellular Mechanoreception in Bone

Each funded NASA Experimental Project to Stimulate Competitive Research (EPSCoR) proposal is expected to establish research activities that will make significant contributions to the strategic research and technology development priorities of one or more of the Mission Directorates and contribute to the overall research infrastructure, science and technology capabilities, higher education, and economic development of the jurisdiction. The goal of NASA EPSCoR is to provide seed funding that will enable jurisdictions to develop an academic research enterprise directed toward long-term, self-sustaining, nationally-competitive capabilities in aerospace and aerospace-related research. This capability will, in turn, contribute to the jurisdiction's economic viability and expand the nation's base for aerospace research and development.

3.4.2.10 Cooperative Agreement Notice (CAN)

Frequency: As needed

Preparation Time for Posting: 4-6 months

Total Time to Award from Inception: Approximately 1 year

Nature of Product Solicited: Complex, multi-year projects

Targeted Investigator Community: Academic researchers

Resultant Award Type: Cooperative Agreement

Type of Merit or Technical Review Required: Peer Review

Performance Review Required: No

Availability of Option Period: No

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: Program

Example of Project: National Space Biomedical Research Institute

The Cooperative Agreement Notice (CAN) is a form of broad agency announcement (BAA). The CAN is used to solicit and competitively select proposals to support NASA program interests that require a high degree of cooperation between NASA and the selected institution. The scope of activities solicited by a CAN may be as modest as those through an NRA or as complex as those through an AO. The cooperative agreements awarded as a result of a CAN are similar to grants except that both NASA and the selected institution are required to provide resources, and both are involved in decisions related to the activities carried out by the selected institution.

3.4.2.11 Direct Contract

Frequency: As needed

Preparation Time for Posting: 1 month

Total Time to Award from Inception: 3 months

Nature of Product Solicited: Specific, well-defined tasks

Targeted Investigator Community: Academic and corporate researchers

Resultant Award Type: Contract

Type of Merit or Technical Review Required: Varies - Research and technology development tasks require merit review; all directed tasks require submittal of HRP Tasks Synopsis form.

Performance Review Required: Yes

Availability of Option Period: Yes

Potential to Negotiate Scope Prior to Award with Company or PI: Yes

NASA supervision: Contracting Officer Technical Representative (COTR)

Issuing Authority: Element or Program

Example of Purchase: MATLAB (numerical computing package)

NASA can prepare a Justification for Other than Full and Open Competition (JOFOC) for a noncompetitive procurement to support the use of noncompetitive procedures. The JOFOC must state why the proposed company is the only company, or sole source, that can provide the expertise needed. The JOFOC must demonstrate this fact, not just state it. In addition, the JOFOC must include a description of the efforts made to ensure that offers are solicited from as many potential sources as practicable; a determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable must included in the JOFOC as well. All procurements using a direct contract over $25K must be synopsized on the NASA Acquisition Internet Service (NAIS). All procurement opportunities displayed in the NAIS are also transmitted to and displayed in Federal Business Opportunities (www.fedbizopps.gov). Procurements between $25K and $100K are set aside for small, disadvantaged businesses for a period between 2 and 30 days.

In addition, if the program requires the services of a consultant with highly specialized expertise that cannot be found through other procurement mechanisms, HRP can use a contract that is already in place with an established NASA vendor to obtain those particular services. If a contract is already in effect with the established vendor, no posting on NAIS is required for additional good or services provided under the terms of the contract. For example, Tietronix Software, Inc. (TSI) is a small disadvantaged NASA contractor that provides website development and software programming capabilities to JSC. REDE/Critique is a small disadvantaged NASA contractor that provides secretarial services to JSC. Finally, Wyle Integrated Science & Engineering Group is a large firm that provides scientific and engineering expertise to NASA.

In some cases, directed research tasks may be warranted. One of the following criteria for utilizing directed research tasks must be satisfied for the project to be considered for funding:

• **Insufficient time for solicitation**. In certain cases, NASA must define scientific activities in a short time (e.g., because of the emergence of new opportunities to carry out activities in space on the Shuttle or the International Space Station). When this is the case, use of a Directed Task may be the only practical way to respond.

• **Highly constrained research.** In this case, the project requires sharply focused and constrained data gathering and analysis that is more appropriately obtained through a non-competitive proposal. For example, the research activity may involve extensive operational practices and the associated flight personnel.

In addition to satisfying one of the preceding criteria, directed research tasks require merit review. The Program Scientist will determine the level of review necessary for a particular task.

3.4.2.12 Unsolicited Proposals

An unsolicited proposal is a written proposal that is submitted to NASA on the initiative of the submitter for the purpose of obtaining a NASA grant, contract, or other agreement and which is not submitted in response to a formal or informal request. NASA encourages the submission of unique and innovative unsolicited proposals which will further the Agency's mission. Submissions must be innovative, unique, and prepared independently without Government supervision. Unsolicited proposals that are deemed appropriate are examined by the Program Scientist to determine which Element should consider it. Section 6.1.2 of the Science Management Plan provides additional details on the unsolicited proposal process.

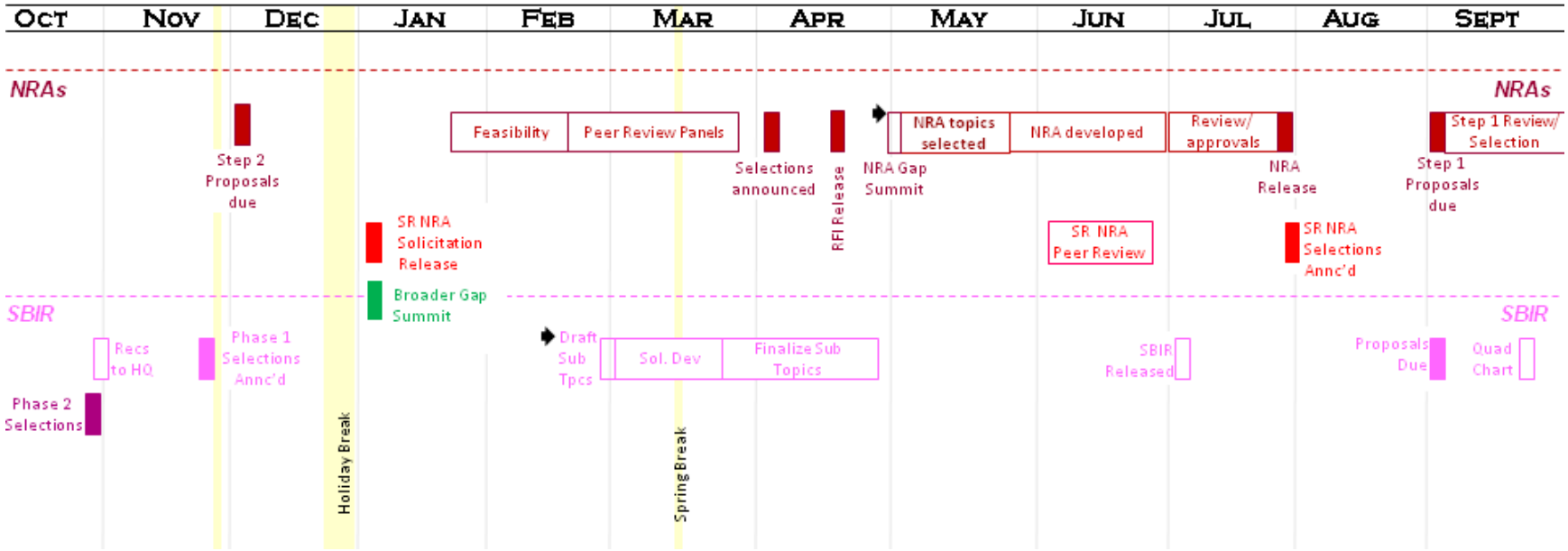


Figure 15 - Annual Cycle for Research Procurement

Table 5 - Procurement Mechanisms

Type of Mechanism	Frequency	Preparation Time for Posting	Total Time to Award from Inception	Nature of Product Solicited	Target Monetary Value per Award	Targeted Investigator Community	Example of Project	Type of Award
NASA Research Announcement (NRA)	1 per year	2 months	Approx. 1 year	Complex, multi-year research projects	Approx. $350K per year	Academic researchers	Developing, Maintaining, and Restoring Team Cohesion	Grant
NASA Specialized Center of Research (NSCOR)	1 per year	2 months	Approx. 1 year	Complex, multi-year research projects which require a team of investigators	Approx. $1.8M per year	Academic researchers	Space Radiation and Intestinal Tumorigenesis: Risk Assessment and Countermeasure Development	Grant
Small Business Innovation Research (SBIR)	1 per year	5 months	Approx. 1 year	Technology development	$100K (Phase 1); $750K (Phase 2); Varies for Phase 3	Small businesses	Fast Neutron Dosimeter for the Space Environment	Contract
Request for Proposals (RFP)	as necessary	1 month	3 months	Technology development, protocol/procedure development, technology assessment	$10's - 100's K	Companies, academic researchers	TBD	Contract
Request for Information (RFI)	as necessary	1 month	N/A	Information collected can be used in writing of future solicitations or strategic planning	N/A	Companies, academic researchers	Crew Health RFI	N/A
Open Innovation	TBD (still in experimental phase)	1 month	4-6 months	Basic research, technology development	Prizes are usually several $K	Professional and amateur solvers, companies	Improved Food Packaging	Generally a monetary prize
Sandpit	TBD (still in experimental phase)	2 months	6-8 months	Problems at the intersection of existing disciplines which can be understood by an intelligent non-domain expert	Varies	Academic researchers	TBD	Grant
Announcement of Opportunity (AO)	1 per year	2 months	Approx. 1 year	Complex, multi-year research projects which involve significant hardware construction	$Millions	Academic researchers	Discovery Program in Science Mission Directorate	Grant
Experimental Project to Stimulate Competitive Research (EPSCoR)	1 per year	3 months	Approx. 1 year	Complex, multi-year research projects	Approx. $250K per year	Academic researchers from jurisdictions that have not in the past participated equably in competitive aerospace research activities	Molecular Mechanisms of Cellular Mechanoreception in Bone	Grant
Cooperative Agreement Notice (CAN)	As needed	4-6 months	Approx. 1 year	Complex, multi-year projects	Hundreds of $K to Millions	Academic researchers	National Space Biomedical Research Institute	Cooperative Agreement
Inter-Agency Agreement (IAA)	As needed	5 months	Approx. 1 year	Specific, well-defined research or projects utilizing the unique capabilities of the non-NASA Government Agency	Varies	Government researchers	NASA/NIH Grant Supplementation to Understand the Potential Risk of Hyperoxia Exposures Similar to EVA in Space	IAA
Direct Contract	As needed	1 month	3 months	Specific, well-defined research	Varies	Academic and corporate researchers	Whitepaper on the Onset of Depression in Astronauts	Contract

APPENDIX A - REFERENCE DOCUMENTS

BCD System User Manual
Federal Acquisition Regulation (FAR)
HRP-47051, Human Research Program, Program Plan
HRP-47053, HRP Science Management Plan
JSC 28330, Space Life Sciences Directorate Configuration Control Management Plan
NASA FAR Supplement
NASA Financial Management Requirements
NPR 7100.1, Protection of Human Research Subjects
NPR: 7120.8, NASA Research & Technology Program and Project Management Requirements
HRP-F01-FERW.R2 – HRP Flight Experiment Resource Worksheet Form
HRP-F02-TSJF.R1 – HRP Directed Task Synopsis & Justification Form
HRP-F03-CSAT.R1 – HRP Customer-Supplier Agreement Template

APPENDIX B - ACRONYMS

ACUC	Animal Care and Use Committee
AIP	Analog Implementation Plan
AO	Announcement of Opportunity
ARC	Ames Research Center
ATP	Authority to Proceed
BAA	Broad Agency Announcement
BCD	Budget Change Directive
BDC	Baseline Data Collection
BM	Book Manager
BPS	Bioastronautics Planning System
CAN	Cooperative Agreement Notice
CB	Control Board
CCB	Configuration Control Board
CFR	Code of Federal Regulation
CM	Configuration Management
CO	Contracting Officer
Co-I	Co-Investigator
COTR	Contracting Officer Technical Representative
CPHS	Committee for the Protection of Human Subjects
CR	Change Request
CSA	Customer-Supplier Agreement
CV	Curriculum Vitae
DCMA	Defense Contract Management Agency
DTO	Development Test Objectives
EPSCoR	Experimental Project to Stimulate Competitive Research
ES	Element Scientist
ESMD	Exploration Systems Mission Directorate
ETDD	Exploration Technology Development & Demonstration
ExMC	Exploration Medical Capability
FAP	Flight Analogs Project
FAPCCP	FAP Configuration Control Panel
FAR	Federal Acquisition Regulation
FTE	Full Time Equivalent
G	Green
GL	Guidelines
HF	Human Factors
HMP	Haughton-Mars Project
HMS	Health Maintenance System
HMTA	Health and Medical Technical Authority
HRP	Human Research Program
HRPCB	Human Research Program Control Board
HSRB	Human System Risk Board
IAA	Inter-Agency Agreement
IMS	Integrated Master Schedule
IMM	Integrated Medical Model
IPD	Integrated Protocol Document
IRB	Institutional Review Board
IRP	Integrated Research Plan
ISS	International Space Station
ISSMP	ISS Medical Project
JOFOC	Justification for Other than Full and Open Competition
JSC	Johnson Space Center
Med-B	Medical Volume B
M&S	Models and Simulations
MRID	Medical Requirements Implementation Document
MRL	Master Risk List
NAR	Non-Advocate Review
NASA	National Aeronautics and Space Administration
NEEMO	NASA Extreme Environment Mission Operations
NPD	NASA Policy Directive
NRA	NASA Research Announcement
NRESS	NASA Research and Education Support Services
NSBRI	National Space Biomedical Research Institute
NSCOR	NASA Specialized Center of Research
NSRL	NASA Space Radiation Laboratory
NSSC	NASA Shared Services Center
OCHMO	Office of the Chief Health And Medical Officer
PCN	Page Change Notice
PEL	Power Equipment List
PES	Program Element Scientist
PI	Principal Investigator
PM	Project Manager
PPBE	Programming, Planning, Budgeting, and Execution
PR	Process
PRD	Program Requirements Document
PS	Project Scientist
PgS	Program Scientist
R	Red
RFI	Request for Information
RFP	Request for Proposals
RMAT	Risk Management Analysis Tool

RMRS	Resources Management Reporting System
RO	Risk Owner
RPWG	Research and Planning Working Group
SA	NASA/JSC Space and Life Sciences Directorate
SAD	Select for Analog Directive
SBIR	Small Business Innovation Research
SDTO	Station Development Test Objectives
SFA	Select for Analog
SFD	Select for Flight Directive
SLSD	Space Life Sciences Directorate
SME	Subject Matter Experts
SMO	Science Management Office
SMP	Science Management Panel
STD	Standard
TCM	Technical Coordination Meeting
TRL	Technology Readiness Level
UPCG	Unique, Processes, Criteria and Guidelines
V&V	Verification and Validation
VNSCOR	Virtual NASA Specialized Center of Research
Y	Yellow

APPENDIX C - FUTURE ADDITIONS

#	ID*	Process Description
1		Process for Determining Level of Peer Review/NAR for Investigation Change in Scope
2	PR-15	Criteria/process to document lessons learned within the Element/Program
3	PR-16	Process for Approving Delivery of HRP Deliverables including OCHMO Standards and Technology Insertion
#	**ID**	**Guideline Description**
1	GL-2	Standing Review Panel Selection Guideline and Standing Review Panel Operating Procedures

*The “ID” column is legacy data from the original HRPCB approved list of processes presented on 12/14/2006

APPENDIX D - CUSTOMER-SUPPLIER AGREEMENT TEMPLATE (WRITEABLE VERSION LOCATED ON THE HRP WEBSITE UNDER “FORMS”)

Human Research Program (HRP)

Customer-Supplier Agreement (CSA)
Between the *Element/Project* *(Insert over Italics)*
and
Name of Organization *(Insert Over Italics)*
Effective as of *MM/DD/YY* *(Insert Over Italics)*

_____ *Date (Insert Over Italics)*

Customer signature

Printed Name of Authorized Official

Title of Authorized Official

_____ *Date (Insert Over Italics)*

Supplier signature

Printed Name of Authorized Official

Title of Authorized Official

_____ *Date (Insert Over Italics)*

Element Manager signature

Printed Name of Element Manager

Name of Element

1.0 Introduction and Definitions

This document or equivalent establishes the formal agreement between the signatories and describes in detail the expectations regarding the responsibilities of each. A signed CSA should be obtained before research or applicable activities begin.

The following definitions are used in this document.

- Customer: the primary recipient and ultimate owner (typically external to HRP) of the resultant deliverables of this agreement (e.g., OCHMO, Commercial Crew and Cargo, Exploration Projects, etc.)
- Supplier: the primary HRP provider of deliverables of this agreement, including Element or Project funded researchers
- Deliverable: final product to which the Customer and Supplier have agreed (see categories defined in Appendix A of this document)
- Stakeholder: an entity with an interest in the deliverables (e.g., ESMD, ETDD, Health and Medical Technical Authority (HMTA), other Elements or Projects, etc.)

2.0 Background

(This section is optional. Otherwise, insert "N/A." Here, the description of the impetus driving the need for the deliverable(s) or other helpful explanatory information may be included.)

3.0 Purpose

(Insert the purpose and scope of this CSA in as much detail as necessary, such that the expected outcome of this agreement is clear and unambiguous. The ultimate use for the deliverable should be described here.)

4.0 Requirements

The requirements of this agreement are the following: *(The agreed-upon requirements shall be provided below such that there is no ambiguity in interpretation of what is expected of each party.)*

(Describe any procedures, testing requirements, etc. to be used to verify and validate deliverables. Include any acceptance criteria such as quality assurance or control to be performed. Copies or links to any standard reference documents may be attached if desired.)

4.1 Review Schedules

(Describe the content or types of reviews, reports, milestones and any other events that are scheduled to occur during the time the CSA is in effect. Using the table below, fill in the applicable start and end dates and any other dates as appropriate. Add additional events as necessary. Depending on the nature of the work, Supplier may opt to conduct quarterly, semi-annual, or final reviews. Optional reviews with

Stakeholders, anomaly recognition, and corrective action reviews, etc. may be included as well as other categories.)

Event	***(MM/DD/YY)***						
Start Date							
Review Dates							
Report Dates							
Milestone Dates							
End Date							

4.2 **Deliverables**

(Describe the deliverable(s) and include a definitive statement as to whether or not full ownership is to be transferred to Customer or is to be partly retained (and to what extent) by Supplier.)

4.3 **Reports**

(Describe requirements for reports that will be delivered, including the scheduled delivery and frequency such as quarterly, midterm and/or final with due dates.)

4.4 Unique Processes

(Describe unique processes or procedures if resulting as (one of) the result(s) of this CSA. If none, enter N/A.)

4.5 Deliverables Table

(Fill in the Deliverables table below completely with the applicable information. If TRLs do not apply to the deliverable, then enter N/A. Use the terminology in Appendix A to identify the deliverable categories. Add as many rows as needed for multiple deliverables.)

Deliverables Table

Risk Title	Task Title	Gap	Deliverable Category	Deliverable Subcategory	Initial TRL	Final TRL	Deliv. Date (MM/DD/YY)

5.0 Change Process

(Describe the process required if either party wishes to make changes or adjustments to this CSA regarding schedule of deliverables, changes to deliverables, etc. Both Customer and Supplier shall sign any changes to this CSA. Other signatories, such as Stakeholders, may be added to the change process if desired.)

6.0 Acceptance of Deliverable

The signature below verifies acceptance of the deliverables. *(At the conclusion of this agreement and acceptance of the deliverable by the Customer, this Section shall be signed by the authorized official.)*

_____ *Date* _____

Customer signature

Printed Name of Authorized Official

Title of Authorized Official

APPENDIX E - CSA DELIVERABLES CATEGORIES & EXAMPLES

Category	Subcategory	Example Customers	Example Deliverables
Requirement	Vehicle/Suit Design	Vehicle/Mission Definition & Development Program	Suit Design Requirements
	Flight Rule/ MRID/Practice Guidelines	Medical/Mission Operations	Questionnaires, Procedures
Technology	Systems Solutions, Prototype H/W	Medical Operations, Vehicle/Mission Definition & Development Program	Food Packaging Technologies, In-flight Blood Analysis Technology
	Clinical Care, Medical Informatics	Medical Operations	Training Protocol for Effective Medical Operations
Tool	Computational Models, Software	Medical Operations, OCHMO, Vehicle/Mission Definition &Development Program	Radiation Risk Assessment Models, Digital Astronaut
	Database	Human Research Program	Database created by gathering existing data, New database created for data input
	Simulation	Medical Operations, Vehicle/Mission Definition &Development Program	IMM Decision Support Tool
Countermeasure	Prescription	Medical Operations, OCHMO	Integrated Resistance and Aerobic Training Study
	Protocol	Medical Operations, OCHMO	Consumables Tracking System, Prebreathe Protocol for Exploration Systems
	Prototype H/W, Pharmaceutical/ Nutritional Supplement	Medical Operations, OCHMO, Vehicle/Mission Definition &Development Program	Pharmaceutical recommendations resulting from Vitamin D Study
Standard	Update	OCHMO	Nutrition Standard Update
	New	OCHMO	Lunar Dust PEL
Risk Characterization, Quantification	Evidence	OCHMO, HSRB	NRA Final Report, RMAT, Evidence Report, Conceptual Model
Study	Customer Requested Study or Analysis	Vehicle/Mission Definition & Development Program	Trade Study Analysis Results and Recommendations