

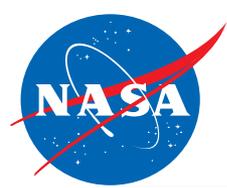
Scientific Merit Review of Directed Research Tasks Within the NASA Human Research Program

John B. Charles, PhD

Program Scientist - Human Research Program

Johnson Space Center

Houston, Texas

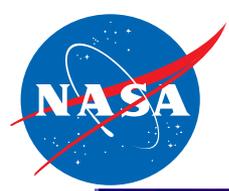


Agenda

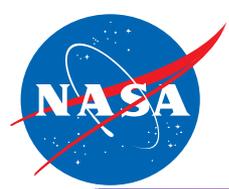


Human Research Program

- Introduction to The Human Research Program (HRP)
- Research Funding Mechanisms in HRP
- Charge to the IOM Panel
- Review Mechanisms for Directed Research Tasks
 - Formulation Review
 - Annual and Final Reporting
 - Status Review
 - Pre-delivery Review
 - Customer Acceptance Review
- Additional Resources



Introduction to The Human Research Program



Origins of the HRP



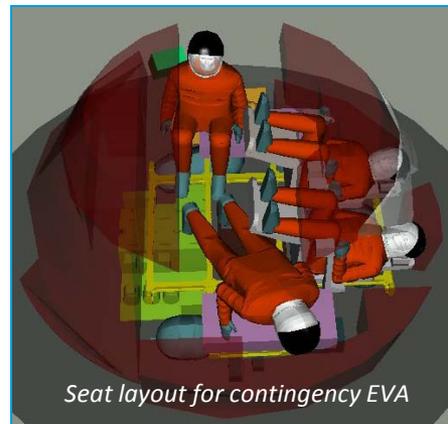
Human Research Program

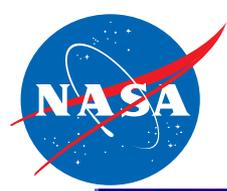
- The HRP Program was established in 2005 as an integral part of the Vision for Space Exploration.
- The predecessor program within NASA was the Bioastronautics Program.
- The Human Research Program (HRP) is a major part of Advanced Capabilities development within the Exploration Systems Mission Directorate.

The goal of HRP is to provide human health and performance

- countermeasures,
- knowledge,
- technologies, and
- tools

to enable safe, reliable, and productive human space exploration.





NASA HRP Organization



Human Research Program

Reporting Structure

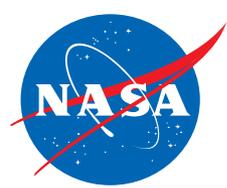
Program: The Human Research Program is instrumental in developing and delivering research findings, health countermeasures, and human systems technologies for spacecraft.



Element: HRP is subdivided into 6 research entities, or Elements. Each Element is charged with providing the Program with knowledge and capabilities to conduct research to address the human health and performance risks as well as advance the readiness levels of technology and countermeasures.



Project: An Element may be further subdivided into Projects, which are defined as an integrated set of tasks undertaken to deliver a product or set of products.



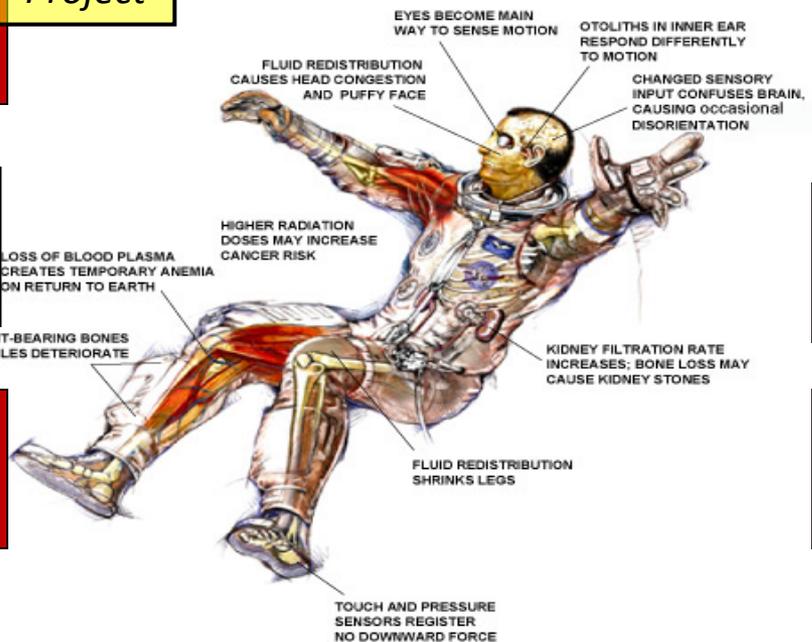
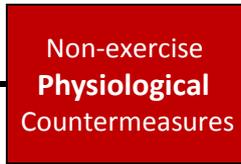
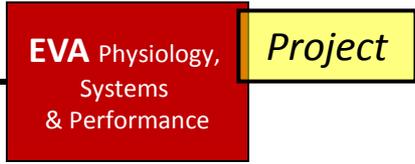
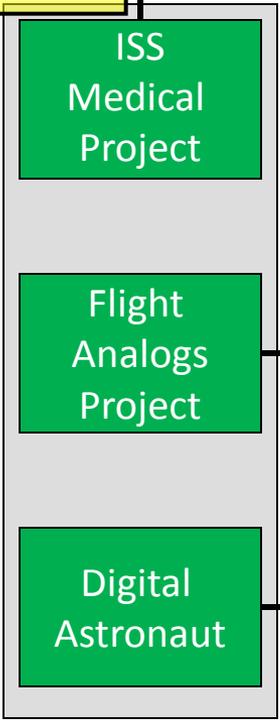
Composition of the HRP

Human Research Program

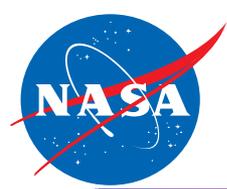


Core Services

Element



Core Services

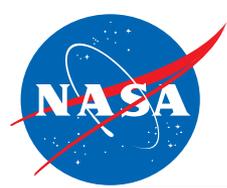


NASA HRP Elements



Human Research Program

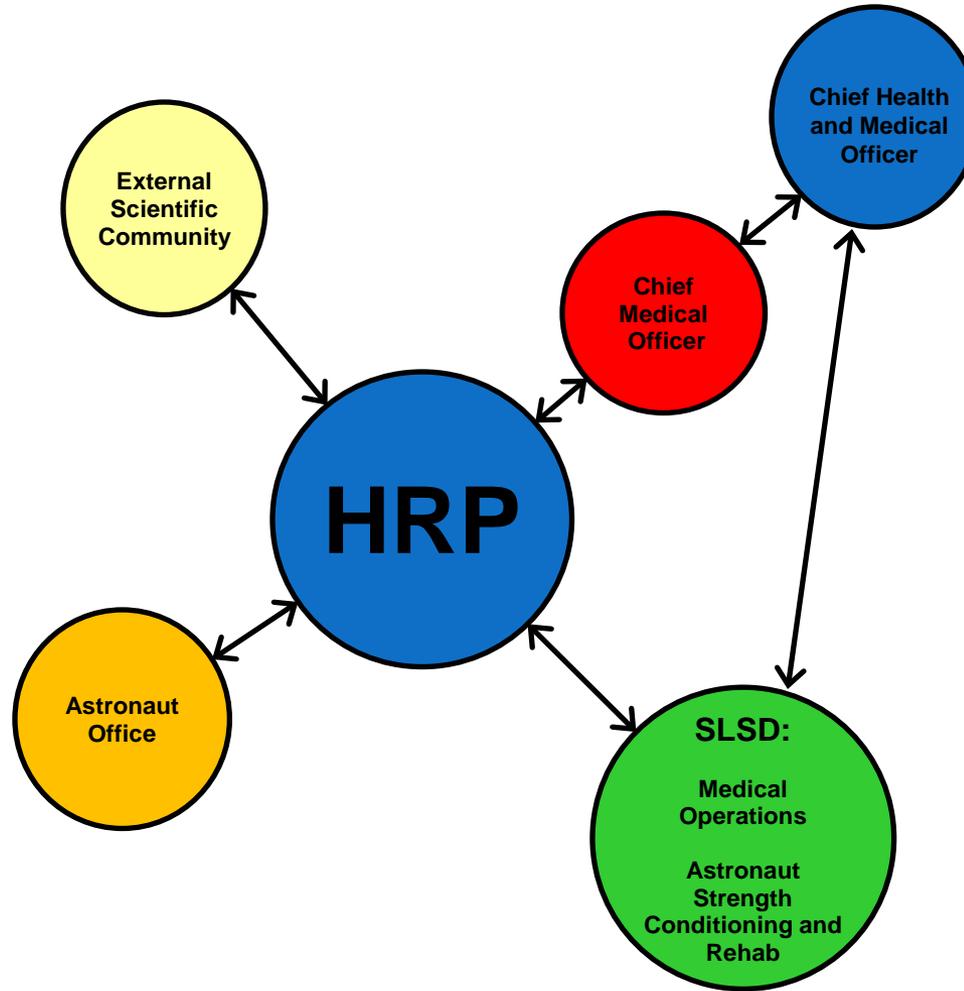
- The HRP is comprised of the following elements:
 - ISS Medical Project (ISSMP)
 - Space Radiation (SRP)
 - Human Health Countermeasures (HHC)
 - Exploration Medical Capability (ExMC)
 - Behavioral Health & Performance (BHP)
 - Space Human Factors & Habitability (SHF&H).
- Each of these elements manages research and technology development projects and tasks that are conducted by external and intramural NASA investigators.

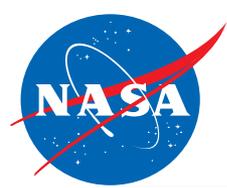


Integration With Other Organizations



Human Research Program



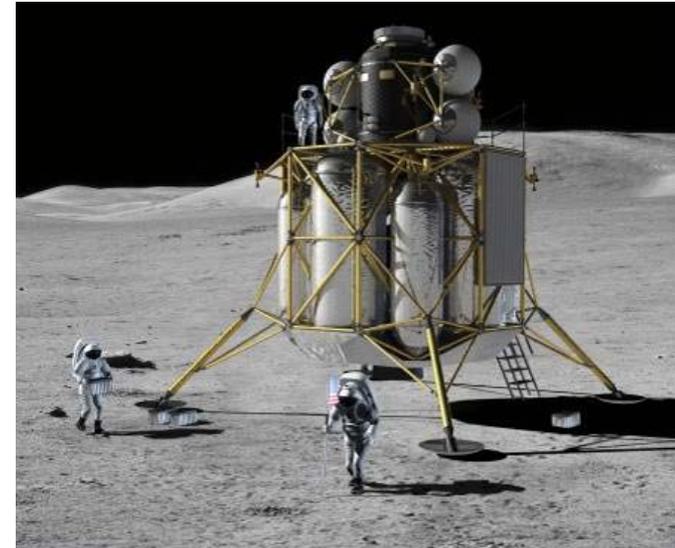


HRP Is An Applied Research Program

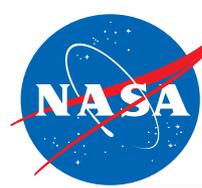


Human Research Program

- Emphasis is on defining and solving problems
 - Increasing basic knowledge is not a requirement
 - Basic research would almost always prolong the research
 - HRP utilizes customer/supplier arrangements to fund and execute research.
- Constraints
 - Schedule
 - Partial, but timely, results influence NASA decisions
 - Late results do not influence NASA decisions
 - Requires some tasks to run, at risk, in parallel rather than serially
 - Flight
 - Mass, power, volume, crew time, number of subjects



HRP must use limited resources to solve as many important problems as possible



Documents and Reviews in the HRP Management Architecture



Human Research Program



Knowledge Gaps

Disposition Gaps

What?
When?
Why?

How?
Who?
Where?

Evidence Book

Program Requirements Document

Evidence Book

Past IOM Review

Standing Review Panels

Integrated Research Plan

IRP Supplement

Grant Peer Review

Research Proposal

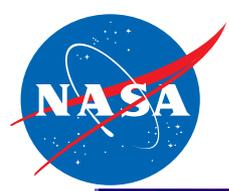
Current CAMMEE Review

Directed task peer review

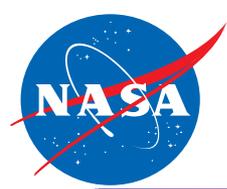
Research Proposal

Customer Acceptance Reviews

Customer Acceptance Agreements



Research Funding in HRP

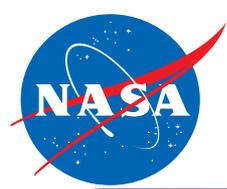


Research Funding Categories in HRP



Human Research Program

- ***Directed research Tasks:*** The task is awarded to a PI through a non-competitive mechanism. The research Element chooses the PI to carry out the work.
 - Internal HRP directed research tasks
 - External HRP directed research tasks
 - Externally submitted unsolicited proposals, that become directed tasks.
 - ***Solicited research:*** Tasks that are awarded through competitive means.
 - NASA Research Announcements (NRA)
 - Requests for Proposals (RFPs)
- * NASA HRP also funds a portion of it's research portfolio through external funding mechanisms such as: Small Business Innovation Research (SBIR), NASA Specialized Center of Research (NSCOR), Congressional Earmarks, and other governmental entities such as NIH, DoD, etc. These funding mechanisms have unique merit assessment requirements outside the purview of the Program Scientist.



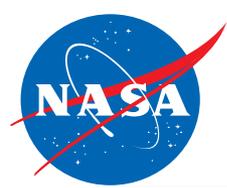
Research Funding in HRP



Human Research Program

In order to be considered for funding as a directed research task, the task must meet one of the following criteria:

1. 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 International Space Station). When this is the case, the use of a Directed task may be the only practical way to respond.



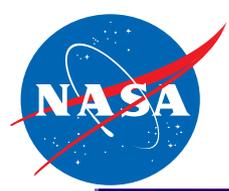
Research Funding in HRP



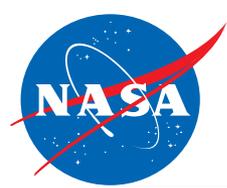
Human Research Program

In order to be considered for funding as a directed research task, the task must meet one of the following criteria:

2. Highly Constrained Research: In certain cases, the project requires sharply focused and constrained data gathering and analysis that is more appropriately obtained through a non-competitive proposal (e.g., the research activity may involve extensive operational practices and the associated flight personnel).



Charge to the IOM Panel



Charge to the IOM Panel – Step 1



Human Research Program

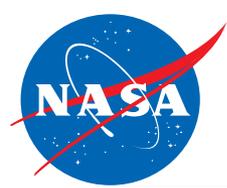
The panel will provide an expert, independent assessment of the adequacy, rigor, strengths and weaknesses in the scientific merit assessment processes used in evaluating directed research tasks within NASA's Human Research Program (HRP).

This activity will be broken into 2 phases, to be completed over the span of 2 years.

Today: The Program Scientist will introduce the Committee to NASA HRPs scientific merit assessment processes for directed research tasks. This introductory presentation will focus on defined and implemented review processes and briefly touch on those processes that are in the pipeline.

No formal response is expected at this time, but questions for the Committee to consider include:

- Is this an adequate suite of options for reviews of directed research and technology tasks?
- Is the range of discretion available to the Program Scientist appropriate?
 - In deciding the level of review for directed task proposals
 - In judging the adequacy of the review and assigning authority to proceed.



Charge to the IOM Panel – Year 2

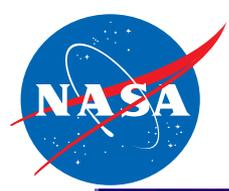


Human Research Program

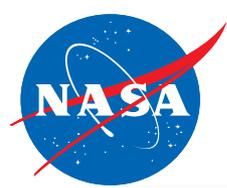
The panel will provide an expert, independent assessment of the adequacy, rigor, strengths and weaknesses in the scientific merit assessment processes used in evaluating directed research tasks within NASA's Human Research Program (HRP).

This activity will be broken into 2 phases, to be completed over the span of 2 years.

1 year from now: The Committee will formally assess the Program Scientist's implementation and adherence to the defined review processes. This will include an audit of the archival documentation for completed directed tasks to date.



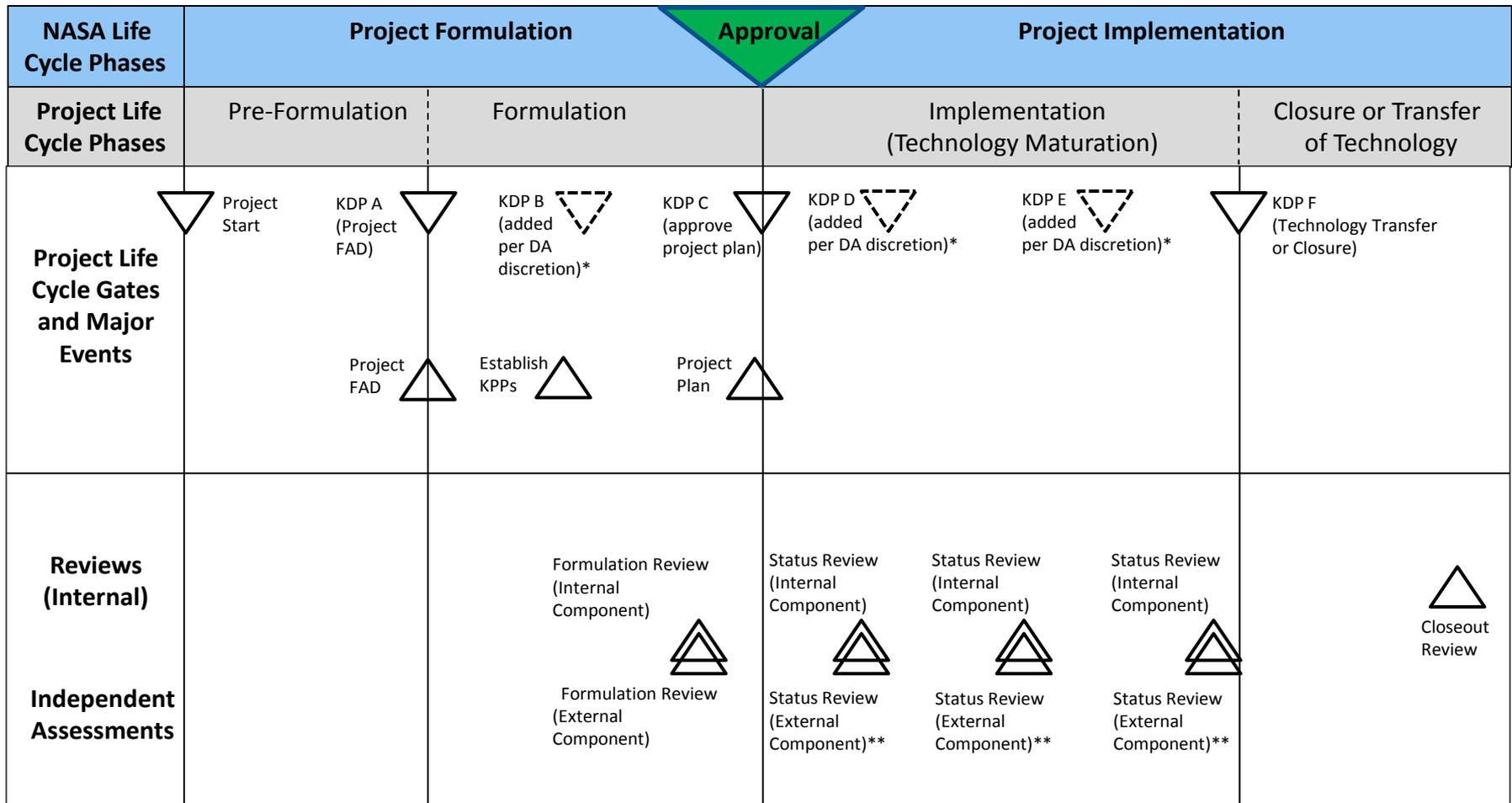
Review Mechanisms for Directed Research Tasks



NASA STD 7120.8 Technology Development



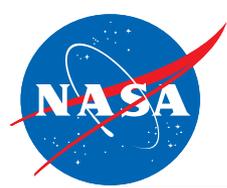
Human Research Program



DA: Decision Authority
 FAD: Formulation Authorization Document
 KDP: Key Decision Point
 KPP: Key Performance Parameter

* KDP: B, D, and E may be added per DA discretion. The DA may also determine these KDPs are not needed.
 ** The external component of the status review helps ensure mature technologies can be utilized when available.

Figure 2.2.1: 'Technology Development Project Life Cycle' in NASA Research and Technology Program and Project Management Requirements (NPR 7120.8)



NASA STD 7120.8-compliant Review Process

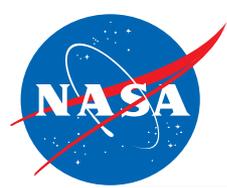


Human Research Program

NASA Life Cycle Phases	Project Formulation		Approval	Project Implementation				
Project Life Cycle Phases	Formulation Review		Annual Report	Status Review	Annual Report	Pre-delivery Review	Customer Acceptance	Closeout Report
Program-level Decisions	Project Start (Element formulates study)	KDP A (PgS examines TS. Rejects or assigns merit review)	KDP C (PgS makes ATP decision.)	KDP D (Report developed yearly and assessed by PgS.)	KDP E (PgS evaluates and issues authority to continue or actions) (Develop mid-way-point review materials.)	KDP D (Report developed yearly and assessed by PgS.)	KDP G (Pre-delivery evaluation of customer-supplier assessment by PgS)	
Element Documents	Project FAD: Task Synopsis submitted to Program.	KPP A: Initial proposal developed.	Project Plan: Finalized proposal. KPPs listed and CSAs in place.					
Reviews (Internal)								
Independent Assessments		Formulation Review (merit review): 1 of 3 levels of merit review [Project (internal), Element (internal or external) or program (external)]		Mid-point Status review (Contains status report and review material commensurate with level prescribed in formulation review)		Pre-delivery Review	Customer Acceptance Review guided by CSA	Closeout Report

FAD: Formulation Authorization Document
 KDP: Key Decision Point
 KPP: Key Performance Parameter
 CSA: Customer Supplier Agreement

Modified from: Figure 2.2.1: 'Technology Development Project Life Cycle' in NASA Research and Technology Program and Project Management Requirements (NPR 7120.8) Process described in Chapter 4: 'Technology Development (TD) Project Requirements'



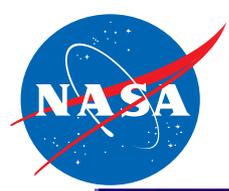
Review Mechanisms for Directed Tasks



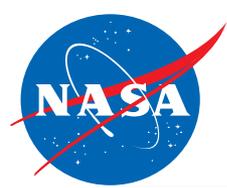
- The Program Scientist is responsible for the scientific integrity of HRP.
- Reviews called for in STD 7120.8 include:
 - Formulation Review: Initial review of a task prior to initiation.
 - Annual and Final Reports: Annual and final progress and findings for a given task.
 - Status Review: Review levied at the Program Scientists discretion as an examination of progress, or in response to a problem or concern.
- HRP Pre-Delivery Review: Opportunity for HRP to examine and evaluate products before they are delivered to customers outside of the Program.
- HRP Customer Acceptance Review: Evaluation of how well the deliverable met the stated requirements specified in the customer-supplier agreement.

Part of today's discussion

Not part of today's discussion



Formulation Review

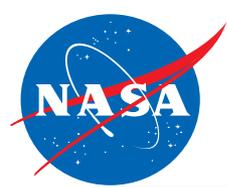


Formulation Review



Human Research Program

- Formulation review is the initial examination of a task by the Program Scientist prior to the initiation of a directed research task.
- The Program Scientist has the ultimate authority in granting a task authority to proceed (ATP).
- The Program Scientist may utilize any resource at his disposal in making the decision on ATP. This can range from the Program Scientists unilateral evaluation of a task to evaluation by a 3rd party non-advocate review panel.
- Steps common to all levels of review
 - PI and Element formulate a task.
 - PI and Element prepare 2-page task synopsis.
 - Element submits task synopsis to Program Scientist.
 - Program Scientist evaluates task synopsis to assess whether the task meets 1 of 2 criteria for directed task funding.

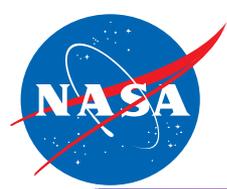


Formulation Review



Human Research Program

- A formulation review typically takes 1 of 3 forms, depending on the type of study planned.
 - Project-led review  Least Programmatic involvement and oversight
 - Element-led review
 - Program-led review  Most Programmatic involvement and oversight
- Based on the information presented in the formulation review, the Program Scientist will decide to:
 - ATP: grant the investigators authority to proceed.
 - ATP with requirements: grant the investigators authority to proceed pending the completion of additional requirements.
 - Rescope: the proposal must be re-scoped and re-reviewed prior to initiation of the task.
 - Rejected: the proposal is outright rejected (does not meet criteria for directed task).

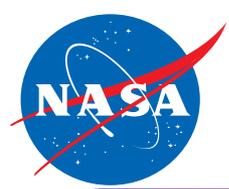


Project-led Formulation Review



Human Research Program

- The level of review that is delegated to the Element.
- Review process:
 1. PI and Project prepare a task proposal that documents the research plan. This proposal is archived by the Program Scientist as evidence of the planned work.
 2. Element Scientist and Element Manager jointly construct a resource and relevance statement certifying that:
 - a. The task meets a research need within the Project .
 - b. The element has the resources (funds, personnel, etc.) to conduct the proposed work.
 3. Products of the review process are archived in the Program Scientist files (subject of audit next year).



Project-led Formulation Review

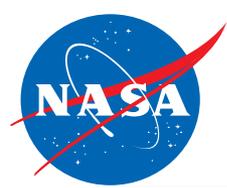


Human Research Program

- Typically applied to:

- data mining tasks
 - Evaluates existing data
- technology watch tasks
 - Non-hypothesis driven
 - Initial data gathering for future tech development
- pilot testing
 - Non-hypothesis driven
 - Data to substantiate or refine future research protocol
 - Small N (N<10)

These are due diligence tasks, or tasks the Program Scientist feels are required components of the Projects research.

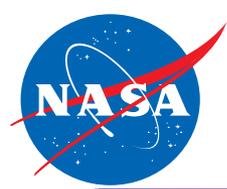


Element-led Formulation Review



Human Research Program

- The level of review that is delegated to the Element.
- Review process:
 1. Program Scientist initiates review by providing Element with a review charge document, detailing the requirements of the review.
 2. PI and element prepare a task proposal that documents the research plan.
 3. The Element identifies 2-4 reviewers who have the necessary background to conduct a quality review. These reviewers must also not have a real or perceived conflict of interest as well as the necessary skills and background to conduct a meaningful review.
 4. The reviewers examine the proposal, per the charge, and provide the element with a critique of the proposal.
 5. The PI responds to the critique of the reviewers and revises the proposal.
 6. The reviewers examine the final changes made to the proposal by the review team and provide a recommendation and numerical score to the Program Scientist.
 7. Program Scientist evaluates the final proposal and the review material (including the reviewers' qualifications).
 8. Program Scientist issues a decision on whether the task has authority to proceed.
 9. Products of the review process are archived in the Program Scientist files (subject of audit next year).



Element-led Formulation Review



Human Research Program

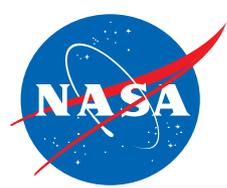
- Typically applied to:

- requirements definition or characterization activities
 - Non-hypothesis driven
 - Goal to capture physiologic needs to support requirements

- medical requirements implementation document enhancement activities
 - Non-hypothesis driven
 - Contributes to space normal database
 - Descriptive enhancements of medical requirements

- hardware tests or engineering evaluations
 - Non-hypothesis driven
 - Feasibility assessment

- analog validation studies
 - Non-hypothesis driven
 - Intramural
 - Low level complexity
 - Intent is to characterize and validate analog environment with flight

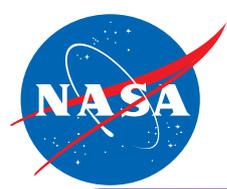


Program-led Formulation Review



Human Research Program

- The review is conducted by a panel of peers with appropriate expertise.
- The members of this panel are identified by 3rd party independent peer review contractor, NASA Research Education and Support Services (NRESS) with oversight from NASA headquarters Advanced Capabilities Division (ACD).
- Review process:
 1. Principal Investigator and Element Scientist prepare a task proposal that documents the research plan and submit the proposal to the Program Scientist.
 2. Program Scientist may iterate with the PI on the proposal until the Program Scientist is satisfied that the proposal is ready for review by the review panel.
 3. Once the proposal is complete, Program Scientist initiates review by providing NRESS and ACD with 1) a NASA memo initiating the review and 2) a review charge document, detailing the requirements of the review.
 4. Reviewers with the necessary skills and background to conduct a meaningful review, who do not have a real or perceived conflict of interest, are identified and recruited.
 5. The reviewers examine the proposal, per the review charge, and develop a list of issues to be addressed by the PI.



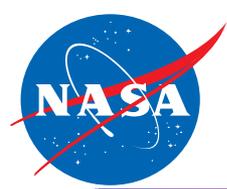
Program-led Formulation Review



Human Research Program

- Review process *continued*:

6. The PI responds to the critique of the reviewers and revises the proposal.
7. The review panel examines the responses and may choose to visit (via telecon or site visit) with the PI.
8. The PI generates final report and score, which is provided supplies to the Program Scientist via NRESS.
9. Program Scientist evaluates the final proposal and the review material.
10. Program Scientist issues a decision on whether the task has authority to proceed.
11. Selection Memo issued by Program Scientist
12. Products of the review process are archived in the Program Scientist files (subject of audit next year).

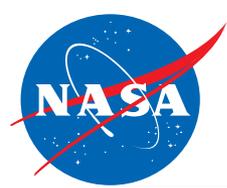


Program-led Formulation Review



Human Research Program

- Typically applied to:
 - full research or technology development activities
 - Hypothesis-driven
 - Non-competed
 - Contributes understanding of normal physiological response to spaceflight
 - Requires flight or highly visible resources
 - Medium to high level of complexity
 - Will produce publishable results



Metrics for Completed Formulation Reviews



Human Research Program

03-15-09 to Present

Review Volume and Outcomes

	Total Number of Reviews Undertaken	Number of Tasks Rejected by PgS	Number of Tasks Withdrawn by PI	Number of Reviews Currently in Process
Project-led reviews	21	0	1	0
Element-led reviews	17	1	1	5
Program-led reviews	8	1	1	6

Program-led Review Stratification

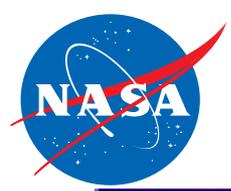
	Total Number
External Non-advocate Review Panel Convened	4
Program Scientist acting as Subject Matter Expert	2

* NASA Research Education and Support Services (NRESS) is the contracted peer review administrator for external review panels.

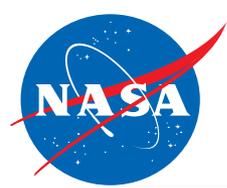
Duration of Review by Type

Project-led reviews (20)	21	11	193
Element-led reviews (15)	114	54	251
Program-led reviews (6)	193	16	247

* Count of days includes Saturdays and Sundays



Annual and Final Reports



Annual Report Content Requirements



Human Research Program

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.

Abstract: The abstract should be a succinct description of the directed task.

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

Specific Aims: A concise list of the specific aims for the task.

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

Results: A list of results (if any) to date that derive from the task.

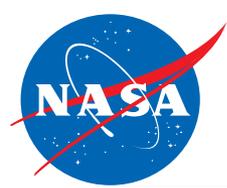
Discussion and Planned Future Work: Recommended follow-on work and any potential updates to the IRP or other programmatic level documentation.

References: A list of references cited in the report.

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

New Technology: A list of any new technology developed as a result of this work.

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



Final Report Content Requirements



Human Research Program

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.

Abstract: The abstract should be a succinct description of the directed task.

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

Specific Aims: A concise list of the specific aims for the task.

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

Results: A list of results spanning the entire task.

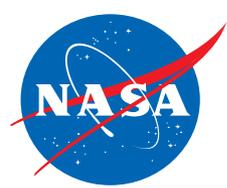
Discussion and Planned Future Work: Recommended follow-on work and any potential updates to the IRP or other programmatic level documentation.

References: A list of references cited in the report.

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

New Technology: A list of any new technology developed as a result of this work.

LSDA and Equipment Archive: data from this experiment that has been made available in the LSDA data archive and a list of any specialized equipment and the location and contact information.



Annual and Final Report Lifecycle



Human Research Program

Annual Reports

- Annual reports due yearly 60 days prior to the anniversary of ATP.
- The PI is sent notification of annual report due date 30 days prior to report due date.

Final Reports

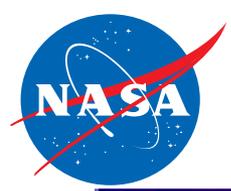
- Final report due 90 days after the period of performance ends.
- The PI is sent notification of final report due date on the date the period of performance ends.

Annual and Final Report Compliance Metrics

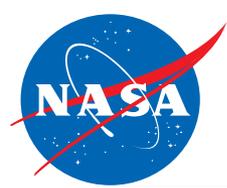
As reported by Task Book for FY 2009

Directed Research Task Reports	78%
All other category of Reports	84%

* Percentages based on tasks that are entered into Task Book.



Status Review

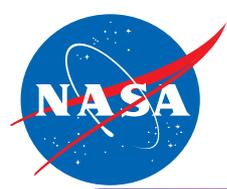


Status Review



Human Research Program

- Review levied at the Program Scientists discretion as an examination of progress, or in response to a problem or concern. Program Scientist can request a status review at any time, for any directed task.
- Status can be used as a mid-term examination of a task by the Program Scientist to assess progress against the stated plan.
- Status reviews can be used by Program Scientist to assess how the research team is addressing concerns raised in the formulation review.
- Status reviews are also assessed if the time from ATP from a formulation review extends beyond a 5 year period.
- Based on the information presented in the status review, the Program Scientist will decide to:
 - grant the investigators authority to continue
 - grant the investigators authority to continue with additional requirements
 - grant the investigators authority to continue with additional requirements and re-review
 - Halt the task

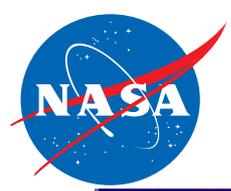


Reviews in Development

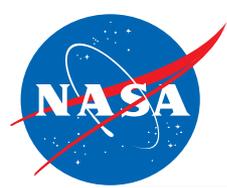


Human Research Program

- HRP Pre-Delivery Review: Opportunity for HRP to examine and evaluate products before they are delivered to customers outside of the Program.
- HRP Customer Acceptance Review: Evaluation of how well the deliverable met the stated requirements specified in the customer-supplier agreement.



Resources

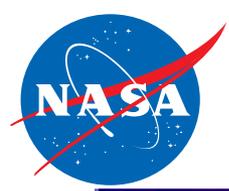


Review Process Resources

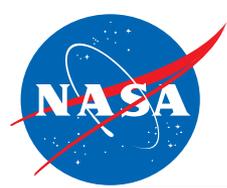


Human Research Program

- *The Human Research Program Science Management Plan*
(HRP-47053; Rev. C, December 11, 2008), sec. 6.1, 6.3 and 6.4, pp. 18-23
- *Human Research Program Unique Processes, Criteria and Guidelines*
(UPCG, HRP-47069; Rev. B PCN1, December 10, 2009), sec. 2.4 and 3.2 to 3.5
- *Advanced Capabilities Division Research and Technology Task Book*
(online resource at: <http://taskbook.nasaprs.com/Publication/welcome.cfm>)
- *The Human Research Program Integrated Research Plan*
(HRP-47065; Rev. B, July 2010)
- *Human Research Program Website*
<http://hrp.jsc.nasa.gov/>



Restatement of Committee Charge



Charge to the IOM Panel – Step 1



Human Research Program

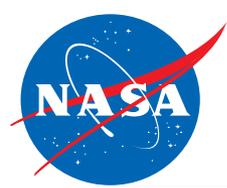
The panel will provide an expert, independent assessment of the adequacy, rigor, strengths and weaknesses in the scientific merit assessment processes used in evaluating directed research tasks within NASA's Human Research Program (HRP).

This activity will be broken into 2 phases, to be completed over the span of 2 years.

Today: The Program Scientist will introduce the Committee to NASA HRPs scientific merit assessment processes for directed research tasks. This introductory presentation will focus on defined and implemented review processes and briefly touch on those processes that are in the pipeline.

No formal response is expected at this time, but questions for the Committee to consider include:

- Is this an adequate suite of options for reviews of directed research and technology tasks?
- Is the range of discretion available to the Program Scientist appropriate?
 - In deciding the level of review for directed task proposals
 - In judging the adequacy of the review and assigning authority to proceed.



Charge to the IOM Panel – Year 2



Human Research Program

The panel will provide an expert, independent assessment of the adequacy, rigor, strengths and weaknesses in the scientific merit assessment processes used in evaluating directed research tasks within NASA's Human Research Program (HRP).

This activity will be broken into 2 phases, to be completed over the span of 2 years.

1 year from now: The Committee will formally assess the Program Scientist's implementation and adherence to the defined review processes. This will include an audit of the archival documentation for completed directed tasks to date.