APPENDIX A: MEDICAL DATA SHARING

Metabolism and nutrition	MR016L	MEDB N3.06	Nutritional Assessments
Neuroscience	MR042L	MEDB 1.5	Neurovestibular Platform Test
Immunology	MR076L	MEDB 1.14	Photodocumentation of Skin
Radiation biology		MEDB N3.04	MEDB N3.04 Biodosimetry
Exercise physiology		MEDB 5.1	Functional Fitness Assessment
Exercise physiology	MR082L	MEDB 5.2	On-Orbit Strength & Conditioning Monitoring
Clinical medicine		MEDB 19.1	Dental Orthopantomogram or Full Mouth X-Ray Series
Cardiovascular physiology	MR071L	MEDB 1.7	24-Hour Ambulatory ECG Monitoring
Clinical medicine,Ocular physiological phenomena	MR014L	MEDB 1.10	Ophthalmology Examination
Behavior and performance		MEDB 7.1	Preflight Psychiatric/Psychological Status Check
Muscle physiology	MR038L	MEDB 6.3	Arm Ergometry Test
Clinical medicine	MR018L	MEDB 1.2	Crew Medical Officer Health Status Evaluations
Clinical medicine		MEDB 2.1	Laboratory Testing
Radiation biology	MR003L	MEDB 3.2	Biodosimetry Testing (Occupational Monitoring)
Clinical medicine,Neuroscience		MEDB 1.15	MRI Brain and MR Angiography
Clinical medicine	MR024L	MEDB 1.13	Body Mass Measurement
Behavior and performance	MR031L	MEDB 7.2	Private Psychological Conferences (MR031L)
Clinical medicine	MR015L	MEDB 1.12	Ultrasound Imaging (Sonography)
Muscle physiology		MEDB 5.4	Calf Volume Measurement
Clinical medicine	MR009L	MEDB 1.1	Pre- and Postflight Physical Exam for Long Duration Crews
Immunology	MR021L	MEDB 2.4	Methicillin Resistant Staphylococcus aureus (MRSA) Nasal Screen and Suppression
Immunology		MEDB 2.3	Tuberculosis
Behavior and performance		MEDB 7.4	Cognitive Assessment
Clinical medicine	MR012L	MEDB 1.9	Dental Examination
Cardiovascular physiology,Clinical medicine	MR011L	MEDB 1.6	Resting ECG
Exercise physiology,Muscle physiology	MR079L	MEDB 5.3	Isokinetic Testing
Radiation biology		MEDB 3.1	Radiation Monitoring/Crew Personal Dosimetry
Skeletal physiology	MR035L	MEDB 1.11	Bone Densitometry
Behavior and performance	MR027L	MEDB 7.5	Behavioral Observation of Training
Clinical medicine,Neuroscience	MR013L/MR086L	MEDB1.8	Hearing Assessment
Immunology		MEDB 2.2	H. Pylori Testing
Clinical medicine	MR017L	MEDB 1.3	Private Medical Conference
Extravehicular Activity (EVA)	MR020L	MEDB 6.1	EVA Medical Monitoring

APPENDIX B: ERD TEMPLATE

Canadian Space Agency
Space Exploration Projects

<Experiment short name> Study
Experiment Requirements Document (ERD)

<Draft 1 - Initial Release upon approval>

Mmm dd, YYYY

Note on how to complete this template

Revision: Initial Release ***Date:*** XY September 2015

Approved by: Senior Program Scientist HLS

The ERD is part of the ISS Payload CSA Mandatory Documentation.

Read and make sure you understand this document before completing it.

All text highlighted in yellow should be replaced with the appropriate information specific to the payload.

Text enclosed in boxes provides guidance to the author. All boxes should be deleted by the author.

Custom information <fields> have been created for this template. Once the author enters some information such as **payload name,** all instances of these fields can be updated.

- To modify these fields' content you must access ***Document Properties***
  1. Click *Office button (Word 2007)or File (Word 2010/2013/2016)* → *Prepare* → *Properties*,
  2. Click *Document Properties*,
  3. Change the content of appropriate fields (those with content) as needed.
- To update all fields in the document (including the **Table of contents**, the list of **Tables** and the list of **Figures**,
  1. Position your cursor anywhere in the document (outside a text box),
  2. Press *Ctrl A*,
  3. Press the **F9** key to update,
     a. Select *Update entire Table* in the **Update Table of Contents** dialogue box,
     b. Click *OK* in the **Update Table of Contents** dialogue box,
     c. Select *Update entire Table* in the **Update Table of Figures** dialogue box,
     d. Click *OK* in the **Update Table of Figures** dialogue box
     e. Repeat steps c and d if required.

Delete any generic section(s) not relevant for your specific payload.

Add any specific section(s) relevant for your specific payload.

Add or deleted rows and columns in tables if needed.

Experimental Requirements [ER] and Experimental Desirements [ED] numbering is performed using the paragraphs numbering function of MS Word. To add ER or ED in any section, simply copy one of the examples given in this template and paste it to the appropriate location (do not forget to include an empty line at the end of your selection). Subsequent ER/ED numbering will adjust automatically. **Never number your ER/ED manually**.

Proceed as follow when referring to an ER/ED anywhere in the document (including in tables):

1. Select the **Reference** tab,
2. In the **Caption** section, select **Cross-Reference**;
   a. Reference type: **Numbered Item;**
   b. Insert references to: **Paragraph number**;
   c. Select the ER/ED in the **From which numbered item** box;
   d. Repeat if needed since only one item can be selected at a time.

Delete this text box prior to finalizing the document.

APPROVALS

This document is the <Experiment short name> Study ERD. It has to be approved by the Canadian Space Agency (CSA) Director of Astronauts, Life Sciences, and Space Medicine (ALSSM).

Prepared by:

Name & Title
Principal investigator

Date (YYYY/MM/DD)

Prepared by:

Name & Title
Payload Mission Scientist
CSA Space Exploration

Date (YYYY/MM/DD)

Prepared by:

Name & Title (if more than one; otherwise, delete)
Payload Mission Scientist
CSA Space Exploration

Date (YYYY/MM/DD)

Concurred by:

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CSA Space Exploration

Date (YYYY/MM/DD)

Concurred by:

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Payload Operations Engineer
CSA Space Exploration

Date (YYYY/MM/DD)

Approved by:

Perry JOHNSON-GREEN, Ph.D.
Senior Program Scientist, Health and Life Sciences
CSA Space Exploration

Date (YYYY/MM/DD)

REVISION HISTORY

REVISION NUMBER	DESCRIPTION	INITIALS	Date (Mmm dd, YYYY)
IR	Initial release	TBD	September 31, 20xx
1	<CSA-Experiment short name-RD-0XX> v.X		
	Add rows as needed		

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To update the table, put your cursor anywhere in the table, press **F9,** then select 'Update entire table and click 'OK'.

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Complete as needed. Delete section if no figure.

1 DOCUMENTATION

1.1 APPLICABLE DOCUMENTS

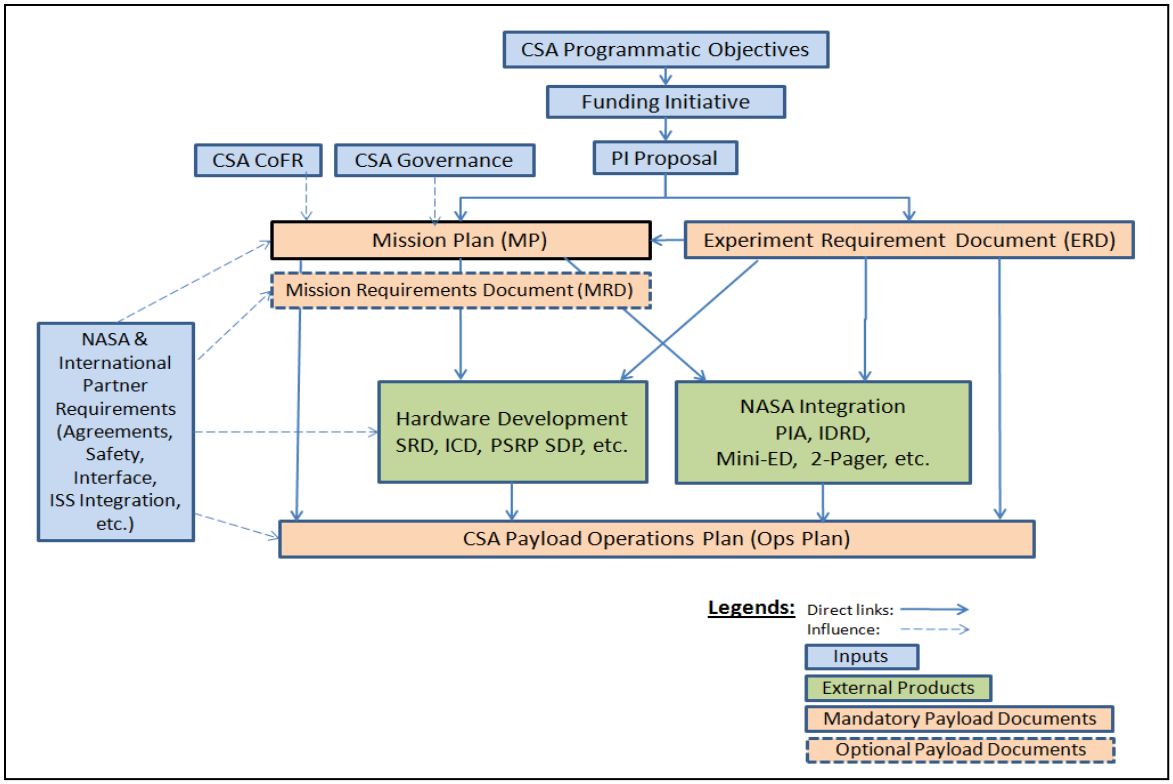
Applicable documents are closely linked to this ERD. Changes to the ERD may affect the content of these documents and any change in the applicable documents must be reflected in the ERD (see FIGURE 1). Applicable documents are listed in **TABLE 1** (exact issue, date and revision level).

This ERD is based on the proposal type proposal title here submitted to the CSA through the type Announcement of Opportunity name and year here.

TABLE 1: APPLICABLE DOCUMENTS

AD	DOCUMENT NUMBER	REVISION	DOCUMENT TITLE
AD1		Initial Release	Mini Experiment Document (Mini ED), if required.
AD2		Initial Release	Mission Requirements Document (MRD)/Mission Plan (MP), if required.
AD3		Initial Release	Payload Operations Plan
AD4			
AD5			
AD6	Add rows as needed		

FIGURE 1: **PAYLOAD DOCUMENT DEPENDENCIES**



1.2 REFERENCE DOCUMENTS

Reference document listed in **TABLE 2** provide additional information or guidelines that either may clarify the content or are pertinent to the history of this ERD.

TABLE 2: REFERENCE DOCUMENTS

RD	DOCUMENT NUMBER	REVISION	DOCUMENT TITLE
RD1			ILSRA-2014
RD2		Initial Release	ISS Payload CSA Mandatory Documentation.
RD3			Kick-Off meeting presentation
RD4			
RD5			
RD6	Add rows as needed		

1.3 CONFIGURATION CONTROL

The responsibility for assuring the maintenance, distribution, and repository functions for this document belongs to the Configuration Management Control of CSA.

1.3.1 Change Request Process

After the ERD has been baselined, all changes must be made using the formal Change Request (CR) process from the Configuration Management Control at the CSA, using their completed CR Form.

Provide a definition for all specific vocabulary used in this ERD.

1.4 DEFINITIONS

The following definitions shall be applicable to this document:

1.4.1 Requirements

Requirements are something needed and by definition mandatory. Requirements are essential items central to the study. They are critical to achieve the science objectives and cannot be cancelled.

1.4.2 Desirements

Desirements are negotiable items. While they represent high scientific value, they **are not required to achieve the science objectives.** Desirements must not delay implementation of the entire study. They will be considered only if crew time and/or hardware become available. Desirements include voluntary participation to identified activities.

1.5 ACRONYMS AND ABBREVIATIONS

List and sort all acronyms and abbreviations used in this ERD.

AD	Applicable Document
ALSSM	Astronaut, Life Science and Space Medicine
BDC	Baseline Data Collection
Bio-M	Bio-Monitor
CoFR	Certificate of Flight Readiness
CR	Change Request
CSA	Canadian Space Agency
d	Day
ED	Experiment Document
ER	Experiment Requirement
ERD	Experimental Requirements Document
GSRD	Ground Support Requirements Document
ICD	Interface Control Document
IDRD	Integrated Data Requirements Document
ILSRA	International Life Sciences Research Announcements
IRB	Institutional Review Board, known in Canada as Research Ethics Board
ISS	International Space Station
L	Launch (refers to the aunch date)
Mini ED	Mini Experimental Document

MP	Mission Plan
MRD	Mission Requirements Document
mth	Month (do not confuse with **m** for meter or **M** for mole or molar).
N/A	Not Applicable
NASA	National Aeronautics and Space Administration
Ops Plan	CSA Payload Operations Plan
PI	Principal Investigator
PIA	Payload Integration Agreement
PSRD	Payload Support Requirement Document
PSRP	Payload Safety Review Panel
PTOC	Payload Telescience Operations Centre
R+	Return days (number of days after landing)
SDP	Safety Data Package
SRD	System Requirement Document
SRR	System Readiness Review
URC	User Requirements Collection

The introduction provides an overview of the entire document. It includes the purpose and scope of this payload.

2 INTRODUCTION

The CSA Astronauts, Life Sciences and Space Medicine (ALSSM) division in collaboration with type PI organization(s) name(s) here plan to sponsor, develop, and implement the <Experiment short name> study on the International Space Station (ISS). CSA roles and responsibilities for the purpose of this experiment are described in the Kick Off meeting presentation. The investigators of type the affiliation of the PI here are responsible for the overall scientific research and analysis for this experiment.

2.1 PURPOSE AND SCOPE

This document is an ERD, produced by the Principal Investigator (PI) in collaboration with the CSA Exploration Scientist assigned as Mission Scientist for the purpose of the <Experiment short name> study. Its intent is to identify all the scientific requirements necessary to design and implement a successful experiment in space. Hence, all non-science requirements and any aspect of the experiment protocols, logistics and operations not directly impacting science have been omitted; they are covered in the Mission Plan (MP). Each requirement is accompanied by a scientific rationale. This document is intended for use by the experiments payload development and management team and constitutes guidelines from which a hardware and software implementation solution is derived to ensure mission success.

In this section, provide a brief overview of the scientific background (lay summary). Explain why this experiment has to be done in space. Explain what knowledge or results are anticipated from the experiment and how it will later benefit the scientific community or industry. Be careful not to provide superfluous information and do not get too deep in unnecessary theory (reference other specific documents on that matter if necessary). Remember that the aim of the ERD is to provide essential scientific requirements/desirements for the experiment. List the main investigator science team members directly involved in the experiment (use table A in annexes for details).

2.2 EXPERIMENT OVERVIEW

Type your overview here...

Additional information can be found in the following documents: Mini-ED (AD-01), MRD (AD-02), and Ops Plan (AD-03).

2.3 SCIENTIFIC OBJECTIVES

Clearly identify and describe the main scientific objectives (as presented in the peer-reviewed proposal) that are directly related to the experiment. Use numerical increment for all objectives. Add or remove items as needed.

Objective 1: Type objective 1 here.

Objective 2: Type objective 2 here.

Objective 3: Add/remove as needed.

Clearly identify and describe the hypotheses that are directly related to the experiment. Use numerical increments for all hypotheses. Add or remove items as needed.

Hypothesis 1: Type hypothesis 1 here.

Hypothesis 2: Type hypothesis 2 here.

Hypothesis 3: Add/remove as needed.

All requirements/desirements in the present document are identified in the text with inserted references as follows: **[ER-X]** for Experiment Requirement and **[ED-X]** for Experiment Desirement. **Use the Paragraph numbering function only**. **Do NOT use manual numbering.** Sections other than the ones presented in this template could be added if necessary.

3 EXPERIMENT REQUIREMENTS/DESIREMENTS

The following sections catalog all scientific requirements/desirements identified to fulfill the science mission of the experiment. In order to facilitate traceability, each requirement/desirement is clearly and uniquely identified in a specific sub-section or paragraph and presented in a logical order. Every requirement/desirement must be accompanied by a concise justification.

3.1 EXPERIMENTAL DETAILS

In the following sections, explain all requirements/desirements related to the proposed experiment.

Additional details are required for research **involving crewmembers as subjects**. The following are examples of requirements that could be of significant scientific importance:

- Number of subjects required for statistical significance.
- Special requirements related to the nature of the subject such as: gender, age, etc.
- Any restriction that the subject(s) should undergo such as: specific dietary regimens, fluid intake regulation, work/rest cycles, exercise, etc.

Indicate (under *Justification*) the impact on the scientific outcome if any of the applicable requirements cannot be met.

3.1.1 Number of subjects/samples/runs required for statistical significance

[ER-1] The minimum required number of subjects/samples/runs needed to meet our primary scientific objective(s) is number in letters (X).
Justification: *Provide the rational here.*

[ER-2] Add information here.
Justification: *Provide the rational here*

[ED-1] This is an example of a desirement automatic numbering. Refer to the definitions in section 1.4.
Justification: *Provide the rational here.*

3.1.2 Constraints for participation

List any constraints and their scientific rationale here. Example: "There are two (2) constraints for participation: Participants need to be non-smokers and have no metallic implants."

[ER-3] Add information here.
Justification: *Provide the rational here*

[ER-4] Add information here.
Justification: *Provide the rational here*

3.1.3 Sample/data collection

This section contains information about the type, number and sample manipulation (stowage temperature, centrifugation, type of container, etc.) and the type of data to be collected (heart rate, blood pressure, etc.). Example: "On Earth: hematocrit samples to measure the proportion of red blood cells."

[ER-5] Add information here.
Justification: *Provide the rational here*

[ER-6] Add information here.
Justification: *Provide the rational here*

3.1.4 Sample/data collection constraints

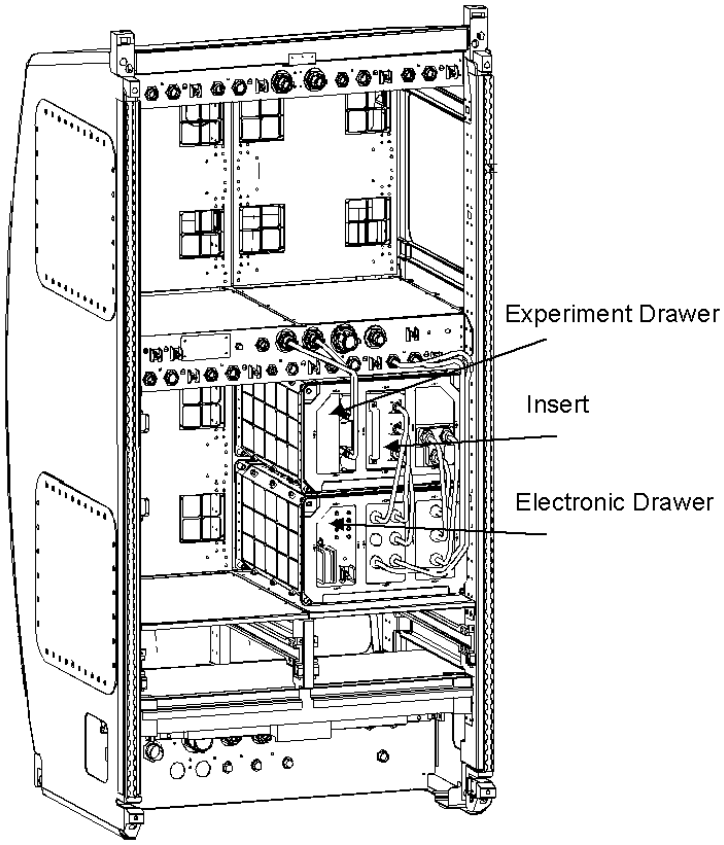
This section includes items such as: timing/sequence, physical activity restrictions, diet, medication/drug restrictions, sleep shift, etc. Example: "Blood collection must happen first in the morning after 6-8 hours fast. Water is OK."

[ER-7] Add information here.
Justification: *Provide the rational here*

[ER-8] Add information here.
Justification: *Provide the rational here*

Add images and graphs as needed (all labeled as FIGURE; use capital letters only, no “smallcaps”). Insert images with adequate resolution. Insert graphs as images instead of imbedded applications.

FIGURE 2: **EXAMPLE OF FIGURE**



3.2 PREFLIGHT REQUIREMENTS/DESIREMENTS

3.2.1 Preflight Session(s)

3.2.1.1 Number of sessions and description

List all scientific requirements necessary to achieve experimental goals that are associated with the preflight session(s). First, indicate the number of sessions, and then describe them. Refer to sample/data collection requirements already described by using their ER number. List and justify required procedures that have to be done such as: waiting time, observation, inspection, heating/cooling, drying, venting, mixing duration/method, etc. Justify any requirements for unattended measurements and explain how they should be done. Training and operation of equipment are described in other documents. Indicate the required timing of sessions (window) and their flexibility (e.g. L-95/-85). Do NOT use the ± notation (e.g. L-90±5 d).

[ER-9] There will be a total of two (X) preflight sessions. This is an example to show how to handle this situation.
Justification: *Provide the rational here*

[ER-10] Preflight BDC Session 1 at L-90.
Justification: *Provide the rational here*

The following is an example of cross-referencing to previously defined ERs:
[ER-22] All blood [ER-5], [ER-6], and [ER-10] will be collected once (1) at L-90/-60.

[ER-11] Preflight BDC Session 2 at L-60.
Justification: *Provide the rational here*

The following table summarizes Preflight activities also known as BDC sessions.

TABLE 3: PREFLIGHT SESSIONS

ACTION	BDC 1	BDC 2	BDC 3
[ER-6] – Blood sample collection	X		
		X	
Add/delete rows/columns as needed			

3.2.2 Training & Briefings

While training and briefing instructions are usually provided in other documents, there might be situations where the quality of the data, and therefore of the science, might be depend of specific training or briefing requirements. Provide such requirements here. Example: “Crewmember should be a certified network engineer.”

[ER-12] Add information here.
Justification: *Provide the rational here*

[ER-13] Add information here.
Justification: *Provide the rational here*

3.3 IN-FLIGHT REQUIREMENTS/DESIREMENTS

3.3.1 In-flight sessions

List all scientific requirements necessary to achieve experimental goals that are associated with the in-flight session(s). First, indicate the number of sessions then describe them. Refer to sample/data collection requirements already described by using their ER number. List and justify required procedures that have to be done such as: waiting time, observation, inspection, heating/cooling, drying, venting, mixing duration/method, etc. Justify any requirements for unattended measurements during flight and explain how they should be done. Training, operation of equipment and in-flight hardware are described in other documents. Indicate the required timing of sessions (window) and their flexibility (e.g. L+85/95).). Do NOT use the ± notation (e.g. L+90±5 d).

3.3.1.1 Number of sessions and description

[ER-14] There will be a total of four (4) in-flight sessions. This is an example to show how to handle this situation.
Justification: *Provide the rational here*

[ER-15] In-flight session 1 at L+4/6.
Justification: *Provide the rational here*

[ER-16] In-flight session 2 at L+8/12.
Justification: *Provide the rational here*

[ER-17] In-flight session 3 at L+80/90.
Justification: *Provide the rational here*

[ER-18] In-flight session 4 at R-10/-1.
Justification: *Provide the rational here*

The following table summarizes In-flight activities. This example contains embedded cross-references to ERs.

TABLE 4: IN-FLIGHT SESSIONS

EXPERIMENT CODE	Session 1 FD 4-6 [ER-15]	Session 2 FD 8-12 [ER-16]	Session 3 FD 80-90 [ER-17]	Session 4 R-10d-R-1d [ER-18]
[ER-3] Blood		X		
Add/delete row column as needed				

Hardware requirements are primarily derived directly from science requirements. For the ERD, though, it is important to define requirements specific to research facilities that are currently on the ISS. For example, if facility 'x' is appropriate for the study, indicate if facility 'x' should be used in 'y' mode, or at a setting that will allow 'z' resolution. Based on current understanding of ISS facilities and resources, list all hardware that could be used for your study. Also list any items that are currently known to be required to be transported to and from the ISS, and any items that could be trashed once used. For these materials, indicate any hazardous materials. Example: "Upmass: height (8) vacutainer canisters per subject."

3.3.2 Items required on ISS (Up Mass/Down Mass)

[ER-19] Add information here.
Justification: *Provide the rational here*

[ER-20] Add information here.
Justification: *Provide the rational here*

3.3.3 Data/Digitized Video Downlink & Uplink / storage

Describe and justify all requirements for data/digitalized video downlink/uplink/storage necessary for the scientific experiment. Specify if real-time data transmittal is required. If real-time data transmittal is required, describe the scientific impacts on the experiment if transmittal were to be interrupted or unavailable for some period of time during flight.

[ER-21] Add information here.
Justification: *Provide the rational here*

[ER-22] Add information here.

Justification: *Provide the rational here*

3.3.4 Ground Support

List all experimental procedures for which ground control is required (such as measurements done from ground control on ISS or synchronous control-sample processing. Explain and justify the implication of the ground control for each of these procedures (exclude normal operational support for astronauts).

[ER-23] Add information here.
Justification: *Provide the rational here*

[ER-24] Add information here.
Justification: *Provide the rational here*

3.4 POST FLIGHT REQUIREMENTS/DESIREMENTS

If any BDC is necessary during the post flight phase of the experiment, list what needs to be accomplished and provide justification for every requirement/desirement. List any other activities or post flight data deliverables required for scientific purposes after the in-flight phase of the experiment (history of various settings, gravitational acceleration monitoring data, etc.

3.4.1 Post Flight Session

3.4.1.1 Number of sessions and description

[ER-25] There will be a total of six (6) preflight sessions. This is an example to show how to handle this situation.
Justification: *Provide the rational here*

[ER-26] Post flight BDC Session 1 at R+0.
Justification: *Provide the rational here*

[ER-27] Post flight BDC Session 2 at R+3/7.
Justification: *Provide the rational here*

The following table summarizes Post Flight activities.

TABLE 5: POST FLIGHT SESSIONS

EXPERIMENT REQUIREMENT	R+ 0 d **[ER-420]**	R+ 3/7 d **[ER-430]**	R+12/15 d **[ER-440]**	R+30/37 d **[ER-490]**	R+6/7 mth **[ER-500]**	R+12/13 mth **[ER-460]**

[ER-410] Blood samples	**[ER-060]**	**[ER-060]**	**[ER-060]**			Add/delete column as needed
Add/delete row/columns as needed						

3.4.2 Early retrieval/late stow

List and justify any need to recuperate experiment samples, data, or equipment shortly after landing (immediate access or earlier than standard timeframe). Describe the impacts on science if early retrieval cannot be accomplished. Also provide any specific requirement related to stowage (provision in case of late launch or return).

[ER-28] Add information here.
Justification: *Provide the rational here*

[ER-29] Add information here.
Justification: *Provide the rational here*

3.5 OTHER REQUIREMENTS/DESIREMENTS

3.5.1 Data sharing

In order to reduce the experiment footprint, it might be necessary/practical to share data with other groups (other investigators, medical operations …). One such situation relates to blood analysis since blood volume is an important limiting factor. It is important to indicate in this section what kind of data sharing agreement you would be ready to support (**desirements**). Also, indicate if some data cannot be part of data sharing agreements (**requirements**). In all cases, provide the appropriate justification. Even if the information is formulated as "desirement", expressing your willingness to share data should not be considered as an obligation on your part to proceed into data sharing. The CSA will support the investigator in preparing the appropriate documents. Example: "Post flight core data blood results can be shared."

[ER-30] Add information here.
Justification: *Provide the rational here*

[ER-31] Add information here.
Justification: *Provide the rational here*

List all software required for measurement or any activity related to the scientific aspect of the experiment. Specify software provider if already determined (Agency or PI). Provide selection rational for commercial software.

3.5.2 Software

[ER-32] Add information here.
Justification: *Provide the rational here*

[ER-33] Add information here.
Justification: *Provide the rational here*

3.5.3 Imagery (photo/video)

Indicate which, if any, imagery requirements are necessary preflight, in-flight and post flight. List all multimedia equipment required. Provide justification. Example: "Historical photo of experimental setup. Photo can be taken at any time during the session."

[ER-34] Add information here.
Justification: *Provide the rational here*

[ER-35] Add information here.
Justification: *Provide the rational here*

3.5.4 Shipping (between PI laboratory and launch/landing site)

Describe any special attention required for a specific item during shipping (may include conditioned stowage, special packaging, express delivery or constant surveillance and care). Do not include information about the carrier (such as UPS…). Include special science requirements for pre/post BDC shipping. Example: "Frozen stool samples must be shipped to PI within 2 days of sampling."

[ER-36] Add information here.
Justification: *Provide the rational here*

[ER-37] Add information here.
Justification: *Provide the rational here*

Describe any other scientific requirements than cannot be listed in the previous sections.

3.5.5 Other scientific requirements

[ER-38] Add information here.
Justification: *Provide the rational here*

[ER-39] Add information here.

Justification: *Provide the rational here*

3.6 SUCCESS CRITERIA

In this section, describe and briefly justify all scientific key criteria that must be respected to conduct a successful experiment (preflight, in-flight & post flight). Provide a success grading system characterizing different level of accomplishments for each criterion.

- Add subsections as needed:
  - Experiment success criteria
  - Subject success criteria
  - Data success criteria
  - Sample success criteria
- Success criteria in this document should only be related to factors essential for getting valid scientific data and be quantifiable as much as possible. It should be stated that they are only guidelines, may change during the course of the activity, and will be reflected in later version of this document.
- For data collection, it might be preferable to clearly indicate the minimal quality and quantity of information required to consider the data usable and therefore avoid any loss of science or subject.

TABLE 6: SUCCESS LEVELS RELATED TO EACH CRITERION

CRITERION/JUSTIFICATION	EXCELLENT	GOOD	POOR	LOSS OF SCIENCE
Nine (9) subjects are necessary to achieve statistical significance for Objective 1	Ten (10) subjects	Nine (9) subjects	Eight (8) subjects	Less than eight (8) subjects
Twenty four (24) hours of usable recording are required for science	24 hours	More than 18	More than 12	12 or less
Add/delete rows as needed				
PREFLIGHT				
Blood samples: L-90/-60	The BDC is scheduled between L-90/-60	Within 30 days of window	N/A	No attendance
Add/delete rows as needed				
IN-FLIGHT				
Data quality				
Add/delete rows as needed				

POST FLIGHT				
Add/delete rows as needed				

4 ANNEXES

TABLE A: INVESTIGATOR SCIENCE TEAM MEMBERS' CONTACT INFORMATION

Provide the required information for each of the following member of the research team: Principal investigators, co-investigators, and study coordinator. This information will be used when communicating with them.

INVESTIGATION TITLE	The <Experiment short name> study				
FUNCTION	**NAME**	**ADDRESS**	**E-MAIL**	**FAX**	**TELEPHONE**
PRINCIPAL INVESTIGATOR	Joe Blow	1234 On this street Ottawa, ON Z6Z R5R	JoeBlow@here.ca	514-555-1234	514-555-3456 Ext: 1234
CO-INVESTIGATOR					
Add/remove as needed					
STUDY COORDINATOR					
NAME AND ADDRESS OF ORGANIZATION CONDUCTING THE RESEARCH					
Add relevant information					
SPONSORING AGENCY					
Canadian Space Agency					

TABLE B: EVOLUTION OF MEASUREMENTS FROM PROPOSAL TO ERD

List all the parameters that will be measured or evaluated and indicate all changes made to the measurements initially planned in the peer-reviewed proposal.

FROM 2009 ILSRA PROPOSAL	PROPOSED <EXPERIMENT SHORT NAME> EXPERIMENT, 2014
Blood draw	No change
Add/remove rows as needed	

Add relevant text here if needed.

TABLE C: SUMMARY OF EXPERIMENT PRIORITIES

For each measurement session, indicate the priority level as defined in Section 1.4 Definitions.

SESSION	PREFLIGHT	IN-FLIGHT	POST FLIGHT	NOTES
MRI	Requirement		Requirement	Cannot be done in-flight
Blood samples (Hematology chemistry and leucocyte)	Requirement	Requirement (Desirement mid-flight)	Requirement	One in-flight blood sample is a desirement.
Stool samples	Desirement		Desirement	Voluntary participation
Add/delete rows as needed				

Add relevant text here.

APPENDIX C: ICB TEMPLATE

Title Principal Investigator	Human Research Program Informed Consent Briefing Date

Science Background

1

Title Principal Investigator	Human Research Program Informed Consent Briefing Date

Objectives

2

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Experiment Design Overview

Preflight	Inflight	Postflight

3

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Test/Session Descriptions

4

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Test/Session Descriptions

5

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Risks & Discomforts

Test	Risks/Discomforts	Mitigation

6

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Test	Risks/Discomforts	Mitigation

7

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Test Constraints

Test	Constraints

8

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Experiment Training Schedule

Session Title	Session Type	Timeframe	Duration	Location	Required for Operators	Required for Subjects

9

Title	Human Research Program Informed Consent Briefing
Principal Investigator	Date

Summary

Preflight	Inflight	Postflight
Total Time:	Total Time:	Total Time:

[This should list each test performed preflight, inflight, and postflight, along with the approximate time frame (e.g. L-60 +/- 10 days; or between L-30 and L-60).]

10

Title Principal Investigator	Human Research Program Informed Consent Briefing Date

Take Home Message

PAO	*(Instructions: summarize the research in 1-2 sentences that the astronaut can use for public affairs)*
Earth Application	*(Instructions: Summarize in 1-2 sentence, what the outcome of the study is expected to be useful for on the ground)*

11

APPENDIX D: IRB PROTOCOL TEMPLATE

Date: _____

1.1 Study Identification Information

a) Study Name:

b) Brief Synopsis / Abstract:

c) Is this a Ground-Based or Space Flight study?

_____Ground-Based Study
_____Space Flight Study

d) What type of data does the research study require?

_____Prospective: Collecting new data
_____Retrospective: Use of archived data
_____Both: Combination of new and archived data

If **"Retrospective"** is selected above, PI must submit a data request through the NASA's LSDA/LSAH Data Request Portal at the following link (https://lsda.jsc.nasa.gov/) to obtain the LSAH-AB feasibility letter that MUST accompany your eIRB protocol submittal.

If **"Both"** is selected above, please ensure both the prospective and retrospective components are clearly covered in the Informed Consent Form.

Investigators requesting NASA subject(s) archived data, agree that ALL publications resulting from this project will be submitted to LSAH for privacy review before submission for publication, including presentations, abstracts, and manuscripts.

e) Name of Principal Investigator

1.2 External Review and Approval

Has the protocol been reviewed by another institution? ____Yes ____No

If “yes”, what was the disposition or determination of the external review? Please list the institution, board and contact information where this protocol was or will be reviewed.

1.3 Conflict of Interest

Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project?
____Yes ____No

Conflict of Interest statements must be submitted upon initial submission and updated as necessary upon continuing review. Please attach COI statements to the study team members section of the eIRB smartform.

If “yes”, Conflicts of interest statements must be submitted by all key personnel on dated, signed, institutional letterhead with the study title identified. The letter must answer affirmatively and disclose the relationship with the company or entity arrangements. A related financial interest does NOT automatically mean that the investigator cannot participate in the research. The IRB will determine if the financial and or other conflict of interest can be reduced, eliminated or managed in order to allow participation in the research project.

If “no”, Conflicts of interest statements must be submitted by all key personnel on dated, signed, institutional letterhead with the study title identified. The letter must include the following statement:

> “I do not receive any research support from non-public sponsors of research. I do not perform any validation research of a drug or device. I do not receive any gifts or income from individuals associated with my research studies. I do not use my position with_____(fill in the blank with name of employer, i.e. NASA, KBRWyle etc) or proprietary or confidential information obtained in performing my duties, in any marketing, investing, or commercial ventures.

1.4 Study Funding Information

Has funding been awarded for this study? Yes ____ No ____

If “yes”, please list all sources of funding:

Please list the funded study title if different from the Study Name listed in this protocol submission:

1.5 Scientific Merit Assessment

Evidence of scientific review of research involving human subjects is required to be included in the application for approval by the IRB. The purpose of this requirement is to assess Risk versus Benefit ratio for the research protocol and to understand the balance between any risks that may be imposed upon subjects and benefits from the investigation. This requirement also enables the IRB to confirm investigational rigor and adequacy of the methods proposed to accomplish research objectives

Has this study received a scientific merit assessment? Yes_____ No ____

If "yes", what organization, review body and or individual conducted the review? *Please include an attachment of peer review comments to the Local Site Documents section of the eIRB smartform.*

If "no", has there been a technical assessment?

Has this study been modified since the last merit review?

If so please describe all modifications to the study:

1.6 Human Genetic Testing

Does the NASA Policy Directive 7170, Use of Human Research Genetic Testing, apply to this study? Yes____ No ____

Definition: Human Genetic Testing is an analysis of human Deoxyribonucleic acid (DNA), Ribonucleic acid (RNA), chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal and biochemical changes. These tests can include the following:

a. Molecular genetic tests that study single genes or short lengths of DNA or RNA to identify variations or mutations.

b. Chromosomal genetic tests that analyze the entire genome or whole chromosomes or long lengths of DNA or RNA.

c. Biochemical genetic tests that study the amount or activity of proteins or metabolites and wherein any noted changes can indicate changes in (or characteristics of) DNA or RNA.

d. Microbiome testing from human subjects (gut, skin, etc.).

(NPD 7170, Attachment A: Definitions)

If “yes”, please mark the study as greater than minimal risk in the protocol document (Section 2.1.a)) and answer the following questions.

Human Genetic Testing Procedures

a) What is the purpose of the human research genetic testing?

b) Will the human research genetic data be extracted from biospecimens?
Yes___ No ___

c) Please describe the process for human research genetic data extraction from the subject and then from the subsequent sample.

d) Please provide a plan to protect human research genetic test data. The following are required to be included or addressed in the plan:

i) Please state that attributable or identifiable human research genetic data will not be publicly released without the prior approval of the individual research subject and other subjects whose anonymity might be affected by the release, as well as the NASA IRB or the Lifetime Surveillance of Astronaut Health Advisory Board.
ii) Outline the procedures to protect the privacy of genetic information. (Including after death of the subject, to avoid unwarranted invasion of personal privacy of surviving family members.)
iii) Please state that no whole genomic sequence data will be published or made public without written consent from the subject or their direct family members who may be impacted by the release of the data.
iv) Please state that all human research genetic testing data will be considered protected data for the purposes of safeguards.
v) Please state that results from human research genetic testing will not be data-mined or cross-referenced with other databases of any kind unless approved by the NASA IRB.
vi) Please state that investigators will not attempt to identify or contact individual participants from whom data was collected without approval from the NASA IRB.
vii) Because it may be possible to reidentify deidentified genomic data, please describe how this research data will be controlled.
viii) Any human research genetic data will be stored in a database separately from data containing personally identifiable information (e.g., sex, age, name, address, phone number, social security number), unless it has been included in the research subject’s Electronic Medical Record (EMR).

e) Please describe the plan to provide genetic counseling. In the plan, please name the genetic counselor(s).

Investigators using human research genetic information will be required to provide genetic counseling by a qualified genetic counselor to research subjects, both before and after obtaining genetic information. The genetic counselor, who is not the PI or Co-investigator, shall discuss the potential importance of genetic testing information for the individual and their biological family. This counseling will also indicate which findings were generated in a non-CLIA laboratory and the analytical validity, clinical validity, clinical utility, and the ethical, legal and social implications of genetic testing results to the subject.

f) Please provide the plan to adhere to IT security and privacy policy practices.

g) Please describe the reporting plan for any inadvertent data release, breach of data security, or other data management incidents.

h) Please provide a plan describing the process to archive at NASA (or elsewhere), return original study data, and destroy all copies of the original study data after the study is complete.

2.0 Background and Significance

a) Background and Significance: *Briefly sketch the scientific background leading to the present protocol.*

b) Preliminary Studies: *Preliminary data often aid reviewers in assessing how valuable the project is likely to be. If graphs or tables are used to convey information, please maintain a consistent style.*

2.1 Level of Risk and Medical Monitor

a) What is this study's level of risk?

_____Minimal
_____Greater Than Minimal

If different parts of the study have different levels of risk, please briefly outline the risks associated with each part in this protocol and consent form. Please note that the use of human research genetic testing is considered greater than minimal risk.

b) What is this study's Medical Monitor level?

____ Level 1
____ Level 2
____ Level 3
____ Level 4
____ Not Required

If not required, please explain.

2.2 Study Summary

a) Expected Start Date:

b) Expected End Date:

c) Type of Subjects (please mark all that apply):

_____Astronaut (US)
_____Astronaut (CSA)
_____Astronaut (ESA)
_____Astronaut (JAXA)
_____ Cosmonaut
_____Non-Astronaut

2.3 Study Location(s): Identify the NASA location(s) where research procedures, including data collection and storage, will be performed.

2.4 Other Sites/Institution(s): Please list any non-NASA sites or institutions where research procedures, including data collection and storage, will be performed.

3.0 Specific Aims and Hypothesis

a) Specific Aims:

b) Hypothesis(es): List hypothesis(es) and an associated primary outcome measure(s) for each specific aim. If the study is not designated to test a hypothesis, describe the goals of the project as related to this specific aim. (ex: "determine hardware/logistic feasibility," "estimate mean and standard deviation of intervention effects," "evaluate degree of association between X and Y")

c) Primary Outcome Measure: (Dependent Variables)

d) Statistical Analysis: Briefly describe what statistical analysis(es) will be applied in order to address the hypothesis/primary outcome.

Note: If the above hypothesis/primary outcome is quantitative, briefly describe how qualitative data will be analyzed.

3.1 Study Design Characteristics

Sample Size:

Indicate how many subjects will be studied and why this number was chosen. Please account for anticipated screen failures and withdrawals for the proposed number.

Power/Sample size calculations should be included for hypothesis-testing studies (may require assistance by a statistician). If power/sample size calculations are not applicable, then indicate as "Not Applicable" below and provide an explanation.

Alternatively, if the purpose of the experiment is to estimate a characteristic of the response measure(s) (e.g. mean, SD of change, etc) then provide evidence that the proposed sample size will enable estimation within a reasonable degree of error.

Novel studies (first-time-ever) and descriptive/feasibility studies benefit from an understanding of the relationship between sample size and precision (may require assistance by a statistician).

4.0 Study Procedures, Tests, Evaluation

a) Study Procedures, Tests, and Evaluations: Please list, in sequence, all study procedures, tests, and evaluations required for the study. *Please attach a copy of all interviews, questionnaires, and surveys to the Local Site Documents section of the eRIB smartform.*

b) Will subjects or their health care provider be given the results of any experimental tests that are performed for the study? Yes____ No ____

If “yes”, please describe the tests, provide a rationale for providing subjects with the experimental test results and explain what, how and by whom subjects and their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.

c) Will subjects undergo any study procedures or tests off-site? Yes ____ No____

d) Time commitment: Indicate how much time will be required of the subjects, both per visit and in total, for the study. Do not include time spent passively, such as periods when a monitoring device is worn, but no special activity is required.

e) Facilities: Please provide a description of the facilities used in this research.

f) Adequacy of Resources: Principal investigators must have the necessary resources required to conduct the proposed research in a way that assumes the rights and welfare of participants are adequately protected. Describe the resources you have in place to conduct this study. Examples may include personnel, funding, and equipment required to perform the study.

g) Please provide/describe the test termination or withdrawal criteria guidelines and associated rationale.

4.1 Equipment Used During Research

In the following section you will provide information on the electrical and mechanical hardware that you will be using during your research. This information is required for approval of your protocol by the IRB.

Unmodified, commercially available devices that are being used in accordance with their intended use and that are already FDA certified or CE marked as being MDD 93/42/EEC compliant do not require additional assessment. An exception to this is any device whose primary function is to radiate or store electrical, thermal, or mechanical energy during their operation. In this case, a safety assessment will be performed to determine the “suitability of intended use” and you could be contacted with a request for specific data.

Any device that is modified from the commercially available version, that will not be used in accordance with the manufacturers recommendations, or that has been designed and built for research purposes will require an additional assessment.

Computers and other equipment used to collect and process your data do not need to be listed however software used to control potentially hazardous test operations should be identified and is subject to review.

Any device that will be in electrical contact with the research subject must show compliance with ANSI/AAMI ES1-1993, *Safe Current Limits for Electromedical Apparatus*.

a) Having read the above statements, will any equipment be used during research (i.e., for retrospective studies answer "No")? Yes ____ No____

If "no", then continue to the next numbered section. If "yes", then answering (b) and (d) are required.

b) Are all of the devices that you are using in this research:

1. **Unmodified and commercially available**
2. **Used in accordance with manufacturers recommendations**
3. **FDA certified or CE marked as being MDD 93/42/EEC**
   Has been previously reviewed by the NASA JSC Test Safety Office

   Yes ____No____

   If "yes"**,** skip to (d). If "no", provide the common name for each device and include the manufacturer and the model number of your specific device(s).

c) For each of the devices listed in 4.1 (b) attach the following additional information so that a safety assessment may be performed. Please attach supporting documentation to the Local Site Documents section.

1. A description of any hardware modifications that have been made to commercially available equipment. Explain how these modifications have not modified the safety of the hardware. Attach design data as required to support these statements.
2. A description of how operations that are not in accordance with the manufacturers recommendations will not affect the research subject safety.
3. Hardware that is not commercially available or that has been built only to support research requires additional information.

For electronic equipment include a:

- block diagram
- detailed schematic
- description of circuit operations
- description and test data for software that controls critical functions For mechanical devices include:

- detailed design data
- structural or loads analysis showing factors of safety

d) Is the primary function of any of the devices used in your protocol to radiate or store electrical, thermal, or mechanical energy that could come into contact with the research subject during their operation? Include devices even if they are FDA certified or MDD 93/42/EEC complaint and CE marked. Do not include radiographic imaging or ultrasound hardware.

Yes____ No____

If "yes", provide the common name for each device and include the manufacturer and the model number of your specific device(s). You will be contacted with a request for specific data if required.

5.0 Remuneration Payment to Participants

Will any subjects receive remuneration for study participation? Yes____ No____

If "yes", please describe the remunerations subjects will receive and in what form.

5.1 Costs Related to Participation

a) Select all categories indicating costs which participants or their insurance companies will be responsible for:

____Participants will have no costs associated with this study
____Study Related procedures
____Study Drugs or Devices
____Other

b) If study participants or insurance companies will assume any costs for this study, describe the procedures, drugs, or devices for which the participants or their insurance companies must assume costs:

5.2 Study Population

a) General description of the study population:

b) Target number of non-astronaut participants:

c) Target number of astronaut participants:

d) Does this investigation have an open ended study population? Yes_____ No_____
If "yes", please describe the rationale for an open ended population.

e) Please list the inclusion and exclusion criteria for enrollment of normal, healthy volunteers (Non-Astronauts) and, if applicable, astronauts :

f) If pregnant women are excluded from participation please provide a justification:

g) If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification. Additionally, if women of child-bearing potential are to be excluded please provide a scientific or medical justification for their exclusion:

5.3 Risk Assessment

a) Please describe the risks associated with this study :

(Women of child-bearing potential or pregnant women: If your study includes pregnant subjects and/or women of child-bearing potential please include the risks to pregnant females and fetuses. If there are currently no known risks please add the following statement "Currently there are no known risks to a pregnant female and a fetus for this protocol. However, unknown adverse fetal events may occur, even in the absence of maternal symptoms.")

b) Please describe how you are going to minimize the risks:

c) Has a hazard analysis been done? Yes_____ No_____

If "yes", please attach the documentation of the analysis.

5.4 Potential Benefits and Alternatives

a) Are there potential direct benefits to study subjects? Yes_____ No_____

If "yes", please describe any potential for direct benefits to participants in this study

b) Please describe any potential benefits to Society or Space Flight:

c) Please describe any alternatives to study participation available to prospective subjects:

6.0 Privacy & Data Confidentiality

Subject privacy and data confidentiality must be maintained in accordance with 1) NASA Policy Directive (NPD) 7100.8, "Protection of Human Research Subjects"; 2) NASA Procedural Requirements (NPR) 7100.1A, "Protection of Human Research Subjects"; and 3) to the extent allowed by Federal law.

Terms:

Privacy concerns people, whereas confidentiality concerns data. Specifically, confidentiality refers to the researcher's plan to handle, manage and disseminate the participant's identifiable private information. Privacy refers to a person's wish to control the access of others to themselves.

Anonymous data: Unidentified (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); information or materials (e.g., data or biospecimens) that cannot be linked directly or indirectly by anyone to their source(s).

Coded: Direct personal identifiers have been removed (e.g., from data or biospecimens) and replaced with words, letters or numbers; but the original identifiers are retained and can be traced back to the source by someone with the code or key.

De-identified: All direct personal identifiers are permanently removed, no code or key exists to link the information or materials to their original source, and the remaining information cannot reasonably be used by anyone to identify the source.

a) Please select all data types that will be collected: (check all that apply)

_____Name
_____Age
_____Gender
_____Race
_____Full Face Photographic Image
_____ Full or partial Social Security Number
_____Telephone number
_____Email Address
_____Mission
_____Relative Day
_____Space Flight Duration
_____Crew Position
_____Other, please specify:

b) How will the data and/or biospecimens for this study be collected, recorded, and by whom?

c) Select how data and/or biospecimens will be identified:

_____No identifiers will be obtained by the investigators.

_____Identifiers are obtained. However, data is coded and an investigator has the code key. The code key is submitted to NASA and locally destroyed at the end of this study.

d) Select how data and/or biospecimens will be stored (select all that apply):

_____Data are kept in locked file cabinet
_____Data are kept in locked office or suite
_____Electronic data is encrypted and protected with a password
_____Data are stored on a secure network
_____Biological samples are kept in a locked freezer
_____Other , please specify:

e) Please describe the encryption method employed to protect the data.

f) Please describe the authentication methods use to ensure the security of the database.

g) Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.

h) How will the investigator maintain data privacy in the test setting(s)?

i) What are the consequences to participants of a loss of privacy (e.g., risks to reputation, insurability, and other social risks)?

j) If coded or identified data will be released, specify the persons/agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will be maintained confidential:

k) When the study is completed and the data is submitted and accepted by NASA, please indicate your plans for the destruction of the local dataset.

l) Is this study collecting or using health information? Yes ____No____

m) Describe any additional steps taken to assure that identities of subjects and any of their health information, which is protected under the law, is kept confidential. If photography, video or audio recordings will be made as part of the study, disposition of these recordings should be addressed here and in the consent form.

n) Please describe how data and biospecimens will be handled if a participant withdraws their consent.

7.0 Process of Consent

a) **Describe when, where, and how potential participants will be recruited.**

b) **Describe how, when, and where the consent process and documentation will be completed.**

c) **Who will obtain informed consent from participants for this protocol?**

d) **Describe the consent withdrawal procedures**

7.1 Drugs, Devices, Biologics, foods and dietary supplements

If no drugs, devices, biologics, foods or dietary supplements are being used please skip this section

a) **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
Yes____ No____

If "yes", please list name(s) here and complete the drug section of the eIRB smartform.

b) **Does the study evaluate the safety or effectiveness of a device?** Yes _____No____

If "yes", please list name(s) and complete the device section of the eIRB smartform.

7.2 Data and Safety Monitoring Plan

If a Data and Safety Monitoring Plan is not required, please skip this section

a) **Please provide a plan for data and safety monitoring for this study.**

b) **Describe the clinical criteria for withdrawing an individual subject from the study due to safety or toxicity concerns.**

c) **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

8.0 References