**Mini Experiment Document**

for

*Experiment Title*

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| Op Nom Name: *Name**Date* **National Aeronautics and Space Administration** Lyndon B. Johnson Space Center Houston, Texas  |

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| **DOCUMENT APPROVAL SHEET****International Partner (IP)****Signature Page** |
| **DATE** |
| *Date* |
| Mini EDfor *Full Experiment Title**(Op Nom)*   APPROVED:  Name DATE Principal Investigator APPROVED:  Name DATE Project ScientistAPPROVED:  Name DATE BDC Representative |
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| **DOCUMENT APPROVAL SHEET****NASA Signature Page** |
| **DATE** |
| *Date* |
| Mini EDfor *Full Experiment Title* *(Op Nom)*  APPROVED:  Name DATE Lead Increment Science Coordinator APPROVED:  Name DATE NASA ISSMP RepresentativeNATIONAL AERONAUTICS AND SPACE ADMINISTRATIONLyndon B. Johnson Space CenterHouston, Texas |
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| DOCUMENT CHANGE/ | PAGE 1 OF 1  |
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| Altered pages must be typed and distributed for insertion. |

Mini ED for *Op Nom Name*

PURPOSE

This document was developed to collect and properly document the baseline data collection (BDC) and data sharing requirements for experiments not managed by the Johnson Space Center International Space Station Medical Project (JSC/ISSMP), but that utilize United States Operating Segment (USOS) crewmember subjects. The document will aid the JSC ISSMP Increment Science Coordinator (ISC) in understanding the experiment’s requirements and the information will flow into the BDC Plan, Informed Consent Briefing (ICB) overview, and Data Sharing Plan (DSP).

Instructions on how to fill out each field in the following tables are provided in Appendix A to assist the Principal Investigator (PI) in filling out the tables for his/her experiment.

It is important that the requirements documented in these tables match the research protocol approved by the applicable institutional review boards (IRB). Once the ICB has been conducted, protocol changes will require a delta-ICB and crew consent form re-signature.

Note: PIs should assume that BDC rooms will be completely empty for each BDC session. The size of the room and all hardware needed (e.g., sinks, refrigerators, gloves, etc.) should be documented in the Hardware or Facility Requirements section of the Preflight/Postflight BDC tables. ISSMP will indicate its ability to furnish hardware or facility requirements that are requested from ISSMP resources. A response of “wilco” indicates that ISSMP can and will provide the requested resource. A “nowilco” indicates ISSMP cannot or will not accommodate the request, which will become the responsibility of the experiment’s sponsor.

CONFIGURATION MANAGEMENT OF MINI ED

After initial signature, changes to this document will be controlled by the Lead Increment Science Coordinator in coordination with the International Partner (IP) BDC Coordinator and/or Payload Integration Manager/Research Program Office (PIM/RPO) representative (hereinafter referred to as BDC Representative) and PI. Changes affecting OZ resource requirements must first be approved in programmatic documents via Change Evaluation Form (CEF) before being changed in the Mini ED and implemented. BDC and data sharing will be implemented/managed through the increment specific plans.

ROLES, RESPONSIBILITIES, AND EXPECTATIONS

Applicable to human life sciences research projects requiring BDC (e.g., ESA/JAXA/CSA and some NASA sponsored payloads) that are not managed by JSC/ISSMP. All projects managed directly by ISSMP will complete nominal documentation as required.

|  | BDC Rep. | PI | ISC | Comments |
| --- | --- | --- | --- | --- |
| RPWG Inputs for inclusion on Increment complement (manifest inputs, crew time inputs, BDC time inputs, etc.) | X | X |  |  |
| IDRD Annex 5 Review | X | X | X[[1]](#footnote-1)  |  |
| Mini-ED inputs | X | X |  |  |
| CPHS submittal and renewal | X | X |  | BDC Representative should provide status to ISC regarding approval status  |
| HRMRB submittal and renewal | X | X |  | BDC Representative should provide status to ISC regarding approval status |
| Applicable IP IRB submittal and renewal | X | X |  | BDC Representative should provide status to ISC regarding approval status |
| ICB scheduling |  |  | X |  |
| ICB briefing presentation development for individual project | X | X |  |  |
| ICB notebook development – to include presentation for each experiment as well as BDC schedule |  |  | X |  |
| TRR Package development | X | X |  | ISC will provide example documentation if requested. |
| Scheduling of TRR  |  |  | X |  |
| Conduct of TRR and Action closure | X | X |  |  |
| BDC Schedule review/input | X | X |  |  |
| BDC Plan development |  |  | X |  |
| BDC Plan inputs/review | X | X |  |  |
| Data Sharing Plan development |  |  | X |  |
| Data Sharing Plan input/review | X | X |  |  |
| IP BDC Session Scheduling (JSC and GCTC) |  |  | X |  |
| IP BDC Session Scheduling at IP Location | X |  |  | BDC Representative should inform ISC of session date, time, and as-run duration |
| BDC Session coordination  | X |  | X |  |
| Inputs for as-run BDC times | X | X |  |  |
| Tracking of as-run BDC times | X |  | X |  |
| Data distribution to PI – only applicable to data requested via data sharing from NASA Space Medicine division or other investigations |  |  | X |  |
| Badging @ JSC/KSC/Dryden | X |  |  |  |

Communication: In order to maintain consistency across increments, allow for accurate documentation of PI requirements, and to ensure that the BDC Representative is aware of all activities, the following flow will be standard practice for all increments. Any and all inputs/documents that are required by the ISC will nominally flow from the PI to the BDC Representative to the ISC. The BDC Representative is expected to function as a liaison between the PI and ISC. However, if direct communication between the ISC and PI is necessary or does occur, such communication should always include the BDC Representative to ensure that all parties have the same information. If issues with potential science impacts are discussed, it will be the responsibility of the BDC Representative to inform and include the IP Project Scientist in the discussions.

Responsibilities of the BDC Representative /PI: It is the responsibility of the BDC Representative and PI to ensure that all required documentation and inputs necessary for inclusion on an increment research complement are completed as required to support BDC/ICB/Data Sharing milestones or deliverables.

For example, in order for a crew to be briefed on a research protocol, Committee for the Protection of Human Subjects (CPHS), Human Research Multilateral Review Board (HRMRB), and applicable IP IRB approvals must be obtained and those approvals must be up to date at the time of the crew briefing. If approvals are not current, the experiment will not be included in the briefing, and either a delay in the briefing or a delta briefing will need to be requested.

Responsibilities of the ISC: It is the responsibility of the ISC to schedule and coordinate all activities that relate to BDC and Data Sharing. Outside of BDC (includes performance of ICB) and data sharing, all other activities, inputs, and requirements levied upon the project for inclusion on a particular increment are the responsibility of the PI and the BDC Representative. To aid the BDC Representative and PI in meeting deadlines for the planned schedule of activities, the ISC will provide them with a schedule of targeted dates for activities such as CPHS, HRMRB, ICB, BDC, data sharing, etc. However, it should be noted that if any milestones or deadlines for activities in relation to BDC, ICB, and data sharing are missed by the BDC Representative /PI, the ISC will only reschedule activities or delay the release of documents if it can be easily accommodated. For example, if the BDC Representative /PI does not submit the documents required for performance of an ICB by the due date, the ISC will only schedule a delta briefing if the crew schedule can accommodate it, and if it does not require a significant amount of rework/coordination by the ISC.

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ACRONYMS AND ABBREVIATIONS

0g Zero Gravity

1-g 1 Gravity

ASI Agenzia Spaziale Italiana (Italian Space Angency)

BDC Baseline Data Collection

BDCF Baseline Data Collection Facility

CEF Change Evaluation Form

Co-I Co-Investigator

CPHS Committee for the Protection of Human Subjects

CSA Canadian Space Agency

DFRC Dryden Flight Research Center

DSP Data Sharing Plan

ECG Electrocardiogram

ED Experiment Document

ESA European Space Agency

FD1 Flight Day 1

GCTC Gagarin Cosmonaut Training Center

GSP Ground Support Personnel

HRMRB Human Research Multilateral Review Board

ICB Informed Consent Briefing

ID Identification

IDRD Integrated Data Requirements Document

IP International Partner

IRB Institutional Review Board

ISC Increment Science Coordinator

JAXA Japan Aerospace Exploration Agency

JSC Johnson Space Center

KSC Kennedy Space Center

L- Launch minus

Min Minutes

N/A Not Applicable

Nowilco ISSMP cannot accommodate request

Ops Operations

USOS United States Operating Segment

PI Principal Investigator

PIM Payload Integration Manager

R+ Return Plus

RPWG Research and Planning Working Group

U.S. United States

Wilco ISSMP will provide requested resource

| TABLE 1 EXPERIMENT OVERVIEW |
| --- |
| **Investigation Title** |  |
| **Ops Name** |  | **Subjects Required** |  |
|  | **Name** | **Address** | **E-mail** | **Fax** | **Telephone** |
| **Principal Investigator** |  |  |  |  |  |
| **Co-Investigator** |  |  |  |  |  |
| **Co-Investigator** |  |  |  |  |  |
| **Co-Investigator** |  |  |  |  |  |
| **Name and Address of Organization Conducting the Research** |
|  |
| **Sponsoring Agency** |
|  |

*Destination of table information: BDC plan, DSP, IRB package and ICB presentations*

| TABLE 2 Experiment summary |
| --- |
| **Experiment Type** | **[ ]  Preflight, In-flight, & Postflight****[ ]  Pre/Post Only****[ ]  In-flight Only** |
| **Experiment Description** |
|  |
| **Objectives** |
|  |
| **Relevance to Space and/or Earth-based Research** |
|  |
| **Baseline Data Collection Summary** |
|  |
| **In-flight Operations Summary** |
|  |

*Destination of table information: One page summary used in DSP.*

| TABLE 3 OPERATIONAL OVERVIEW |
| --- |
| **Preflight** | **Session Time****(1 g minutes)** | **In-flight** | **Crew Time****(0 g minutes)** | **Postflight** | **Session Time****(1 g minutes)** |
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| **Total Crew Time (minutes)** |  | **Total Crew Time (minutes)** |  | **Total Crew Time (minutes)** |  |

*Destination of table information: IRB package and ICB overview presentation*

| TABLE 3.1-1 PREflight Experiment Session Overview  |
| --- |
| **Session Title** |  | **Medical Monitoring** |  | **Session ID** |  |
| **Schedule** |  | **Session Time (min)** |  | **Location** | [ ]  JSC [ ]  GCTC[ ]  KSC [ ]  DFRC |
| **Session Scenario** |
|  |
| **No.** | **Session Flow** | **Projected Time (min)** |
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| **Scheduling Constraints** |
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| **Session Constraints** |
|  |
| **Session Unique Information** |
|  |
| **Hardware** | [ ]  Yes [ ]  No | **Software** | [ ] Yes [ ]  No |
| **Samples** | [ ] Yes [ ]  No | **Measurements** | [ ] Yes [ ]  No |
| **Facility Requirements** | **Timeframe for Facility Access** |
|  |  |
| **Hazardous Waste** |  |
| **Gas Mixtures** |  |
| **If a Launch Slip of**  |  | **days occurs, the L-** |  | **Session(s) will need to be repeated** |
| **ISSMP Disposition** | [ ]  Wilco [ ]  No Wilco | **Comments:** |  |

*Destination of table information: BDC Plan*

| TABLE 3.2-1 postflight Experiment Session Overview  |
| --- |
| **Session Title** |  | **Medical Monitoring** |  | **Session ID** |  |
| **Schedule** |  | **Session Time (min)** |  | **Location** | [ ]  JSC [ ]  GCTC[ ]  KSC [ ]  DFRC |
| **Session Scenario** |
|  |
| **No.** | **Session Flow** | **Projected Time (min)** |
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| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 5. |  |  |
| 6. |  |  |
| **Scheduling Constraints** |
|  |
| **Session Constraints** |
|  |
| **Session Unique Information** |
| 1.  |
| **Hardware** | [ ] Yes [ ]  No | **Software** | [ ] Yes [ ]  No |
| **Samples** | [ ] Yes [ ]  No | **Measurements** | [ ] Yes [ ]  No |
| **Facility Requirements** | **Timeframe for Facility Access** |
|  |  |
| **Hazardous Waste** |  |
| **Gas Mixtures** |  |
| **For a mission greater than**  |  | **days in duration, this session should be performed.** |
| **ISSMP Disposition** | [ ]  Wilco [ ]  No Wilco | **Comments:** |  |

*Destination of table information: BDC Plan*

| TABLE 3.3 SAMPLES |
| --- |
| **Samples Acquired** | **Session ID(s)** | **Units** | **Volume/ Accuracy** | **Comments** |
|  |  |  |  |  |

*Destination of table information: IRB package and DSP*

| TABLE 3.4 MEASUREMENTS |
| --- |
| **Measurement Name** | **Session ID(s)** | **Units** | **Range** | **Accuracy** | **Sample Rate** | **Acquisition Method** | **Comments** |
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*Destination of table information: DSP*

| table 4 Baseline data collection hardware and Software |  |
| --- | --- |
| **Hardware/Software Item** | **Session ID(s)** | **Total Qty.** | **Provided By** | **Location and Dates for BDC Activities** | **ISSMP Wilco/****Nowilco/****N/A** |
| **JSC** | **KSC** | **Dryden**  | **Russia**  | **Other** **(Specify)** |
| **Scheduled Days** | **Qty.** | **Scheduled Days** | **Qty.** | **Scheduled Days** | **Qty.** | **Scheduled Days** | **Qty.** | **Scheduled Days** | **Qty.** |
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| TABLE 5 TRAINING SUMMARY |
| --- |
| **Session Title** | **Timeframe** | **Session Duration** | **Required No. of Sessions** | **Location of Training** |
|  |  |  |  |  |
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*Destination of table information: IRB package and ICB overview presentation*

1. Only responsible for review of BDC Session times. [↑](#footnote-ref-1)