Приложение 2b

MULTINATIONAL SPACE STATION
HUMAN RESEARCH INFORMED CONSENT*

1. I, the undersigned, _____ ___do voluntarily give my informed consent for my participation as a test subject in the following research study, test, or investigation:

NAME OF INVESTIGATION

_____

__

MISSION TO WHICH ASSIGNED_____

PRINCIPAL INVESTIGATOR_____

RESPONSIBLE PROJECT
SCIENTIST_____

I understand or acknowledge that:

(a) This procedure is part of an investigation approved by *The State Corporation for Space Activities "**Roscosmos**" (FSA)*

(b) I am performing these duties as part of my employment with *The State Corporation for Space Activities "**Roscosmos**" (FSA)*

This research study has been reviewed and approved by Biomedical Ethics Comission (BEC) of IBMP and the Human Research Multilateral Review Board (HRMRB) which has also determined that the investigation involves _____risk to the subjects
(minimal or reasonable)

(d) Definitions:

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Reasonable risk" means that the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The research procedures were explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered to my

satisfaction. A layman's description was provided to me.**

I consider myself physically and mentally qualified to participate in the investigation.

(g) I know that I can refuse to participate in the tests at any stage of their performance, and my refusal will be honored, except in those cases when, in the opinion of the responsible physician, termination of the tests could have detrimental consequences for my health and/or the health of the other subject. However, understanding the significance of the investigations (tests), I will give every effort to perform the full scope of the program.

(h) In the event of injury resulting from this study, I understand that I will receive medical attention and available treatment. I also understand that I will be compensated for any injuries to the extent permitted under current laws and regulations of *Russian Federation* and the provisions of the contract between me and *The State Corporation for Space Activities "**Roscosmos**" (FSA).* My agreement to participate shall not be construed as a release of *The State Corporation for Space Activities "**Roscosmos**" (FSA)* or any third party from any liability which may arise from, or in connection with, the above procedures.

(i) Consistent with statutory and Agency-approved routine uses under *The State Corporation for Space Activities "**Roscosmos**" (FSA)*
regulations, the confidentiality of any data obtained as a result of my participation as a research subject in this study shall be maintained, so that no data may be linked with me as an individual without my written permission. However, if a "life-threatening" abnormality is detected, the investigator will notify me and the Responsible Project Scientist of *The State Corporation for Space Activities "**Roscosmos**" (FSA).*
Such information may be used to determine the need for care or medical follow-up, which, in certain circumstances, could affect my professional (flight) status.

_____

Test Subject Date

2. I, the undersigned, the Principal Investigator of the investigation designated above, certify that:

(a) I have accurately described the procedure and related risk(s) to the test subject.

(b) The test setup involves _____risk to the test subject as determined by the
(minimal or reasonable)
BEC and the HRMRB.

(c) All equipment to be used has been inspected and certified for safe and proper operation.

(d) The test subject is qualified to participate in my experiment protocol.

(e)The test protocol has been approved by the BEC and the HRMRB.

Principle Investigator _____ Date_____

Notes:

* This form is valid for the period including preflight, in-flight, and postflight data collection sessions for the mission. Before the first baseline data collection, the Principal Investigator will

repeat the briefing concerning risks involved in the investigation. A signed, dated copy of this form with attachments must be forwarded to Chair, Human Research Multilateral Review Board.

** A detailed description of the investigation will be attached to this consent form. The Principal Investigator is responsible for formulating this document, which should be in layman's terms such that the subject clearly understands what procedures will be required and the risks associated therewith. The detailed description of the research procedures must specifically list the risks associated with the procedures to be employed, the possible adverse reactions of all medications to be administered, and the risks/hazards resulting from exposure to ionizing radiation. Further, the investigator must clearly specify all forms of subject behavior interdicted by the research protocol (exercise, diet, medications, etc.)