**CONSENT FORM FOR**

**PARTICIPATION IN HUMAN RESEARCH FOR THE EUROPEAN SPACE AGENCY ISOLATION AND CONFINMENT STUDIES**

**ABOUT THIS RESEARCH CONSENT FORM**

You may be eligible to take part in a research study as part of your mission(s) in Concordia.

A research study is carefully planned and designed to increase scientific knowledge.

This consent form describes important information related to participation in a research study including the purpose, planned procedures, and potential risks. The study has been reviewed approved by ESA and by the Concordia Steering Committee.

Please take time to review this information carefully. Talk to the researchers or their representative(s) about the study and ask any questions you have. **Make sure you fully understand what will be expected of you and the risks associated with participating in this study.** If you decide to be a participant, you will need to sign this form and you will be given a copy.

Taking part in this study is completely **voluntary**. The decision to participate is yours. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you.

**Note: Failure to disclose pre-existing medical conditions may place you at greater risk for injury or other adverse events resulting from your participation in this study.**

**1. GENERAL INFORMATION**

* 1. Your study title is: **[Investigators: Please insert study title here]**
  2. Your study team includes a Principal Investigator, Co-Investigator, Key-Personnel (names, degrees, affiliations): **[Investigators: Please insert names/degrees/affiliations here]**
  3. This study is sponsored or funded by:**[Investigators: Please insert sponsor/funder here]**
  4. Key Information: **[Investigators: Please provide a short summary of this study to help participants decide whether or not to be a part of this study. More detailed information should be listed later in this form.]**

**2. PURPOSE OF THIS STUDY (History and Background)**

2.1 You are being asked to join this study because:

**[Investigators: Please insert a brief summary about the purpose of the study here]**

**3. STUDY PARTICIPANTS**

* 1. In order to be eligible to participate, you may be asked to undergo the following screening tests or procedures:

**[Investigators: Please insert pertinent screening tests for study inclusion here. If there are no screening tests or procedures, then type “not applicable.”]**

* 1. You are one of \_\_\_\_\_\_subjects.

**4. STUDY DESCRIPTION**

4.1 In this section you are provided a study description in layman’s terms that you should easily understand and that provides you the following as applicable: a detailed explanation of each test, including what data will be collected and what equipment will be used; the amount of time each test will take; the frequency of testing, and whether testing is continuous or intermittent; a chart or calendar as a possible addition to the explanation of the tests; the study’s duration and when it will be completed; any need for follow-up examinations or tests; the location of the testing; the amount of blood, urine, saliva, other biological samples and/or tissue that will be taken and how often; whether joining this study limits your chance to join other studies; whether “standard” medical procedures are included in the study; how your other activities may be affected by the study (exercise, diet, medications, physical activities, etc.); and a detailed list of any data that have been collected by other means that will be used by or shared with this study.

**[Investigators: Please insert the pertinent information here]**

4.2 You are being told if the study you are joining includes one of the following categories:

* *“Randomized”* means that you are put into a study group by chance (e.g., like flipping a coin). Neither you nor the principal investigator will choose what study group you will be in. You will have a chance of being placed in any study group.
* *“Blinded”* means you will not know what study group you are in.
* *“Double-Blinded”* means that neither you nor the Principal Investigator (double-blinded) will know what study group you are in.
* *“Placebo”* means a pill with no medicine. In a placebo-controlled study, you may be given a study medication and it will contain either (name of drug) or placebo (pills with no medicine).
* *“Not Applicable”*

**5. DRUGS, BIOLOGICS or NEWMEDICAL DEVICES or PRODUCTS**

In this section you are being told whether the study uses any drugs, blood or blood components, allergenic substances, vaccines, investigational new medical devices or other similar products used to investigate human anatomy or physiology or to prevent or treat disease or injury.

\_\_\_\_\_No study drug, biologic, or investigational new medical device or product will be used.

\_\_\_\_\_Yes, the study drug, biologic, and/or investigational new medical device or product is:

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If “Yes” is checked above, then the investigator(s) will also provide you with a description of the drug or other substance and/or investigational new device. For investigational new drugs or devices, the investigator will also provide you with any relevant investigational regulatory approval number(s). In all cases the investigator(s) will also provide you with any other materials you require to best assist you with making an appropriately informed decision regarding your participation.

**[Investigators: Please insert the pertinent information here, if applicable]**

**6. INFORMATION ABOUT RISKS AND HAZARDS**

6.1 You are joining a study that is:

* “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.

6.2 Hazards represent conditions that have the potential to cause harm. Risks, in turn, originate from hazards. For example “A wet deck on a boat” is a hazard, whereas potential risks associated with that hazard might include slipping and falling down or overboard.

6.3 The risks of joining the study and the steps taken to protect against harm include:

**[Investigators: Please insert the pertinent information here]**

6.4 The hazards and the steps used to minimize the hazards include:

**[Investigators: Please insert the pertinent information here]**

**7. TREATMENT, INJURY AND COMPENSATION INFORMATION**

Even though the investigators have taken steps to minimize the risks, you may experience problems or side effects. Therefore the following statement applies for you the participant: “In the event of injury resulting from this study, I understand that I will receive medical attention and available treatment.

**8. BENEFITS INFORMATION**

8.1 Potential benefits to You: Participation in the European Space Agency Isolation and Confinement studies generally result in no direct benefit to you as an individual. It is hoped that the information learned from this research study will help the European Space Agency learn more about human physiological changes fur to isolation and confinement in extreme environments, in preparation for future human space exploration.

8.2 Potential benefits to the Researchers: The research team will utilize this section to inform you whether any member of the research team might potentially receive additional financial or other benefits through the conduct of this research, for example through his/her business affiliations, holdings of stocks or other securities, patents or patent applications, trademarks or trademark applications, etc.

\_\_\_\_\_The researchers declare that they have no otherwise undisclosed potential financial benefits.

\_\_\_\_\_Potential additional financial benefits to the researchers are (include researcher name(s) and nature of benefit(s)):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**9. NEW FINDINGS**

9.1 If new information is obtained during the study after you have joined, you will be informed. You may change your mind about continuing in the study. You may be asked to sign a new consent form that includes the new information.

**10. STUDY WITHDRAWAL and/or TERMINATION**

10.1 You may withdraw from the study at any time. If you decide to leave before the study is finished, please tell the investigator or study staff. Your withdrawal could have undesired consequences for your health and/or the health of other subjects. The investigator or study staff will tell you if there could be any harm to you if you decide to leave before the study is finished. If you tell the researchers your reasons for leaving the study, that information will be part of the study record.

10.2 Your withdrawal or refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

10.3 If you decide not to join the study, or to withdraw from it you may nevertheless be eligible to participate in other studies.

10.4 Researchers may need to stop your participation in the study even if you want to continue participation. The research may also be stopped at any time by the European Space Agency or Concordia Steering Committee if the research would endanger any Crew Member, including you, otherwise threaten the mission success, or for any other reason. Some examples of possible reasons include:

* The researcher believes that it is not in your best interest to stay in the study
* Any problem with following study related instructions
* Any problem with following clinic or laboratory policies and procedures
* Any serious complication during the study
* Inappropriate behavior
* The study is suspended or canceled
* The subject’s information is or becomes unusable for any reason
* Events beyond the European Space Agency or Concordia Steering Committee’ control occur, for example: fire, explosion, disease, weather, floods, terrorism, wars, insurrection, civil strife, riots, government action, or failure of utilities
* Existing data reveal answers earlier than expected

**11. COST and FINANCIAL INFORMATION**

11.1 There are no costs or bills to you for participation in this study. You will also not receive any financial compensation for participating in this study.

**12. SUBJECT RECORD CONFIDENTIALITY AND AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION (PHI)**

12.1 Your privacy and the confidentiality of data collected or used as a part of this research study will be protected from unauthorized disclosure according to applicable law.

12.2 Your protected health information (such as name, geographic identifier, dates, phone number) maybe used or shared for research oversight or quality assurance, medical monitors, and researchers for the reasons below:

* To conduct and oversee the research;
* To make sure the research meets European Space Agency Isolation and Confinement requirements;
* To conduct monitoring activities (including situations where you or others may be at risk of harm or reporting of adverse events);
* To become part of your medical record if necessary for your medical care;
* To review the safety of the research.
* To support operational clinical activities where clinical experts evaluate relevant medical and research data to recommend clinical practice guidelines or medical requirements specifically for isolation and confinement in extreme environments. These data will not include names although other information may implicitly link the information to you.

12.3 For the purposes of ensuring the safety of the study and yourself, and of verifying compliance with applicable laws and regulations, information about you, including protected health information, may be used or seen by the researchers or others, on a need-to-know basis, during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The European Space Agency, Concordia Steering Committee and other government officials may need the information to make sure that the study is performed in a safe and proper manner.
* Other officials may need to review the information if the study involves the use of an experimental drug or device.
* Safety monitors, medical personnel, or safety committees may review your research data, stored biospecimens and/or medical records for the purposes of medical safety, for verification of research procedures, or if any injuries or other adverse events occur.

12.4 In addition to the cases mentioned in 12.2 and 12.3 above, your protected health information obtained through this research may be used or shared with others through separate Data Sharing Agreements to which you have also concurred beforehand by providing a separate signature. The results may be used by the research team and possibly be presented/published in journals or at scientific conferences, but in such cases will not include information that could identify you, directly or by inference, without your consent.

12.5 You have the right to withdraw your consent for the researchers to use or share your protected health information. The researchers will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or to ensure quality of the study.

12.6 You have the right to request access to your study records after the study is completed. To request this information, you must do so in writing by contacting the researcher. Should your personal data in those study records be incorrect, you have the right to request that this be corrected.

12.7 Any data (including but not limited to standard measures, laboratory data, psychological, or physiological measurements) or biospecimens obtained from you for this research study may become part of the the European Space Agency or Concordia Steering Committee’ data archives. These data or biospecimens may be used in this research, may be used in future research without your additional informed consent, and may be shared with other organizations. All applicable laws, regulations, and policies concerning the privacy and confidentiality of these data will be followed. Records or biospecimens stored in these archives will not be released or used in a way that identifies you by name – a code will be assigned. However, records or biospecimens may be implicitly linked to you through fields such as assigned Concordia Winter-over season, gender, age, etc.

**13. CONTACT INFORMATION**

13.1 You may contact the Principal Investigator to:

* Obtain more information about the study;
* Ask a question about the study procedures;
* Report an illness, injury, or other problem;
* Leave the study before it is finished;
* Express a concern about the study.

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**14. RECORD of INFORMATION PROVIDED**

14.1 Your signature in the next section means that you have received copies of all of the following documents:

* This “Consent to be Part of a Research Study” document;
* Video, Audio, and Photo Consent, as applicable;
* Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**15. SIGNATURES**

**Research Subject Understanding:**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with \_\_\_(Principal Investigator or Study Coordinator name)\_ and I hereby give my consent to participate in this study as a research subject. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact the study team. I understand that I will receive a copy of this form at the time I sign it and later upon request.

Signature of Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (Print legal name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Video, Audio, and Photo:**

I understand that this study will utilize video, audio and/or still photography to analyze study results and I consent to the use of these materials.

□I accept

□I do not accept

□Not applicable(study will not utilize video, audio or still photography)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Note:**

Principal investigators and the European Space Agency are required to retain a signed, dated copy of this form with any attachments for at least 3 years beyond the date of the completion of the study.