# MULTINATIONAL CONSENT FORM FOR SPACEFLIGHT-RELATED PARTICIPATION IN HUMAN RESEARCH

## ABOUT THIS RESEARCHCONSENT FORM

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

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. Both the study and this form have been reviewed and approved by the Human Research Multilateral Review Board (HRMRB).

Please take time to review this information carefully. Talk to the researchers 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.** You may also wish to talk to others (for example, your friends, family, or doctors) about your participation in this study. If and when you decide to be a participant, you will be asked 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

1.1. Your study title is: ElectroMyoStimulation (EMS body suit) protocol to improve exercise outcome in space missions (EasyMotion-2)

Your study team includes a Principal Investigator, Co-Investigator, Key-Personnel (names, degrees, affiliations):

Note: Removed for PII data security

1.3 This study is sponsored by the *European Space Agency (ESA)* and funded by: *German Aerospace Board (DLR e.V.), Bonn-Oberkassel, Germany*

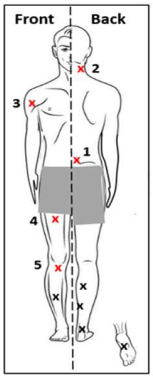
Key Information: This is a prospective spaceflight study involving an investigational device called the EasyMotionSkin for whole body electric muscle stimulation (WB-EMS) onboard the International Space Station.
The purpose of this study is to show:

- optimized exercise outcome with EMS in human spaceflight
- demonstrate efficacy of EMS as alternative inflight exercise protocol
- provide a time-saving and reliable EMS-assisted exercise protocol compliant to astronauts for later use in planetary habitats and future deep space exploration

Eight (n=8) astronauts on long duration missions will take part in this study. This experiment uses the following HW & SW (see illustrations A-D below): A) EasymotionSkin suit (dry electrode muscle stimulation), B) non-invasive hand-held Myoton device (muscle data collection) with C) a customized

Myoton body template suit (elastic yoga suit with customized anatomical reference labels and small 2x2 cm perforations to aid inflight Myoton data collection) at only 5 skin measurement points (skin MPs), neck, back, shoulder, legs, see the 5 red "x" skin measurement points on body chart, D), and two on-the-ground standard test, muscle strength (dynamometry) and magnetic resonance imaging (MRI) solely for research purposes. (Credits: A) Easymotion GmbH., B) myoton.com; C-D) Principal Investigator).

A) B) C) D)




Research activities take place at JSC, EAC and on ISS, and include the following procedures preflight, inflight, and postflight:

**Preflight** Baseline Data Collection (JSC or EAC)

- Astronaut training I (Myoton template suite fitting & prep., once- 30 minute session)
- Astronaut training II (EMS suit size fitting and EMS-assisted exercise compliance tests, once- 45 minute session)
- Myoton sessions (5 skin measurement points/Myoton template suit, once- 10 minute session)
- MRI (once - 45 minute session)
- Dynamometry (once- 30 minutes session)

**Inflight** (onboard ISS)

- Myoton pre EMS sessions (5 skin measurement points/Myoton template suit, twice- 15 minute session)
- 12 single EMS sessions (between R-60 and R-21), 12 times- 20 minute session)
- Myoton post EMS sessions (5 skin measurement points/Myoton template suit, twice- 15 minute sessions)

**Postflight** BDC (JSC or EAC) – recovery data collection

- Myoton sessions (5 skin MPs/Myoton template suit, twice- 10 minute session)
- MRI (once- 45 minute session)
- Dynamometry (once- 30 minute session)

The main risks involved include: EMS contra-indications (for example, heart disease, diabetes, wearing active medical implants, pregnancy, others) that may not apply for Astronauts with active medical approval. Muscle soreness and strain after extensive EMS stimulation may occur (as mitigated by customized impulse rate, duration, and tolerable frequency stimulation settings).
There are no expected direct benefits to you in this study. However, a potentially improved muscle health condition during the mission and recovery (increased passive muscle stiffness as health indicator) may be expected, and a feeling for "improved body energy" as reported from one Astronaut who already used EMS previously onboard ISS. There is no compensation for participation in this study. Data will be identifiable but

will be coded for storage. You may choose to participate or not participate in this study. Participation is voluntary.
1.4

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

2.1 You are being asked to join this study because:

In a previous space analog study (60 days RSL bed rest, Cologne, 2015) on n=24 voluntary particiants followed by an experiment on ISS (MYOTONES 2015-2023) we used non-invasive Myoton technology to detect digital biomarkers (passive muscle tone and stiffness) on twelve (n=12) study participants together with clinical imaging (MRI), muscle strength tests (dynamometry), and blood samples (biosamples) to study muscle properties and adaptation in microgravity following routine inflight exercise in Astronauts on the ISS compared to pre and postflight baseline conditions. One of the MYOTONES Astronaut already tested a space-qualified Easymotion skin suit (Demo-Tech Experiment, DLR) that was used for about 20 minutes on top of the daily routine exercise protocol in order to optimize inflight training outcome by EMS technology in spaceflight. Preliminary results (n=1) showed feasibility of the novel EMS technology in spaceflight and suggested improved muscle health parameters (increased tone and stiffness) found in some muscle from torso and limbs compared to a non-EMS mission crewmember. Easymotion-2 is designed to replicate similar changes in passive muscle parameters (resembling muscle health) in eight (n=8) more ISS Astronauts for robust statistical analyses to:

(i) show optimized exercise outcome with EMS in human spaceflight

*(ii)* demonstrate efficacy of EMS as alternative countermeasure protocol for example in future designed space-limited spacecrafts

*(iii)* provide a protocol for EMS assisted exercise compliant to astronauts as alternative countermeasure for later use, for example, in planetary habitats in future deep space explorations (Moon/Mars).

## 3. STUDY PARTICIPANTS

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

- Regular flight medical screening (standard screening of Flight Doctors from your Space Agency)
- As a first pre-test you may want to use the EMS suit on the ground during your routine exercise protocols prior to launch for familiarization and decision making to sign-up as potential study participant

3.2 You are __1__ of _8__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.

**Protocol description**

During the Informed Consent Briefing (ICB) solicited by your Space Agency you will be instructed about the study Easymotion-2. During this conversation, you will be allowed sufficient time for questions and answers. We will discuss study inclusion/exclusion criterias and also talk about our recommendation for a pre-testing of the functional Easymotion (EMS) skin suit, which includes training sessions with the EMS suit on the ground at your discretion. This will allow for prospective evaluation of the possible effects of EMS stimulation , such as the "booster effect" for more physical body energy, during your flight. This information will help decision making about study participation. If you decide to participate, the staff will review the consent form with you and finalize sign-up. All study data will be coded (pseudonymized) and only provided to the study team for privacy reasons.

You should participate if you meet/have the following criteria:

- Flight medical approval (routine and standard)
- Available time needed onboard ISS: 12 x 20 minutes = 240 minutes (for EMS)
- Tests (Location, pre/in/postflight):

**EMS** (JSC/ISS/N/A) **Preflight** (Johnson Space Center): You will wear the space-qualified EasyMotionSkin suit on the ground for familiarization. You will be allowed to pre-test if needed. This will be the suit you use later during your regular inflight exercise countermeasures.
**Inflight** (ISS): You will undergo intermittent inflight testing for 3-4 weeks ($2^{nd}$ half of flight). During this testing you will undergo donning/doffing and activation of the EMS body suit (this should take 10 minutes) + a maximum stimulation of 20 minutes. Please note, you will be able to preset your own tolerable intensity using the Easymotion App via iPAD. You will undergo exercise blocks as an integrated part of your regular inflight countermeasures (T2/CEVIS/aRED, freely selectable) of 12x20 minutes with at least 1-4 days in between each session. Note: the minimum mission duration is 130 days.
**Postflight** no research activities planned for EMS.

**Myoton** (JSC/ISS/JSC) **Preflight** (Johnson Space Center/EAC): You will be provided during the baseline data collection session with a personalized and fitted Myoton suit. This suit is an elastic yoga suit with small holes of 2x2 cm in the fabric over five muscle locations of interest and will be used to collect data on passive tone and stiffness of your muscles during EMS. After fitting, baseline data will be collected once by the Science Team, during which you will wear the Myoton suit lying fully relaxed on a guerney for a period of 15-20 minutes.
**Inflight** This special template suit will be your own payload to the ISS that you will wear only for a short time during the Myoton sessions (and trashed thereafter) to aid Myoton data collection on five selected surface muscles as operated by a second crew mate.
Myoton data collection will be done four times onboard, that is twice for pre-EMS data collection (prior to EMS session start) and twice again for Myoton post-EMS data collection (with 48h interim) between sessions.
**Postflight** (Johnson Space Center): One Myoton data collection session is planned lying fully relaxed on a gurney (15-20 minute session). Wearing of a Myoton suit will be obsolete as data collection will be done by the Science Team on site.

**Dynamometry** (JSC/EAC) **Pre & Postflight:** This is a standard functional muscle strength test during which you will be sitting on the device and perform leg press and back extension used in many physiology laboratories, on the ground tests only.

| | | |
|---|---|---|
| | | This will occur only once preflight and once again postflight (30 minute sessions each) for research purposes only. |
| **MRI** | (JSC/EAC) | **Pre & Postflight:** This is a standard medical imaging protocol routinely used in clinics for overall muscle structure (trunk and limbs), during which you will be lying fully relaxed on a table that will be moving inside the 3-Tesla device tunnel back and forth for imaging of your lower back and legs for research purposes only once preflight and once again postflight (45 minute sessions) for research purposes only. |
| Other studies | | Participation to whole-body EMS (Easymotion-2) may limit your participation in other studies using comparable muscle stimulation protocols, for example, targeted to upper/lower limb musculature. |
| Other data | | EMS muscle data (Easymotion-2, PI Blottner) will be used by and shared with data from same five muscles available from the recent MYOTONES study (non-EMS participants) for comparison (PI Blottner). |
| Follow-up tests | | Myoton, Dynamometry and MRI test (as above) after return (NET R+30 days) for research purposes only |

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).
- ☐ ***X*** *"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.

___X__Yes, the study drug, biologic, and/or investigational new medical device or product is:

Easymotion-2 Suit (targeted muscle stimulation).

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.

Easymotion-2 uses a commercially available off-the-shelf (COTS) EasyMotionSkin™ suit (Easymotion Inc., Leipzig, Germany) as Space-qualified by OHB, Bremen, Germany (ESA/DLR contractor), for safe use in Space (Flight Safety Data Package available). EasyMotionSkin™ suit is usually used in many sport and fitness clubs in Germany and around other EU countries and probably also worldwide by otherwise healthy people and sports athletes to increase muscle power and strength for a noticeable improved body energy.

This is an investigational non-significant risk device, with IRB approval for use.

EMS has contraindications (obviously not applicable for astronauts) excluding use of this technology for safety reasons:

- Heart disease
- Liver disease
- Diabetes
- Thrombosis
- Extreme blood pressure
- Abdominal & inguinal hernias (bulges)
- Strong neurological diseases
- Pregnancy
- Cancer

EMS does not have major health risks (contraindications) other than listed above. However minor health risks mainly include muscle soreness (muscle strain) due to extended and extensive (high frequency/intensity) EMS stimulation in combination with high intensity training (HIT) otherwise well-known as a tolerable exercise-relevant muscle strain phenomena linked to moderate muscle pain sensations (usually creeping out after few days post-exercise). Extensive and continuous EMS stimulation for longer periods without wash-out periods (1-4 days interim phase between EMS sessions) may cause elevated serum creatinine kinase (CK) levels (HyperCKemia, a well-known diagnostic serum biomarker in clinics) as indication for muscle tissue micro-lesions.

## 6. INFORMATION ABOUT RISKS AND HAZARDS

6.1 You are joining a study that is:

**X** "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:

Hazard: Electromyostimulation (electric power) using dry skin electrodes overlapping surface musculature for involuntary muscle contractions.

Potential risks:

- Muscle soreness (muscle strain)
- elevated serum CK levels (biomarker/muscle micro-lesions)

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

- Digitally controlled electric power control via customized Easymotion App (frequency/duration presettings according to own tolerable intensity parameters as preset on the ground) but also adjustable to own tolerable frequency/duration presettings for EMS inflight.
- EMS exercise sessions lasting max. 20 minutes each with interim phase of 1-4 days between next EMS session (total of 12 EMS sessions in second half of flight, missions > 130 days

## 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. I also understand that I will be compensated for any injuries to the extent permitted under the laws and regulations applicable to me and the provisions of the contract between me and __(space agency of crewmember subject)____. My agreement to participate shall not be construed as a release of liability which may arise from or in connection with the above procedures for _(space agency providing funding)_ or any third party.

## 8. BENEFITS INFORMATION

8.1 Potential benefits to You: Participation in _ESA/DLR___(Principal Investigator agency) _____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 international science partners learn more about human physiological changes for future space flight missions.

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.

_X____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): n/a

## 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. A responsible physician 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 Human Research Multilateral Review Board (HRMRB), the Crew Surgeon or other assigned medical monitor, the Flight Director, or the ISS Commander, as appropriate, if the research would endanger any ISS 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 participating agencies' 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.

## 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 by ESA/DLR offices of 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 ESA/DLR 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 space flight. 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 participating agencies 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.
- A data and safety monitoring board (DSMB) may oversee the research, if applicable.

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 yourself 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. To withdraw your consent, you must submit a written request to do so to the researcher and, if relevant, the Data Sharing Agreement administrator.

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 participating agencies' archives, based on each specific agency's arrangements with their investigators. These data or biospecimens may be used for future research. For de-identified data or biospecimens

additional informed consent is not needed unless your consent is required by your primary Agency. 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 mission duration, gender, age, etc.

12.8 A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, this website will include a summary of the study results. You can search this website at any time.”"

## 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: removed on PII data security

Email Address: removed on PII data security

Mailing Address: removed on PII data security

Telephone: removed on PII data security

Study Coordinator: see above

Email Address_____

Mailing Address: _____

Telephone: _____

You may express a concern about this study by contacting the Bioethical committee of your Space Agency or the Human Research Multilateral Review Board (HRMRB) listed below:

Office of Research Assurance: Research Integrity & Protection of Human Subjects
Attention: Human Research Multilateral Review Board Administrator
2101 NASA Parkway
Mail Code SA
Houston, Texas 77058
NASA-IRB@nasa.gov
Visit: https://irb.nasa.gov/?p=irbContactInfo

## 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 Multinational Space Station "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 _Dieter BLOTTNER 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: _____

**Principal Investigator (or Designee):**

I have given this subject information about this study. I believe this to be accurate and complete. The subject has indicated that he or she understands the nature of the risks and benefits of participating in this study.

Name: _____ Title: _____

Signature: _____ Date: _____

**Note:**

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