Announcement of Opportunity

Life Science Research Using The Human Spaceflight Analogue “Bed Rest”

AO-13-BR

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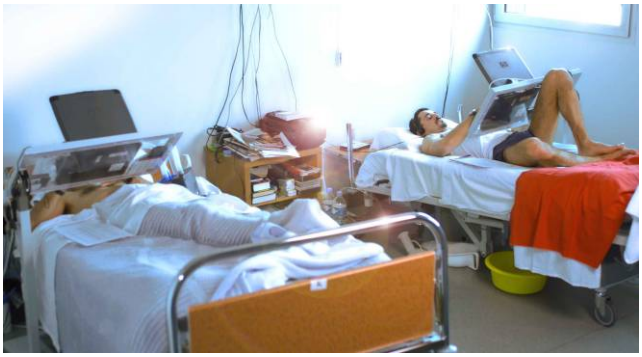

Image : ESA/Vista S.T.I.

Letter of Intent due:

November 4th, 2013

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Proposal due:

January 6th, 2014

Summary for the Bed Rest Study Research Opportunity

- The Human Spaceflight and Operations Directorate of the European Space Agency announces an opportunity to propose life science research using the human spaceflight analogue “bed rest”. One bed rest study is targeted with this AO. It will be a long-duration study, i.e. with a 60-day head down tilt period.

- Proposals of new countermeasures are NOT part of this Announcement

- Eligibility: The scientific institution for which the coordinator of a proposal is working must be located in one of the ESA member or associated member states that contribute to the ELIPS Period 4: **Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Italy, The Netherlands, Norway, Romania, Sweden, Switzerland, United Kingdom**. Scientists from ESA Member States that do not contribute to the ELIPS Programme and scientists from other European countries having a cooperation agreement with ESA, are encouraged to enquire with their national space organisation about the conditions for their participation in proposals to ESA.

- Submission of Letters of Intent and proposals will be done electronically. The LoI and the proposal must use the template from the AO website. Submission of LoI and proposal will be as PDF to the email address

bedrest@esa.int

- For questions related to this announcement of opportunity please contact:

Dr. Oliver Angerer
Tel. +31 855607603
Announcement-specific email: bedrest@esa.int

- Important dates:
  - Letter of Intent due: 4th of November 2013
  - Proposal workshop (at ESA/ESTEC, NL): 11th of November 2013
  - Proposals due: 6th of January 2014

- Implementation schedule: Preparation of the study will start in the second half of 2014. Start of the study is foreseen for the second half of 2015.

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1 Introduction

When exposed to weightlessness in space, the human body undergoes a variety of adaptations, incl. bone mass loss, muscle mass loss, fluid shift, cardiovascular deconditioning etc. These changes are problematic when returning to a gravity environment, or potentially in emergency situations.
Different exercises and other measures (referred to as “countermeasures” in the space context) are employed in an attempt to limit these adaptations. However the currently employed suite of countermeasures encompasses the use of large equipment and requires a significant amount of time, and yet it has been shown that these measures do not fully prevent the changes.
Continuous exposure of healthy volunteers to a -6º head-down tilt position while resting in beds has been shown to be a good model for many of the physiological changes that take place in spaceflight. In addition to providing the opportunity to study the physiological mechanisms, these bed rest (BR) studies also allow to test the effectiveness of countermeasures and protocols. This is of special importance in preparation of future human exploration.
Obviously, the results of these BR studies are very relevant also for e.g. clinical environments, where patients also undergo bed rest for a variety of different reasons.

2 ESA’s Approach to Bed Rest Studies

ESA has been conducting a very successful BR study programme since many years. In 2005, based on the experience gained, and taking into account some new factors (need for structured countermeasure evaluation in preparation of human space exploration, need for faster availability of core study results etc.), the organisational approach was modified.
Now, the priorities for the countermeasures protocols to be evaluated are defined for a few years ahead, i.e. for multiple BR studies. The protocols for these studies are defined by expert groups that have proven experience for that type of countermeasure.
Also, a standard set of “gold standard” measurements, called Bed rest Core Data (BCD) is collected in each ESA BR, so that the evaluation of countermeasure effectiveness between different studies is possible.
On top of this, an Announcement of Opportunity (AO, like the one you are currently reading) is published for a given set of BR studies. Experiments selected through these AOs are distributed to the best suited planned BR study, complementing the strategic countermeasure evaluation with high-quality fundamental research.

2.1 Bed Rest Core Data (BCD)

BCD are defined for the main physiological areas incl. bone, muscle, cardiovascular system, nutritional status etc. A detailed list of the BCD measures relevant for this AO can be found in Annex 1.
BCD will be analysed by the expert groups that defined the countermeasure protocol to derive the countermeasure effectiveness.
Data from BCD measurements is in principle also available for research projects, if the BCD has been requested in the proposal. In such a case priority for publication of a BCD measurement will usually be given to the selected experiment (within the limits of the general ESA BR data approach, see section 6).

2.2 Bed Rest Standardisation

When initiating the strategic approach for BR it became clear that one of the prerequisites to be successful in this approach was the standardisation of BR study conditions. To this end, an ESA standardisation document was produced, that details many aspects around BR studies, incl. study management and project communication, study protocol, volunteer selection, volunteer rules, (para) medical care, nutrition standardization, handling of biological samples, data management and a description of Standard Operating Procedures for many activities. Some of these standards, e.g. inclusion/exclusion criteria for test subjects, only represent the minimum required to allow some comparability between studies. If your experiment requires general study conditions that are very specific (e.g. specific range of VO_2max etc.) this should be stated in the proposal and will be discussed at the Investigator Working Group meeting of the relevant bed rest study.

3 Bed Rest Studies Targeted by this AO

This AO is soliciting proposals to be implemented in one long-duration BR study in male subjects. Long-duration BR studies are defined in the ESA standardisation as having a baseline data collection period of 14 days, a head-down tilt period of 60 days, followed by a recovery period of again 14 days.
The foreseen countermeasure protocol that will be tested is a nutritional supplementation with a “cocktail” of anti-inflammatory, anti-oxidant substances. While the exact definition of the “cocktail” is currently still ongoing, it is likely to include Resveratrol, Vitamin E+C, Lycopene and Epigallocatechin. There will be one control, and one intervention group.
The detailed protocols will be elaborated at a later point in time, and some modifications may yet occur. However for the proposals in response to this AO, this countermeasure protocol should be regarded as the baseline. Preparation of the Study will start in the second half of 2014. Start of the study

is foreseen for the second half of 2015. It is foreseen that this study will be conducted at the Medes space clinic in Toulouse, France.

4 Proposals solicited by this AO

Proposals should address physiological areas, which could be affected by bed rest and countermeasure use. Any type of research field can be addressed, for example:

- Integrative physiology
- Bone
- Muscle
- Nutrition and metabolism
- Neurology
- Cardio-vascular system
- Rehabilitation Medicine
- Pharmacology
- Gastro-intestinal, splenic, renal, hepatic, and pancreatic function
- Immunology
- Endocrinology
- Others

It has been repeatedly discussed and highlighted that the recovery period of the BR studies is a very interesting and relevant, yet understudied period. Therefore projects that are investigating that period and/or rehabilitation schemes and aspects are especially encouraged.

Please bear in mind that during the head-down tilt phase no testing can be performed in a sitting or standing position. Tests requiring a degree of physical activity should be kept to an absolute minimum or be avoided during the bed rest phase. Instead, such testing should be scheduled before and after bed rest. In this way countermeasure effects caused by testing procedures are minimised. However, if compelling scientific reasons exist, a trade-off will be made assessing the value of the procedure from a selected proposal in the context of the specific study.

While the subject number is not fully fixed at this time, it can be expected to be in the typical range of 8-12 subjects per group. Consequently, the investigators should ensure to pick such scientific questions that can be adequately addressed with 8 subjects.

5 Proposal Evaluation and Selection Procedures

An independent scientific merit (peer) review will perform the scientific evaluation, before ESA, supported by the concerned bed rest facility staff, undertake a technical and implementation feasibility evaluation.

5.1 Scientific Merit Review

Programme-compliant proposals submitted in response to this AO will undergo a scientific merit (peer) review. Only those proposals most highly rated in the merit review process will undergo the additional review for feasibility.
All of the following criteria will be used in determining the merit score:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field?

Approach: Are the theoretical framework, experimental design, data analysis and interpretation methods adequately developed, well integrated, and appropriate to the aims of the project? Is the proposal hypothesis-driven? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas?

Innovation: Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Personnel: Are the scientific personnel appropriately trained and well suited to carry out this work? Is the evidence of the personnel's productivity satisfactory? Are the functions and responsibilities of the team members adequately described and appropriate? Does the project employ useful collaborative arrangements?

Environment: Does the institutional environment, in which the work will be performed, contribute to the probability of success?

In the review, each proposal will receive a scientific merit score between 0 and 100 points. As a result of the scoring the proposals will receive one of the following marks:

- Outstanding 100 - 91 points
- Excellent 90 - 81 points
- Very Good 80 - 71 points
- Good to Fair 70 - 46 points
- Unacceptable 45 - 0 points

The scoring will be weighted according to the 5 sub-criteria:

- Significance 30%
- Approach 25%
- Innovation 20%
- Personnel 15%
- Environment 10%

The peer board will also evaluate the proposal's relevance to the bed rest setting. Again, scores between 0 – 100 will be given, resulting in a second mark.
Only proposals receiving a mark of "Very Good" or better for both, the scientific merit score as well as the bed rest relevance score, will proceed in the evaluation process.

5.2 Evaluation of Feasibility

For the most highly rated proposals following the peer review, a second evaluation will determine the feasibility of the proposed protocols. The assessment of feasibility refers to the extent as well as the adaptability of the proposed work, and how well it can be integrated into an overall study scheme. It will be in favour of the research proposal, which is being evaluated, if it utilises the measurements of BCD instead of proposing similar redundant protocols. Indeed, BCD will be performed in any case independent of any specific experiment selected. Proposed measurements should not interfere with or disturb the foreseen BCD. Flexibility in scheduling the additionally required measurements will also be of advantage. The tests required in addition to the BCD should ideally have a high "value for effort ratio", i.e. yield a maximum amount of valuable scientific data with as little technical effort and time constraints as possible.
The parties involved reserve the right to select only a part of a Science Team Coordinator's (STC) project if this portion is still of high scientific merit. The applicant will be given the choice to accept or decline such a partial opportunity.
The outcome of all these evaluation steps, with support by ESA's advisory bodies, will be used in the development of ESA's selection recommendation to its relevant Programme Board (PB-HME). The current aim is to propose the experiment selection to the PB-HME meeting in the May 2014 timeframe.
Thereafter an integrated protocol with the BCD measurements and the protocols from the selected experiments will have to be developed before being submitted to the institutional review board for final acceptance. This process is typically done using Investigator Working Group meetings and will start in the second half of 2014.

6 Data Rights

6.1 General

The general data policies of ESA's Directorate for Human Spaceflight and Operations will apply to all data resulting from the experiments in the context of this AO. The main relevant aspects, in their specific implementation for bed rest activities, are described in this and the following paragraphs.
Final results of the study shall be made available by the scientific teams to the scientific community through publication in appropriate journals or other established channels as soon as practicable and consistent with good scientific practice. In the event such reports or publications are copyrighted, ESA shall have a royalty-free right under the copyright to reproduce, distribute, and use such copyrighted work for their purposes.

6.2 Practical implementation of data policies

Three types of experiment data are identified:

Category 1 data will be obtained and processed under the responsibility of a Science Team Coordinator for the experiment protocol. Data not requested by any other STC may be used exclusively by the STC for scientific purposes. For data requested by more than one STC, each STC must agree before the study starts as to the conditions for the data usage for scientific purposes. This category of data shall be referred to as "STC proprietary data." The STC proprietary data may be used by the sponsoring agencies for internal purposes. The sponsoring agencies agree that this data will not be made public for 1 year after the completion of the study's clinical phase (last point of data collection in the ambulatory recovery period following the bed rest).

Category 2 data comprise BCD, as defined and owned by ESA. STCs can apply, and are even encouraged to use BCD. ESA, in consultation with the bed rest steering committee, will decide on the first publication rights for BCD. Scientific merit of the respective proposal and thematic relevance will be the key factors influencing the ranking.

There will also be common clinical data (**Category 3**) for usage by all STCs/STMs. This will be distributed to STCs.

In case follow-up points long after the bed rest per se are required for a project, a STC can apply for extension of the one-year exclusive publication period by submitting a scientific report in the format of a manuscript 1 year after the completion of the study's clinical phase.

6.3 Data Access

A STC can access proprietary data from other STCs participating in the study through a written data sharing agreement (signed by involved STCs). ESA will ensure that a data-sharing plan among the participating STCs is established prior to the beginning of the respective bed rest study.
All STC proprietary data and BCD will be treated as medical confidential information by the participants and ESA.

6.4 The Erasmus Experiment Archive (EEA)

The EEA is an ESA service to the international scientific community. Abstracts, from all European microgravity experiments performed to date are collected in this database. Experimenters sponsored by ESA have the obligation to provide these abstracts themselves. Special emphasis is placed on the completeness of the list of references of articles where the experiment results can be found.
The database includes a full-text search capability to retrieve information on experiments in a certain discipline, subject, mission, or by investigator name. The EEA covers both physical and life sciences, and can be found at the following URL:

http://eea.spaceflight.esa.int

This database includes also a large number of pictures, as well as video sequences documenting experiment abstracts.
Scientists in Europe who have performed experiments, be it in orbiting or ground- based facilities (drop-tube, drop-tower, parabolic flights, sounding rockets, Foton capsules, the Space Shuttle or the ISS), are urged to either provide an abstract on each of their experiments, or to provide information enabling the updating of their existing abstracts, in particular the list of articles published.
An abstract features the following contents:

- Mission Name and Date
- Team Members and Affiliations
- References
- Processing facility
- Experiment Objectives
- Experiment Procedure and Results
- Attachments

Please e-mail your new abstracts (in attachment) or the updated information for already existing abstracts to the EEA Curator.

6.5 Acknowledgement

Any publication on the results generated during bed rest studies solicited in this AO must acknowledge ESA's sponsorship of the study.

6.6 Support of Education and Outreach

The activities covered in this AO provide an opportunity for ESA to enhance and broaden the public's understanding and appreciation of research facilitated by ESA's Human Spaceflight and Operations Directorate.
Therefore the investigators of selected experiments are expected to promote and communicate their experiments to a wide audience (general public, colleagues, involvement of students) and to support ESA in the event of organised press conferences, educational events, publications etc.

7 Proposal Preparation Guide

7.1 Contact

For questions related to this Announcement of Opportunity please contact

Dr. Oliver Angerer
Tel. +31 855 607 603
Announcement specific email address: bedrest@esa.int

It is planned to organise a proposal workshop in connection to this research announcement on 11th of November 2013. The workshop will take place at ESTEC, Keplerlaan 1, Noordwijk, The Netherlands. This will be an opportunity to clarify potential questions or gather contacts for cooperative research projects. **Please indicate your interest in participating in this workshop to the abovementioned contact email, for planning, registration and logistical information distribution purposes, at the latest by 4th of November 2013.**

7.2 Time Schedule

Letter of Intent due:	4th of November 2013
Proposal workshop	11th of November 2013
Proposals due:	6th of January 2014

7.3 Letters of Intent

To facilitate timely proposal processing (e.g. organisation of peer review), potential investigators are requested to confirm their plans to submit a proposal in response to this announcement. The Letter of Intent (LoI) is not binding.
LoIs will be distributed to the participants of the proposal workshop to facilitate possible cooperations. This should be taken into account when formulating the LoI, e.g. by avoiding inclusion of unpublished data.
The LoI is requested by **4th of November 2013**. LoIs should be prepared using the template found on the AO website. LoIs should be submitted as PDF file to the email address

bedrest@esa.int

7.4 Proposals and Funding

Costs related to access to the bed rest facility and subjects are covered by ESA. However, ESA can not financially support the work of selected experimenters. Any additional expenses related to the proposed work of an experimenter, including costs for travel (e.g. to meetings) and subsistence, are considered investigator-related costs, which are not sponsored by ESA. Funding from national agencies / organisations, universities, or other institutions is required to cover investigator-related costs.
Due to the experience in recent years, ESA strongly advises STC/STMs to contact their national representatives (see ANNEX 2) to investigate possible national funding procedures and timelines as well as probability of funding in order to identify alternative funding sources if necessary. As a minimum it is recommended to submit the proposal to their national bodies in parallel with their application in response to this AO, in order to commence applying for national funding as early as possible.
If the proposed experiment is selected a proof of appropriate funding is mandatory before commencing implementation of the proposals.

7.5 Proposal Submission

For this research announcement it is foreseen to have exclusively electronic submission of proposals. The proposals must be received by Email by:

6th of January 2014

Proposals are to be sent to the following address:

bedrest@esa.int

All proposals to be uploaded must be contained in one single and non-protected pdf document, using the proposal template provided on the ESA bed rest AO website.
The proposal template covers the following material:

- Cover Page
- Project Description
- Management Approach
- Biographical Sketches
- Supporting Budgetary Information
- Ethics & Safety
- Experiment Data Sheet

7.5.1 Cover Page

Contact information of STC and STMs, and title of the project.

7.5.2 Project Description

The length of the Project Description section of the proposal should not exceed twenty (20) pages using regular (12 point) type. The proposal should contain sufficient detail to enable a reviewer to make informed judgments about the overall merit of the proposed research and the probability that the investigators will be able to accomplish their stated objectives. The proposal should clearly indicate the relationship between the proposed work and the research emphasis defined in this Announcement of Opportunity. The development of a clear hypothesis, along with the available data evidence, should be emphasized in this section.

7.5.3 Management Approach

Each proposal must specify a single Scientific Team Coordinator, who is responsible for carrying out the proposed project and coordinating the work of other personnel involved in the project. The scientific institution for which the coordinator of a proposal is working must be located in one of the ESA member or associated member states that contribute to the ELIPS Period 4: **Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Italy, The Netherlands, Norway, Romania, Sweden, Switzerland, United Kingdom.** Scientists from ESA Member States that do not contribute to the ELIPS Programme and scientists from other European countries having a cooperation agreement with ESA, are encouraged to enquire with their national space organisation about the conditions for their participation in proposals to ESA.

In proposals that designate several senior professionals as key participants in the research project, the management approach section should define the roles and responsibilities of each participant, and note the proportion of each individual's time to be devoted to the proposed research activity. The proposal should state clearly and unambiguously whether the key personnel have reviewed the proposal and endorsed their participation.

Despite the fact that cooperative research proposals are favoured, big clusters of research proposals are not welcome because of the difficulty for the peer reviewers to make their judgement and later on the difficulty of implementation with the other selected protocols.

The STC is the main ESA point of contact for a team and must participate in the conduct of the research. He/she is responsible for direct supervision of the work and efficient communication among STMs.

7.5.4 Biographical Sketches

A short curriculum vitae (not exceeding 3 pages) of the Science Team Coordinator, which includes her or his current position, title and educational background, list of principal publications (up to 20), and any exceptional qualifications should be included. Give similar biographical information on other senior professional personnel who will be directly associated with the project (STM). Universities should list students or other assistance involved, together with information as to their level of academic achievements. Any special industry-university cooperative arrangements should be described.

7.5.5 Supporting Budgetary Information

Please describe briefly the status of (co-)funding availability and/or applications.

7.5.6 Ethics & Safety

A statement from the proposal's institution is required which states that the proposed work will meet all local human subject requirements if applicable. A letter signed by the chairperson of the local Institutional Review Board (IRB) regarding approval of the experimental protocol and using human subjects, should be included with the proposal. In addition, the proposal must be compliant with applicable European laws and guidelines for human biomedical research. If due to the timing of IRB meetings a final approval letter should not be available by the proposal submission deadline, the ethics approval application status should be described. In those cases, the final approval letter needs to be provided after the deadline, in order for the experiment to be considered for implementation.
Safety hazards and assessments, including a description of possible hazardous situations for the test subjects, must be provided.

7.5.7 Experiment Data Sheet

Please fill the details of your experimental protocol in the Experiment Data Sheet form that is part of the Proposal template.

Annex 1: Bed Rest Core Data (BCD) and Data Collection Sessions

Measurement	Data collection sessions
Cardiovascular	
Plasma Volume	BDC: 1 fam test and 1 test HDT60*
Tilt test +LBNP	BDC: 1 fam test and 1 test (BDC-2*) R+0
VO2max	BDC: 1 test R+2
Muscle performance	
Isometric MVC	BDC: 1 fam test and 1 test R+0
Muscle fatigue test	BDC: 1 fam test and 1 test R+0
Nutrition	
Bodyweight	Daily
DEXA for body composition	Every 2 weeks
Bone	
Urinary DPD	As for pQCT
Urinary NTX&CTX	As for pQCT
Serum BAP&PINP	As for pQCT
Osteocalcin	As for pQCT
DEXA	At selection BDC: shortly before BR HDT: monthly R+: 1 test, post 1 and 2 years
Conventional pQCT	BDC: 1 test HDT 20, 40, 60 R+2 weeks, 4 weeks and on each follow-up visit
Neuro-vestibular	
MSQ: MSSQ- short RSQ If provocative CM as centrifuge	BDC: 1 test HDT: directly after vestibular provocative CM R+0, R+3
DGI	BDC: 1 test R+0, R+3, week 2
Posturography	BDC: 1 test R+0, R+3, week 2
Psychology	
Log of critical incidents	Anytime, when applicable
Device specific questions (acceptability of the CM)	Every week
POMS (Profile of Mood State): questionnaire	BDC-10, -4 HDT: every 2 weeks R+2, R+10
PANAS (Positive and Negative Affect Schedule): questionnaire	BDC-10, -4 HDT: every week R+2, R+10

BDI (Beck's depression Inventory without the item on suicide): questionnaire	HDT 40
Sleep assessment (Pittsburgh Sleep Diary): questionnaire	BDC-10, -4 HDT: every week R+2, R+10
GHQ (General Health Questionnaire)	BDC-10, -4 HDT: every week R+2, R+10

* Flexible date, ± 2 days
BDC- Before bed rest
HDT During bed rest
R+ After bed rest

Annex 2: National Points of Contact

First Name	Surname	Email	Address Part 1	Postal Code / Town	Country	Corp. Name Long Version	Phone Number	FAX Number
André	Peter	andre.peter@ffg.at	Sensengasse 1	1090 Vienna	Austria	Austrian Research Promotion Agency	+ 43 5 77 55 33 09	+43-57 75 59 33 09
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