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Travaux publics et Services gouvernementaux Canada
Place Bonaventure,
800 rue de la Gauchetière Ouest
Voir aux présentes - See herein
Montréal
Québec
H5A 1L6
FAX pour soumissions: (514) 496-3822

SOLICITATION AMENDMENT
MODIFICATION DE L'INVITATION

The referenced document is hereby revised; unless otherwise indicated, all other terms and conditions of the Solicitation remain the same.

Ce document est par la présente révisé; sauf indication contraire, les modalités de l'invitation demeurent les mêmes.

Comments - Commentaires

Title - Sujet Facilities for Inactivity study	
Solicitation No. - N° de l'invitation 9F008-190215/A	**Amendment No. - N° modif.** 002
Client Reference No. - N° de référence du client 9F008-190215	**Date** 2019-10-28
GETS Reference No. - N° de référence de SEAG PW-$MTB-130-15474	
File No. - N° de dossier MTB-9-42085 (130)	**CCC No./N° CCC - FMS No./N° VME**
Solicitation Closes - L'invitation prend fin **at - à 02:00 PM** **on - le 2019-11-05**	**Time Zone** **Fuseau horaire** Heure Normale du l'Est HNE
F.O.B. - F.A.B. **Plant-Usine:** ☐ **Destination:** ☑ **Other-Autre:** ☐	
Address Enquiries to: - Adresser toutes questions à: Caty, Mélanie	**Buyer Id - Id de l'acheteur** mtb130
Telephone No. - N° de téléphone (438) 340-1557 ( )	**FAX No. - N° de FAX** (514) 469-3822
Destination - of Goods, Services, and Construction: **Destination - des biens, services et construction:**	

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Delivery Required - Livraison exigée	**Delivery Offered - Livraison proposée**

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Name and title of person authorized to sign on behalf of Vendor/Firm (type or print)
Nom et titre de la personne autorisée à signer au nom du fournisseur/ de l'entrepreneur (taper ou écrire en caractères d'imprimerie)

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Amendment 002

This invitation is, hereby, modified as follow:

A. Bring the following changes to the RFP

1. Under Annex A - Statement of Work
Campaign description

Delete:

Data collection will occur before, during, and after the bed-rest campaign. It is acceptable for the facility to conduct the study using successive cohorts (the timeline example displays a potential of three cohorts). Intervention and control groups must be in the same cohorts. Staggered starting time within cohorts for **half** the participants may be needed within each cohort in order to accommodate the data collection performed by individual Principal Investigators (PI) from the 8 scientific teams collecting data to assess the effects of the exercise countermeasure.

Insert :

Data collection will occur before, during, and after the bed-rest campaign. It is acceptable for the facility to conduct the study using successive cohorts (the timeline example displays a potential of three cohorts). Intervention and control groups must be in the same cohorts. Staggered starting time within cohorts for the participants may be needed within each cohort in order to accommodate the data collection performed by individual Principal Investigators (PI) from the 8 scientific teams collecting data to assess the effects of the exercise countermeasure.

2. Under Annex C - Mandatory Technical Criteria, Point Rated Technical Criteria and Self-Evaluation
Table 1 – Mandatory Technical Criteria
M1 - *Proposal Submission*

Delete:

The Bidder must have the **best** rest facility located in Canada. He must confirm by providing the address in writing.

Insert :

The Bidder must have the **bed** rest facility located in Canada. He must confirm by providing the address in writing.

3. Under Annex C - Mandatory Technical Criteria, Point Rated Technical Criteria and Self-Evaluation
Table 2 – List of point rated technical criteria

Delete:

3.2. ***Corporate*** *Management Expertise and Approach*

Insert :

3.2. ***Project*** *Management Expertise and Approach*

4. **Under Annex C** - Mandatory Technical Criteria, Point Rated Technical Criteria and Self-Evaluation
   Appendix A – Technical Rated Criteria
   3.2 Project Management Experience and Approach (Max 8 points, min 4 points)

Delete:

D) Excellent: The Bidder's proposed project manager has sufficient experience in project management (more than 1 completed study) related to human research requiring recruitment of more than 8 participants, as well as project management experience with at least one study with multiple teams of investigators, invasive protocols, and magnetic resonance imaging. Methods2 for coordinating the work, and tracking and controlling the progress are provided and are correlated to the requirements of the bedrest study. **7 points**

Insert :

D) Excellent: The Bidder's proposed project manager has sufficient experience in project management (more than 1 completed study) related to human research requiring recruitment of more than 8 participants, as well as project management experience with at least one study with multiple teams of investigators, invasive protocols, and magnetic resonance imaging. Methods2 for coordinating the work, and tracking and controlling the progress are provided and are correlated to the requirements of the bedrest study. **8 points**

B. Share the following documents following the bidders` conference:

1- Bidders' Conference Minutes
2 - The slides covers the answers to questions that were raised prior to the bidders' conference and during.

All other terms and conditions remain unchanged

BIDDERS' CONFERENCE MINUTES

A. BACKGROUND

As stated under Part 2, section 2.7 of the *Request for Proposal* (RFP) document, all parties who intend to submit a proposal in response to the RFP were invited to attend a Bidder's Teleconference. This Teleconference presented as a good opportunity for any interested bidder to seek clarifications about the bid solicitation document.

The teleconference/WebEx was held as planned, on Thursday October 17 2019.

B. ATTENDEES

Approximately 6 people attended the session.

C. MINUTES OF THE MEETING

Introduction

Mélanie Caty first welcomed the participants and then followed by introducing himself as the PSPC Contracting Officer in charge of managing this procurement activity for CSA.

She introduced the representatives from PSPC and CSA that were present. She then informed all participants that the conference would be recorded. All participants were instructed to voice their objection before the start of the recording of the session, to not participate in the session and if they did participate, that it would automatically implies their consent to the recording.

Mélanie Caty carried on by informing all participants on the conduct and the agenda of the Bidder's conference. She also specified that there would be a question period at the end of the presentation and that we would write down all the Questions and Answers that would arise from the conference and those Q&As would be posted on www.buyandsell.gc.ca, in both languages, a few days after the event.

Presentation

A reading of the slides was done by the CSA's senior program scientist, focusing on the project's highlight, the high level bed-rest requirements, the contractor and science team main responsibilities and the key project milestones.

The Contracting Authority reiterated a few points to keep in mind when submitting the bid. We sre talking about the maximum funding that should not be exceeded, the explanation of Annex B-Basis of payment, the bidder's self-evaluation and the Annex C to meet the mandatory technical criteria and the point rated technical criteria.

Question Period

The slides covers the answers to questions that were raised prior to the bidders' conference and during. For purposes of clarity, questions and answers have been rephrased or summarised and some answers have been elaborated.

Agenda

- Project Highlights
- High level bed-rest requirements
- Key Project Milestones
- Contractor Main responsibilities
- Scientists Main Responsibilities
- Application process
- Submitted Questions
- Other questions

Project Highlights

- The Microgravity Research Activity (MRA): Understanding the Health impact of Inactivity- A bed rest study contract will provide the services and facilities necessary for the execution of a head-down tilt bed rest study, including the accommodation of research needs for the 8 scientific teams selected by the Canadian Institutes of Health Research (CIHR).

- CSA and the CIHR partner Institutes (Institute of Aging, Institute of Circulatory and Respiratory Health, and the Institute of Musculoskeletal Health and Arthritis) in collaboration with the Canadian Frailty Network are supporting this study to provide new knowledge on the process of aging, and determine the effectiveness of the exercise countermeasure to mitigate the health impacts associated with inactivity and weightlessness.

• High level bed-rest requirements

- 14 days of head down tilt (24 hr)
- Exercise countermeasure only
- Host 8 research teams funded by CIHR and Frailty Network
- Host working group workshop
- Recruitment of proper age group (55 to 65 years old)
- Integrated protocol including standard measures, and science performed by 8 teams
- Data collection will occur before, during, and after the bed-rest campaign.
- Possibility to conduct the study using successive cohorts of subjects

Contractor Main responsibilities

- Provide facilities, equipment, insurance coverage, volunteer recruitment and selection, and personnel to guarantee supervision and care of participants.
- Development of the integrated study protocol, Informed Consent Form, and submission and approval of study protocol to a research ethics board .
- Perform data collection, management and analysis of “Standard Measures” , and final reporting of the effectiveness of the countermeasure
- Accommodate data collection by the 8 science teams (ST) and provide them access to MRI, Dexa scans, etc. (cost charged to ST)
- Perform invasive procedures such as blood draws or biopsies for ST (cost charged to ST)

Science team main responsibilities

- Follow training and rules provided by the facility
- Provide to facility contractor the experiment data sheet
- Participate in person to investigator working group workshop
- Collect specific ST data except for invasive procedures
- Analyse data collected to their specific research including data provided under data sharing agreements
- Provide preliminary report on assessment of countermeasure efficacy to facility contractor for its final reporting
- Provide independent assessments of countermeasure efficacy (via publications)

Key Project Milestones

Item	Milestones Payments: Client Support section of the Statement of Work (SOW)
No.1	KICK OFF Meeting + minutes
No.2	Investigator Working Group Workshop
No.3	Study Protocol for the Ethics Submission
No.4	Approval of final study protocol by the Research Ethics Board
No.5	Mid-term review and report
No.6	Draft Final report
No.7	Final Report

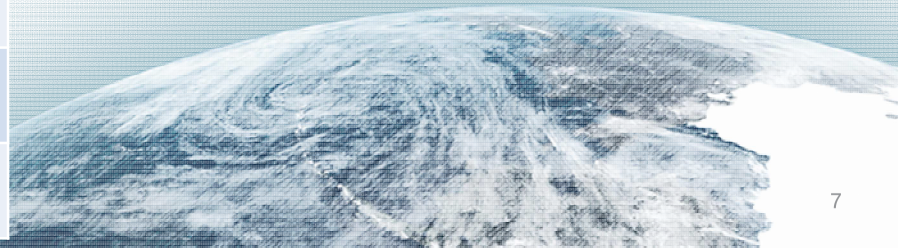
Maximum Funding

Item	Milestones Payments: Client Support section of the Statement of Work (SOW)	% of Total Firm Price	Firm Price $	Deadline for the Delivery date
No. 1	Kick off meeting + minutes	0.87%	*$_____	Contract award + 2 weeks
No. 2	Investigator Working Group Workshop	3.50%	*$_____	Contract award + 10 weeks
No. 3	Study protocol for the ethics submission	4.37%	*$_____	Contract award + 11 weeks
No. 4	Approval of final study protocol by the Research Ethics submission Board	36.16%	*$_____	Contract award + 23 weeks
No. 5	Mid-term assessment review and report	36.16%	*$_____	Contract award + 45 weeks
No. 6	Draft Final Report	18.09%	*$_____	Contract award + 65 weeks
No. 7	Final Report	0.85%	*$_____	Contract award + 76 weeks
TOTAL		100%	*$_____	

Maximum Funding
The budget available for the contract resulting from this bid solicitation is **$1 748 950**, all applicable taxes extra. Bids valued in excess of this amount will be considered non-responsive. This disclosure does not commit Canada to pay the maximum funding available.

Do Not Forget these documents when submitting the Bid:
Financial Bid**: Basis of Payment in Annex "B**

* All taxes applicable Extra
Technical Bid **: Mandatory Technical Criteria (Fill Table 1 in Annex C)**
: Point rated technical evaluation criteria (Annex C).



Application process

- Cost proposal
- Technical proposal
- Selection criteria

Submitted Questions

Q1

With regard to the test battery that will be performed on the participants and more specifically for the muscle biopsies (see brief justification below), the suggestion is to proceed with 2 participants per cohort for the bed rest phase of the protocol (14 days).

One of the measurements performed on the biopsies of the vastus lateralis muscle is mitochondrial function. The assessment of mitochondrial respiration and reactive oxygen species production need to be performed on fresh biopsy tissue as soon as possible after the biopsy. The duration of mitochondrial function measurement including tissue preparation for the measurement is a minimum 4-5 hours long. Hence, we can process a maximum of 2 subjects throughout the day. This is important as the tissue (muscle fibres) cannot be left for too long in the iced solution, which could potentially affect the measurement/data. In addition, the measurement should be performed by one technical person to avoid any discrepancies in the results. At the same time, these subjects would need to satisfy the requirement of the other protocols for which it is not feasible on the same day done in more than 1 subject at a time. For this reason, we propose to study cohorts of a maximum of three subjects at a time with a two-day interval between them. This implies that we would be able to study the 24 subjects in 8 cohorts of three, requiring each one month of stay, for a total time span of the study of 8 months.

Submitted Questions

A1 REVISED ANSWER:

The facility provider will be responsible to develop the integrated study protocol, in close collaboration with all eight individual science teams (section 3 of Annex A - Statement of work), in order to minimize study conflicts, respond to requirements by the Research Ethics Board, and to accommodate the logistical requirements (schedule requirements, for example). As indicated in the Annex A - Statement of Work, the entry of participants into each bed-rest campaign can be staggered (for example, two participants one day, two the next, two more the day after). This gives considerable flexibility with regards to design of the campaigns, as long as each campaign (cohort) has a minimum of 6 participants.

The following section of the Annex A - Statement of Work is pertinent: General Description –Campaign Description (p 3). Note that the pertinent sentence now reads, 'Staggered starting time within cohorts for the participants may be needed within each cohort in order to accommodate the data collection performed by individual Principal Investigators (PI) from the 8 scientific teams collecting data to assess the effects of the exercise countermeasure.'

The milestone table from the Request for Proposals is also pertinent. Specifically, note:

Milestone #5 (Mid-term assessment review and report); this milestone must be delivered after the first two cohorts (12 to 16 participants) have completed the study, and must be completed within 45 weeks after the contract award;

Milestone #6 (Draft Final Report); all data collection from the participants must be completed, and a draft final report submitted, within 65 weeks from the contract award.

If the staggering plan to perform the integrated protocol can accommodate this schedule, it is permissible.

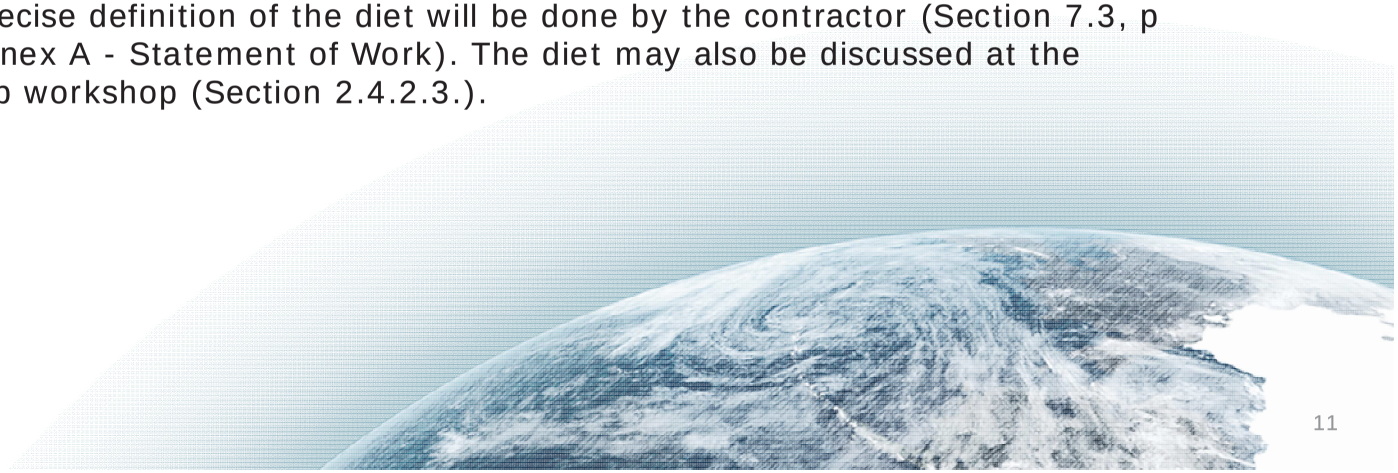
Submitted Questions

Q2

Will the exercise program and diet be defined at the AGTC meeting alongside the harmonization of the 8 study protocol?

A2

The exercise program is defined in Section 10 (pp 69-74) of Appendix 1 of the Annex A - Statement of Work. Diet guidelines are provided in Section 7 (pp 42-47) of Appendix 1 of the Annex A - Statement of Work. The precise definition of the diet will be done by the contractor (Section 7.3, p 46 of Appendix 1 of the Annex A - Statement of Work). The diet may also be discussed at the Investigator Working Group workshop (Section 2.4.2.3.).



Submitted Questions

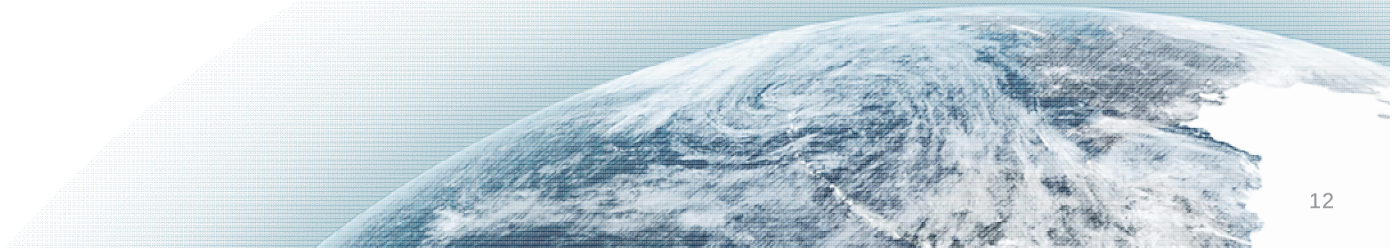
Q3

Is the provider responsible for hiring all the staff (e.g. study coordinator, physiotherapist, psychologist, MD)?

A3

REVISED ANSWER:

The provider is required to hire all staff needed to fulfill the staffing requirements defined in the Annex A - Statement of Work. Salaries will be paid by the provider. Provisions for staff salaries are to be included in the total price of each associated milestone.



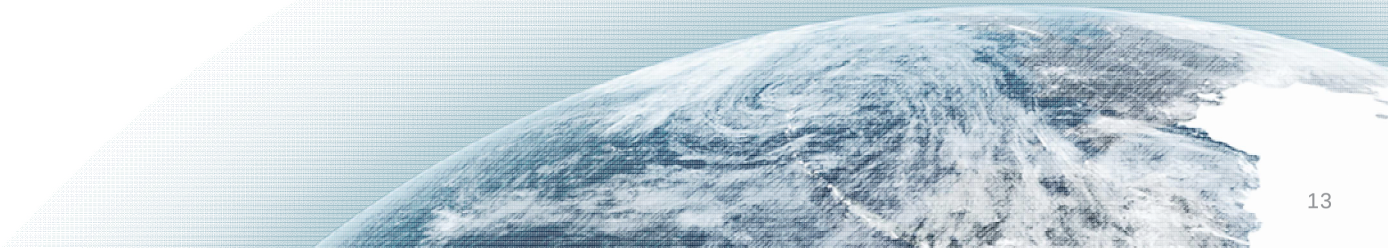
Submitted Questions

Q4

What are the responsibilities of the provider in terms of recruitment?

A4

REVISED ANSWER: Recruitment responsibilities are defined in section 4.1 of the Annex A - Statement Of Work. Note that the provider is responsible for all recruitment processes, including announcements in public media and screening of potential participants. Section 4 of the Annex A - Statement of Work defines the screening process. Additional discussion about criteria for recruitment can be done with the 8 scientific teams at the investigator working group workshop.



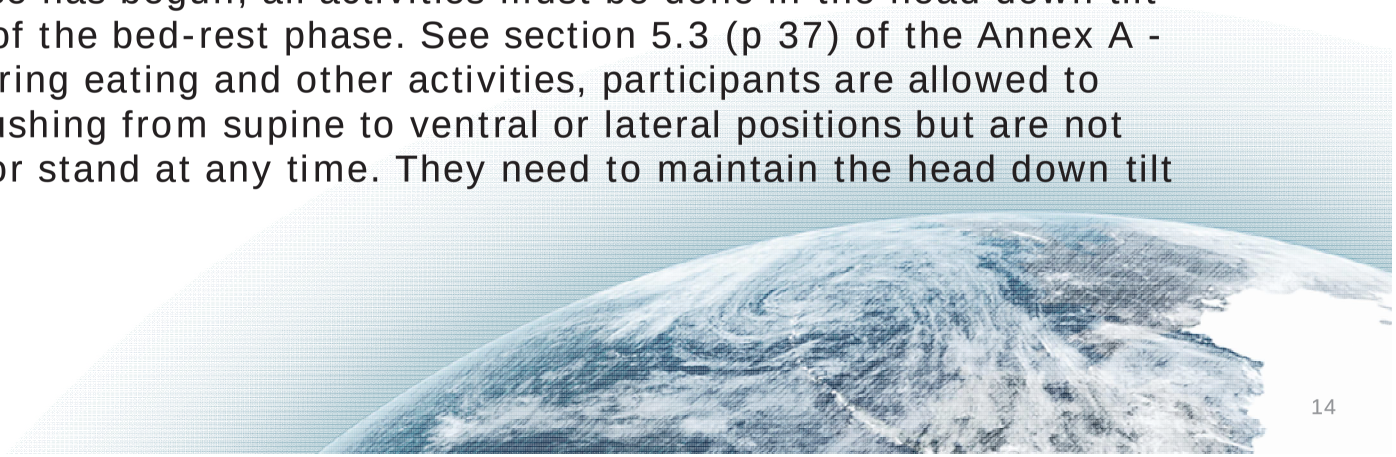
Submitted Questions

Q5

During the 2 weeks of bed rest, what is allowed to participants? Can they shower, pee and pass a bowel movement in the bathroom? During meals, can they raise their heads?

A5

Once the bed-rest phase has begun, all activities must be done in the head down tilt position, until the end of the bed-rest phase. See section 5.3 (p 37) of the Annex A - Statement of Work. During eating and other activities, participants are allowed to move slowly without pushing from supine to ventral or lateral positions but are not allowed to get up, sit, or stand at any time. They need to maintain the head down tilt position at all times.



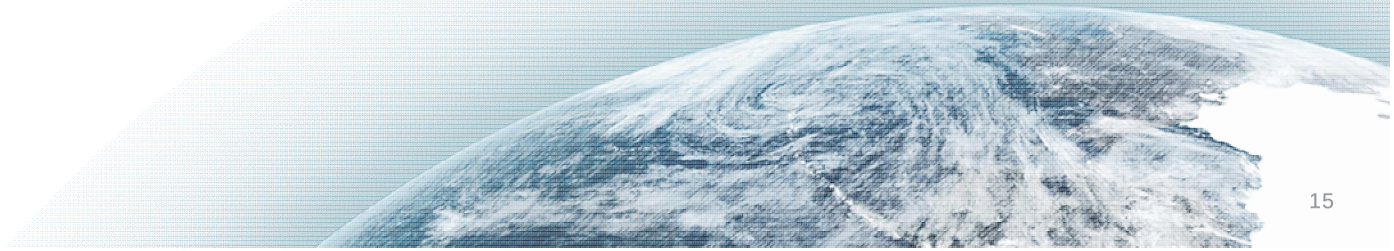
Submitted Questions

Q6

During night time, are cameras in the rooms enough to prove inactivity of the participants?

R6

This could be a solution to monitor the compliance with the inactivity requirement. However, it is stated in the Annex A - Statement of Work in section 2.2 (p 16) that there must be 24hr supervision of participants by a Registered nurse or nurse assistant during their participants' entire stay in the facility to monitor compliance of the subjects with the study requirements and provide support for the well-being of the participants.



Submitted Questions

Q7

Is the use of a curtain, or any other type of removable division, considered sufficient to respect the privacy of participants?

R7

Yes, a curtain or other movable divider can be used, as long as it can be displaced to allow socialising as stated in the Annex A – Statement of Work section 5.3 rules and conditions during the bed rest phase.