

## RCloud Tasking Form – Part B: Statement of Requirement (SoR)

<b>Title of Requirement</b>	<b>REDACTED</b>
<b>Requisition No.</b>	<b>1000167398</b>
<b>SoR Version</b>	<b>0.1</b>

<b>1.</b>	<b>Statement of Requirements</b>
<b>1.1</b>	<b>Summary and Background Information</b>
	<p><b>REDACTED</b> is investigating the stressors that influence the gut microbiome to identify if, and how, it can be manipulated to improve physical and cognitive performance. <b>REDACTED</b> wishes to understand:</p> <ol style="list-style-type: none"> <li>1) How changes in the human gut microbiota might influence and/or be linked to adopting a rigid and disciplined lifestyle <b>REDACTED</b></li> <li>2) How the human gut microbiota changes in response to physical and/or mental challenges, and identify any correlates of physical and cognitive performance.</li> </ol> <p>This work will inform future strategies and interventions aimed at manipulating an individuals' gut microbiome, to improve their performance and the resilience of their microbiome <b>REDACTED</b></p> <p>The human body plays host to, and exists in symbiosis with, a number of microbial communities, including those of the skin, lungs, the oral and vaginal mucosae and, most prominently, the gut (Nicholson et al., 2012). This relationship extends beyond simple commensalism to represent a major regulatory influence in health and disease. The gut microbiome also has a measurable impact on the brain, influencing stress, anxiety, depressive symptoms and social behaviour (Cryan and Dinan, 2012). It is not surprising therefore that changes in abundance of members of the faecal microbiota have been associated with numerous pathologies, including diabetes, hepatic diseases, inflammatory bowel disease, viral infections, autism and neurodegenerative disorders (Forslund et al., 2015; Ley et al., 2005; Manichanh et al., 2006; Turnbaugh et al., 2009; Qin et al., 2014; Monaco et al., 2016; Smith et al., 2013). However, a lack of reproducibility due to the complexities of these studies, has hampered the translation of microbiome research to the clinic. This has led to renewed interest in defining the boundaries of a healthy gut ecosystem and the identity of confounder effects.</p> <p>A range of studies have identified physical (age, sex and BMI), lifestyle (environment, diet, medication) and behaviour variables as major contributors to the established covariates of human microbiome variation (Falony et al., 2019). However, the significance of these covariates is questioned by the very nature and design of the studies and in particular, the inability to account for, or to control, different living conditions and environments and fluctuating lifestyles, diets, levels of physical and mental activity and stress etc. In addition, some of this work is also constrained and limited by a single sample and timepoint of analysis to demonstrate changes in gut microbe populations. The use of different methodologies and techniques applied to different microbiome</p>

	<p>studies to date also limits their usefulness and validation, and ability to compare data across different studies.</p> <p>We have taken the limitations in existing human cohort microbiome studies and considered these when designing the current project. This will be a cohort study to assess the impact key environmental and behaviour factors have on the gut microbiome. <b>REDACTED</b></p>
<p><b>1.2</b></p>	<p><b>Requirement</b></p>
	<p><b>Objective</b></p> <p>The requirement is to deliver a PhD project that investigates the impact of lifestyle and behaviour on the human gut microbiota in young adults. Specifically, the objectives are:</p> <ol style="list-style-type: none"> <li>1. To investigate how changes in the human gut microbiota might influence and/or be linked to adopting a rigid and disciplined lifestyle.</li> <li>2. To determine how the human gut microbiota changes in response to physical and/or mental challenges, and identify any correlates of physical and cognitive performance.</li> </ol> <p><b>Approach</b></p> <p>Phase 1: Recruit PhD student. The Supplier will be responsible for advertising the PhD opportunity and handling applications. Both <b>REDACTED</b> and the Supplier will be involved in reviewing and down-selecting promising applications and will support interviews of candidates. The final decision on the successful candidate will be made jointly by <b>REDACTED</b> and the Supplier. The Supplier will provide direct supervision to the successful PhD candidate; <b>REDACTED</b> will provide two additional external supervisors to support.</p> <p>Phase 2: Preparation of Trials Documentation and Seeking Ethical Approval. The student and Supplier will be responsible for acquiring favourable opinion of MODREC for all stages of the proposal, <b>REDACTED</b> will support where required. In the event that MODREC approval is not achieved, the Supplier and the student will be responsible for proposing and submitting an alternative protocol that addresses MODREC recommendations whilst still meeting the requirements of the Statement of Requirement.</p> <p>In parallel with the MoDREC process, the student will produce trials documentation to enable assurance of trial delivery. This must include a pilot run-through of the test-day procedures and data collection.</p> <p>Phase 3: Delivery of the trial following favourable opinion from MoDREC. On receipt of favourable ethical opinion from MODREC, the experimental studies can commence. The student will carry out the trial in accordance with the approved protocol. The student will be expected to have access to hardware / software to enable delivery of experimental volunteer trials of this nature through the association with the Supplier e.g. access to open access literature databases and journals for the literature review, access to data processing software (such as SPSS, R, Excel, Matlab). <b>REDACTED</b> will provide access to software to allow delivery of cognitive tests (e.g. standardised off-the-shelf test batteries administered by computer /</p>

tablets or programming software to programme standardised tests such as E-Prime, VBA, Python). **REDACTED**

**REDACTED** will lead and support the collection of psychological and physiological data, involving the PhD student as much as possible to support practical training in these data collection techniques.

The student will then write up the final deliverables in accordance with the deliverables schedule in Section 1.6.

### **Communication Plan**

Communications will involve a formal start up meeting with **REDACTED** and the Supplier via teleconference (TC) to agree roles and responsibilities, as well as finalise the project timeline. This start up meeting is to be held within 2 weeks of contract award (CA). The Supplier will provide a Record of Decisions (RODS) by email.

This will be followed by a PhD Initiation Meeting once a student has been recruited. The successful student is to hold a PhD Initiation Meeting with **REDACTED** and the Supplier via TC to present and agree the details of the PhD study and the format and structure of study outputs. The start-up meeting is to be held within 1 month of commencement of the PhD. The student will provide RODS by email.

In the first year there will be a monthly TC with **REDACTED** to provide a verbal update on progress, on completion of which the student will provide RODS by email. This will be attended by a minimum of one **REDACTED** representative, one representative from the Supplier and the student. In the second year, we will review the frequency of these meetings and potentially move to a bimonthly TC with a written update by email for the non-meeting months.

At the end of the project, a project closure meeting will be held via TC. It will be attended by **REDACTED**, the student and the Supplier within 2 months of the delivery of the final thesis.

### **Overview of the Study**

**REDACTED** will fund a full time PhD project to deliver the required study. **REDACTED** will work in partnership with the Supplier, as well as the **REDACTED** to deliver the study at **REDACTED**. This is a collaborative project and **REDACTED** will remain engaged and consulted on the technical direction throughout.

The delivery dates are dependent on the timing of **REDACTED** but the project will likely last 3.5 years.

**REDACTED** will be invited to participate in a longitudinal study, involving sampling (blood and stool) in parallel with the standardised training regimen. Standardised assessments of physical, cognitive and psychological performance will be part of the study.

The **REDACTED** lasts for 44-weeks and is broken down into three 14-week terms. Between each term, there are **REDACTED** (lasting between 1-2 weeks) followed by 2-3 weeks of leave.

Sampling will be at specific time-points throughout their 44-week training programme intervals targeting specific physical and mental challenges, which considers environmental factors specific to **REDACTED** training:

- Standardised diet;
- Sleep/wake regimen;
- Elevated stress;
- Joint living and training conditions;
- Completing specific training tests;
- **REDACTED**

In parallel with this, and when possible, additional measures will be taken to allow collection of the **REDACTED** baseline characterisation information, and subsequent objective and subjective evaluations of physical, cognitive and psychological performance. Including, standardised assessment of body composition (examples include: weight/height(body fat/lean muscle mass ratios; DEXA scans and bioelectric impedance analysis [BIA]) and an estimated level of physical fitness (standard multistage fitness test done in groups), computerised/tablet-based cognitive tests (working memory, attention and decision-making) and subjective measures (such as sleep & alertness, workload, perceived exertion, mood and anxiety, and depression), IQ, demographics and general well-being.

The number and intervals of data and sample collections (baseline and repeated measures) will be balanced against the logistics and practicalities of doing so, ensuring that normal training activities and the ability to complete the training course remain unaffected. A minimum of 6 samples is envisaged to include baseline measurements, prior to and after specific physical/mental challenges, and upon completion of each term).

As a proof-of-concept study that aims to generate hypotheses for future larger (multiple) cohort studies we have not undertaken a power calculation. However, a recruitment target of 60 study participants will allow us to develop, refine and validate study protocols which if successful, will allow us to consider extending the data collection period to include more participants.

### **International Research Collaboration**

Methods will be developed in collaboration with colleagues in **REDACTED**

### **Additional costs**

The proposal should include costs including bursary, bench fees (equipment and consumables) and supervisory fees.

### **Payment Plan**

Progress payment 1: end of PhD Year 1 - **REDACTED**

Progress payment 2: end of PhD Year 2 - **REDACTED**

Progress payment 3: end of PhD Year 3 - **REDACTED**

	<p>Milestone 1: PhD Thesis – on completion of PhD Year 3.5 - <b>REDACTED</b></p> <p><b>NOTE: Payment will be annually in arrears, and upon satisfactory completion of all deliverables at the end of each PhD Year.</b></p> <p><b><u>Additional Definitions</u></b></p> <p>“PHD Year” A consecutive twelve (12) Month period during the Term, commencing on the date that the Authority formally confirms approval of the student in writing</p> <p><b><u>Research Workers</u></b></p> <p>Supervisor - <b>REDACTED</b></p> <p>Student – To be advised</p> <p>Work will not commence until a student has been identified and security checks, where applicable, have been carried out and confirmed by the Authority. <b>REDACTED</b> reserves the right to terminate this contract in the event that a student is not identified or security checks successfully completed within a reasonable timeframe.</p> <p>Completion and acceptance of security checks is at the Authority’s sole discretion.</p>
<p><b>1.3</b></p>	<p><b>Options or follow on work</b> <i>(if none, write ‘Not applicable’)</i></p>
	<p>The Supplier are also to consider opportunities to embed <b>REDACTED</b> personnel in the experimental trials team to support data collection, analysis and reporting (subject to personnel receiving any required training for this role). This could range from shadowing a particular element of the data collection so that the team member could learn a new data collection technique, to being given full responsibility for aspects of the data collection, analysis and reporting. This will be dependent upon the skills of the individual and the requirement for capability development, the exact conditions must be agreed between the PhD Supervisory team and will be formally documented in terms of the responsibilities of each party. This will be done at no extra cost to the Supplier and the option would only be pursued if it did not impede on the learning, development and experiences of the PhD candidate, and did not create any conflict of interest with regard to supervision of the PhD.</p> <p>There is an additional option to support assessment of impact and exploitation activities. This could include demonstrations of the testing procedures, additional presentations to stakeholders, attendance and contribution to workshops or conferences, development of Impact Statements and Bulletins, and gathering feedback from stakeholders. Each activity would be agreed on a case-by-case basis between the <b>REDACTED</b> Technical Partner and Project Management team and the Supplier.</p> <p>The student is encouraged to publish work at relevant conferences and publications. Any publications or promotional material will require review by the <b>REDACTED</b> prior to submission to editors. Typically, this process takes about three weeks but it could take longer. It will assist the Permission to Publish process if evidence of supplier internal peer review is provided. <b>REDACTED</b> will be included as co-authors of any publications / presentations. <b>REDACTED</b> will not cover costs</p>

	for conference attendance to deliver such presentations, this should be covered by the student / Supplier.
<b>1.4</b>	<b>Contract Management Activities</b>
	Not Applicable
<b>1.5</b>	<b>Health &amp; Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement</b>
	All experimental work must be carried out under a MODREC protocol.

1.6 Deliverables & Intellectual Property Rights (IPR)						
Ref.	Title	Due by	Format	Expected classification (subject to change)	What information is required in the deliverable	IPR Condition
D - 1	Project output: MoDREC Protocol	<p>Protocol submitted to SAC within 6 months of the PhD Initiation Meeting.</p> <p>An advance copy of the protocol is to be passed to the <b>REDACTED</b> supervisor in sufficient time to allow early review, prior to submission to <b>REDACTED</b></p>	MoDREC template in Microsoft Word	Official	<ul style="list-style-type: none"> <li>MoDREC Protocol should contain all criteria laid out in JSP536 guidance</li> <li>The experimental protocol must be prepared and submitted to <b>REDACTED</b> for review and then subsequently submitted to the MODREC. A minimum of 3 months review time from submission to <b>REDACTED</b> should be allowed for this.</li> </ul> <p>MODREC submission should request permission to re-use anonymised data in future studies.</p>	Default RCloud Agreement Terms and Conditions shall apply

Official

D - 2	Project output: Letter of favourable opinion from MoDREC	Within 1 year from CA	PDF / Word Document	Official	As received from MODREC	Default RCloud Agreement Terms and Conditions shall apply
D - 3	Project output: Trials Documentation	Draft documents within 1 months of commencement of PhD. Version 1 of the documents within one month of MoDREC approval	Microsoft Word	Official	<ul style="list-style-type: none"> <li>This must include trials plan, risk assessment and Local Operating Procedures.</li> <li>The trials plan should articulate what the trial objectives are and how they should be met, including: method, dates, location, risk assessments, key roles and responsibilities, plans for management of change, the need for and personal protective equipment, emergency plan and incident reporting.</li> </ul> <p>Version 1 is defined as the first version that has been signed off by the responsible safety authority.</p>	Default RCloud Agreement Terms and Conditions shall apply
I - 1	Annual progress report	Annually (end of each PhD year)	Microsoft Word	Official	Report summarising the work carried out in-year. Exact contents to be agreed with the supervisory team prior to delivery.	Default RCloud Agreement Terms and Conditions shall apply

Official

D - 4	Formal Deliverable: Thesis	The final thesis should be delivered to <b>REDACTED</b> as submitted for examination and a final version of the thesis following examination (~6 months after passing the Viva voce).	Microsoft Word	Official	The format of the PhD thesis will be agreed by the supervisory team. The thesis should provide clear information on the application of any novel analysis techniques with enough open access information to allow other data analysts to replicate the analysis.	Default RCloud Agreement Terms and Conditions shall apply
D - 5	Formal Deliverable: Technical Summary Report	Within one month of student passing PhD examination or CA + 3.5 years	Microsoft Word	Official	<p>Report on the experimental trials to include method, results, conclusions and recommendations. Clear information on the application of any novel analysis techniques with enough open access information to allow other data analysts to replicate the analysis.</p> <p>Raw anonymised data files containing the data collected during the trial must also be provided electronically, in a format easily readable using commonly available tools.</p> <p>Additionally, if any novel methods of data collection and analysis are developed</p>	Default RCloud Agreement Terms and Conditions shall apply

Official

					<p>specifically as part of the study (e.g. to allow administration of cognitive or physiological tests, collection of questionnaire data through a tablet or automated analysis of any sort), the software, data files, source code, executable code, algorithms and any training needed to use these methods must be delivered to <b>REDACTED</b> for use on a standard standalone PC or tablet. The purpose of this is to enable <b>REDACTED</b> to re-use any methods that are developed for the specific project.</p>	
D - 6	Formal Deliverable: Final summary presentation	Within one month of student passing PhD examination or CA + 3.5 years, whichever is sooner	Microsoft Powerpoint	Official	Presentation to provide an overview of the PhD research	Default RCloud Agreement Terms and Conditions shall apply

<b>1.7</b>	<b>Deliverable Acceptance Criteria</b>
	<ul style="list-style-type: none"> <li>All Reports included as Deliverables under the Contract e.g. Progress and / or Final Reports etc. must comply with the <a href="#">Defence Research Reports Specification (DRRS)</a> which defines the requirements for the presentation, format and production of scientific and technical reports prepared for MOD. The exception to this is the Thesis deliverable, which must instead meet the existing requirements for theses as defined by the Supplier.</li> <li>Technical and final reports will be delivered in a Word Document and pdf by e-mail to address the research questions posed in the requirement and should include information / summary tables of any research reviewed for the literature reviews, the design of the research, the results, conclusions and any limitations of the research. The reports on the experimental work should include all relevant technical details of any hardware, software, process or system developed there under. The technical detail shall be sufficient to permit independent replication of the trial.</li> <li>Summary / Letter Report: The report should detail, document, and summarise the results of work done during the period covered and shall be in sufficient detail to comprehensively explain the results achieved; substantive performance; a description of current substantive performance and any problems encountered and/or which may exist along with proposed corrective action.</li> <li>Final Summary Presentation: Shall describe the entire work performed under the Contract in sufficient detail to explain comprehensively the work undertaken and results achieved.</li> <li>All Reports shall be free from spelling and grammatical errors and shall be set out in accordance with the Statement Of Requirement (1) above.</li> </ul> <p>Failure to comply with the above may result in the Authority rejecting the deliverables and requesting re-work before final acceptance.</p>

<b>2</b>	<b>Evaluation Criteria</b>	
2.1	Method Explanation	
	Evaluating this based on technical compliance and affordability.	
2.2	Technical Evaluation Criteria	
	Confirmation that the proposal fully meets the Authority's Statement of Requirement. Pass/Fail	
2.3	Commercial Evaluation Criteria	
	Tenderer has submitted a commercially compliant bid.	
	Firm priced version submitted within budget	Pass/Fail
	Labour rates and price as per rates uploaded to R Cloud	Pass/Fail

Official

	Completion of Research Workers Forms Completion of Statement Relating to Good Standing	Pass/Fail Pass/Fail
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