



## QUESTIONS AND ANSWERS

### Request for Proposal (RFP): Ethical, Social, Cultural, and Regulatory Considerations for Human Gut Microbiome-based interventions

#	Supplier Question	Wellcome response
1	What is the envisaged target audience of the report?	The intended target audience is a broad range of researchers and policymakers to inform future directions for research within gut microbiome interventions, areas for further ethical inquiry and potential policy changes in line with emerging findings.
2	One of the evaluation criteria is that the proposed methodology should be aligned with 'our needs'. What are these needs?	The needs to relate to how well the deliverables meet the stated research questions and aims articulated in the RfP (page 2-4).
3	Do you have an indicative budget in mind for this effort?	You should budget according to research needs and costs to meet the brief, in line with the scope of the work being proposed.
4	As it will help us scale our proposal to align with expectations, what is the target budget range for this project?	See response above (3).
5	Are you open to proposals to deliver on the requested scope in a shorter timeline than the timeframe indicated in the RFP?	Yes, so long as the deliverables meet appropriate standards of quality. Timelines should also consider cross-collaboration with any additional suppliers should more than one contractor be selected to complete the full scope of work.
6	In the budget area of the response, the RFP specifies that (section 6 on page 7) funds should be allocated to two senior academic consultants/senior research software engineers. Can Wellcome please provide more information on this, particularly in relation to the software engineer?	With apologies, this text is included in error. This section of the RfP should read as follows: Provide a detailed budget including all costs and expenses, specifying all day rates of individuals involved, the allocation of days between members of the team, and the cost of activities.
7	In the RFP response table, it says 'The budget must include allocation of funds for at least two senior academic consultants/senior research software engineers.' Is this indeed a requirement for this project, or is this text from the 'Sensors for Mental Health RFP' which is named in the same paragraph?	See response above (6).



<b>8</b>	What format would Wellcome like budget information in? We expect to provide a table but can also provide a narrative description (we understand this may be necessary based on the word count item).	The budget table should be included in the 300-word count. Feel free to include any accompanying narrative justification for expenses that may require further explanation.
<b>9</b>	For providers that only bid for one area of the RFP, will Wellcome facilitate collaboration between suppliers of each area?	Yes, Wellcome will facilitate collaboration between suppliers as needed.
<b>10</b>	Regulators are an important stakeholder in this space, although they may introduce real or perceived conflicts of interest in the study. In what ways does Wellcome expect regulators to engage in this study? Should they strictly be participants in the study, or is it acceptable to have regulators sit on expert panels, or partner in delivering this study?	Consultations with or participation of regulatory bodies and actors in this work would be appropriate and acceptable, as needed to meet the brief. Participation of all members who may hold conflicts of interests should be disclosed and managed in line with their role in the work. If primary interviews are being conducted with representatives of regulatory bodies, all standard human subjects research ethics protocols should be followed.
<b>11</b>	If we submit a proposal to complete the ethical, social, and cultural considerations, will we also need to specify 6–8 geographically varied national settings? Must the settings align with those selected for the regulatory science work package?	It is not necessary, but it could be helpful to identify specific geographies to elucidate contextualised considerations, ideally in alignment with at least some of the areas that are selected for the regulatory pathway analysis. As above, Wellcome will facilitate cross-collaboration as needed, and this can be discussed among selected suppliers.
<b>12</b>	Who will be responsible for planning activities for and facilitating the convening workshop to generate insights on the interplay between the two work packages?	Wellcome will be responsible for these activities.