



Request for Proposal (RFP) for Mucosal Vaccines Assays and Sampling Techniques Paper

About Wellcome and the Novo Nordisk Foundation

Wellcome is a politically and financially independent global charitable foundation. We support science to solve the urgent health challenges facing everyone. Wellcome supports discovery research into life, health and wellbeing, and is taking on three worldwide health challenges: mental health, climate and health and infectious diseases. In 2021, Wellcome established the Infectious Disease Health Challenge, whose vision is a world in which escalating infectious diseases are under control in communities most affected.

Established in Denmark in 1924, the Novo Nordisk Foundation is an enterprise foundation with philanthropic objectives. The vision of the Foundation is to improve people's health and the sustainability of society and the planet. The Foundation's mission is to progress research and innovation in the prevention and treatment of cardiometabolic and infectious diseases as well as to advance knowledge and solutions to support a green transformation of society.

Wellcome and the Novo Nordisk Foundation are co-commissioning this report on sampling techniques and assays to assess human mucosal immune responses, in mucosal tissues and associated lymphoid tissues.

1. RFP background and objectives

A major barrier to better understanding of human mucosal immune responses is the lack of consistency in sample collection methods and standardisation of assays amongst human studies. Given the clear knowledge gaps in this developing area, Wellcome and NNF would like to commission a focussed analysis on sample collection methods and assays in the human mucosal immunology and vaccine field with the following objectives:

Objective 1: To gain an understanding of human respiratory, enteric and genitourinary sampling methodologies that are currently used or in development to assess human mucosal immune responses and provide a critical evaluation of these methodologies

Objective 2: To review the Immunological assays used in scientific studies to investigate human mucosal immune responses for respiratory, enteric and genitourinary pathogens (infections and vaccines) and provide an analytical assessment of the quality of the data derived from current assays, their advantages and limitations.

Objective 3: To identify innovative approaches used in fields outside of vaccinology (such as asthma & allergy, autoimmunity) that could inform best practices for mucosal sampling and analysis.

Objective 4: To develop and prioritise a set of recommendations based on the reviews above highlighting knowledge gaps and actions centred around human mucosal sampling and assays.



The **goals** of the report are:

- To establish the baseline for human mucosal sampling and analysis in current use
- Develop recommendations and areas for future investment.

2. RFP Specification

This section sets out the specification of services for this RFP exercise. Suppliers should use this section to fully understand Wellcome and NNF's requirements and to inform their response.

We are interested in understanding the different sampling techniques and assays utilised in human (children and adult) scientific studies across the vaccine field especially for vaccines (mucosal and systemic) targeting respiratory, enteric and genitourinary pathogens.

We would therefore like to commission a report based on a literature review/landscape analysis and interviews with experts. The experts should be currently involved in developing and using assays and sampling techniques in vaccine development for respiratory, enteric and genitourinary pathogens.

We are interested in developing and prioritising a set of recommendations, strategies and actions which will aid in creating a uniform way of developing sampling and assays across the field. We would like to identify potential global stakeholders ideally positioned to play a role in the identified priority strategies and develop a Plan of Action for Engagement.

Part 1: Literature/Landscape Analysis

The study should include a comprehensive analysis of published and grey literature, studies and websites to investigate current methods of human airway, intestinal and genital tract sampling methodologies and assays used to study immune responses induced through either infection (natural or controlled) or vaccination. This would include innate and adaptive immune responses at mucosal surfaces. In addition, any data that establishes the relationship between systemic (blood) and mucosal responses should also be included.

The anticipated outcome would be a comprehensive overview and analysis of the current methods (incl. novel, innovative methods in development) of sampling and assay techniques used to measure mucosal immune responses (in response to controlled/natural infection and local/systemic immunisation) including a summary of the data derived and an analytical assessment of the quality of data produced to date.

It would be useful to gather information directly from experts currently involved in sampling and assay utilisation.

Part 2: Review and Development of Recommendations

The analysis conducted in Part 1 should identify knowledge gaps and action points within the field. With consideration of the current guidelines available by outside consortia and working groups (eg. WHO, FDA, EMA) if available, the study should conclude with a list of recommendations and an outline of the potential role global stakeholders, including Wellcome Trust and NNF, could play.

Part 3. actions



It would be valuable if the report could identify the key activities likely to promote consistency and standardisation in sampling and analysis techniques and build a better understanding of human mucosal immunity for respiratory, enteric and genitourinary pathogens, in the short, medium and longer term.

Of interest would be the identification of specific areas and/or interventions where stakeholders including Wellcome and NNF could assist and have impact.

Proposed methodology

As part of your response, we are interested in your proposed methodology, particularly:

- Methodology for literature search
- Selection of interviewees and suggested interview process
- Approach for analysis, including quantitative and qualitative approach
- Proposed changes or additions to the categories outlined above

Scope

We are interested in understanding the sampling and assay techniques process used in understanding mucosal immune responses including those which inform vaccine development for respiratory, enteric and genitourinary pathogens and developing recommendations on how Wellcome Trust and NNF can support the development of this field.

We use the term mucosal immunity but technically we consider this to also include deeper/submucosal local tissue sampling and potentially also sampling from locally adjacent lymphoid tissues.

Out of scope: The study will exclude the development of guidelines and best practice guidance on sampling and assay techniques.

Deliverables

- I) A peer reviewed journal article that will be published in an open access forum. The intended audience will be vaccine developers, researchers, regulators, and funders, Suppliers should include in their response to this RFP how they will create an informative, accessible and clear (including graphics) article.
- II) Slide deck summarising report findings including graphics and high-level summary.

3. RFP Timetable

#	Activity	Responsibility	Date
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1	RFP issue to Suppliers	WT	15 th January 2024
2	Submission of expression of interest to RFP via the following form	Supplier	16 th February 2024
3	Submission of Supplier Q&A to Wellcome & NNF	Supplier	16 th February 2024
4	Review of EoI's and shortlisting for full application	WT & NNF	19 th Feb – 1 st March
5	Return of Supplier Q&A to Suppliers and invitations for full applications	WT	1 st March
5	Submission of RFP Response and TPSRA2 form	Supplier	19 th March 2024
6	RFP Evaluation Period	WT & NNF	20 th March -12 th April 2024
7	Supplier Presentations	WT, NNF, Supplier	W/C 15 th April 2024
8	Notification of Contract Award	WT & NNF	Mid April 2024
9	Contract Negotiation	WT, NNF & Supplier	MidApril 2024
10	Contract Start Date	WT, NNF & Supplier	Mid April 2024

4. Response Format

The following headers support the timetable by providing further detail of the key steps.

Expression of Interest

Suppliers are asked to submit a short expression of interest via this [form](#).

We will review expressions of interest to ensure that proposals fit within the scope of the RFP. Where we are satisfied of this, we will invite organisations to submit a full proposal to the RFP in accordance with the RFP timetable. Please note that you should only submit a full proposal to the RFP if you have been invited to do so.

Submitting an EOI is not a binding commitment to submit a full proposal should your organisational priorities change, you will not then be penalised for future opportunities

Supplier Q&A

Prior to the submission of your RFP response, Suppliers are provided the opportunity to submit any questions they have about the exercise by the timeframe set out in the RFP Timetable above. All questions will be collated, anonymised, answered and returned to all Suppliers who have submitted an expression of interest in the RFP process.



Please make sure you ask all questions at this stage. Once Wellcome have responded to all questions If you have any additional questions after this deadline these will not be answered to ensure that this is a fair and equitable process.

5. RFP Response

Suppliers submitting a full proposal should cover the following areas in their response:

#	Question	Max pages
Team		
1	A brief overview of your organisation, including your track record and expertise relevant to analysis of the type outlined in this RFP as well as the diversity and inclusion considerations within your organisation. Please also include a brief description of who would be involved in the project team, their qualifications/experience and their main responsibilities.	1
2	What makes you best placed to fulfil Wellcome and NNF's requirements set out in this RFP?	1
Approach		
3	Your proposed approach to this work, including the proposed: <ul style="list-style-type: none"> • Methodology • Timeframes • Management plan, including role of team members • Plan for engagement with Wellcome and NNF during contract • Plan for production of final report, including copy editing, formatting and graphics • Diversity and inclusion planning (how you will ensure that: the literature reviewed, and interviews conducted will be inclusive to different groups of people and locations; your methodology does not introduce bias). 	6
4	Case studies of where you have successfully provided similar services to those described in this RFP	1
5	Highlight any risks you foresee in meeting the RFP requirements and any mitigation you will undertake	1
Costs		
6	Cost proposal detailing and justifying the proposed costs to meet our requirements including breakdown as necessary	1
Other		
7	Provide details of any existing restrictions that may impact your ability to meet Wellcome's and NNFs requirements. These should include (but not be limited to): <ul style="list-style-type: none"> • Conflicts of interest with other clients • Conflicts of interest with internal Wellcome and NNF staff • Restrictions on your licence to operate in certain jurisdictions 	1

Evaluation Criteria

Proposals will be assessed against the following criteria:

Methodology	<i>Quality:</i> Is the proposed methodology aligned with our objectives?	40%
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	<i>Utility:</i> Will the proposed methodology deliver the desired, credible, and useful results? <i>Diversity:</i> Does the proposed methodology promote positive research cultures? Is it ethical, engaged and inclusive?	
Team and experience	<i>Skills and Experience:</i> Does the applicant/s have the relevant skills, experience, and contextual understanding to deliver this work?	20%
Delivery and outputs	<i>Delivery plan:</i> Is the proposed delivery plan appropriate and achievable? <i>Feasibility:</i> How feasible is the delivery plan? Are there significant risks associated with the proposed timelines, and how well are they mitigated?	30%
Budget	<i>Value for Money:</i> Is the proposed work within budget and good value for money?	10%

Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. This is the suppliers' opportunity to provide negotiation points on Wellcome's terms and conditions, we will not consider negotiations that are only raised after the contract has been awarded so as not to delay the contracting process. Please ensure you engage with a relevant legal contact if applicable. Contract feedback is to be incorporated into your proposal as an annex and in the following format;

Clause #	Issue	Proposed Solution/Comment

Suppliers submitting proposals as a registered company should review Wellcome's Standard terms and Conditions [document](#).

Individuals submitting proposals as a sole trader (not registered) should review this [document](#).

Individuals submitting proposals through their own personal services company please highlight this to the Wellcome contact immediately (see point 6 below).

Information Governance

Wellcome is committed to upholding data protection principles and protecting your information. The [Wellcome-Privacy-Statement-2023.pdf](#) explains how, and on what legal basis, we collect, store, and use personal information about you. This includes any information you provide in relation to this proposal.

Under [GDPR/Data Protection law](#), Wellcome must keep a record of all personal information it is processing (i.e., collecting, using, and sharing). This record will be made available to the Information Commissioner's Office upon request.

This is Wellcome's record of data processing activities which meets GDPR article 30 requirements.



Suppliers will be asked to complete the [TPSRA2](#) assessment before presentation stage to assess how you handle data.

6. About Wellcome

Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we're taking on three worldwide health challenges: mental health, global heating and infectious diseases. Find out more about Wellcome and our work at: [wellcome.org](https://www.wellcome.org).

7. Non-Disclosure and Confidentiality

Prospective Suppliers should be aware that inappropriate publicity could have a serious effect upon Wellcome's business. The information contained within this document or subsequently made available to prospective suppliers is deemed confidential and must not be disclosed without the prior written consent of Wellcome unless required by law.

8. Prospective Suppliers Personnel - IR35 and Off Payroll Working Rules

Before the RFP response deadline, Prospective Suppliers must make the Wellcome Contact aware if they are intending to submit a proposal where the services will be provided by any individuals who are engaged by the Prospective Supplier via an intermediary i.e.

- Where the Prospective Supplier is an individual contracting through their own personal services company; or
- The Prospective Supplier is providing individuals engaged through intermediaries, for the purposes of the IR35 off-payroll working rules.

9. Independent Proposal

By submission of a proposal, prospective Suppliers warrant that the prices in the proposal have been arrived at independently, without consultation, communication, agreement or understanding for the purpose of restricting competition, as to any matter relating to such prices, with any other potential supplier or with any competitor.

10. Funding

For the avoidance of doubt, the output of this RFP exercise will be funded as a **Contract** and not as a Grant.

11. Costs Incurred by Prospective Suppliers

It should be noted that this document relates to a Request for Proposal only and not a firm commitment from Wellcome to enter into a contractual agreement. In addition, Wellcome will not be held responsible for any costs associated with the production of a response to this Request for Proposal.



12. Sustainability

Wellcome is committed to procuring sustainable, ethical and responsibly sourced materials, goods and services. This means Wellcome seeks to purchase goods and services that minimise negative and enhance positive impacts on the environment and society locally, regionally and globally. To ensure Wellcome's business is conducted ethically and sustainably, we expect our suppliers, and their supply chains, to adhere to these principles in a responsible manner.

13. Disability Confident

The Wellcome Trust is proud to be a Disability Confident Employer (DC Level 2) and we encourage all our partners and suppliers to do the same. More information about this can be found on the government website [Disability Confident employer scheme and guidance - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/guidance/disability-confident-employer-scheme). Disability Confident is creating a movement of change, encouraging employers to think differently about disability and take action to improve how they recruit, retain and develop disabled people.

14. Accessibility

Wellcome and NNF are committed to ensuring that our RFP exercises are accessible to everyone. If you have a disability or a chronic health condition, we can offer adjustments to the response format e.g. submitting your response in an alternate format. For support during the RFP exercise, contact the Wellcome Contact.

If, within the proposed outputs of this RFP exercise, specific adjustments are required by you or your team which incur additional cost then outline them clearly within your commercial response. Wellcome is committed to evaluating all proposals fairly and will ensure any proposed adjustment costs sit outside the commercial evaluation.

15. Diversity & Inclusion

Embracing [diversity and inclusion](#) is fundamental to delivering our mission to improve health, and we are committed to cultivating a fair and healthy environment for the people who work here and those we work with. As we learn more about barriers that disadvantage certain groups from progressing in our workplace, we will remove them.

Wellcome takes diversity and inclusion seriously, and we want to partner with suppliers who share our commitment. We may ask you questions related to D&I as part of our RFP processes.

16. Wellcome Contact Details

The single point of contact within this RFP exercise for all communications is as indicated below;



Name: Alyce O'Connor
Role: Procurement Officer
Email: RFP@Wellcome.org