



Request for Proposal (RFP) for Bioethics Horizon Scanning for Mental Health Research

1. RFP Background & Objectives

Summary

Pursuing mental health research gives rise to a myriad of ethics considerations and challenges. These range from the macro issues of setting priorities for MH research, to the appropriate design and review of different kinds of MH studies, to new questions emerging around novel technologies and experimental therapeutic options, as well as broad questions surrounding equity and respect in the investigations around pathophysiology/biopsychosocial drivers of MH and development and delivery of therapeutic interventions.

As Wellcome pursues an ambitious agenda in Mental Health to drive a step change in early intervention in anxiety, depression and psychosis—through research to improve **understanding** of aetiology & progression, develop effective **interventions**, and **stratify**/tailor therapeutic approaches—it will be important to proactively identify and attend to the inherent bioethics challenges in these research areas. This horizon scanning exercise will be the first step to map the wider range of MH bioethics challenges, and thus enable more in-depth bioethics research, analyses, and tool development that will advance the field.

Objectives

The MH Ethics Horizon Scan will provide a wide-ranging overview of key ethics issues that are central to advancing MH research addressing anxiety, depression, and psychosis. This should include issues that already present complexities in conducting studies on aetiology, pharmacological and non-pharmacological interventions, as well as those issues most likely to arise with novel approaches being pursued in the mental health space.

The key outputs will include:

- Identification and classification of key ethics issues relevant to MH research addressing anxiety, depression, and psychosis
 - Classification could include: relevance to areas of the MH portfolio (understanding, stratification, intervention); primary ethics issue(s); maturity of the issue (longstanding, current/new, emerging/future); salience and importance to people with lived experience, etc.
- Summary of current norms, frameworks, resources that exist in practice/the literature (*or analogous resources from other areas of health research that may attend to or be easily adapted to the MH research space*)
- Identification of issues where there are significant gaps, barriers, and/or major areas of contention in how to attend to ethical complexities in MH research. Identification of issues of the most importance to people with lived experience, and lived experience perspectives on the literature around these issues
- A prioritisation matrix that will enable identification of most urgent and important areas of bioethics research to support MH



The outcome will be a comprehensive stock-taking exercise that will enable Wellcome's MH and RE teams to prioritise future funds in developing a portfolio of bioethics work that attends to areas central to the mission of the MH health challenge area.

2. RFP Specification

Scope and Exclusions

The horizon scanning of bioethics issues in mental health research should align with the focus on the Mental Health challenge area, and therefore be limited to those that facilitate a step change in earlier and more effective intervention in anxiety, depression, and psychosis. While these conditions^{1[1]} are broadly defined (and include OCD, PTSD, schizophrenia, bipolar disorder, and post-partum psychosis), issues specifically arising in research on other mental health conditions should not be included in this horizon scan (e.g., substance misuse and addiction, eating disorders, neurodevelopmental disorders)

Some broad categories regarding the kinds of bioethics issues that this horizon scanning exercise should surface include (but are not limited to):

- **Classic ethics issues related to the conduct of clinical research** that have unique complexities or particularly nuanced considerations in the context of mental health research. For example:
 - o Issues related to autonomy, respect for persons, and self-determination interests, including in study inclusion/exclusion criteria, consent processes, and handling of acute states of mental ill health that arise during the conduct of the research study
 - o Fair subject selection, equity/bias in sampling and enrolment, disaggregated reporting of findings
 - o Privacy, confidentiality, and protection against stigma
 - o Post-trial access and scalability of novel interventions
 - o Research with paediatric and adolescent populations
- Issues related to mental health **research prioritisation and design**
 - o e.g., approaches to involving people with lived experience in agenda setting, prioritisation, and study design

¹ We recognise that there are a variety of terms to refer to mental ill health as well as specific conditions or mental states. For the purposes of this document, we have adopted "mental health conditions" as a way of being inclusive of perspectives that may not adopt or favour biomedical explanatory models or terminology. We also recognise that search terms used to conduct the bioethics horizon scanning may necessarily include the wider range of terminology that some may medicalising or stigmatising. We encourage suppliers be thoughtful about how they plan to use contested terms in the information gathering stages as well as in framing the bioethics issues in the final deliverables.



- Issues specific to studies on **aetiology, pathophysiology, and biopsychosocial drivers**. For example:
 - Issues arising with new neuroimaging techniques, genetic and epigenetic studies, and other biomarkers or predictors of mental ill health
 - Links between infectious diseases and anxiety, depression, or psychosis; the role of the microbiome; the role of inflammation
 - Equitable study accounting for sex differences/life-course approaches (e.g., role of hormonal changes and onset/course of MH conditions); intersectional approaches to understanding pathogenesis and progression
 - Implications of identifying and disclosing risk factors for future mental illness for identity, relationships, and other potential psychosocial harms
- Issues specific to **interventional studies and therapeutic approaches**, including:
 - New technologies (e.g., brain stimulation therapies & implants, VR-based CBT, chatbots); Psychedelics and alternative substances
 - Potential challenges with stratification, differentiated care pathways, personalised medicine
 - Scalability & equitable access and uptake of interventions in the pipeline, in light of health system constraints and provider supply issues, including lack of diversity among providers
 - Discontinuation of pharmacological interventions

Deliverables and Timelines

- A broad cataloguing of bioethics issues related to MH research on anxiety, depression & psychosis, with key research questions outlined and highlights of any existing research, frameworks or tools that address the issue (9 months).
- An interim report on findings, including emerging and/or salient high-priority areas for further bioethics research. (5 months)
- A matrix tool of the issues that highlights critical areas for further bioethics research based on urgency, importance, current gaps, conceptual debate, expressed views of people with lived experience, and other relevant factors (preliminary review of tool at 5 months; final populated tool at 9 months)
- A high-level summary document and/or graphics to communicate findings with internal and external audiences (9 months)

The work will cover a period of up to nine months, though we are happy to consider shorter timelines.

Details requested in the Proposal

- Detailed methodology outlining the approach for surfacing bioethics issues from relevant information sources (e.g., literature, meetings & conferences, clinical trial registries, provider and patient networks, social media, expert consults, etc.) and proposed approach to organising issues by sub-themes
- A proposed set of priority-setting criteria and plans for assessing surfaced bioethics issues against those criteria



- A proposed plan of how people with lived experience will be involved in the design, delivery and governance of this project
- Details on how you plan to address issues of bias and inequity in many existing data sources, including how you plan to include perspectives of minoritised groups and experience from LMICs
- A breakdown of costs, including the estimated time required to complete the deliverables

All deliverables must be made available under the Creative Commons Attribution licence (CC-BY).

Suppliers should request the appropriate budget needed to deliver the required outputs over a period of 9 months. Payments will be linked to deliverables which will be agreed with the supplier.

Involvement of lived experience is considered an essential part of Wellcome-funded projects, and we would expect our Supplier to embed people with lived experience expertise of anxiety, depression or psychosis in the design, implementation and/or dissemination of the work².

3. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	24/10/2022
2	Submission of expression of interest* to RFP and submission of Supplier Q&A <i>*Please note that suppliers who do not submit an expression of interest can still submit a full proposal by the deadline date. However, no questions will be answered that were not submitted by the EOI deadline</i>	Supplier	04/11/2022
4	Return of Supplier Q&A to Suppliers	WT	11/11/2022
5	Submission of RFP Response	Supplier	05/12/2022
6	RFP Evaluation Period	WT	07/12/2022-21/12/2022
7	Supplier Presentations	Supplier	w/c 09/01/2023
8	Notification of Contract Award	WT	January 2023
9	Contract Negotiation	WT & Supplier	January/February 2023
10	Contract Start Date	WT & Supplier	February 2023

² For more on lived experience involvement in Wellcome's mental health work, see <https://wellcome.org/news/lets-talk-about-lived-experiences-mental-health-challenges> and <https://youtube.com/playlist?list=PLSKM2Zm6MngIRHU5mJRD3M5G3i4HbCYaR>



4. Response Format

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

Expression of Interest

Suppliers are asked to send in a short expression of their intent to submit a proposal by e-mail to the Wellcome Contact in accordance with the RFP timetable. Please include:

- Confirming whether you are a company or individual, if company please provide full company name, address, and company registration number.
- A non-binding cost estimate as a single figure in GBP.

The date provided for this 'expression of interest' is suggested to aid in our planning purposes, but those who miss this date may still provide a note of interest and submit a full proposal. However, any questions must be submitted by the deadline in the RFP timetable.

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 and the activity. All questions will be collated, anonymised, answered and returned to all Suppliers who have submitted an expression of interest in the RFP process as well as posted online. 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.

RFP Proposal

Suppliers are required to submit proposals which respond to the following sections;

Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. 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 this [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 7 below).

Information Governance

Suppliers are asked to complete the [TPSRA2](#) assessment before the RFP submission deadline for Wellcome to assess how you handle data.

RFP Questions

This section requests responses from Suppliers specific questions in relation to this RFP exercise.

#	Question	Max
1	Provide a short proposal outlining how you would approach the work and the proposed methodology, including h outlining the approach for surfacing bioethics issues from relevant information sources (e.g., literature, meetings & conferences, clinical trial registries, provider and patient networks, social media, expert consults, etc.) and proposed approach to organising issues by sub-themes. Please also include a proposed set of priority-setting criteria and plans for assessing surfaced bioethics issues against those criteria as well as a proposed plan of how people with lived experience will be involved in the design, delivery and governance of this project.	1000 words
2	Provide a proposed delivery plan outlining the project deliverables and timelines	250 words
3	Outline the proposed project team with a brief description of their relevant experience	250 words
4	Outline your approach to equality, diversity and inclusion, both in relation to your proposed methodology for the project, and within your organisation (this includes details on how you plan to address issues of bias and inequity in many existing data sources, and how you plan to include perspectives of minoritised groups and experience from LMICs)	250 words
5	Describe your approach to collaborating and communicating with the Research Environment team at Wellcome to ensure deliverables align with organisational needs	250 words
6	Provide a cost proposal which details and justifies the proposed costs to meet our requirement	250 words



7	What makes you best placed to fulfil Wellcome’s requirements set out within this request? This could include networks, previous experience etc	250 words
8	Outline any major risks and challenges you foresee with meeting Wellcome’s requirements, including engaging with researchers across a large geographical area, adapting to Covid-19 restrictions as they arise, and staying within budget. Please include your mitigation strategies for these risk and challenges.	250 words
9	Provide 2-case studies of where you have successfully provided services similar to those described in this RFP	500 words

Proposals will be assessed against the following criteria:

Methodology	<i>Quality:</i> Does the proposed methodology align with our objectives? <i>Utility:</i> Will the proposed methodology deliver the desired, credible, and useful results?	45%
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?	20%
Budget	<i>Value for Money:</i> Is the proposed work within budget and good value for money?	10%
Risk Management	<i>Identifying and Mitigating Risks:</i> Are there significant risks to completing the proposed work, and how well are they mitigated?	5%

5. About Wellcome

Wellcome improves health for everyone by funding research, leading policy and advocacy campaigns, and building global partnerships. Collaborative research that involves a diverse range of people from different fields of interest is key to progress in health science – and to achieving our aim of fostering a healthier, happier, world. We’re taking on the biggest health challenges facing humanity – climate and health, infectious disease, and mental health – to find urgent solutions and accelerate preventions. Find out more about Wellcome and our work at: [wellcome.org](https://www.wellcome.org).

6. 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.

7. 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.

8. 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.

9. Funding

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

10. 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.

11. 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.

12. 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.

13. Accessibility

Wellcome is 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.

14. 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.

15. Wellcome Contact Details

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

Name: Olivia Donovan
Role: Procurement Officer
Email: RFP@wellcome.org