

# Case study: Mental Health at Wellcome

## 1. Background

Mental Health at Wellcome aims to lead a step change in early intervention for anxiety, depression and psychosis. To do this involves considering how the brain, body and environment interact in mental health problems; understanding how interventions work and enabling connections and shared metrics across the full breadth of the Mental Health science community, including drawing on the expertise of those with lived experience of mental health problems.

More information on Mental Health at Wellcome is at <https://wellcome.org/our-priorities/mental-health>

## 2. Funding call selected as the basis for the INFORM work

*'Mental Health Award: Accelerating scalable digital mental health interventions'*

The call link is: <https://wellcome.org/research-funding/schemes/mental-health-award-accelerating-scalable-digital-mental-health>

Although Wellcome's challenge-led funding calls are customised for each topic, they typically follow a similar overall pattern to the *'Mental Health Award: Accelerating scalable digital mental health interventions'*. However, given that there are differences between calls, it should be remembered that this case study focuses on this call rather than all Wellcome calls.

This call funded research to evaluate and further develop scalable digital interventions to advance early intervention in depression, anxiety and psychosis. This call was open when INFORM discussions started, and randomised trials were funded by the call. It provided a good model for Wellcome's approach to future trial funding calls in mental health, as well as other clinical areas.

## 3. Package of materials used in this call

The materials and resources connected to the call are given in Table 1 below.

| Document | Description | Link |
|----------|-------------|------|
|----------|-------------|------|

|                                                                                                                 |                                                                                                                                                                                                                                                          |                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Pre-launch scheme page                                                                                          | Short form of the scheme page to announce that the call is coming, high level info on remit and eligibility                                                                                                                                              |                                                                                                                     |
| Funding call webpage*                                                                                           | Gives a full overview of the scope of the funding call and eligibility criteria                                                                                                                                                                          | <a href="#">Mental Health Award: Accelerating scalable digital mental health interventions - Funding   Wellcome</a> |
| Timeline for the call*                                                                                          | Timeline for call from launch to final decision. Can give a more granular timeline if needed e.g. time for committee review                                                                                                                              | Linked on scheme page                                                                                               |
| Info webinars                                                                                                   | Webinars that give information on the funding scheme and opportunity for potential applicants to ask questions                                                                                                                                           | Linked on the scheme page                                                                                           |
| Networking events                                                                                               | Targeted at companies developing digital mental health interventions, opportunity for networking and promoting the funding                                                                                                                               | Linked on the scheme page                                                                                           |
| Application form*                                                                                               | 2024 version of the Wellcome application form that was used for the funding call                                                                                                                                                                         | <a href="#">DA full</a> linked on the scheme page                                                                   |
| Committee briefing - shortlisting (external committee to shortlist applications to take forward for interview)* | An online briefing took place with the shortlisting committee a few weeks prior to the shortlisting committee meeting. Slides were presented and a guidance document sent to the committee. The briefing was recorded and sent to all committee members. | Digital Shortlisting Committee briefing.pptx<br><br>Shortlisting Committee Guide Digital.pdf                        |

**Table 1** The materials and resources connected to the Mental Health Award: Accelerating scalable digital mental health interventions call. The starred (\*) items are the ones considered by INFORM. While INFORM had access to committee briefing materials, these are confidential and cannot be shared publicly.

#### 4. What INFORM discussed with Wellcome

Wellcome provided the INFORM team with all the starred items listed in Table 1. The items that are not starred did not influence the work presented here.

When looking through materials The INFORM team had in mind the findings of our literature review [1], content analysis [2], interview study [3] and the 12 good practice actions that came from our mapping exercise [4].

##### Funding call webpage

The funding call webpage was able to fund trials but was not a trial-specific call. The guidance was therefore general enough to support different study designs. Many of the 12 INFORM good practice actions were mentioned multiple times, although in some cases the guidance could have been made a bit more concrete. An annotated version of the

web-based guidance that references INFORM good practice items is given in Supplementary file 1.

### **Timeline**

The timeline was given on the scheme page; the time between the call opening and the submission deadline was around 4.5 months. Wellcome also scheduled information and networking webinars to support applicants.

### **Application form**

Wellcome's application forms are designed to accommodate a wide range of study designs within a single funding scheme, providing flexibility and consistency across funding decisions. Although not trial-specific, the forms capture both scientific and scheme-specific considerations, and show strong alignment with INFORM good practice recommendations. An annotated version of the Wellcome form that also references INFORM good practice items is given in Supplementary file 2.

### **Committee briefing**

Note: The Committee briefing materials we reviewed were tailored for the *Mental Health Award: Accelerating scalable digital mental health interventions* call.

Wellcome produced a comprehensive guide for the funding committee members. The committee meeting had an independent chair who facilitated discussion but did not score grant applications. Each proposal had three lead reviewers, one of whom was a lived experience advisor as well as three more designated scorers. This means each proposal was scored by six members of the funding committee, as well as being discussed by the full membership. There were clear rules about conflicts of interest.

While the INFORM team had access to committee briefing materials, Wellcome considers these confidential and cannot be shared publicly.

The committee were asked to consider four criteria when scoring:

1. The proposed methodology, the potential for scalability and sustainable impact (40%)
2. Suitability and expertise of the team (20%)
3. Lived experience involvement (20%)
4. Suitability of research location and approach to research environment (20%)

The committee briefing gave comprehensive guidance on how to score each of these four criteria. Each of the four criteria is scored on a scale from 1 (Not fundable) to 4 (Outstanding), with guidance against each of the four scores.

## **5. Changes suggested to the Wellcome process for future mental health funding calls**

The principle change proposed was to make Wellcome's forms more trial specific drawing on the INFORM structured grant form for trials as a basis of the changes.

### **The INFORM structured grant form for trials**

Funders provide potential grant applicants with a lot of information, as Table 1 shows for Wellcome. However, the only part of the support process that all applicants *must* comprehensively engage with is the grant application form, which makes its role in improving the future informativeness of trials central to INFORM.

One of INFORM's good practice actions (D4; see [https://www.trialforge.org/inform\\_action\\_4/](https://www.trialforge.org/inform_action_4/)) is to make use of structured design tools, established frameworks, and Open Science practices to improve trial quality, transparency and reproducibility. Examples given in INFORM D4 include SPIRIT, a protocol reporting standard (<https://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>), COMET, an initiative that support core outcomes in trials (<https://www.comet-initiative.org/>), and trial preregistration to improve transparency.

This INFORM finding led to designing a grant application form for trials that is structured around SPIRIT, the protocol reporting standard. The form can be downloaded at <https://www.trialforge.org/wp-content/uploads/2026/04/Grant-form-6-3-2026.docx>.

To develop the form the INFORM team took SPIRIT and cross-checked it with INFORM's 12 good practice actions [4], themselves a result of mapping across our literature review [1], content analysis [2] and interviews [3]. Many of the SPIRIT questions directly matched the requirements of the 12 good practice actions. Where an INFORM finding was missing,

we added a question, or modified guidance to a question to make the INFORM requirements more explicit.

The INFORM Structured Grant Form for Trials

([https://www.trialforge.org/structured\\_grant\\_form/](https://www.trialforge.org/structured_grant_form/)) has 34 questions covering topics such as the rationale for the trial, who the participants are, patient and public involvement, intervention and comparison descriptions, how outcomes were selected, recruitment and retention, analysis, oversight and data sharing. The current form is version 1 because we do anticipate changes over time as more experience is gained from its use, or new evidence comes to light around how to improve the likelihood of an informative trial.

## **6. The changes Wellcome introduced**

The INFORM grant form was used to make changes to questions on the existing Wellcome grant form for studies involving human participants.

Wellcome compared the INFORM structured form to their own and found that the majority of questions were covered; the task was to make those questions clearer by using the INFORM grant form text. For example, there was one existing longer question that covered many aspects of trial design and one question that asked about recruitment. These questions were identified as areas that could be strengthened to give greater clarity on what information is required. Wellcome therefore proposed five key questions on research design in light of the INFORM work. An important thing to note is that the questions needed to be suitable for all research involving human participants.

Some of the changes were minor, for example modifications to how a question was asked to bring an INFORM finding more explicitly into the Wellcome form. Other changes were more substantial, such as adding a new piece of text to make a specific request for additional information. An example of the latter is to explicitly ask who in the team provides the analysis expertise. These changes were discussed within the INFORM team. The final version of the Wellcome five questions and subquestions together asked 19 of the 34 questions on the INFORM structured grant form. An additional 4 of the 34 INFORM questions unrelated to design were also already on the Wellcome form. The five Wellcome questions, together with the reference to the INFORM Structured Grant Form for Trials question numbers are given in Supplementary file 3.

Other sections of the existing Wellcome grant form already asked 5 of the remaining INFORM questions, for example regarding dissemination and ethical approvals. In total the modified Wellcome grant form asked 24 of the 34 INFORM structured grant form questions despite the Wellcome form remaining largely as it was.

Changes to the assessment criteria and committee guidance have been suggested to align with the changes to the Wellcome application form. Wellcome is considering how these recommendations could be integrated into assessment criteria and guidance to committee members. The suggested changes are summarised in Table 2.

| Key features of suggested modifications to guidance for Wellcome committee members                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <ul style="list-style-type: none"><li>• More explicit reference to reviewing who is to be included in the study</li><li>• Guidance to ensure there is a clear demonstration that the study team has the methodological and statistical competence to design, deliver and analyse the study.</li><li>• Extra emphasis on reviewing why the selected outcomes, especially the primary, were chosen.</li><li>• More explicit requirement to review the justification for non-primary outcomes.</li><li>• Extra emphasis on ensuring that the study has been future-proofed, especially where technology is concerned.</li><li>• Extra emphasis of reviewing the recruitment, content and retention processes, and whether the feasibility of these has been demonstrated.</li><li>• More explicit reference to review plans for external oversight.</li></ul> |

**Table 2** Summary of assessment criteria and committee guidance changes suggested to Wellcome.

## 7. Introduction of the changes by Wellcome

The grant form changes will be introduced to the Wellcome application forms in August 2026. Wellcome is currently considering how the impact of these changes could be evaluated.

## 8. Summary

Wellcome demonstrated its commitment to funding the most informative and impactful research by implementing key improvements identified through INFORM, further

strengthening an already robust application and review process. In other words, even where constraints exist, it is entirely possible to make changes that can be expected to lead to trials that are more likely to be informative.

## References

1. Prowse S, Treweek S, Brazzelli M, Bruhn H. Improving trial informativeness: A rapid review of global research on how to ensure trials are useful. *Journal of Evaluation in Clinical Practice*, 2025; 31:e70147. <https://doi.org/10.1111/jep.70147>.
2. Prowse S, Brazzelli M, Bruhn H, Treweek S. Do Funders, Regulators, and Ethics Bodies Support Informative Trials? A Content Analysis of Global Guidance Documents. *J. Evaluation in Clinical Practice* 2026, 32: 1. <https://doi.org/10.1111/jep.70356>
3. Prowse SR, Brazzelli M, Green HR, Treweek S. International Stakeholder Guidance for Improving Informativeness of Randomized Clinical Trials. *JAMA Netw Open*. 2026 Jun 1;9(6):e2619487. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2850562> [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=5905842](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5905842)
4. Prowse SR, Brazzelli M, Bain J, Treweek S. Trial informativeness across research practices: Initial findings from a mapping exercise. *Journal of Clinical Epidemiology* 2026, <https://doi.org/10.1016/j.jclinepi.2026.112274> .

## Supplementary documents

1. An annotated version of the web-based guidance that references INFORM good practice items.
2. An annotated version of the Wellcome form that also references INFORM good practice items.
3. The five Wellcome questions, together with the reference to the INFORM Structured Grant Form for Trials question numbers.