

Themed call for expressions of interest in the area of pandemic influenza

Specification document

Introduction

As part of the collaborative effort into research concerning pandemic flu with MRC and Wellcome, the Director General for Research and Development at the Department of Health has asked the National Institute for Health Research to undertake a themed call for research that will inform policy and patient care in the current influenza pandemic. This call is being managed by the NIHR Evaluation, Trials, and Studies Coordinating Centre. It is limited to research that will have rapid practical benefit to the NHS and to NHS patients.

Remit of this Call

The main focus of this call is the prevention, diagnosis or immediate management of patients with H1N1 swine influenza or its complications during the pandemic. This includes behavioural, prognostic, therapeutic, organisational and other research. The setting may be community or hospital care.

Only research which will produce evidence to guide clinical and public health policy during the current pandemic will be considered.

Expressions of interest invited

Short expressions of interest (on an application form) are invited. These should briefly state the research question and study design, and should explain how the results would influence the response to the current pandemic. These expressions of interest will be scrutinised by a committee and the most promising of them will be invited to submit full proposals for research. Applicants must be able to start the research within weeks and complete it (and provide preliminary reports of results) before the end of the year. A much accelerated approval process is being developed to support this. The criteria for assessment of the full proposals will be as below. It is not expected that the expressions of interest will be able to demonstrate all these, but the committee will decline any that it considers unlikely to be competitive at the next stage.

These studies may also provide an opportunity to collect clinical materials/samples for later study, to be funded separately; applications may consider this and a small extra cost to facilitate this would be considered.

The Board will assess proposals against the following criteria.

1. Importance of the results in guiding policy and practice in the management of pandemic flu.
2. Ability of the team to deliver robust research very quickly. We will only consider proposals from teams with the experience and skills to complete this research to time. All clinical trials will need the active involvement of specialist clinical trials expertise. NIHR will broker support for important projects from an appropriate clinical trials unit if this is not already available to the researchers. The NIHR clinical research networks will give priority support to all relevant projects funded through this call.
3. Current evidence base; applicants should explain how their research builds on current evidence
4. Views of policy makers and clinicians actively involved in managing pandemic flu.
5. Scientific quality.

Further guidance on submission

Applicants should consider:

Ethical, Legal and Social Issues

All those involved in research must adhere to the strictest ethical and legal standards. Ethical, social and legal issues must be considered in relation to all stages of the research cycle. Applicants are asked to consider documents such as the MRC Ethics Guide: Medical research involving children; (DH 2004), Seeking Consent (DH 2001), Direction of Travel for Urgent Care (DH 2006), Mental Capacity Act (2005).

Applicants should follow the Medical Research Council's Good Clinical Practice guidelines (<http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/GoodResearchPractice/index.htm>) when planning how studies, particularly RCTs, will be supervised.

In view of the urgency of this research special measures will be used to speed up the approval processes.

Public involvement

It would be very welcome if researchers involve patients and the public in the planning and conduct of their study, but we realise the practical difficulties of doing so in this urgent timescale.

Required expertise

Research funded through NIHR is a multidisciplinary enterprise. It may need to draw on the expertise and knowledge of clinicians and of those trained in health service research methodologies such as health economics, medical statistics, study design and qualitative approaches. HTA expects applicants to use a qualified trial manager for appropriate projects. Applicants will need to show a commitment to team working and may wish to consider a collaborative approach between several institutions.

Making an application

If you wish to submit an expression of interest in response to this call, complete the electronic application form and return it to the NIHR Evaluation, Trials and Studies Coordinating Centre (www.netsec.ac.uk/) by 13.00 hrs on 26 June 2009 by email to htatcall@soton.ac.uk.

Please note that applicants may submit more than one expression of interest if required. Without an initial expression of interest applicants will not be able to progress to the next stage.

Shortlisted applicants will be notified by 8th July 2009 and asked to submit a full application by 27th July 2009. We acknowledge that this timescale is very short so we accept that the full applications may not be complete at the time of submissions. Some aspects of costs, for instance, may be missing. On this occasion there is flexibility, but the full application must contain enough detail to allow peer review and for the board to assess the proposal.

Expressions of interest received after 26 June 2009 will not be considered.