#### NIHR Pandemic Influenza themed call

## **Specification document**

### Introduction

NIHR commissioned influenza research in the 2009 pandemic (Lancet. 2010;375(9720):1063-5). The urgency and rapid timetable was challenging but important research has been completed and published (<a href="http://www.netscc.ac.uk/supporting\_research/pandemic\_flu.asp">http://www.netscc.ac.uk/supporting\_research/pandemic\_flu.asp</a>). The NIHR wishes to fund a further portfolio of research projects in this health topic before another pandemic occurs. Our intention is to peer-review and assess applications, then award contracts to successful researchers who would subsequently obtain ethical and other regulatory approval for their research. The research itself will not normally start unless and until a pandemic occurs and affects the UK. Projects will receive only minimal maintenance funding until research starts. NIHR will decide when research should begin in discussion with funded researchers; only after this point will full scale funding be made available. We anticipate that projects will be 'on-hold' up to 3 years.

### Remit of this call

The main focus of this call is the prevention, diagnosis or immediate management of patients with influenza during a pandemic. This may include community or hospital care. Only research which will produce evidence to guide clinical and public health policy during the same pandemic will be considered. We are interested in proposals for research that would normally be within the remit of the NETS programmes, in addition to this, applications that can demonstrate practical benefit to the NHS and to NHS patients will also be considered.

# **Expressions of interest invited**

Expressions of interest, using the form provided, are invited. These should briefly state the research question and study design, and should explain how the results might influence an active pandemic. These expressions of interest will be competitively assessed by a committee and the most promising of them will be invited to submit full proposals for research. Successfully funded applicants will be notified in November 2011.

Applicants must be able to start the research at short notice in the event of a pandemic and complete it (and provide preliminary reports of results) within months to inform policy and practice in that same pandemic. Project teams that are asked to submit a full proposal will be required to explain how they will be able to meet this requirement in detail. NIHR will support an accelerated process so that the necessary regulatory approvals are in place before the research needs to start. 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 fully demonstrate all these, but the committee will decline any that it considers unlikely to be competitive at the next stage.

The committee will assess proposals against the following criteria:

- 1. The importance of the results in guiding policy and practice in the management of pandemic flu. Projects that address the current priorities of policy makers and clinicians actively involved in managing pandemic flu are particularly encouraged.
- 2. Proposals for research must make clear how the project will build on current evidence and address gaps in existing knowledge.
- 3. Scientific quality. Proposals should be carefully designed to ensure rigorous research is undertaken.
- 4. The ability of the team to deliver robust research quickly. We will only consider proposals from teams with the experience and skills to complete this research to time. Research staff from the NIHR networks may be diverted into pandemic flu projects if needed during a pandemic.

Applicants should also 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 (<a href="http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Researchpractice/index.htm">http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Researchpractice/index.htm</a>) when planning how studies, particularly RCTs, will be supervised. Special measures may be used to speed up the approval processes if necessary in the event of pandemic.
- Public involvement Applicants are actively encouraged to involve patients and the public in the planning, conduct and reporting of their study, but we realise the practical difficulties of doing so in a short timescale and in pandemic.
- 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. For clinical trial proposals, we expect applicants to use a
  qualified trial manager to support the study. Applicants will need to show a commitment to
  team working and may wish to consider a collaborative approach between several
  institutions.

Applicants should also note that research outputs from this call will be published in a NIHR journal series.

# Making an application

All documents associated with this call can be found on our website: <a href="https://www.netscc.ac.uk/funding/pandemicflu">www.netscc.ac.uk/funding/pandemicflu</a>. If you wish to submit an Expression of Interest (EoI) in response to this call, complete the EOI application form and return it by email to <a href="mailto:flu@netscc.ac.uk">flu@netscc.ac.uk</a> by 13.00 hrs on 5<sup>th</sup> May 2011.

Without an initial expression of interest applicants will not be able to progress to the next stage.

Expressions of interest received after 13.00 hrs on 5<sup>th</sup> May 2011 will not be considered.

Please note that applicants may submit more than one expression of interest.

Short listed applicants will be notified by the end of June 2011 and will be asked to submit a full application early September 2011.

#### **Briefing** event

We shall be holding an online briefing event 10am to 11am on 15/04/2011. This event will provide an opportunity for applicants to hear more about the call and to ask questions. If you wish to participate in this event please email <a href="mailto:flu@netscc.ac.uk">flu@netscc.ac.uk</a> by 08/04/2011 to register your interest. A transcript of the event will be available online following the briefing event.