

Ref:

**Norfolk & Suffolk Primary and Community Care Research Office**

Hosted by: South Norfolk CCG

Lakeside 400

To

Old Chapel Way

Practices in CRN:Eastern

Broadland Business Park

Thorpe St Andrew

Norwich

NR7 0WG

Tel: 01603 257200

Fax: 01603 257292

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E-mail: [clare.symms@nhs.net](mailto:clare.symms@nhs.net)

<http://nspccro.nihr.ac.uk/>

**Changes in NHS Permission for Research  
Information for Primary Care Providers**

Dear Practice

You may be aware that the way research in the NHS is approved is changing. The Health Research Authority (HRA<sup>1</sup>) are in the process of rolling out a new system for approving research in the NHS in England, called HRA Approval, which will replace existing arrangements for NHS Permission / Assurance. This process is being implemented in phases, and the next phase (Cohort 2), which is being launched on 10<sup>th</sup> August 2015 will include primary care studies. I am therefore writing to clarify what this means for you and to confirm the arrangements that are in place to support you following this change.

All studies approved through HRA will be issued with an HRA Approval Letter. This provides assurance that the study meets all regulatory and legislative requirements relative to the study type (including ethical approval, where required). Practices will continue to have the final decision on whether to undertake a study, however locally, practices are expected to work together with their local R&D Office and CRN to confirm they have the capability and capacity to undertake the study and that any local arrangements are in place (e.g. local labs, letters of access for researchers). Please be aware that receipt of the HRA approval letter **does not mean** that all support arrangements are in place locally, this will need to be confirmed by the Sponsor, however we are working to ensure that the impact of this change on practices is minimal and please be assured that the arrangements that are already in place to support you will continue.

HRA approval is being implemented in phases, and until this is fully implemented (expected to be December 2015) some studies will be approved via the HRA and others via existing processes, so you will receive both types of approval letters. Researchers may approach you directly about a study with their HRA approval already in place – please contact the R&D office if you are approached in this way to enable us to confirm any local support arrangements that may need to be put into place before the study can start.

I would also like to take this opportunity to reiterate your responsibilities as a practice hosting research, which remain unchanged.

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<sup>1</sup>The HRA was established in December 2011 to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research

<p><b>As research sites practices will be responsible for:</b></p> <ul style="list-style-type: none"> <li>• Agreeing to host, based on capability and capacity</li> <li>• The conduct of the study at your practice</li> <li>• The care / treatment of patients taking part in that study at their practice</li> </ul>	<p><b>As Participant Identification Centres<sup>2</sup> (PICs) practices will be responsible for:</b></p> <ul style="list-style-type: none"> <li>• Agreeing to act as a PIC</li> <li>• The appropriateness of referrals to the research site for the purposes of the study</li> <li>• The conduct of all PIC activities (e.g. mailshots) at their practice</li> </ul>
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Further information is available on the [HRA website](#) and I have attached the flyer HRA have produced for GPs, however if you have any questions about this change and what it may mean for your practice, please do not hesitate to contact me. We will update you with any new information that becomes available. Please be assured that together with the CRN team we are working to ensure that in reality you experience very little change to the systems already in place.

Yours sincerely



Clare Symms  
**Research Manager**  
 Norfolk & Suffolk Primary & Community Care Research Office

<p><b>Cambridgeshire Primary and Community Care RMG Centre</b>          providing services on behalf of Primary Care (CRN:Eastern West corridor) and Cambridgeshire Community Services</p> <p>Viv Shaw - CRN: Eastern RM&amp;G Manager  <a href="mailto:V.shaw@nhs.net">V.shaw@nhs.net</a>          01223 725466</p>	<p><b>Norfolk &amp; Suffolk Primary &amp; Community Care Research Office</b>          providing services on behalf of Primary Care (CRN:Eastern East corridor), Norfolk Community Health &amp; Care and East Coast Community Healthcare</p> <p>Clare Symms – Research Governance Manager  <a href="mailto:clare.symms@nhs.net">clare.symms@nhs.net</a> / <a href="mailto:snccg.RandOffice@nhs.net">snccg.RandOffice@nhs.net</a>          01603 257020</p>
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<sup>2</sup> Where potential participants will be identified through NHS organisations other than the research sites themselves, these organisations are termed "Participant Identification Centres" (PIC) IRAS Question Specific Guidance - Part C Version 2.2 dated April 2009