

Ref: 2014GP47 (161432)	
Dr Andrew M Wilson University of East Anglia Biomedicine Group School of Medicine, Health Policy and Practice Norwich Research Park Norwich Norfolk NR4 7TJ United Kingdom	Norfolk & Suffolk Primary & Community Care Research Office Hosted by: South Norfolk CCG Lakeside 400 Old Chapel Way Broadland Business Park Thorpe St Andrew Norwich NR7 0WG Tel: 01603 257283 Fax: 01603 257292 E-mail: snccg.randdoffice@nhs.net http://nspccro.nihr.ac.uk http://www.camstrad.nhs.uk
20 May 2015	

Dear Dr Andrew M Wilson

Re: 2014GP47 (161432). At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

REC Number: 14/WA/1211

Chief Investigator: Dr Andrew M Wilson

Sponsor: University of East Anglia

Primary care Localities: Practices in CRN Eastern

Thank you for submitting your application for the above study, your application has been reviewed by the **Norfolk & Suffolk Primary & Community Care Research Office**. We provide assurance to primary care providers¹ in CRN Eastern that research proposals meet nationally agreed research governance criteria to assist primary care providers in deciding whether to take part in a research study.

This assurance letter confirms that the Research Management Team has reviewed your submission in accordance with Department of Health Research Governance Framework for Health and Social Care for the above practices/localities and that your submission has satisfied the governance criteria.

Please note that a copy of this letter together with governance checks must be provided to Primary Care Providers. This letter does not place any obligations on them to participate in this study. You must obtain confirmation from each provider of their willingness to take part in the study.

It is understood that practices will be acting as *research sites* and will be responsible for:

- Providing a nominated contact (Respiratory Nurse or other staff member) for the study (Asthma Champion will be appointed to lead the study in the practice)
- Registering with CPRD (if not already registered) to provide anonymous data to UEA
- Ensuring data extraction has taken place
- Performing initial 'at risk' asthma patient identification algorithm search

¹ Primary care providers include GP practices, Pharmacists, Dentist and Opticians

- Using of Computerised Decision Support System and ensuring Flags are applied to appropriate patient records -Intervention arm only
- Completion of two web-based Training Sessions by at least one member of staff from each relevant group (GP, Nurse, Receptionist, and Pharmacist (if relevant))-Intervention arm only
- Completion of Study Questionnaires
- Providing a Summary Sheet of 'At –risk' Register Changes to Norwich Clinical Trials Unit- Intervention arm only

General conditions follow:

The project must follow the agreed protocol and be conducted in accordance with policies and procedures in relation to data protection, health and safety and information governance standards.

Please let us know of any deviations from the protocol or protocol breaches including any urgent safety measures taken in order to protect research participants against any immediate hazard to their health or safety.

Please ensure that any amendments are submitted to the research ethics committee and the Research Management Team for review as appropriate.

Members of the research team must where instructed, have appropriate substantive or honorary research contracts or letters of access for research access in Primary care prior to commencing work on the study. Additional researchers joining the study must also hold a suitable contract or letter of access.

You are required to notify us, the sponsor and the chief investigator of any serious adverse events relevant to the conduct of research and of all incidents or complaints occurring during the research within CRN Eastern.

You are also required to notify us of the study conclusion and/or termination of the study.

Primary care providers are expected to follow guidance issued by their relevant professional bodies in relation to research².

You need to ensure that recruitment data is uploaded onto the national portfolio in a timely manner and the data is attributed to the correct practice / site. The practices need to make sure that their practice name and address are clearly marked when recruitment data are notified to the research team.

Please note that the granting of NHS Assurance for this study does not commit either the practice or commissioning bodies to on-going financial support for any intervention trialled.

You should ensure an agreement is put in place to clarify the distribution of responsibilities between the Sponsor and participating sites.

May I take this opportunity to wish you well with your research and we look forward to hearing the outcomes for the study. Please contact the Research Management Team should you have any further queries. Please note, the reference number for this study is **2014GP47 (161432)** and this should be quoted on all correspondence.

Yours sincerely



Clare Symms

Research Governance Manager, Norfolk & Suffolk Primary & Community Care Research Office

cc. Helen MacDonald, Division 5 Manager, CRN:Eastern
 Heather Leishman, Primary Care Coordinator (Norfolk & Waveney)
 Cristina Page, Primary Care Coordinator (Suffolk & North East Essex)
 Deborah Graver, Sponsor Representative, UEA
 Stanley Musgrave, Study Coordinator, UEA

² E.g GMC Guidance on research - http://www.gmc-uk.org/guidance/ethical_guidance/research.asp