GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Research & Development Department
Dr Lisa Seale, Senior R&D Manager – lisa.seale@wales.nhs.uk
Chris Tattersall, R&D Manager – chris.tattersall@wales.nhs.uk
Alison Armitage-Hicks, R&D Coordinator – alison.armitage-hicks@wales.nhs.uk
Rachel Roberts, Portfolio Coordinator – rachel.roberts3@wales.nhs.uk

Ref: CT/KP/Ref: HD/16/027
Date: 3rd November 2016

CONTACT: Chris Tattersall
Research & Development Manager
Withybush General Hospital
Fishguard Road
Haverfordwest
Pembrokeshire
SA62 1PZ
Tel: 01437 773813

Ysbyty Cyffredinol Llwynhelyg
Heol Abergwaun, Hwlffordd,
Sir Benfro, SA61 2PZ
Rhif Ffôn: 01437 763813

Dr Andrew M Wilson
Clinical Senior Lecturer/Consultant
University of East Anglia
Norwich Medical School
University of East Anglia
Norwich
NR4 7TJ

Dear Dr Wilson

R&D Ref	**HD/16/027**		
Project Title	**ARRISA-UK: At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK**		
REC Ref	**14/WA/1211**	**IRAS Ref**	**161432**
Latest Protocol	**1.1**	**Protocol Date**	**24 June 2016**
Site	**GP Practices**	**PI**	**Prof Chris Butler**

Thank you for submitting your proposal to us for approval for the project to be carried out within this Health Board. Among the documentation considered in support of your application are the following documents, which are currently approved for use:

Document	Version	Dated
Protocol	1.1	24 June 2016
Letter of Invitation to Participant (Focus Group Invitation)	1.2	13/06/2016
Letter of Invitation to Participant (Interview Invitation)	1.2	13/06/2016
Participant Information Sheet (Focus Group)	1.3	13/06/2016
Participant Information Sheet (Patients - Interview)	1.3	13/06/2016
Participant Information Sheet (Practice)	1.2	13/06/2016
Participant Information Sheet (GP Practice Staff)	1.3	13/06/2016
Participant Information Sheet (Practice Staff Interview)	1.3	14/06/2016
Consent Form (Patient Focus Group)	1.2	14/06/2016
Consent Form (Patient Interview)	1.2	14/06/2016
Consent Form (Practice Staff Focus Group)	1.2	14/06/2016
Consent Form (Practice Staff Interview	1.2	14/06/2016
REC Approval Letter		26 Nov 2014

This approval includes all relevant amendments up until the date of this approval letter.

All Research Governance checks have been completed and passed. I have received the comments from the review panel and have not received any objections to the project

going ahead. Please accept this letter as approval for the project to proceed in Hywel Dda University Health Board at the sites listed, following study initiation visits if appropriate.

Please endeavour to recruit participants to your estimated time and target and for the first participant to be recruited within 30 days of approval. If there is any assistance you feel we can help with to achieve this, please be in touch.

Under Research Governance, you are required to:

- Adhere to the protocol approved by the REC and inform the R&D office of any changes (including changes to the end date of the project) and ensure any changes are referred to the Research Ethics Committee(s) or any other regulatory authorities as appropriate.

- Ensure all study personnel adhere to the sponsors Standard Operating Procedures (including Consent, etc). Health Board sponsored SOPs can be found on the Health Board Intranet site or via the R&D office.

- Inform the R&D Office of any relevant adverse/serious adverse events that may occur, whilst also reporting these through the proper channels in the Health Board, and according to the sponsor's protocol and procedures.

- Complete any interim and final reports requested by the R&D Office. If sponsored by this Health Board, you will be asked to present your findings on completion.

- Comply with the Welsh Government Research Governance Framework for Health & Social Care in Wales (2nd Edition 2009) and co-operate with any audit inspection of the project files.

- Ensure that your research complies with regulatory requirements and legislation relating to: Clinical Trials, Data Protection Act 1998, Health & Safety, Caldicott Guidelines, ICH Good Clinical Practice (GCP) and the use of Human Tissue for research purposes, as appropriate for the duration of the study.

- Ensure that all training courses requested by the Sponsor are completed successfully by all relevant members of the research team before any research activity is carried out. All research staff undertaking clinical trials of an investigational medicinal product (CTimps) must be GCP trained, and should continue to update their GCP training every 2 years. Copies of GCP certificates should be filed in the TSF and forwarded to the R&D Department.

- Ensure that all researchers are in receipt of the relevant Personnel/HR documentation in order to conduct research activity in the Health Board, and inform the R&D office of any additional study staff.

In addition:

- It is the local research lead's responsibility to upload recruitment data in all portfolio studies using the following link:

http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment . If you need any support in uploading this data, please contact the Research & Development Department.

- For non-portfolio studies the local research lead should inform the R&D department of their quarterly recruitment figures (or as requested by the department) and the date of first recruited patient.

- To apply for adoption onto the NISCHR CRP, please go to: http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at: http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571 and/or from your NHS R&D office colleagues.

- Please note that if you wish to extend your project to other sites within the Health Board, or to other Health Boards or NHS bodies you must obtain the approval of all NHS bodies concerned. If the project is sponsored by this Health Board you must notify the R&D Office. Failure to notify may result in suspension or closure of the project.

With all good wishes for the research.

Yours sincerely

Dr Sam Rice
Deputy Director of Research & Development
Hywel Dda University Health Board

cc.
Prof Chris Butler
Univeristy of Oxford
Nuffield Department of Primary Health Care Sciences
Radcliffe Observatory Quarter
Woodstock Road
Oxford
OX2 6GG