

7 September 2018

Supersedes letter dated 4 July 2018

Professor Lyn March
Department of Rheumatology, Royal North Shore Hospital
PO Box 139
St Leonards, NSW, 2065

Dear Lyn,

NSLHD reference: RESP/17/264

Study Title: The Australian Arthritis and Autoimmune Biobank Collaborative (A3BC)

HREC reference: HREC/17/HAWKE/339

Thank you for your letter, dated **09/04/2018**, responding to the Northern Sydney Local Health District HREC's request for additional information/modification for the above project, which was first considered by the HREC at its meeting held on **09/10/2017**. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting on **04/07/2018** has granted ethical and scientific approval of the above **multi centre** project. The HREC were satisfied that this project meets the requirements of the National Statement.

The project is approved to be conducted at:

New South Wales (NSW)

- Royal North Shore Hospital
- St Vincent's & Mater Health Sydney
- Liverpool Hospital
- Campbelltown Hospital
- St George Hospital
- Prince of Wales Hospital
- Westmead Hospital
- Children's Hospital at Westmead
- Sydney Children's Hospital Randwick
- John Hunter Hospital
- Royal Prince Alfred Hospital
- The NSW Health Statewide Biobank
- Hunter Medical Research Institute
- Ingham Institute for Applied Medical Research
- BJC Health
- Institute for Bone and Joint Research (USyd)
- Intersect Australia

Queensland (QLD)

- Princess Alexandra Hospital
- Logan Hospital
- Metro South Research Biorepositories
- Royal Brisbane Women's Hospital
- Redcliffe Hospital
- Lady Cilento Children's Hospital
- Gold Coast University Hospital

Western Australia (WA)

- Royal Perth Hospital
- Fiona Stanley Hospital
- Perth Children's Hospital

South Australia (SA)

- Flinders Medical Centre
- Noarlunga Hospital
- Royal Adelaide Hospital
- The Queen Elizabeth Hospital
- Women's and Children's Hospital
- Lyell McEwin Hospital
- Basil Hetzel Institute

Australian Capital Territory (ACT)

- Canberra Hospital
- ACT Health – Pathology, Canberra Hospital

Victoria (VIC)

- Australian Rheumatology Assoc. Database (ARAD)
- Murdoch Children's Research Institute
- The Royal Children's Hospital
- Monash Children's Hospital
- Monash Medical Centre
- Royal Melbourne Hospital
- Baker Heart And Diabetes Institute

You are reminded that this letter constitutes **ETHICAL** and **SCIENTIFIC** approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

Document	Version	Date
A3BC Cover Letter	-	25/09/2017
A3BC Protocol	3.0	04/04/2018
A3BC PICF – Self	3.0	04/04/2018
A3BC PICF – Parent and Guardian	3.0	04/04/2018
A3BC PTC.CRF	2.0	25/01/2018
A3BC Access Application	1.0	25/09/2017
A3BC Access Application – Review	1.0	25/09/2017
A3BC HREA	-	-
ARAD Entry 12-18	2.0	20/11/2015
ARAD Entry Under 12	2.0	20/11/2015
ARAD Entry	7.0	20/11/2015
ARAD Follow Up 12-18	2.0	20/11/2015
ARAD Follow Up Under 12	2.0	20/11/2015
ARAD Follow Up	7.0	20/11/2015
ARAD HAQ-C	2.0	15/11/2007
ARAD HAQ-S	2.0	15/11/2007

ARAD PedsQL-Child-5-7	2.0	01/12/2007
ARAD PedsQL-Child-8-12	2.0	01/12/2007
ARAD PedsQL-Child-13-18	2.0	01/12/2007
ARAD PedsQL-Parent-2-4	2.0	01/12/2007
ARAD PedsQL-Parent-5-7	2.0	01/12/2007
ARAD PedsQL-Parent-8-12	2.0	01/12/2007
ARAD PedsQL-Parent-13-18	2.0	01/12/2007

The following documents have been noted:

- 40 Investigator CV's
- NLSHD HREC Method of Payment Form

The National Ethics Application Form reviewed by the HREC was **HREA AU/1/D50135**.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **04/07/2023**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report to the Institution beginning in **August 2019** as well as a final study report at the completion of the project using the template available on the Research Office website. An annual report is due **every year on 30 August**.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trial Registry www.anzctr.org.au) if applicable.

Should you have any queries about your project please contact the Research Office, Tel: 9926 4590, email NSLHD-Research@health.nsw.gov.au.

Please quote **NSLHD reference RESP/17/264** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,



Jodi Humphreys
Research Manager, Clinical Research, Governance and Support