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NSW GOVERNMENT | Health
Northern Sydney
Local Health District

24 October 2016

A/Prof Gregory King
Department of Respiratory Medicine
Royal North Shore Hospital
St Leonards NSW 2065

Dear Gregory

NSLHD reference: RESP/16/166
Study Title: Investigation of nasal deposition using a nasal mesh nebuliser
HREC reference: HREC/16/HAWKE/256

Thank you for your letter, dated **18 October 2016**, 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 **11 July 2016.** 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 **21 October 2016** has granted ethical and scientific approval of the above **single centre** project.

The project is approved to be conducted at**:**

- **Royal North Shore Hospital**

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
Study Protocol	2.0	23 September 2016
Investigator Brochure	1.0	24 June 2016
Participant Information Sheet and Consent Form	3.0	18 October 2016
Advertisement Brochure	2.0	23 September 2016
Recruitment Phone Script	2.0	13 September 2016
Follow-Up Phone Script	1.0	16 June 2016
Part I. Personal Information sheet - Data collection sheet	-	3 July 2016
Part II. Baseline Respiratory Health - Data collection sheet	-	3 July 2016
Form For Withdrawal of Participation	1.0	16 June 2016

The following documents have been noted:
Radiation Safety Report signed by Nicholas Forwood (Medical Physicist and Radiation Safety Officer) at NSLHD on 16 June 2016

The National Ethics Application Form reviewed by the HREC was **NEAF AU/1/3117217**

As this study involves the use of an unapproved device (Nasal Mesh Nebuliser) this study must be conducted under the Clinical Trial Notification (CTN) scheme. Please ensure that the isotonic saline solution is also listed on the CTN form.

Please note that it is the responsibility of the Sponsor to submit the Clinical Trial Notification (CTN) to the Therapeutic Goods Administration (TGA) online. The Research Office recommends that CTN submission is completed only once HREC approval *and* site governance authorisation are granted.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **21 October 2021.** 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 2017** 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/16/166** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely

Monique Macara
Research Ethics Manager
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

cc. Prof Dale Bailey, Prof Paul Young
TRIM RESD/16/7895