***Contact:*** Sydney Local Health District Human Research Ethics Committee – CRGH
*Concord Repatriation General Hospital (CRGH)*
*Concord NSW 2139*
*Telephone:* *(02) 9767 5622*
*Email:* SLHD-ConcordEthics@health.nsw.gov.au
***Local Ref:*** *CH62/6/2020-143*

CONCORD
REPATRIATION GENERAL
HOSPITAL

15 April 2021

A/Prof Yuresh Naidoo
C/- Ms Catherine Bennet
The ENT Centre
Hornsby
NSW 2077

Dear A/Professor Naidoo,

**Re:** **Local reference number:** CH62/6/2020-143
**REGIS ethics application number:** 2020/ETH02712
**REGIS project ID number:** 2020/PID03036
**Project title:** A single-blinded randomised trial evaluating the efficacy of chitosan-dextran (Chitodex) gel with topical steroid versus PureRegen gel on post-operative outcomes in the treatment of Chronic Rhinosinusitis (CRS)

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 10 December 2021. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

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.*

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018*.

The documents reviewed and approved include:

| | **VERSION** | **DATE** |
|---|---|---|
| Human Research Ethics Application (HREA) | 3 | 23/03/2021 |
| Protocol | 5.2 | 24/03/2021 |
| Master Participant Information Sheet & Consent Form | 4.4 | 15/04/2021 |
| Data Collection Checklist | 1.2 | 07/04/2021 |
| Research Data Management Plan | 2.0 | 13/10/2020 |
| Chitogel Brochure (noted) | – | – |
| Chitogel Application Brochure (noted) | – | 12/2019 |
| Chitogel instructions for use (noted) | 2.94 | – |
| PureRegen Gel Brochure (noted) | – | – |
| Therapeutic Drugs Administration (TGA) Public Summary ARTG Entry: 49226 (noted) | – | Produced at 22/11/2020 |
| Therapeutic Drugs Administration (TGA) Public Summary | – | Produced at |

| | | |
|---|---|---|
| ARTG Entry: 264407 (noted) | | 07/08/2020 |
| ICH GCP Certificate - Arj Ananda (noted) | – | 15/03/2021 |
| ICH GCP Certificate - Raymond Sacks (noted) | – | 12/03/2021 |
| ICH GCP Certificate - Yuresh Naidoo (noted) | – | 21/05/2020 |

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital
2. The ENT Centre*
3. Macquarie University Private Hospital*
4. North Shore Private Hospital*
5. Campbelltown Private Hospital*
6. Sydney Adventist Hospital*

*** Note: SLHD is unable to sponsor studies being conducted in other institutions but can sponsor studies being conducted in an SLHD site. In the case where the research is being conducted in other institutions, for example private sites, the private site will act as the sponsor for that research that is conducted at their site and lead by an investigator at that site. If necessary, SLHD will issue a letter of agreement rather than enter into a contract with the site. The site's RGO is responsible for submitting their CTN to the TGA – SLHD is not acting as their Sponsor.**

**You are reminded that this letter constitutes ethical approval only.** You must not commence this research project at any site until you have submitted a Site Specific Assessment (SSA) Form to the Research Governance Officer (RGO) and received separate authorisation from the Chief Executive or delegate at that site.

Please note the following conditions of approval:

1. HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the HREC by **30/04/2022.** You must also provide an annual report to the HREC upon completion of the study.

2. You will adhere to the study protocol at all times, as failure to do so will invalidate the Indemnity agreement.

3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review.

4. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.

5. You will immediately report anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability of the project, (including Significant Safety Issues).

6. It is noted that SLHD REDCap will be used for secure research data collection, management and storage in the study. Once the SLHD REDCap project has been set-up, using the SLHD Master Code Sheet Project, please provide a copy of the REDCap Project Codesheets with a version number and date to the Ethics Committee for review and approval prior to study commencement. Please note, the SLHD Research Data Manager and REDCap Administrator can be contacted for assistance and bookings via email or online for consultation if necessary.

7. You agree that you will not commence the trial named above until the Clinical Trial Notification (CTN) has been submitted to the Therapeutic Goods Administration (TGA) using the online form. This HREC approval letter fulfils the documentation

required to indicate the approval of the Human Research Ethics Committee responsible for monitoring the trial. A copy of the TGA acknowledgment of receipt of a CTN must be submitted to the CRGH Research Office as soon as it is available.

8. It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.

9. Where appropriate, the Committee recommends that you consult with your Medical Defence Organisation or relevant governing body to ensure that you are adequately covered for the purposes of conducting this study.

10. It is a condition of approval that the investigators follow the relevant jurisdictional public health guidelines in relation to COVID-19 site requirements.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: https://www.slhd.nsw.gov.au/concord/Ethics/Ethics.html

We wish you every success in your research.

***Please quote the local reference number at the top of this letter in all correspondence.***

Yours sincerely,

**Professor David Le Couteur**
*Chair*
**Sydney Local Health District Human Research Ethics Committee – CRGH**
CC: Lucy Nigro, Concord Hospital Clinical Trials Pharmacist