

Fwd: APPROVED: Project amendment

Yazeed Al Suliman <yazeedalsuliman@gmail.com>

Fri 29/05/2020 1:26 PM

To: Megow, Anna (Health) <Anna.Megow@sa.gov.au>;

Hi Anna,

This is the ethics approval email.

Regards,
Yazeed

----- Forwarded message -----

From: Health:CALHN Research Ethics <Health.CALHNResearchEthics@sa.gov.au>

Date: Wed, Aug 21, 2019 at 11:55 AM

Subject: APPROVED: Project amendment

To: Yazeed Al Suliman <yazeedalsuliman@gmail.com>

Dear Yazeed

Approval Date: 20 August 2019

HREC reference number: HREC/17/TQEH/245

CALHN Reference number: Q20171012

Project title: Chitosan-dextran (Chitodex) gel with and without Deferiprone and Gallium-Protoporphyrin-wound healing and post operative outcomes in the treatment of Chronic Rhinosinusitis (CRS)

CPI: Professor Peter-John Wormald

Please accept this e-mail as **Acknowledgement of Receipt, Review and APPROVAL** of the document(s), on behalf of **Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) and CALHN Research Governance**, and retain a copy for your records.

Approval is effective from the date of this email. For multi-centre studies a copy of this email must be forwarded to Principal Investigators at every site approved by the CALHN HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents.

Documents reviewed and approved:

Document	Version	Date
Protocol	V2.6	16/08/2019
Patient Information Sheet and Consent Form	V2.6	16/08/2019

29/05/2020

Fwd: APPROVED: Project amendment - Megow, Anna (Health)

This approval is subject to the conditions outlined in the original ethics approval letter.

Should you have any queries about this matter please contact the Executive Officer of the HREC on 08 7117 2229 or via email at Health.CALHNResearchEthics@sa.gov.au

Kind regards

CALHN Research Services

for

Mr Ian Tindall

Chair, Human Research Ethics Committee

Central Adelaide Local Health Network

Phone: 08 7117 2223 | Email: Health.CALHNResearchEthics@sa.gov.au



Government of South Australia

SA Health

Central Adelaide Local Health Network Inc.

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From: Yazeed Al Suliman [mailto:yazeedalsuliman@gmail.com]

Sent: Friday, 16 August 2019 3:09 PM

To: Health:CALHN Research Ethics

Subject: Project amendment

Hello,

I'm Yazeed Alsuliman, Fellow in ENT department

I'm sending you the documents required for our group project under the following details:

HREC reference: HREC/17/TQEH/245

CALHN reference: Q20171012

Project Title: Chitosandextran (Chitodex) gel with and without Deferiprone and GalliumProtoporphyrin: wound healing and postoperative outcomes in Chronic rhinosinusitis.

This the same study that Dr. Rajan Vediappan was coordinating.

<https://owa.statenetmail.sa.gov.au/owa/#viewmodel=ReadMessageItem&ItemID=AAMkADIwNmJmYTE3LTY1MjktNGFhOS05NjI2LTdmNTAyNjRkYTU0N...> 2/3

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We are requesting the amendment for following reasons:

- We will add 2 arms of treatment groups using lower dose of one of the drugs used in the trial (Deferiprone) as we believe that lower dose to be more effective according to recently published study of our group.
- We will use another technique to test same outcome measure (adding Microbiome analysis to culture to test bacterial status postoperative)
- We need to apply this technique to our new arms and compare them to the existing arm (CD gel arm) and since this arm has been recruited already, we will need to recruit more patients in this arm to apply this technique.
- Microbiome analysis is being done routinely for our patients in ENT department at time of surgery. In the study will also do it again at 12 weeks postoperative using swab specimen.

Since we recruiting more patients in an existing arm, can we start the recruitment process while waiting for the approval?

Please let me know if more information / documents required?

Regards,

Yazeed

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Dr.Yazeed Al Suliman

MBBS, SB-ORL, KSUF, EB-ORL

Department of Otolaryngology, Head and Neck surgery
King Fahad medical City "KFMC"
Riyadh, KSA

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