

2021_ETH00246 Decision notification e...

潮牟蠡祗牀來獾緝慥塗 獮 潛 咳

Sat 02/04/2022 14:17

To: 楷焚燹 璉扯敦桀慥塗 獮 潛 咳 <楷焚燹 璉扯敦桀慥塗 獮 潛 咳>

Cc: 楷焚燹 璉扯敦桀慥塗 獮 潛 咳 <楷焚燹 璉扯敦桀慥塗 獮 潛 咳>

Date of Decision Notification: **14 Apr 2021**

Dear William Stobie,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2021/ETH00246: ENDOmetriosis appearance with hormonal COntraceptives at LaparOscopy: a pRospective cohort study (ENDO-COLOR Trial)

This Application was reviewed as a **Low risk review pathway** and was initially considered by the **South Eastern Sydney Local Health District HREC** at its meeting held on **INITIAL MEETING DATE**.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been Approved to be conducted at the following sites:

- **Sutherland Hospital**

The following documentation was reviewed and is included in this approval:

- HREA version 2, 11/03/2021
- Appendix D_EHP-30.pdf
- Cover Letter in Response to REGIS HREC Feedback_V01_2021_03_20.docx
- ENDO-COLOR Trial_Protocol_v06_2021-03-20_TrackedChanges.docx
- Inclusion_Exclusion_Criteria_v03_2021-03-20_TrackChanges.docx
- Participant Invitation Letter_v03_2020-12-11.docx
- Patient Information Sheet and Consent Form_v03_2021-03-20_TrackChanges.doc
- Patient Information Sheet and Consent Form_v03_2021-03-20.doc
- 036572_Project Registration.docx.zip

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.01

Date: 30 Mar 2021

The approval is for a period of 5 years from the date of this e-mail (**14 Apr 2021**)

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS

Re: 2021/STE00633: RGO Request for Information - Decision Pending

SES LHD-RSO [Download](#) [Share](#) [Reply](#) [Reply All](#) [Forward](#) [More](#)
Mon 01/11/2021 07:29

To: William Stobie (Northern Sydney LHD)

[2021_ETH00246 Decision not...](#)
24 KB

Hi William,

Apologies for the delay. We have been inundated with emails and are short-staffed.

Please find an email attachment as requested.

Kind Regards,
Nitisha

From: William Stobie (Sydney LHD)
Sent: Monday, 25 October 2021 23:44
To: SESLHD-RSO
Cc: Nitisha Kulkarni (South Eastern Sydney LHD)
Subject: Re: 2021/STE00633: RGO Request for Information - Decision Pending

Hi Nitisha,

I was wondering if you could send through the ethics approval for the project 2021/ETH00246, I can't seem to find the acceptance paperwork.

Thanks,

Will Stobie

From: SESLHD-RSO <SESLHD-RSO@health.nsw.gov.au>
Sent: Friday, 1 October 2021 02:32
To: William Stobie (Sydney LHD) <WILLIAM.STOBIE@health.nsw.gov.au>
Cc: Nitisha Kulkarni (South Eastern Sydney LHD) <Nitisha.Kulkarni@health.nsw.gov.au>
Subject: Re: 2021/STE00633: RGO Request for Information - Decision Pending

Hi William,

Thank you for your email.

You are required to add the Health information unit HOD in Regis as you added Obstetrics & Gynecology HOD. Please add Health information unit HOD to Regis and obtain HOD approval.