Mr Thomas Santarius
Consultant Neurosurgeon and Affiliated Lecturer
Cambridge University Hospitals
Department of Neurosurgery
Box 166
Addenbrooke's Hospital
CB2 0QQ

Email: approvals@hra.nhs.uk

09 July 2021

Dear Mr Santarius

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Assessment of changes in quality of life and symptoms over time in patients with symptomatic pineal cyst treated with surgery or conservatively - a prospective observational cohort study**
IRAS project ID:	**292313**
REC reference:	**21/NI/0120**
Sponsor	**Cambridge University Hospitals**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **292313**. Please quote this on all correspondence.

Yours sincerely,

Alex Thorpe

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mr Angelos Kolias, Sponsor's Representative*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_18062021]		18 June 2021
IRAS Application Form XML file [IRAS_Form_18062021]		18 June 2021
IRAS Checklist XML [Checklist_07072021]		07 July 2021
Non-validated questionnaire [Pineal cyst questionnaire - conservative]	Version 2020-11-28	28 November 2020
Non-validated questionnaire [Pineal cyst questionnaire - before]	Version 08.05.2021	08 May 2021
Non-validated questionnaire [Pineal cyst questionnaire - 3m]	Version 08.05.2021	08 May 2021
Non-validated questionnaire [Pineal cyst questionnaire - 12m]	Version 08.05.2021	08 May 2021
Non-validated questionnaire [Pineal cyst questionnaire - 24m]	Version 08.05.2021	08 May 2021
Non-validated questionnaire [Pineal cyst questionnaire - 36m]	Version 08.05.2021	08 May 2021
Other [Correction of A6-1 section]	1.0	29 June 2021
Other [Response to Committee feedback]	1.0	28 June 2021
Other [Revised PIS]	1.2	28 June 2021
Other [Revised PIS with changes tracked]	1.2	28 June 2021
Other [Research protocol]	1.2	28 June 2021
Other [Research protocol with changes tracked]	1.2	28 June 2021
Participant consent form [Consent]	1.1	08 May 2021
Summary CV for Chief Investigator (CI) [TS_CV]		08 May 2021
Validated questionnaire [QLQ-C30]	3.0	

IRAS project ID	292313

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
This is a single site study sponsored by the participating NHS organisation therefore there is only one site type.	This is a single site study sponsored by the participating NHS organisation. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This is a single site study sponsored by the participating NHS organisation therefore no agreements are expected.	No external study funding has been sought	A Principal Investigator should be appointed at study sites.	The sponsor has confirmed that local staff in participating organisations in England who have a contractual relationship with the organisation will undertake the expected activities. Therefore no honorary research contracts or letters of access are expected for this study.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.