

ENQUIRY TO QUERIES LINE

Dear Danyal,

Your query was reviewed by our Query Line Advisors.

RE: CRANIAL: CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base – A National Prospective Service Evaluation on Incidence and Management

Thank you for your email seeking additional clarity on whether your project should be classified as research and whether it requires ethical review by a NHS Research Ethics Committee (REC).

You provided the following information:

- An summary outlining your proposal
- A PDF /screenshot of the results page of the decision tool(s)
- An explanation of why you/R&D office disagree with the outcome of the decision tool(s)
- Further information received via email from you dated 30/10/2019 and 01/11/2019
- Email communication from the R&D office dated 31/10/2019

Based on the information you have provided, our decision is that the project is **not considered to be research and does not require review by an NHS Research Ethics Committee.**

In giving this decision our advisors agreed that this project was a service evaluation; a project that is designed and conducted solely to define or judge current care.

This decision is in line with:

- The harmonised UK-wide edition of the [Governance Arrangements for Research Ethics Committees](#) (GAfREC) 2018;
- [UK Policy Framework for Health and Social Care Research](#) (2017)
- The National Research Ethics Service (NRES) guidance "[Defining Research](#)" and the algorithm *Does my project require review by a Research Ethics Committee?*

This decision should not be interpreted as giving a form of ethical approval or endorsement to your project on behalf the HRA. However, it may be provided to a journal or other body as evidence if required.

You should also be aware that:

- This response only covers whether your project is classified as research and whether it requires review by an NHS REC. You are strongly advised to consider other approvals that may be required for your project.
- All types of study involving human participants should be conducted in accordance with basic ethical principles, such as informed consent and respect for the confidentiality of participants. Also, in processing identifiable data there are legal requirements under the Data Protection Act (2018). When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation.

Regards,

Queries Line
[REF 786/55/89/81](#)

The Queries Line is an email-based service that provides advice from HRA senior management, including operations managers based in our regional offices throughout England. Providing your query in an email helps us to quickly

direct your enquiry to the most appropriate member of our team who can provide you with an accurate written response. It also enables us to monitor the quality and timeliness of the advice given by the HRA to ensure we can give you the best service possible, as well as use queries to continue to improve and to develop our processes.

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