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24 November 2025

Dear Dr Boregowda

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

Study title:	Quality of life after primary therapy for Graves' disease: long-term anti-thyroid drug versus radioiodine-induced hypothyroidism and thyroidectomy
IRAS project ID:	347660
Protocol number:	SBU18
REC reference:	25/WM/0186
Sponsor	Swansea Bay University Health Board

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 **347660**. Please quote this on all correspondence.

Yours sincerely,
Rekha Keshvara

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Ms Ann-Claire Owen*

List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>	
GP/consultant information sheets or letters [GP information sheet]	V2	15 July 2025	
GP/consultant information sheets or letters [GP letter V3]	V3 clean copy	05 August 2025	
IRAS Application Form [IRAS_Form_15082025]		15 August 2025	
Letters of invitation to participant [Invitation letter for participants who need a blood test]	V3 with tracked changes	05 October 2025	
Letters of invitation to participant [Invitation to participants who need a blood test]	V3 clean copy	05 October 2025	
Letters of invitation to participant [Participants invitation letter with tracked changes]	V1	05 October 2025	
Letters of invitation to participant [Participants invitation letter V2]	V2 clean copy	08 August 2025	
Letters of invitation to participant [Participants reminder letter]	V1	05 August 2025	
Organisation Information Document [Organisation information document]	V2	27 August 2025	
Other [Response to REC review]	V1	14 October 2025	
Other	V2	03 November 2025	
Participant consent form [Consent form]	1	27 June 2025	
Participant consent form [consent for for participants who need a blood test]	V1 27.06.2025	27 June 2025	
Participant consent form [Consent form for participants who do not need a blood test]	V1	14 October 2025	
Participant information sheet (PIS) [PIS]	V3 with tracked changes	14 October 2025	
Participant information sheet (PIS) [PIS]	V3 clean copy	14 October 2025	
Participant information sheet (PIS) [Patient information sheet]	V2	15 July 2025	
Research protocol or project proposal [Study protocol]	V2 with tracked changes	14 October 2025	
Research protocol or project proposal [Study protocol]	V1	26 June 2025	
Schedule of Events or SoECAT			
Summary CV for Chief Investigator (CI) [CV Chief investigator]	Word	27 December 2024	
Validated questionnaire [General quality of life questionnaire]			
Validated questionnaire [Thy-pro questionnaire]			

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
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	Study funding arrangements are detailed in the Organisation Information Document	A Local Principal Investigator should be appointed at participating NHS organisations.	Where an external individual who does not already hold an NHS employment contract will be taking blood samples from participants at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access. These should confirm Occupational Health Clearance. These should confirm enhanced DBS checks and appropriate barred list checks. Where an external individual will have access to participants completed questionnaires only at this site type then they would be expected to hold a Letter of Access. This should be issued

					be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm Occupational Health Clearance.
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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.