**TPL051 Confirmation of Sponsorship and permission to activate research sites**

**Ref: P0XXXX**

**Study Title: xxxxx**

**IRAS: xxxxxx**

**CI: xxxxx**

**PI: xxxxx**

Dear xxxxxxxxxxx,

On behalf of Royal Papworth Hospital NHS Foundation Trust and following discussion at the xx/xx/xxxx RGPAS committee meeting, I can now confirm the above study has received confirmation of Sponsorship and can proceed to activate site(s). Sponsorship by Royal Papworth Hospital NHS Foundation Trust (RPH NHSFT) *(and XXXX– delete as appropriate)* is granted under the understanding that you as Chief Investigator will conduct the study in compliance with all applicable RPH NHSFTpoliciesand procedures *(and XXXX organisational policies and procedures – delete as appropriate),* which can be found on the Trust website, and in compliance with the Department of Health’s UK Policy Framework for Health and Social Care Research. Please also refer to the ‘Memorandum of understanding (MoU) for Clinical Trial Delegation of Sponsorship Responsibilities’ (FRM028) for the agreed division of responsibilities between Sponsor and CI.

**Please note that this is not Trust Confirmation of Capacity and Capability (TCCC) or notification of Sponsor Green Light and therefore you must not start any research activity, including recruiting patients, at this time.**

Individual Site activation is delegated to yourself as Chief Investigator. Prior to activating any site, including Royal Papworth Hospital NHS Foundation Trust, please ensure sites have obtained relevant local approvals, and comply with Sponsor and Clinical Trials Unit/Trial specific Standard Operating Procedures.

**Only sites listed and approved by the Sponsor, Research Ethics Committee and the Health Research Authority may be activated. Please ensure that Trust Confirmation of Capacity and Capability is issued for each site prior to activation.**

This permission to activate site(s) *(delete if not applicable)* is dependent on Sponsorship combined with Trust Confirmation of Capacity and Capability being in place and all conditions being met.

Please be aware that you must contact the R&D office via papworth.randdenquiries@nhs.net if any of the following occurs:

1. The start or end date of your study changes. Please note the end date of this study is xx/xx/xxxx and any activities after this date will constitute a breach, please contact us to inform us of **any** changes.
2. Funding details change.
3. Any amendments made to the study (including study extensions), regardless of the content must be submitted to papworth.randdenquiries@nhs.net for Sponsor review prior to submission to the regulatory bodies.
4. Changes made to the study team, particularly at PI level or those responsible for seeking patient consent.
5. Should a study non-conformance (breaches in protocol, GCP requirements, sponsor SOPs and RPH policy) occur inform us immediately as per SOP050 and SOP051.
6. Annual safety reports should be communicated as per SOP062 and national guidance.
7. Annual Progress Reports (APR) are no longer required, accept where the study involves Confidentiality Advisory Group (CAG) approval. If this is the case, an APR must be submitted to the CAG using the form on IRAS. Please submit the draft APR  (<https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/>) to us 2 months in advance of this date for review.
8. At study closure, an end of study declaration and final study report to the Research Ethics Committee (REC) and to the Trust is required.

If you have any questions, please do not hesitate to ask.

Kind regards,

Dr Patrick Calvert,

Clinical Director of Research & Development

Royal Papworth NHS Foundation Trust

Cc:

Dr Victoria Hughes, Senior Manager of R&D.

Xxxxxxxxx CPM

papworth.randdenquiries@nhs.net