**Study Short Title:**

**P0:**

This document is for Royal Papworth Hospital Sponsored Studies where there is no operational delivery team, or CTU team support required for the life cycle of this study.

As a Principal Investigator for the above-named study, I declare that:

**Please initial box**

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| --- | --- |
| I acknowledge the roles and responsibilities to be undertaken as Principal Investigator at Royal Papworth Hospital as defined in the *UK Policy Framework for Health and Social Care Research* and *Good Clinical Practice*. |  |
| I am free to participate in the study and am not restricted by any third-party obligations which might prevent or restrict my performance of the obligations as Principal Investigator. |  |
| I have considered the facilities required for the study, and am satisfied that Royal Papworth Hospital can, and will continue to, make appropriate facilities available for the proper performance of the study, where feasible. |  |
| I shall conduct the study at Royal Papworth Hospital in accordance with the Protocol. |  |
| I consent to the Sponsor(s), and to any relevant third-party providing support, products, and/or services to the study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study. |  |
| I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud. |  |
| During the study, I will not serve as an investigator or other significant participant in any study for another sponsor if such activity might adversely affect my ability to perform my obligations as Principal Investigator to the study. |  |
| I confirm that I have declared any conflicts of interest relevant to the study, and these have been reviewed and/or mitigated at an RGPAS committee meeting. |  |
| I will refresh my GCP training and update my research CV when required (at least every 3 years). |  |
| I will keep up to date with new SOPs and SOP revisions as required. |  |
| I will provide / have oversight of [delete as appropriate] ongoing maintenance of the Trial Master File for this study and will participate in training in order to do so, where required. |  |
| I will provide / have oversight of [delete as appropriate] ongoing maintenance of the study’s record on EDGE including updating any milestone dates and recording participant recruitment in a timely manner. |  |
| I will add the study to the R&D Information Asset Register, as well as complete quarterly maintenance. |  |
| If Senior Management deem it appropriate, I will complete the NIHR PI Essentials Training prior to any study activity. |  |
| I will follow study closure procedures, including archiving, as detailed in SOP011 and agreed at an RGPAS committee meeting. |  |

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Principal Investigator name Signature Date