**Study Title**

**Short Study Name**

**Sponsor reference number:**

**MONITORING PLAN – Version #** *(Please note: the monitoring plan will be decided at the start of the study and a new version created if the plan needs updating)*

The monitoring plan for this study is agreed as follows:

Pragmatic risk assessment categorisation:

Trust risk assessment: RNN =

This monitoring plan was originally agreed at the RGPAS meeting XX/XXX/XXXX.

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**On-site monitoring:**

Monitoring will consist of X% monitoring of:

1. Inclusion/exclusion criteria
2. Informed consent
3. CRF completion and source data verification (SDV)
4. Sponsor File contents for completion
5. Site File contents for completion
6. Screenings logs
7. Deviation logs
8. Reporting of AEs/SAEs
9. Completion of annual progress and safety reports (as appropriate)
10. Completion of previously raised findings and actions (as appropriate)

Additional triggered monitoring may be conducted at the discretion of the project management/QA team.

**Remote monitoring:** *(applicable if the study is a Papworth sponsored multi-site study)*

Monitoring will consist of X% monitoring of:

1. Some site documentation to be collected by Royal Papworth from the sites *(please list)* ahead of green light/site activation:

* Delegation log (updated version to be sent if additional study team leave or join)
* CV’s and GCP certificates
* Local approval documents
* Contracts/costing
* Localised PIS and consent form

1. Patient informed consent forms (ONLY applicable if being sent via OpenClinica)
2. eCRF completion and data cleaning
3. eCRF audit logs
4. Patient diary source data verification (SDV) where possible using GP summaries and discharge letters to verify the patient entries *(if applicable*).
5. Monthly screening and recruitment logs (anonymised)
6. Deviation logs
7. Recording and reporting of AE’s and SAE’s
8. Completion of annual progress and safety reports (as appropriate)

**The Sponsor File will be 100% monitored**

In the event that there are issues with the sites in regards to documentation, consent or completion of the data in OpenClinica then additional triggered monitoring may be conducted at the discretion of the project management/QA team. Triggers for triggered monitoring may include:

* Consistently incomplete or incorrectly completed consent forms
* Incomplete data sets: Numbers of incomplete data may either trigger a warning or triggered site monitoring
* Consistently missing data entry timelines *(if applicable):* the site may either receive a warning or triggered site monitoring
* Missed reporting of per protocol reportable AE’s/SAE’s.

**Central Monitoring:**

The following metrics can be used to assess the overall performance of a site (this list is proposed as guidance only – for a full range of central monitoring metrics please refer to the following reference: *“Development of a standardised set of metrics for monitoring site performance in multicentre randomised trials: a Delphi study.”*

*Whitham et al: Trials (2018) 19-557).*

* Total actual recruitment versus total target recruitment %
* Percentage of potential participants eligible who have consented
* Percentage of randomised participants who have withdrawn consent to continue
* Percentage of randomised participants with a query for primary outcome data
* Percentage of randomised participants with complete data for primary and important secondary outcomes
* Number of adverse events reported per number of randomised participants
* Percentage of randomised participants with at least 1 protocol deviation
* Percentage of randomised participants receiving allocated intervention as intended per protocol

---------------------------------- (Clinical Project Manager)

Signed: Dated:

---------------------------------- (Study Monitor)

Signed: Dated:

­­­­­­­­­­­­­­­­---------------------------------- (Principal Investigator)

Signed: Dated: