

Key

Blue surround =
Sponsor action

Green surround =
Papworth Research Team
action

Red surround = R&D
Governance team action

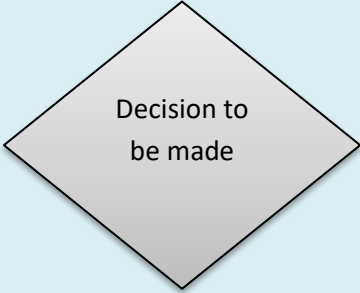
Team Leader & / PI
informed of progress by
Governance Team.



Next step



Document(s) to be
reviewed



Decision to
be made

End of Stage

Milestone – Do Not Progress Until All Other Actions
Have Been Completed

EXPRESSION OF INTERESTED STAGE

FEASIBILITY STAGE

EOI may come to R&D Governance team via team leader / direct from Sponsor to R&D Enquiries inbox (papworth.randdenquiries@nhs.net)

R&D Governance team review EOI

Specialty not relevant to Trust; decline EOI

Team Leader &/ consultant contacted by R&D team to assess capacity for study.

No capacity; decline EOI

EOI is responded to & sent back to Sponsor /CRO accepted

CDA requested & reviewed. Feasibility form first draft done by team leader

Unable to reach agreement; CDA process stops

CDA should be in standard wording with minimal changes

Gov team to consult with CRN (commercial studies) or PI (non-commercial) to assess if non-standard wording can be accepted

Support services & clinic capacity confirmed

Recruitment timeline established

Study progresses; contract and budget agreement in principle agreed. Team leader informed.

Checkpoint 2

Prequalifying Site Selection visit to review Feasibility of site (IF APPLICABLE)

Unable to reach agreement in principle on standardised draft budget /contract; study paused

R&D Governance team commence initial draft contract & draft budget review process. Documents not in standardised format to be requested with CRO / Sponsor

Checkpoint 1

Protocol, PIS, IRAS form, draft budget & draft contract received

Local PO # given, study registered & site file created. Team leader informed.

Checkpoint 3

Sponsor decides to continue based on CDA &/ Feasibility

Sponsor declines site

STOP
DO NOT PROGRESS UNTIL CONFIRMATION OF REGULATORY APPROVALS RECEIVED & AGREEMENT IN PRINCIPLE OF DRAFT CONTRACT & BUDGET COMPLETED WITH CRO/ SPONSOR.

Team Leader(s) review team capacity & agree to proceed with study.

Monitoring process agreed
Arrange / hold team & investigator / sponsor meetings.
Engagement from clinical teams sought prior to RGPAS.
Protocol reviewed/understood.
Patient pathway/ recruitment logistics agreed.
Blinded / unblinded personnel.
PI to attend RGPAS

RGPAS Committee meeting held

RGPAS declines study

RGPAS Agree to proceed

GOVERNANCE TEAM REQUESTS LOCAL INFORMATION PACK (ALL STUDIES). SETUP BEGINS

STOP
DO NOT ARRANGE SIV BEFORE THIS STAGE IS COMPLETED

Governance team agree with research team for SIV to be booked

