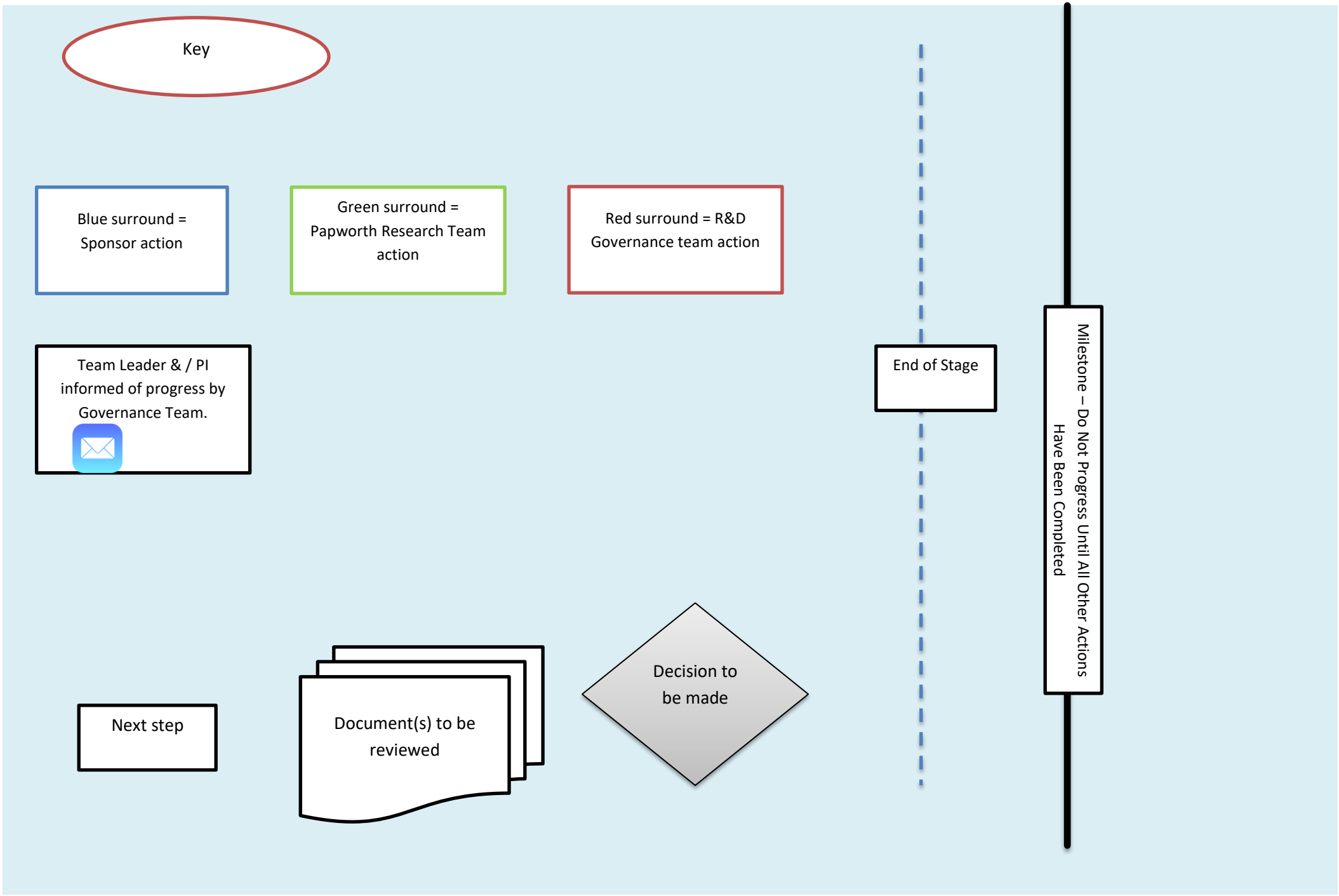
Key
Blue surround = Sponsor action
Green surround = Papworth Research Team action
Red surround = R&D Governance team action
Team Leader & / PI informed of progress by Governance Team.
End of Stage
Milestone – Do Not Progress Until All Other Actions Have Been Completed
Next step
Document(s) to be reviewed
Decision to be made

Royal Papworth Hospital NHS Foundation Trust Research & Development Non-Papworth / Commercial Governance Process v4.0

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

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

Unable to reach agreement; CDA process stops

Support services & clinic capacity confirmed

Recruitment timeline established

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

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

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

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

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

Local P0 # given, study registered & site file created. Team leader informed.

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

SETUP STAGE

STUDY OPENS

CVs & GCP certificates checked

Insurance & liability arrangements confirmed

Actions from RGPAS checked

Directorate Authorisations given

Budget finalised– agreed in principle /finalised prior to SIV

Continued review of contract – agreed in principle /finalised prior to SIV

Clinic space confirmed

Training on EDC, Study specifics

Final Review of LIP

Pathology registration completed

Pathways finalised

Contract & Budgets signed

Capacity & Capability notification issued

R&D team issue approval for SIV to be booked

SIV held with sponsor

Delegation log signed

Staff training held during SIV

Prepare study specific monthly invoicing requirements

Invoice for set-up fees

Costs loaded onto EDGE

Meet with study team to hand over study and recap invoicing

Sponsor green light requirements completed

STOP

DO NOT PROGRESS BEOFRE SPONSOR GREEN LIGHT AND R&D PERMISSION TO OPEN STUDY IS GIVEN

EDGE updated with recruitment, key dates & study status is updated throughout study life

Invoicing process starts

EDGE updated with first patient

1st patient consented & recruited

Screening & first visit commences