Royal Papworth Hospital NHS Foundation Trust Research & Development Process – External Run CRF Studies v1.0

EXPRESSION OF INTEREST STAGE

An Expression of Interest (EOI) form comes to R&D Governance team via team leader, the Clinical Research Network (CRN), the Clinical Research Facility (CRF) or from the Sponsor / CRO to R&D Enquiries inbox (papworth.randdenquiries@nhs.net)

R&D Governance team review EOI for patient cohort and potential impact.

Specialty not relevant to Trust; decline

CRF team contacted by R&D team to assess capacity and initial feasibility for study.

No capacity; decline EOI.

EOI is responded to & sent back Sponsor /CRO. Site is sent a Confidential Disclosure Agreement (CDA) (if applicable) or is site selected without CDA in place.

CDA requested & reviewed. Feasibility form completed by team leader.

CDA should be drafted using 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; EOI process stops.

No

CRF to run study?

yes

CDA signed.

FEASIBILITY STAGE

CRF team to plan patient pathway & share with the RPH Gov' team. CRF to draft Directorate Authorisations (DA's) and risk assessments at this stage. RPH to perform cursory review impact.

CRF team will commence initial draft budget review process. RPH Gov' team to perform a cursory review of draft budget.

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

Recruitment timeline established.

Study progresses; contract & budget agreed in principle. RPH Gov' team informed.

Checkpoint 2

CRF capacity confirmed in principle.

EDGE profile created as non- recruiting site.

Site File created (File Note added to Governance Folder dictating external CRF use only).

Monitoring process agreed.

Arrange team & investigator / sponsor meetings.

Engage with clinical teams / directorates prior to RGPAS.

Protocol reviewed & understood.

Patient pathway & recruitment logistics agreed.

Blinded / unblinded personnel identified.

PI to attend RGPAS.

Scientific Advice Board (SAB) application form drafted but not submitted.

DAs sent to services.

Support services contacted.

CRF delegate to attend. Decision to approach SAB / not and costs are confirmed. Decision to utilise local labs and costs are confirmed.

Checkpoint 3

RGPAS meeting

RGPAS declines study.

RGPAS Agree to proceed.

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

Email sent to study team and PI to inform 80 / 62 clock to first patient recruited has begun.

Checkpoint 4

CRF team commences Sponsor Green Light Activities.

PTO

STOP

DO NOT PROGRESS UNTIL CONFIRMATION OF REGULATORY APPROVALS RECEIVED

&

CRF & RPH HAVE REACHED AGREEMENT IN PRINCIPLE OF DRAFT CONTRACT & BUDGET WITH CRO/ SPONSOR.

CRF to review Protocol, PIS, IRAS form & review impact. CRF to keep RPH Governance team informed, who will provide oversight on behalf of the Trust.

Checkpoint 1

Local CRF# given, study registered & site file created. CRF team informed.

CRF team informs RPH of use of facility by external site.

continues

Sponsor decides to continue based on CDA &/ Feasibility.

Sponsor declines the site.

Sponsor informed of CRF use & costs.

SET UP STAGE

STUDY OPENING

STOP

DO NOT ARRANGE SIV.

DISCUSS WITH GOVERNANCE BEFORE BOOKING.

- CVs & GCP certificates checked.
- Actions from RGPAS checked.
- Directorate Authorisation sent & approvals received.
- LIP documents added to N Drive and Site File.
- Pharmacy approval received, plus costs.
- 2nd Risk assessment review prior to C&C.
- Study teams to arrange CRF visits as applicable. CRF added to delegation log.
- CRF form sent to SAB, if applicable.
- Clinic space confirmed.
- Protocol specific training completed.
- Final Review of LIP. Missing information requested.
- Pathology registration form completed.
- Patient pathways finalised.

Checkpoint 5

Contract & Budgets signed. PI/ Team leader asked to prepare for C&C.

Checkpoint 6

Trust Confirmation of Capacity & Capability notification issued.

Study team agree with Governance team the SIV may be booked.

SIV held with sponsor.

- Add calendar reminders for invoicing requirements.
- Supporting services are paid for their work.
- Sponsor green light requirements completed.

Checkpoint 7

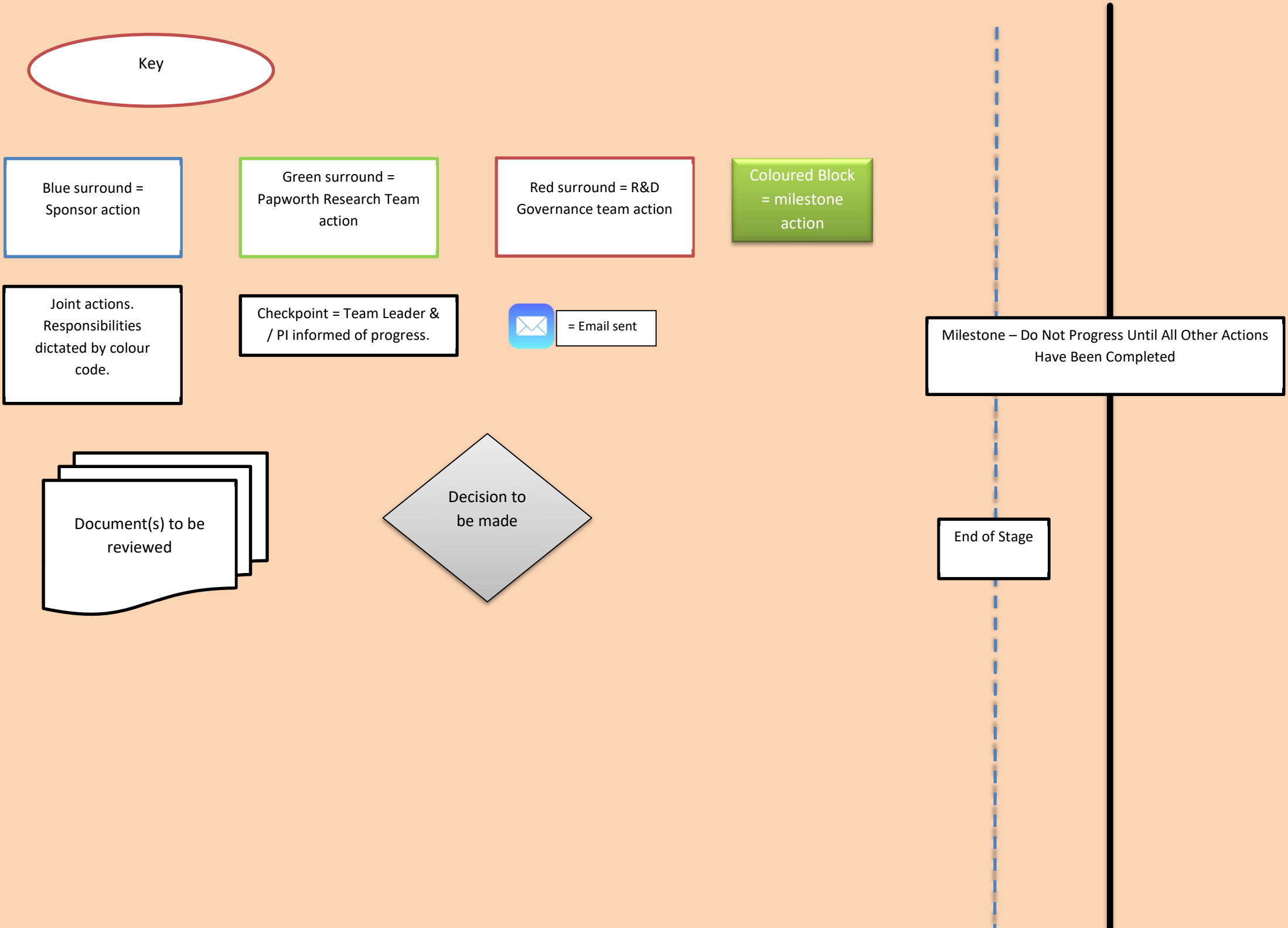
Handover meeting with study team held and recap invoicing & EDGE specifics.

- Invoice for set-up fees.
- Costs loaded onto EDGE.
- Delegation log signed.
- Staff training held during SIV.

STOP

DO NOT UNDERTAKE RESEARCH ACTIVITIES PRIOR TO RECEIPT OF C&C AND SPONSOR GREEN LIGHT.

Sponsor Green Light Date added to EDGE.


Key
Blue surround = Sponsor action
Green surround = Papworth Research Team action
Red surround = R&D Governance team action
Coloured Block = milestone action
Joint actions. Responsibilities dictated by colour code.
Checkpoint = Team Leader & / PI informed of progress.
= Email sent
Milestone – Do Not Progress Until All Other Actions Have Been Completed
Document(s) to be reviewed
Decision to be made
End of Stage