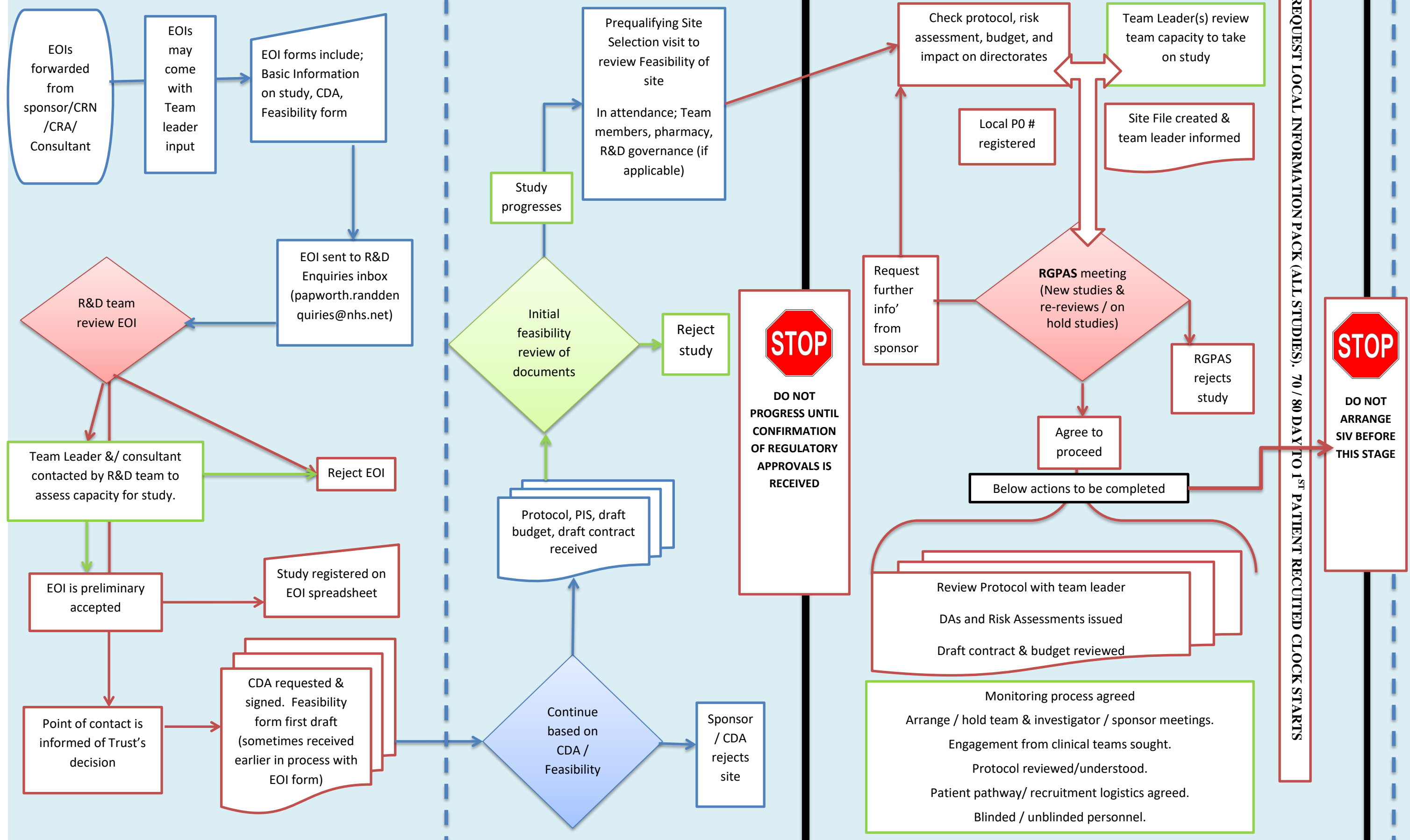


**EOI STAGE**      **SITE SELECTION STAGE**      **FEASIBILITY STAGE**



START UP STAGE

STUDY COMMENCES



- CVs & GCP certificates checked
- Actions from RGPAS checked
- Directorate Authorisations Agreed
- Budget Agreed in principle
- Initial Review of contract – agreed in principle
- Training on EDC, Study specifics
- Final Review of Documents
- Pathology registration completed
- Pathways finalised

R&D team issue (Amber light) for SIV to start

Staff training held during SIV

SIV held with sponsor

Delegation log signed

Capacity & Capability notification issued

Contract & Budgets signed

Invoice for set-up fees

Prepare study specific monthly invoicing requirements

Costs loaded onto EDGE

Sponsor green light requirements completed

Sponsor green light given

**STOP**  
DO NOT PROGRESS BEFORE SPONSOR GREEN LIGHT AND R&D PERMISSION TO HOST STUDY IS GIVEN

Screening

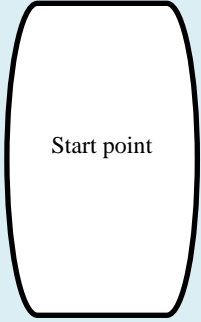
Invoicing process started

1<sup>st</sup> patient recruited

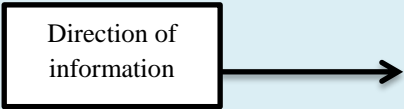
CLOCK STOPS



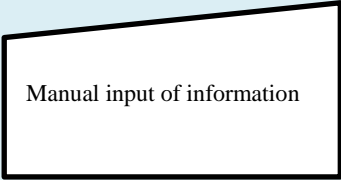
Key



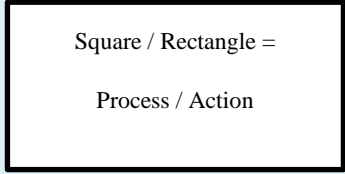
Start point



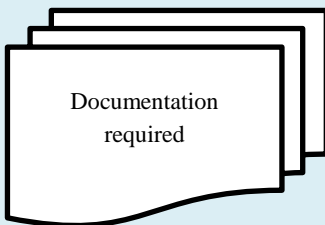
Direction of information



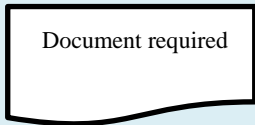
Manual input of information



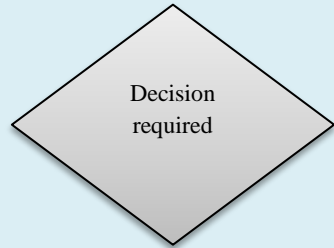
Square / Rectangle =  
Process / Action



Documentation required

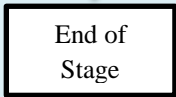


Document required



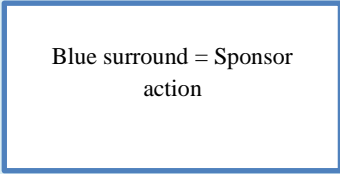
Decision required

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

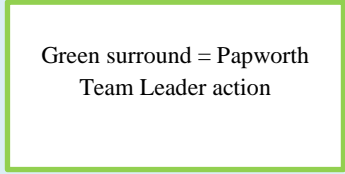


End of Stage

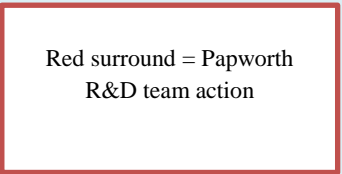
- EOI – Expression of Interest
- R&D – Research & Development
- RGPAS – R&D Governance committee meeting
- PIS – Patient Information Sheet
- ICF – Informed consent form
- CDA – Confidential Disclosure Agreement
- CRN – Clinical Research Network ('the Network')
- CRA – Clinical Research Associate



Blue surround = Sponsor  
action



Green surround = Papworth  
Team Leader action



Red surround = Papworth  
R&D team action