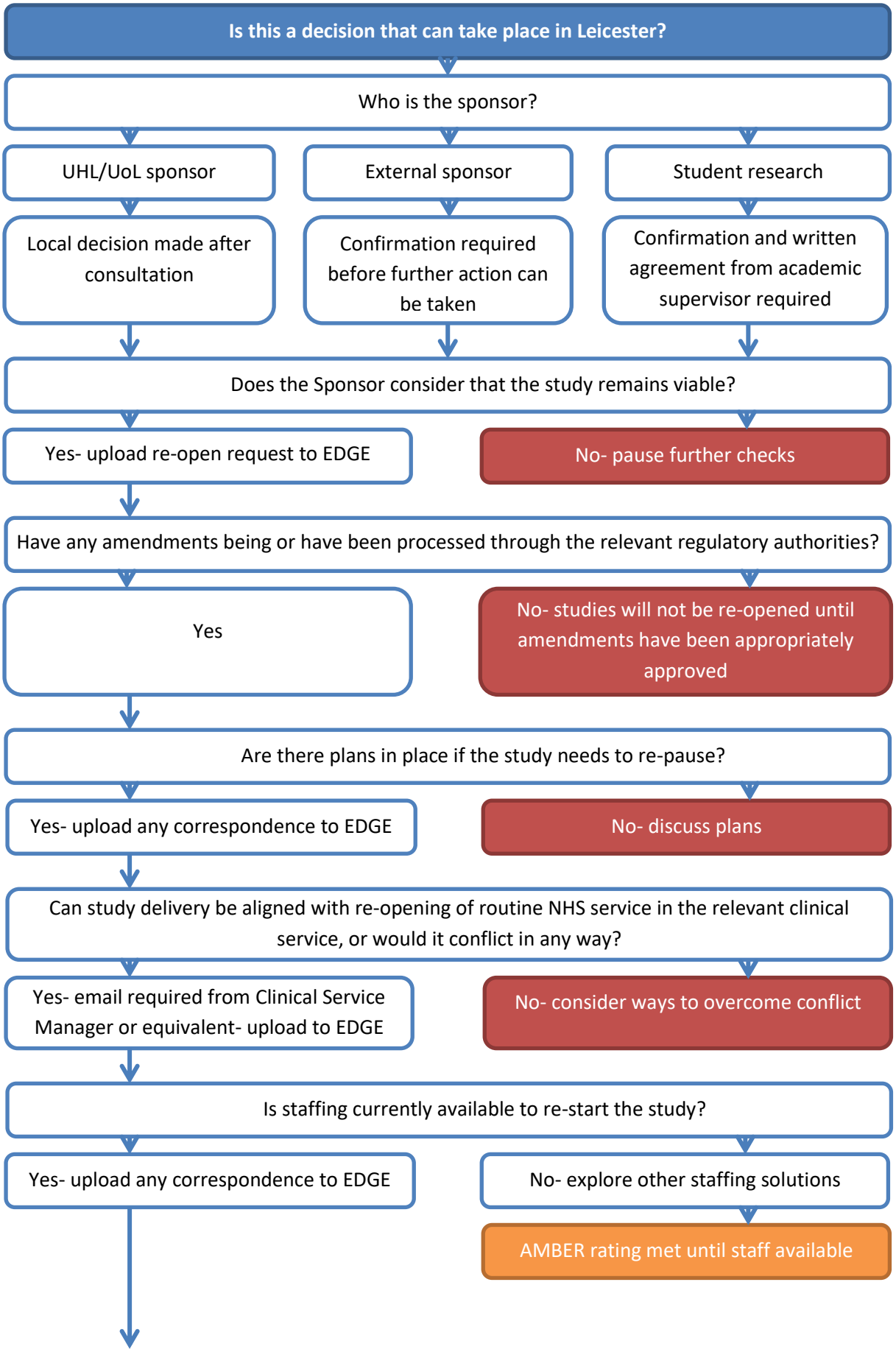
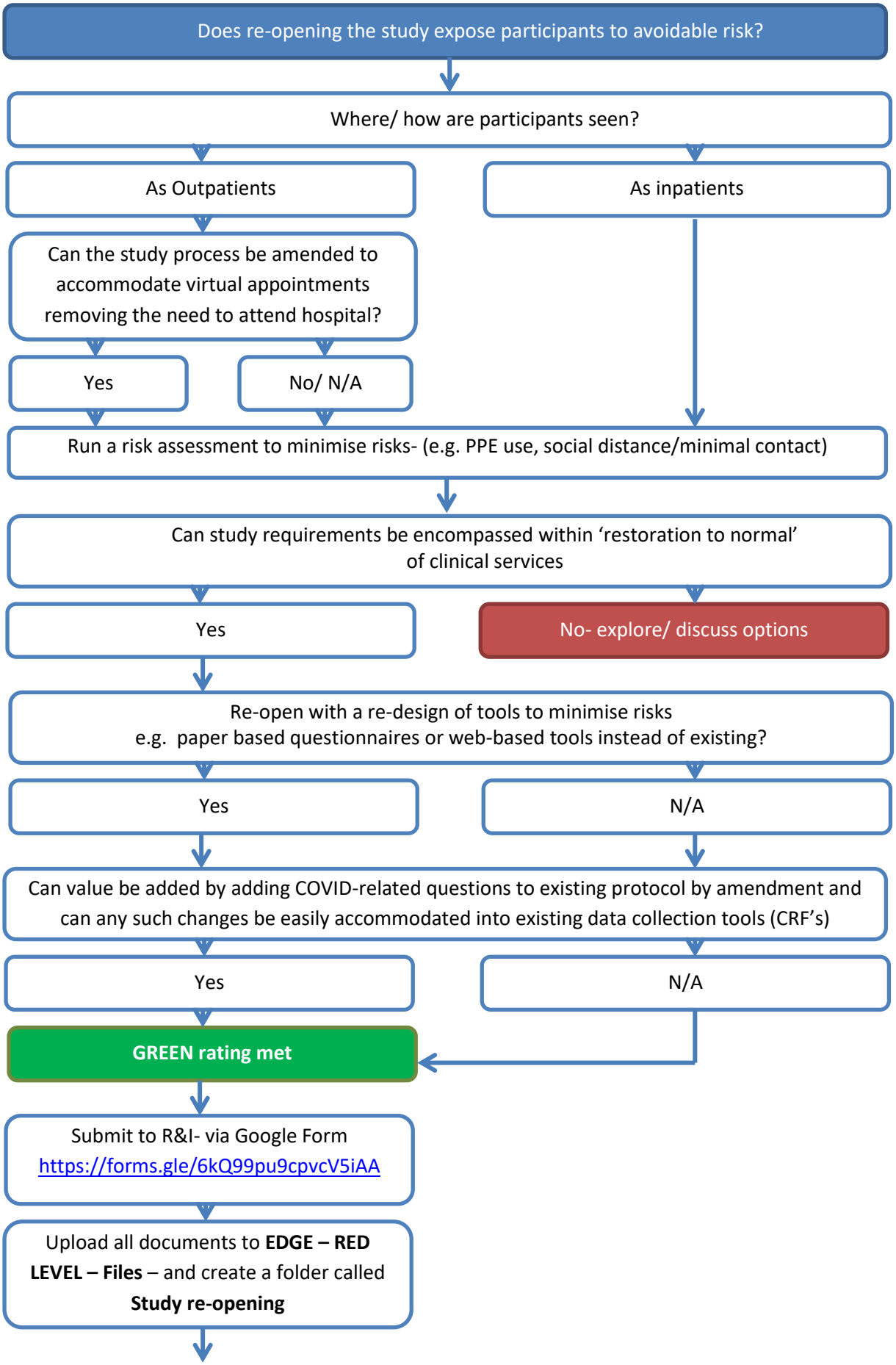
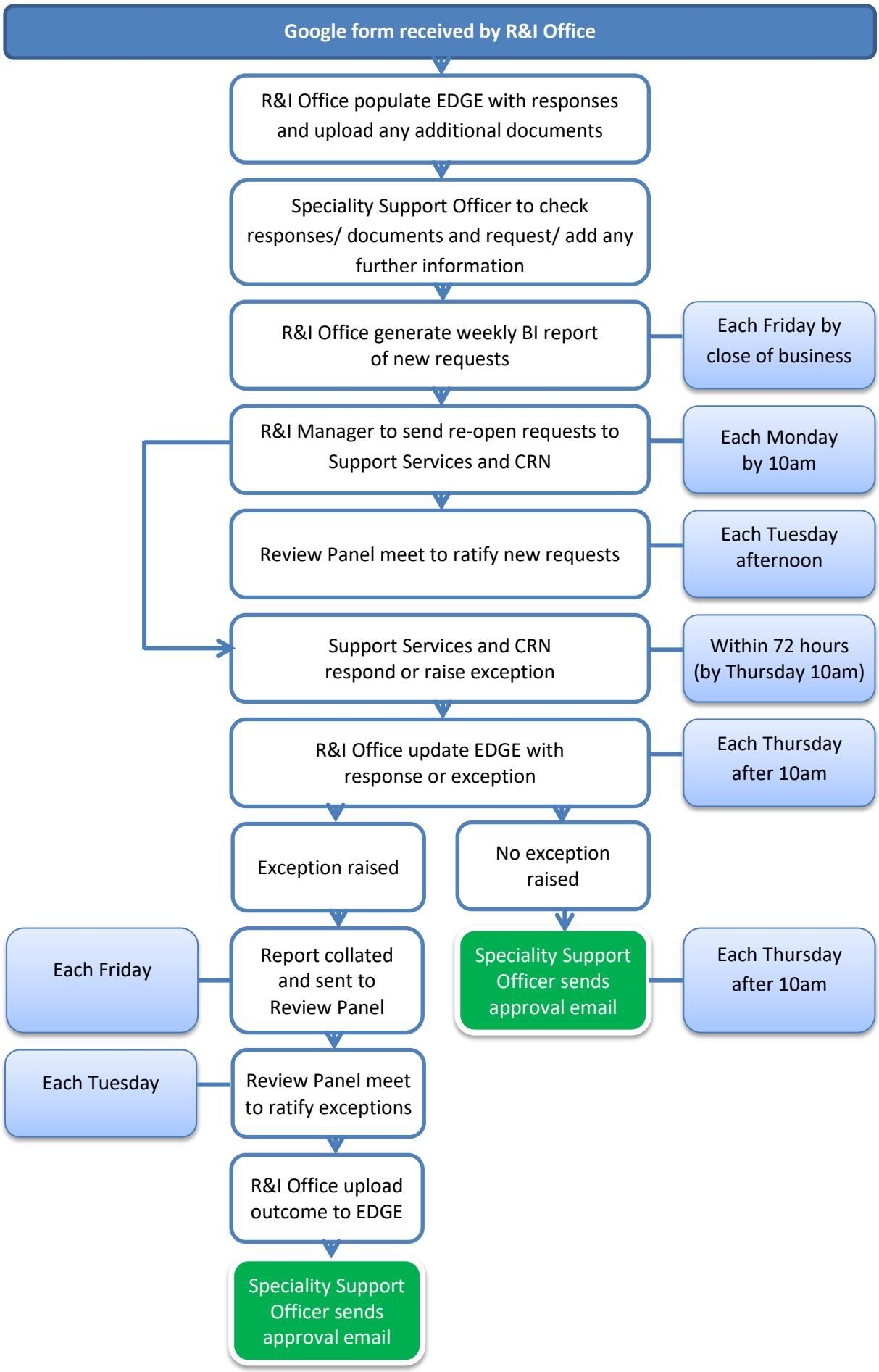
Appendix 2- SOP-C-2027: Re-opening Studies During Pandemic Flowchart




Does re-opening the study expose participants to avoidable risk?
Where/ how are participants seen?
As Outpatients
As inpatients
Can the study process be amended to accommodate virtual appointments removing the need to attend hospital?
Yes
No/ N/A
Run a risk assessment to minimise risks- (e.g. PPE use, social distance/minimal contact)
Can study requirements be encompassed within 'restoration to normal' of clinical services
Yes
No- explore/ discuss options
Re-open with a re-design of tools to minimise risks e.g. paper based questionnaires or web-based tools instead of existing?
Yes
N/A
Can value be added by adding COVID-related questions to existing protocol by amendment and can any such changes be easily accommodated into existing data collection tools (CRF's)
Yes
N/A
GREEN rating met
Submit to R&I- via Google Form https://forms.gle/6kQ99pu9cpvcV5iAA
Upload all documents to EDGE – RED LEVEL – Files – and create a folder called Study re-opening


Google form received by R&I Office
R&I Office populate EDGE with responses and upload any additional documents
Speciality Support Officer to check responses/ documents and request/ add any further information
R&I Office generate weekly BI report of new requests
Each Friday by close of business
R&I Manager to send re-open requests to Support Services and CRN
Each Monday by 10am
Review Panel meet to ratify new requests
Each Tuesday afternoon
Support Services and CRN respond or raise exception
Within 72 hours (by Thursday 10am)
R&I Office update EDGE with response or exception
Each Thursday after 10am
Exception raised
No exception raised
Each Friday
Report collated and sent to Review Panel
Speciality Support Officer sends approval email
Each Thursday after 10am
Each Tuesday
Review Panel meet to ratify exceptions
R&I Office upload outcome to EDGE
Speciality Support Officer sends approval email