Restart Risk Assessment Checklist
Study Level / Site Level

(*delete as required*)

Study Title: **Sponsor:**

R & D Ref: **Site** (*if applicable*)**:**

Chief Investigator (CI)/Principal Investigator (PI) (*delete as required*)**:**

Research Nurse (if applicable) :

This restart risk assessment checklist is to document the consideration and potential impact of restarting the above study following the peak of the COVID-19 pandemic and the lift on the halt to recruitment at site. The aim is to assess whether it is viable to restart the study and to identify, document and mitigate risks before restarting to ensure continued safety of existing and new participants and clinical staff members.

Study Viability	**Yes**	**No**	**N/A**	**Comments** (include suggested risk mitigation where possible)
Sponsor has assessed and agreed to restart (hosted studies only)?				
Funder have assessed and agreed to restart (if applicable)?				
Regulatory approvals in place?				
All necessary research funding is confirmed?				

Safety	**Yes**	**No**	**N/A**	**Comments** (include suggested risk mitigation where possible)
Risk of exposure to COVID-19 for patients and staff has been mitigated?				
Physical access complies with government restrictions on social distancing?				
Assessment of COVID-19 testing and PPE requirements completed?				
Study arrangements comply with local organisation / site policies in respect of COVID-19?				
Considered all Health & Safety issues and confirmed provisions in place e.g. COVID testing, PPE and participant information provision?				

Capacity & Capability **(PI must contact support departments and suppliers to confirm)**	**Yes**	**No**	**N/A**	**Comments** (include suggested risk mitigation where possible)
Local clinical lead (Principal Investigator) confirmed and in place?				
Research staff in place?				
Pharmacy (including emergency unblinding where required)				
Imaging/Radiology				
Labs (NHS Labs)				
Labs (University)				
Research Nursing Support				
Other contributors e.g. third party supplier (specify)				
All necessary supplies have been procured and are in place (including IMPs and PPE)?				
Physical access arrangements for participants have been assessed and are satisfactory?				
Any additional local site requirements to restart recruitment have been completed?				
NOTE: Evidence of communication with relevant department should be filed with this checklist in the Investigator Site File (ISF) or note under 'comments' who project restart has been discussed with in each department.				

Screening, recruitment and data collection	**Yes**	**No**	**N/A**	**Comments** (include suggested risk mitigation where possible)
Do you have resource to undertake screening & recruitment?				
Do you have resource to undertake randomisation?				
Do you have resource to collect baseline data?				
Do you have resource to maintain data collection for active participants?				
Does the team request refresher protocol/SOP training prior to re-opening to recruitment?				
Any deviations/violation which have occurred during recruitment halt have been documented at site and reported as required?				
Any AEs which occurred during the recruitment halt have been recorded and assessed?				

Participant study visits	Yes	No	N/A	Comments (include suggested risk mitigation where possible)
Does the clinical trial involve participants attending hospital for additional appointments over and above their inpatient admission or routine outpatient appointments (is this possible)?				
Will you continue to conduct participant visits over the telephone/virtually for the trial?				
Are there any safety concerns if participants cannot attend the hospital site for scheduled visits?				
Does the trial involve any procedures which may put others (including clinical staff) at additional risk of contact with the COVID-19 virus?				
Is there sufficient medical/PI resource to identify and report adverse events?				

Investigational Medicinal Products (IMP) and Drug Accountability	Yes	No	N/A	Comments (include suggested risk mitigation where possible)
Is there a safety risk to participants if they run out of IMP due to resupply issues?				
Are there any concerns around emergency unblinding if pharmacy/clinical resource (e.g. access to IVRS) become scarce?				
*Where participants self-administer IMP at home could IMP be safely shipped to participants by courier if required? (Please consider storage conditions and stability)				
Is it important/critical to perform drug accountability checks while the COVID-19 pandemic is ongoing? NOTE: this should be discussed with the Sponsor and site pharmacies before a decision is made.				

Clinical Resource and Supplies	Yes	No	N/A	Comments (include suggested mitigation where possible)
Do sites have sufficient supplies to continue trial visits (including IMP)?				
Where the trial involves samples do sites have sufficient storage to store samples if shipments to lab are not possible?				
Are there any concerns around emergency unblinding if pharmacy/clinical resource (e.g. access to IVRS) become scarce?				
Are there any safety concerns for ongoing participant follow up if clinical resource becomes scarce (e.g. are there essential safety procedures which must be carried out within the protocol and cannot be carried out remotely?)				
Is all equipment used for this project within calibration and preventative maintenance dates (including lab equipment)?				

Data Collection	Yes	No	N/A	Comments
Randomisation system re-activated to allow recruitment to restart?				
Database/CRF updated in line with any protocol changes made during COVID-19 outbreak?				
Support confirmed from database/eCRF provided for restart to recruitment?				

Additional Comments
Please include any additional comments/risks or considerations required for the study as part of this risk assessment

File completed/signed risk assessment in the Investigator Site File

CI/PI Signature (*delete as appropriate)*: _____

Date: _____

Options based on the completed risk assessment (To be completed by R & D staff)

1. Restart recruitment
2. Continue halt to recruitment
3. Plan a reduction in study visits (amendment required)
4. Change the nature of the study visits e.g. phone calls to participants (amendment required)
5. Change to mode of IMP supply to participants (contact your Sponsor)
6. Implement temporary halt e.g. to recruitment (amendment required)