Restart Risk Assessment Checklist

Study Title: **Sponsor:**

Research Ethics Committee Ref: **Site** (*if applicable*)**:**

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

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.

For study level checklists to restart recruitment please complete parts A, B, C, D.
For site level checklists to restart recruitment at local sites or NHS Tayside site (including hosted studies) please complete parts E, F, G, H. For categories a-d, research activity should not resume in Tayside until you have confirmation from local R&D that we have the necessary capacity and capability to so do safely.

Note: Study level and NHS Tayside site level checklist can be completed on the same form for TASC Sponsored studies.

PART A: Study Viability	**Yes**	**No**	**N/A**	**Comments** (include suggested risk mitigation where possible)
Funder has assessed and agreed to restart (if applicable – please provide evidence with completed checklist)?				
Regulatory approvals in place?				
Other contributors e.g. third party supplier have confirmed capacity to restart (specify supplier in comments)				
Central trial management team have resource to support trial?				
All necessary research funding is confirmed?				

PART B: 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 government guidance in respect of COVID-19?				
Health & Safety issues considered and confirmed provisions in place e.g. COVID testing, PPE and participant information provision?				
Any updates to the study protocol/other study documents required to incorporate any safety measures required have been made?				

Part C: 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?				
Is enough IMP available to restart recruitment? (Consider batch expiry dates, stock levels at sites and 3rd parties where applicable)				
Are there any concerns around emergency unblinding if pharmacy/clinical resources (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.				

PART D: Data Collection	**Yes**	**No**	**N/A**	**Comments**
Randomisation system re-activated to allow recruitment to restart?				
Database/Case Report Form (CRF) updated in line with any protocol changes made during COVID-19 outbreak?				
Support confirmed from database/eCRF provider for restart to recruitment?				

For NHS Tayside (NHST) site checklists (includes hosted studies) part E, F, G and H must be completed in full.

For non-NHST sites, where a local study restart R&D checklist has been completed by the PI (approved by local R&D), only questions not covered by the local checklist require completion.

Please provide a copy of the completed local checklist to the Trial Manager (UoD/NHST Sponsored CTIMPs and studies with a monitoring plan).

For sites where no local R&D checklist is in place part E, F, G and H must be completed in full.

PART E: 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 capacity confirmed (including emergency unblinding where required)				
Imaging/Radiology capacity confirmed (If your study involves imaging facilities in NHS Clinical Radiology or CRIF, please contact Jacqui Sugden, R&D Imaging Manager to establish capacity: jacquisugden@nhs.net)				
Labs (NHS Labs) capacity confirmed				
Labs (University) capacity confirmed				
CRF/Nursing Support capacity confirmed				
Other site level contributors' capacity confirmed e.g. third party supplier (specify)				
All necessary supplies have been procured and are in place at site (including IMPs and PPE)?				
Physical access arrangements for participants have been assessed and are satisfactory?				
Study arrangements comply with local organisation / site policies in respect of COVID-19?				
Any additional local site requirements to restart recruitment have been completed?				
NHS Tayside hosted studies only - Sponsor has assessed and agreed to restart?				
NHS Tayside hosted studies only - 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.				
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.				

PART F: Screening, Recruitment and Data Entry	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 breaches 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?				

PART G: 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)?				
If participants do have to attend hospital for additional appointments, is this in keeping with current government guidance?				
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?				
Is there sufficient medical/PI resource to identify and report adverse events?				

PART H: Clinical Resource and Supplies	Yes	No	N/A	Comments (include suggested mitigation where possible)
Where the trial involves samples do sites have sufficient storage space to hold samples if shipments to lab are not possible?				
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)? (If no please record deviation)				

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

Options based on the completed risk assessment

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)

File completed/signed risk assessment in the Investigator Site File and Trial Master File.

For all studies, sponsored by NHS Tayside/ University of Dundee or non-commercial studies hosted here in Tayside, please return a copy of this assessment tascgovernance@dundee.ac.uk for review prior to restarting recruitment.

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

Date: _____

(Electronic signature or confirmation of signature by email from CI/PI accepted where wet ink signature is not possible)

(Adapted from ACCORD, NHS Lothian with permission)