Tayside Medical Science Centre (TASC)
Ninewells Hospital
Research & Development Office
Residency Block, Level 3
George Pirie Way
DUNDEE
DD1 9SY
Telephone Number 01382 383900
Fax Number 01382 740122
w: tasc-research.org.uk

Date: 4 June 2020

Enquiries to: Professor Jacob George
Extension: 83204
Direct Line: 01382 383204
Email: j.george@dundee.ac.uk

Dear Investigator

As the Scottish Government moves towards easing the current lockdown, we can now begin planning for the resumption of clinical trials activity impacted by the pandemic. We will do this in a risk-proportionate and controlled manner based on various considerations listed in the NIHR guidance document for the re-start of clinical trials activity and the Scottish Government's Covid-19 framework for decision making.

a) Studies that are solely ward-based such as many of the Oncology/Hematology studies, Renal Dialysis Unit studies, acute stroke studies or run from routine outpatients specialty clinic or community pharmacies **and do not require any additional research specific/ research only visits, local CRC or other local resource**, can resume once Sponsor approval in place. Studies that require no direct patient contact (e.g. telephone questionnaires etc) which have been temporarily halted due to Covid-19 can also resume with immediate effect.

   PI ACTION: 1) Obtain Sponsor approval via email
   2) The research team should inform TASC (tasctayside@nhs.net) via email of the study resumption date.

b) For all other **Tayside sponsored** clinical research studies (CTIMP and non-CTIMP) that have been paused, we will work with you as Investigators to ensure safe and appropriate measures are in place to allow activity to resume within the framework for decision making provided by Scottish Government route map mentioned above. I would be grateful if you could complete and return the attached checklist for each study to facilitate this process. The aim of the checklist is to assess whether it is viable to re-start your study and to assist in identifying, documenting, and mitigating risks before restarting to ensure the continued safety of existing and new participants and clinical staff. We will not be able to recommence

all studies at the same time and this document will provide Sponsor with the required information to prioritise activity. Please work with your research nurse team (whether in CRC or elsewhere) or trial manager to complete this document. It is the responsibility of the Chief Investigator to notify the funder of re-start plans.

PI ACTION: 1) Complete checklist and email to tascgovernance@dundee.ac.uk and crcstudies.tayside@nhs.net (if CRC involved),
2) Notify funder

c) For **commercially** sponsored studies, in addition to the nurse team supporting the trial, please also work with your commercial sponsors to complete the checklist. Please contact the TASC Commercial team if you have any queries regarding this (tascfeasibility.tayside@nhs.net).

PI ACTION: 1) Complete checklist and email tascfeasibility.tayside@nhs.net and crcstudies.tayside@nhs.net (if CRC involved)
2) Obtain approval from Sponsor before restarting activity

d) For **investigator initiated (commercially funded) Tayside sponsored** studies, please follow (b) above

e) For **hosted** studies, completion of this Restart Risk Assessment Checklist is required for studies in Tayside that involves NHST support departments and/or UoD labs. These restart risk assessments do not need to be submitted to TASC for approval but should be filed in the Investigator Site File (ISF). Signature of the risk assessment the PI will approve restart of these projects. The PI must send this communication to R&D (email address: tasctayside@nhs.net) clearly stating in the e-mail *'As the Principal Investigator of 'STUDY TITLE' [IRAS Number xxxx], I confirm that I have completed the TASC Restart Risk Assessment Checklist and all necessary resources to restart this study have been verified by me. On this basis, I plan to restart this study on DD/MMM/YYYY'*. The NHST R&D team will acknowledge these e-mails and this acknowledgment should be filed in the study Investigator Site File (ISF).

PI ACTION: 1) Complete TASC checklist and file in ISF; If a separate Sponsor checklist is available, this is an acceptable alternative
2) Obtain Sponsor approval before restarting activity
3) Notify tasctayside@nhs.net and crcstudies.tayside@nhs.net (if CRC involved)

If you are Principal Investigator for more than one study with our site, please complete a separate checklist for each study. I would be grateful if you could return this by **15th June 2020**. If you have any queries or are unable to complete this by the 15th of June please contact tascgovernance@dundee.ac.uk soon as possible. **Please note, 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.

Thank you for your continued support during these unprecedented times.

Best wishes,
Jacob George

Professor Jacob George
Director of Research &Development,
Tayside Medical Sciences Centre
TASC Research and Development Office
Residency Block, Level 3,
George Pirie way,
Dundee DD1 9SY