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Dear Investigator

NHS A&A framework for restarting Clinical research activities which have been paused due to COVID-19.

Following national guidance, we implemented the decision to suspend recruitment into all clinical research studies other than those which were categorised as providing “essential clinical care” within NHS A&A in mid-March. Since then we have continued to treat and follow up patients on CTIMPs and focus on new trials involving the treatment and investigation of COVID-19.

April and May 2020 represented an intense period of research activity in terms of patient recruitment. This was enabled by our hard working and dedicated multi-disciplinary COVID-19 research teams based across University Hospital Crosshouse and University Hospital Ayr within NHS A&A and our outstanding patients who have participated in these studies.

We appreciate that many research teams are keen to re-start clinical trial activity. NHS Research Scotland is in discussion with UK colleagues to enable a return to research activity, consistent with the Scottish Government’s COVID-19 framework for decision making (<https://www.gov.scot/publications/coronavirus-covid-19-framework-decision-making/>)

There are a number of pre-conditions (safety, capacity and readiness) that must be in place before studies can receive R&D approval to re-start.

The underlying principles are that

- Research should only restart/start when safe to do so and safety of research participants and personnel is of paramount importance.
- Government guidance on social distancing, travel and PPE requirements above standard of care needs to be considered
- Pace of restart and the commencement of new studies should be commensurate with capacity and readiness within NHS A&A services
- Delivery of research will be dependent on relevant health and care services being ‘open for business’

These are reflected within our local NHS A&A Checklist which must be completed prior to any study recommencing recruitment. In order to facilitate this process of re-opening studies, please send any requests to the Lead Clinical Trials Nurse Danielle.Gilmour@aapct.scot.nhs.uk in order for the Checklist process to commence.

All activity will need to be prioritised (due to the current level of COVID-19 research) along the following lines (<https://www.nihr.ac.uk/documents/restart-framework/24886>):

Level 1: essential studies providing evidence for pandemic management, i.e. nationally prioritised COVID-19 Urgent Public Health (UPH) Research Studies.

Level 2: Studies where the research protocol provides patients or participants with an urgent treatment or intervention without which they would come to harm. These might be studies that provide access to essential treatment not otherwise available to the patient.

Level 3: All other studies (including new COVID-19 studies not in Level1).

The above information is subject to revision due to any changes in National circumstances and guidance.

Should you have any queries please direct them to myself or Danielle Gilmour at Danielle.Gilmour@aapct.scot.nhs.uk

Yours sincerely

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