

25th May, 2020

Dear Investigator,

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

In mid-March, we took the difficult decision to suspend recruitment and all face to face visits into all clinical research studies others than those which were categorised as providing “essential clinical care”. Since then we have continued to treat and follow up patients in these studies and focus on new trials involving the detection, investigation, treatment and prevention of COVID-19.

April 2020 represented our most intense period of research activity in terms of participant recruitment on record and May is proving even busier. This has been enabled by our hard working and dedicated multi-disciplinary COVID-19 research teams and our outstanding patients and volunteers who have participated in these studies. We have also deployed research nurses and R&D staff to clinical service.

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-scotlands-route-map-through-out-crisis/>). There are pre-conditions (safety, capacity and readiness) that must be in place before studies can receive R&D approval to restart.

The underlying principles are that

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

These are reflected within our local NHS Grampian study exemption request form, sent out on 23<sup>rd</sup> May and available on our website, which must be completed prior to any study recommencing recruitment. **At this time, we only are only reviewing requests for exemptions in the following settings:**

1. Essential critical care activities where the research takes place at the same time as the clinical care activity/ or provides an essential treatment not otherwise available. Any follow up visits would need to be done as part of the clinical care visits or virtually.
2. If non-essential services resume and patients are attending for face to face or virtual (Near-me or telephone) clinic appointments. Studies that can recruit/ consent at the clinic visit with all follow up research activity being done as part of clinical care visits or virtually (with appropriate amendment to allow for virtual clinical contact).

In order to facilitate the process of re-opening studies, please send any requests along with the exemption form and your sponsor confirmation to NHS Grampian R&D [grampian.randd@nhs.net](mailto:grampian.randd@nhs.net).

Studies will be prioritised along the following lines:

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 Level 1).

Should have any queries please direct them to myself or [grampian.randd@nhs.net](mailto:grampian.randd@nhs.net)

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Maggie Cruickshank', written in a cursive style.

Professor Maggie Cruickshank  
R&D Director  
NHS Grampian