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28<sup>th</sup> May 2020

Dear Chief Investigator,

**Framework for restarting face to face recruitment to studies sponsored by NHS Grampian, University of Aberdeen or co-sponsored by NHS Grampian and University of Aberdeen.**

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 been focusing on advising and supporting colleagues on amending studies, to enable them to continue without face to face visits, and on expediting the set-up and start of new trials involving the detection, investigation, treatment and prevention of COVID-19.

We appreciate that many research teams are keen to restart clinical trial activity. NHS Research Scotland is in discussion with UK colleagues to develop guidelines to support a return to research activity, consistent with the [NIHR Restart Framework](#) and the [Scottish Government's COVID-19 framework for decision making](#). These frameworks set out the safety, capacity and readiness pre-conditions that must be in place before studies can receive Sponsor approval to restart.

The underlying principles are:

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 need to be considered.
3. Pace of restart and the commencement of new studies should be commensurate with capacity and readiness within NHS services.
4. Delivery of research will be dependent on relevant health and care services being ‘open for business’ – for multi-centre studies not all sites may be ready to restart at the same time.

Following the publication today of the [CSOs Statement on the Restart Framework](#), we will now start to review requests for restarting/ starting face to face recruitment in the **following** scenarios:

- 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 conducted as part of the clinical care visits or remotely.
- **When** non-essential clinical services resume and patients are attending for face to face or remote (Near-me or telephone) clinic appointments. Studies which can recruit/ consent at the clinic visit with all follow up research activity being done as part of clinical care visits or remotely (with appropriate amendment to allow for remote clinical contact).

If you feel your study meets this criteria please contact [researchgovernance@abdn.ac.uk](mailto:researchgovernance@abdn.ac.uk) by email including:

1. Full study title and sponsor reference number of your study.
2. A brief summary of your study.
3. A full justification for restarting/ starting the project.
4. Confirmation that staff, facilities and equipment for the study are available.
5. The measures to be put in place to safeguard both participants and staff working on the project e.g use of PPE.

#### **Other studies requiring face to face contact**

Unfortunately we will **not** be able to allow studies which involve face to face visits (other than the scenarios described above) or healthy volunteers studies to restart/ start at this point. However, ongoing contingency planning is underway and further correspondence will follow as the situation changes.

#### **Local Site Permission**

Studies that meet the above criteria and are given approval by Sponsor will **also** require approval from the Health Board and/or Trust where the research is taking place prior to restarting/ starting. For NHS Grampian please send any requests along with the exemption form (<http://www.nhsresearchanddevelopment.scot.nhs.uk/wp-content/uploads/2020/05/Study-Exemption-request-form.docx>) and your sponsor confirmation to NHS Grampian R&D [grampian.randd@nhs.net](mailto:grampian.randd@nhs.net).

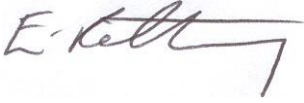
#### **Studies involving no face to face contact**

The Sponsor guidance for these studies is unchanged and participants may still be approached about observational studies or pre-screening studies where this participation requires no additional visit attendance by the participant or face-to-face contact with the study team and the study team have capacity.

For all studies, where possible amendments should be made to the study protocol to allow visits to take place remotely. Please contact the research governance team regarding these as per normal practice.

Should you have any queries please direct them to [researchgovernance@abdn.ac.uk](mailto:researchgovernance@abdn.ac.uk).

Yours sincerely,

Handwritten signature of E. Rattray in black ink.

Dr E. Rattray  
Director Research and Innovation  
University of Aberdeen

Handwritten signature of Maggie Cruickshank in black ink.

Professor Maggie Cruickshank  
R&D Director  
NHS Grampian