

[Type here]

[Type here]



**The Newcastle upon Tyne Hospitals**  
NHS Foundation Trust

8<sup>th</sup> January 2021

Dear Colleagues

I am writing on behalf of the senior leadership team in Clinical Research and should start by wishing you all a Happy New Year. With another national lockdown announced earlier this week it is already feeling very similar to last year. However, compared to March 2020 there are some important differences in our response to this lockdown, which I will outline below.

Thanks to the hard work of the research teams during 'restart' the studies we have open are well adapted to the pandemic and we expect the vast majority to continue as normal. It is worth noting that when comparing the number of studies which are open and recruiting between trusts, NuTH is currently one of the top three most research active Trusts in the UK.

In general, we are keen to avoid pausing studies as we learned from the first lockdown that it is easier to ramp up an open study, than restart a paused study. We accept that there may be constraints on a research team's ability to recruit new participants to some studies but hope these will be relatively short lived. There may also be occasions when some participants feel unable to attend follow up visits. Any protocol deviations should be reported via the usual routes and we will monitor these in the Newcastle Joint Research Office (NJRO) for studies where the Trust is the sponsor and via the Team Leads for hosted studies. The Team Leads are meeting at least weekly with Hannah and Aileen and also have easy access to the NJRO to discuss any governance issues.

We will continue to progress new studies through the local approvals process with the Team Leads and Research Clinical Leads continuing to oversee which studies are submitted and when. Over the last few months, we have also seen the clear benefits of closer working and open lines of communication between Clinical Trial Coordinators and staff in the NJRO. The NJRO team are there to help, so please contact them to discuss any issues regarding study approvals. For example, you may wish to progress a study through local approvals but hold off getting a green light.

We are also working in step with the rest of the Trust with regards to external visitors to the Trust premises. Wherever possible, Site Initiation Visits and monitoring should be conducted remotely virtually by Microsoft Teams. Access to full remote access using Swivel Pin will be piloted by specific teams in the future. There is a Standard Operating Procedure, Working Instruction and IT Account Request Form for remote monitoring available on the NJRO website <https://newcastlejro.com/research-in-newcastle/resources/documents/>. Physical in person monitoring visits should be limited to those required for patient safety, while we remain in Tier 5 restrictions.

For all issues related to patient care, patient safety and infection prevention and control our response mirrors that of the other clinical directorates.

While the numbers of inpatients with COVID are not quite at the level we saw in April they are not far short. Clearly, we hope that that we can ride this third wave out but there are some uncertainties and plans may need to change. I hope the above is helpful and our approach proportionate and sufficiently light touch to allow research teams to manage their own portfolio of studies. If you have questions please contact any of the senior leadership team and we'll try our best to help.

Kind regards

Stephen Wright  
Clinical Director, Directorate of Clinical Research