

Dear Sponsor Representative,

As part of our response to the COVID-19 pandemic, it has been necessary for University Hospital NHS Foundation Trust (UHS) to implement a number of measures with immediate effect. These measures will enable our research workforce to focus on delivering the nationally sponsored COVID-19 studies or redeployment to frontline care where necessary. These measures will remain in place until further notice.

The specific measures implemented are detailed below:

1. With the exception of COVID-19 studies and some studies where it has been decided the study offers an advantage to patients coping with COVID 19 or there is no input from clinical staff, recruitment of new patients to all studies has been suspended.
2. Patients already receiving active treatment will continue to receive treatment. The logistics of IMP delivery may need to be adjusted.
3. Essential follow-up activity will continue e.g., safety monitoring or when stopping the follow-up activity will be detrimental to the patient.
4. To reduce the spread of COVID-19 all non-essential visits to site have been cancelled. Where possible, essential monitoring should be undertaken remotely in line with recent emergency MHRA recommendations. The Trust will accommodate this remote monitoring for as long as it can. Where this is not possible, monitoring visits should be cancelled. They can be rescheduled at a later stage once normal clinical services resume.

<https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/>

5. All Site Initiation Visits and Site Selection Visits have been cancelled until further notice unless they relate to a COVID-19 study. In that instance, these visits should be carried out remotely.
6. All site set-up activities that do not relate to nationally sponsored COVID-19 studies have been put on hold.
7. Expressions of Interests (EOIs) for potential studies will not be facilitated within our normal timelines.
 - a. At the current time the NHS is undergoing a preparation exercise to ensure the maximum number of clinically qualified staff are able to respond to the COVID 19 pandemic. Staff previously working solely on research are being

re-trained to take up clinical roles. For this reason we are not responding to EOIs for new research studies unless directly related to COVID 19. We would however like to keep these EOIs on record so that when the current crisis eases and we are in a position to respond we can do so in a timely manner. Please do not send EOIs through to our clinical staff but rather to the R&D office researchmanagement@uhs.nhs.uk

8. Only amendments related to COVID-19 studies, amendments that require implementation due to COVID-19, or amendments that relate to on-going studies where essential follow-up will continue, will be reviewed.
 - a. We are currently receiving a number of amendments from sponsors to suspend study recruitment and to accommodate COVID 19 into existing protocols. These amendments are being prioritised and processed as quickly as possible. We are also receiving a number of amendments loosely related to the COVID 19 outbreak in that they are extensions to timelines and/or recruitment numbers to compensate for the temporary suspensions. These are in addition to the usual amendment workload. We ask for your understanding at this time in that we do not have the capacity to assess if we can accommodate these amendments within the 35 day timeframe. We may not be able to assess them until the crisis has passed and our workforce stabilised. As soon as we have been able to assess the amendment we will communicate with you and send through an acknowledgement.
9. Sign off of CDAs will not be facilitated within our normal timelines. Please also note that the temporary suspension of clinical research will make it difficult for us to meet some contractual obligations.
10. If Sponsor requires a formal notice from the Trust (site) regarding suspension of the study due to Force Majeure please let us know as soon as possible.
11. Please contact Olivia.Chalwin@uhs.nhs.uk if you require anything further from us with regard to our contractual obligations with the sponsor.

We will contact all sponsors as soon as we are in a position to resume normal research activity.

Thank you for your support and cooperation during this challenging time.

Regards,

Christine McGrath, Director of R&D, UHS