University Hospitals Bristol
NHS Foundation Trust

COVID-19 outbreak

University Hospitals Bristol NHS FT advice to researchers

11 March 2020

1. Introduction

COVID-19 is a new strain of coronavirus first identified in Wuhan City, China in December 2019. You will be aware of the rapid spread of the virus which this month has been associated with deaths in the UK. University Hospitals Bristol NHS Foundation Trust is following national guidance in terms of managing the COVID-19 outbreak, **and at present we will continue our research activities as usual until further developments, or national guidance to the contrary.**

However, as the situation may change rapidly, we must all make plans to ensure the safety of our patients and staff. This document relates to research involving the patients of UHBristol.

This guidance is subject to change at short notice and will be updated on a regular basis. This guidance complements that provided by the Trust to all patients, staff and visitors. Where guidance from external organisations proves inconsistent, instructions from the Trust will take precedence.

2. Research staff

- In the event of the 'normal business' of the trust being suspended, clinically qualified research staff may be required to support clinical services within their scope of practice, which will take precedence over their usual research duties (see appendix A).

- All clinically qualified research staff working on hospital premises should acquaint themselves with guidance issued within their clinical service, and discuss what their appropriate clinical activities may be on an individual basis. In some cases, this will include fit-testing for face masks and training in use of protective clothing. Please seek advice from your divisional management structures or from the research matron and R&I senior team if you are unsure.

- Where appropriate, we may plan for non-clinical staff to support clinical services by working directly within clinical divisions.

- In the event that this is not required, remote working from home for some non-clinical research staff may be appropriate following discussion with line managers. Line managers should work with their teams to ensure appropriate facilities are available to allow home working.

- Other than the above, unless there is a clear justification, we would recommend research staff do not routinely visit wards or other clinical areas where patients infected with COVID-19 are being treated. chief and principal investigators should prioritise all patient facing research activities in light of this.

3. **Maintaining essential research activity during pandemic episodes**

- As the outbreak develops we expect that we will see reductions in participants attending for research visits and/or a reluctance to do. In order to support the clinical services and any government-recommended communications around non-essential travel and social distancing, we may reduce or suspend research activity in certain areas.
- The safety of research participants will be prioritised and they will be advised not to attend hospital if it puts them or others at risk. Conversely, some research participants' care may be research-driven and therefore continuity of treatment/monitoring should be prioritised.
- In order to support that process principal/chief investigators and their research teams should review all active studies and categorise them into the groups below.
- Principal investigators may wish to consider discussing the situation with study sponsors, in particular for commercial trials, in order to identify studies that could safely be suspended.
- In most cases, principal investigators should postpone patient recruitment to new clinical studies until after the outbreak subsides. R&I will cascade information about the timing of when such decisions should be implemented.

Category	**Description**	**Likely action in full scale emergency scenario**
A	Pandemic and urgent health research	Recruitment to and delivery of these studies will continue
B	Research where clinical care is research protocol dependent and the benefits to patient safety of continued participation outweigh the risks of stopping treatment.	Recruitment to and delivery of these studies will continue
C	Research where treatments have the potential to improve the capability for patients to respond to COVID-19 infection (ie overall safety benefit), eg CF trials.	Recruitment to and delivery of these studies will continue
D	Research where there is no identified positive or negative impact of recruitment/participation continuing	Where resource permits, delivery will continue, but further recruitment will be suspended.
E	Research which has the potential to increase the risk to patient safety in the event of exposure to/infection with COVID-19	Recruitment to these studies will be suspended.
F	Non-essential/non-urgent research	Recruitment and delivery of these studies will be suspended

For research which is suspended, patient safety and data integrity remain a priority and patient safety and monitoring via telephone follow up should be carried out where possible.

Allocation of research staff to address research in categories A, B and C will remain a priority and will be factored into the process of allocating clinical research delivery staff to support clinical areas.

a. Monitoring

- Following the agreement to deploy clinical research staff to clinical areas the R&I team will support divisional teams to monitor the allocation of resources and continually review against the essential research needs, if required.
- If there is a risk to the safety of research participants due to lack of research delivery staff the research matron and or director/deputy director of research will discuss with senior executive on duty in order to consider recalling clinical research delivery staff or consider whether further research activity should be suspended

b. **Considerations**

- Clinical research staff supporting clinical areas should not be allocated to work in areas where they are at risk of contracting an infection that may then be passed onto vulnerable research participants.
- Clinical research delivery staff must be up to date with all mandatory training and professional registrations. It must be recognised that some clinical research delivery staff may not have worked in clinical areas recently and therefore must only be expected to undertake activities which they are fully trained in and feel confident and competent to do so.
- Usual agreed patterns of work may be dependent on childcare/family arrangements. This needs to be taken into consideration when asking clinical research delivery staff to work in areas that operate different working patterns to their current arrangements. Any unsocial hours work must be recorded on health roster and the member of staff paid appropriately for these hours.

4. UHBristol sponsored research

Chief Investigators should work with R&I to discuss whether their trial(s) should be suspended nationally at all sites so we can support this decision making and actions following it.

5. Contracting and finance

- It is possible that the temporary suspension of clinical research may make it difficult to meet contractual obligations. This is a particular concern for commercial research.
- If a decision is taken to suspend any study activities at UHBristol, in order to avoid a breach of contract we need to follow due process. It is therefore imperative that decisions about study suspensions are made in full consultation with R&I office staff.

- NIHR has confirmed that no financial penalties will be enforced if a project is suspended. It is anticipated that AMRC registered charities will fall in line with the main UKRI guidelines. However, the requirement remains to notify funding bodies on a project by project basis. Such decisions must therefore be made together with R&I office staff to ensure such notices are issued promptly.

David Wynick, Director of Research & Diana Benton, Head of R&I

Appendix A

Decision making process for triggering deployment of clinical research delivery staff to clinical areas:

1. Senior Trust Executive on duty identifies need to deploy research staff, and identifies location and level of support required
2. Senior Executive contacts divisional research unit manager
3. Divisional research unit manager reviews research in priority research categories (A-C) to ensure staffing levels can be maintained.
4. Divisional research unit manager liaises with R&I senior team to identify (further) projects for suspension and allocates staff from category D-F projects to support clinical areas.
5. Research matron may review staffing across research delivery teams (trustwide) in order to identify additional resource if required and liaise with other divisional research unit managers to advise of resource need.