Implications of the COVID-19 outbreak for clinical research at North Bristol NHS trust

Guidance for our investigators and research staff

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. NBT 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 NBT. 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.

General advice for 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. Decisions to redeploy research staff will be managed through the R&I senior team and NBT emergency control room.

- 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. This should be discussed with your line manager in each research team and will take into account your role, ability to work from home and facilities available to support this.

- 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.

- In the event of a severe outbreak, it is possible that the CRC and other research facilities/space would be redeployed in support of the care of non-research patients. However, the care needs of patients participating in clinical research must also be addressed, in particular where research patients require ongoing treatment (see below). Enquiries about use of research space should be directed to R&I.

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. Based on the requirements of our clinical services and any government recommendations we may need to reduce or suspend activities on selected research studies.

- 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.

- We deliver a very wide variety of patient research and it is not appropriate to issue blanket rules about which studies should continue and which should be suspended.

- 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.

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

- 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.

- As the situation evolves Principal Investigators may need to 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.
- We have created a categorisation system for research studies which will help identify actions that will be required and at what point in escalation of the Trusts emergency procedures to do so.

Category	**Description**	**Likely action in full scale emergency scenario**
A	Pandemic studies and those highlighted by CRN as urgent health studies	Recruitment to and delivery of these studies will continue
B	Studies delivering clinical care for patients where not seeing the patient would create a risk or safety risk for the patients e.g. cTIMPs, studies delivering cancer treatment etc	Delivery of these studies for patients already recruited will continue but recruitment of new patients to these studies could be suspended
C	Studies where patient care could be compromised by research visits being suspended but this does not provide a	Delivery of these studies for patients already recruited will continue in all but the most extreme scenarios but

	risk to patient safety	recruitment of new patients to these studies will likely be suspended
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	These studies will be suspended
F	Studies that do not provide direct patient care	These studies will be suspended

NB: **Currently we are business as usual and this should continue until further notice**

- R&I will issue guidance based on advice from NBT about the when different levels of studies should be suspended. This will be influenced by the need for redeployment of research staff, reduction of facilities/services by the Trust, guidance or notice from sponsors.

- Redeployment of research staff and facilities will be managed and monitored by R&I.

Contracting and performance

- 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 NBT, 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.

- We should anticipate a short-term reduction in our performance; this is expected and recognised nationally. This should ease when we return to business as usual. Delivering patient care remains our primary focus.

The above points are subject to regular change as the incident develops.

R&I Office staff will be available to advise staff on any decisions during the outbreak. In order to facilitate prompt communication, we ask that you channel related queries to research@nbt.nhs.uk to ensure these promptly reach the most appropriate available staff member.

David Wynick, Director of Research & Becca Smith, Deputy Director of Research