Durham Tees Valley
Research Alliance
(DTVRA)

COVID-19 briefing to all staff involved in delivering research 13/02/2020

We encourage all staff to follow the latest guidance from the Trust, Public Health England and the Department of Health in relation to the Coronavirus pandemic. We are also in regular contact with the National Institute for Health Research (NIHR) and Health Research Authority (HRA) for guidance on how to appropriately manage our research activity.

This is a rapidly changing situation and as such we need to plan for future changes to how we deliver our service whilst maintaining patient safety. As the situation escalates we anticipate the following step-wise approach listed below showing our current status for each step:

Stage	Description	Current Status
1	**Stop all external visits to the Trust for research related activities from study monitors, external visitors and PPI members.** Use this briefing note as confirmation to sponsors that this is a Trust R&D decision. Consider using videoconferencing options via for e.g. www.zoom.us	ACTIVATED 12/03/2020
2	**Stop all external visits to other sites for monitor visits, external meetings, non-essential training and conferences**. Use this briefing note as confirmation to sponsors that this is a Trust R&D decision. Consider using videoconferencing options via for e.g. www.zoom.us	ACTIVATED 12/03/2020
3	**Review current clinical pathways for research patients and inform sponsors if changes to protocol might be needed**	ACTIVATED 12/03/2020
4	**Review all studies to identify non-essential activities that could be suspended** in the event of depleted staffing and complete "COVID-19 Study assessment sheet"	ACTIVATED 12/03/2020
5	**Suspend the setting up of new studies**	To be reviewed daily
6	**Suspend non-essential recruitment and follow-up activities identified in Stage 4** to allow for available staff to support essential activities and COVID-19 study specific requirements.	To be reviewed daily
7	**Discussions with staff to facilitate working from home if possible**	To be reviewed daily
8	**Decision made re: assisting with frontline clinical duties as appropriate**	To be reviewed daily

As Stage 6 suggests, we may decide to reduce or suspend activities on selected research studies to minimise non-essential travel to hospital for patients. Please start to think about how you are clinically assessing risk of COVID-19 in research patients before they are approached / seen to ensure your safety and that of the research delivery staff. It's not feasible for the R&D department to issue blanket guidance – this decision should be made collaboratively between the Principal Investigator (PI), Team Leads and research delivery staff. The decision to suspend activity should be made by clinically qualified staff based on clinical criteria – in most cases this will be the PI / CI . Any decisions should be communicated to study sponsors and the R&D office (stees.dtvra@nhs.net)

It is possible that temporary suspension of research may make it difficult to meet contractual obligations, this is of particular concern for commercial research. From national discussions and guidance from other Trusts I have seen, we feel we can rely on the "Force Majeure" clauses in research contracts in the event of temporary suspension due to COVID-19. If a decision is taken to suspend study activity then the sponsor needs to be notified immediately in order to avoid potential breach of contract. This notice must be issued promptly to the sponsor and we would advise you to collaborate with the R&D office to assist with this.

UKRI and NIHR have confirmed that no financial penalties will be enforced if a project is suspended however it's imperative you notify the sponsor if you need to suspend activities at our sites.

At the moment we do not expect staff to be called in to assist in clinical areas – we are continually reviewing this and in discussions with both the trust's Nursing directorate and the NIHR should the situation change. If you receive any direct requests to assist in clinical areas please direct these to your team leader who will liaise with myself and Tarn. We would not expect any of our research staff who are in any "at risk groups" (due to age or co-morbidity) to be called into frontline clinical work.

MHRA have issued guidance for Clinical Trials which we would ask you all to read https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/

For CTIMP (drug) studies- Consider how you might supply IMP to patients not attending hospital for visits. Alternative distribution arrangements need to be discussed and approved with the Sponsor ensuring the pharmacy department are informed of these arrangements (+ relevant CTU if it's a Trust sponsored study)

Specific guidance for PIs (supported by research staff)

- You should risk assess your studies in collaboration with your research delivery staff and team leads to identify which essential activities need to be undertaken and which activities can be temporarily suspended without impacting on patient safety. As a general rule we should be avoiding bringing patients into the trust for research specific appointments.
- Speak to study sponsors if you can identify any activities that could be done remotely (telephone follow-up) so that an amendment to protocol can be submitted by them
- Research Team Leads will populate the R&D COVID-19 spread sheet to indicate which studies can be "stepped down", which require on-going support and what Pharmacy dispensing will be required
- Inform R&D of any studies where the sponsor has already contacted you with alternative arrangements / suspension of recruitment / amendment to protocol.
- Inform your study sponsor of your plans re: local delivery of your study or temporary suspension of activity.

In addition to the above - Guidance for Chief Investigators (CIs)

- Communicate with your Clinical Trials Unit (where relevant) to develop a plan to identify and deliver "essential" trial activities for all participating sites and communicate this to the R&D office and your participating sites
- A decision should be made re: suspension of active recruitment and focussing on essential follow-up / safety activity and communication of this to HRA, R&D and participating sites
- Consider whether you can implement amendments to protocol to facilitate trial related activities outside of the hospital setting to reduce risk or alternative methods of patient follow-up (telephone / text). Changes to protocol for this reason can be implemented as urgent safety measures to accommodate continuation of certain trial related activities for patient safety reasons – HRA are happy that these are implemented and they are notified to avoid delays but you must notify HRA and R&D

Guidance for COVID-19 specific studies

For Active COVID-19 studies we would anticipate that all patient facing tasks can be completed by the treating clinical team. Research staff should liaise with the PIs to confirm this and co-ordinate the supply of all trial related materials and paperwork to the clinical team.

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