Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

COVID-19 – Research Plan
1/7/2020 Update

We encourage all research staff to follow the latest guidance from the Trust, Public Health England and the Department of Health in relation to Coronavirus. We are closely following the National Institute for Health Research (NIHR) and Health Research Authority (HRA) for guidance on how to appropriately manage our research activity, as well as communicating with the national R&D Director/ regional R&D Manager Groups.

R&D Priorities during COVID-19 are as follows:

- ✓ **Protect participants and staff**
- ✓ **Protect study integrity**
- ✓ **Support wider hospital, clinical and research communities**
- ✓ **Maintain recruitment, treatment and follow-up of research participants where safe and logistically possible**

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 and staff safety.

As the situation escalates and deescalates, we will review and implement the following step-wise approach which shows our current status for each step:

Step	Description	Status as of 20/03/2020	**Update as of 01/07/2020**
1	**Stop all external visits to the Trust for research related activities from study monitors, external visitors and PPI members.** Consider using videoconferencing options	ACTIVATED	Restart study monitoring remotely and use videoconferencing facilities for external meetings
2	**Stop all external visits to other sites for monitor visits, external meetings, non-essential training and conferences**. Consider using videoconferencing options	ACTIVATED	Restart study monitoring remotely and use videoconferencing facilities for external meetings
3	**Review current clinical pathways for research participants and inform sponsors if changes to protocol might be needed**	ACTIVATED	Sponsored studies: Submit Cat C amendments for COVID Safe Measures or complete *Sponsor Restart Assessment* form for studies that were fully suspended. Hosted studies: Complete *Local Restart Checklist* form.

4	**Review all studies to identify non-essential activities that could be suspended**	ACTIVATED	Sponsored studies: Submit Cat C amendments for COVID Safe Measures or complete *Sponsor Restart Assessment* form for studies that were fully suspended. Hosted studies: Complete *Local Restart Checklist* form.
5	**Suspend the setting up of new studies**	ACTIVATED	New study set up on a case by case basis. COVID Safe Measures must be in place and approved by Sponsor and regulatory bodies where applicable.
6	**Suspend non-essential recruitment and follow-up activities**	To be reviewed daily – remote data collection being implemented	Restart recruitment and follow up activity on a case by case basis with COVID Safe Measures in place and approved by Sponsor and regulatory bodies where applicable.
7a	**Discussions with staff to facilitate working from home if possible**	ACTIVATED	ACTIVATED Risk Assessment in place for any essential office working
7b	**Decision made re: assisting with frontline clinical duties as appropriate –** research staff supporting clinical services	ACTIVATED	ACTIVATED
8	**CNTW research staff availability to support Covid19/urgent public health studies if required**	ACTIVATED	ACTIVATED
9	**Update: Safely Restart Studies where possible – risk assess and amend**		ACTIVATED

It is not feasible for the CNTW R&D department to issue blanket guidance. Decisions regarding study activity should be made collaboratively between the Chief Investigator (CI) or Principal Investigator (PI) and research staff. Any decisions should be communicated to study sponsors or to CNTW R&D when sponsor, copying in the R&D inbox (research@cntw.nhs.uk).

To support discussion and decision making, studies will be categorised as follows:

Category	Description	Likely action in escalation of OPEL
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. A risk graded approach will be used for individual studies and participants where appropriate.
C	Research where there is no identified negative impact of recruitment/participation continuing	Where resource permits, delivery will continue, but further recruitment will be suspended during further escalation.
D	Non-essential/non-urgent research	Recruitment and delivery of these studies will be suspended

National Guidance

MHRA and HRA have issued the following guidance:
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/

https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19

Specific guidance for PIs (supported by research staff)

- UPDATE 1/7/2020: You should risk assess your studies to identify what could be reactivated by implementing COVID Safe Measures. If you wish to reopen you should discuss this with the study sponsor, or follow the advice given by the sponsor. To reopen please complete the *Local Restart Checklist Form*.
- You should risk assess your studies to identify which essential activities need to be undertaken and which activities can be temporarily suspended without impacting on patient safety.
- 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 considered by them.
- The *R&D COVID-19 Delivery Plan* categorises each open study to support decisions on which studies could be "stepped down" and which require on-going support.
- Inform R&D (research@cntw.nhs.uk) of any studies where the sponsor has already contacted you with alternative arrangements/suspension of recruitment/amendment to protocol.

Specific guidance for CIs (supported by research staff)

- UPDATE 1/7/2020: If your study was suspended due to COVID19 and you wish to restart, please complete the *Sponsor Restart Assessment Form*.
- Please talk to the R&D department regarding your decision making. Please copy any emails to sites to research@cntw.nhs.uk
- Please continually risk assess your studies, documenting this where appropriate, and follow trust guidance on which activity can continue and which cannot.
- Consider amendments to protocol to allow for remote study activity. These CVOID19 related changes are processed as Cat C non-substantial amendments and are confirmed by sponsor only. Please complete the Amendment Tool and submit your tool to CNTWSponsormanagement@cntw.nhs.uk

In addition to the above:

- Site Files are to remain in locked, safe filing cabinets at the research site.
- GDPR , GCP and REC must be considered in alternative arrangements

Contact R&D using research@cntw.nhs.uk