COVID-19 pandemic: R&D action plan – updated 18/03/2020

Stage	Action	Status
0	**Preliminary email communication** asking research teams to begin to consider a) their priority studies, b) whether follow-up appointments could be done by telephone, c) not to open new studies, and d) to inform research staff that there may be requests from the Trust for volunteers to help support clinical services.	Effective 12/03/2020
1	**a. Not open any new studies.** Research teams can still progress studies through the local Capacity and Capability approval process but no new studies are to be given a 'green light' to start recruitment. The Newcastle Joint Research Office may have to prioritise other work over local C&C approvals. **b. Review all Site assessment, training and initiation visits.** Research teams should consider whether it is worth arranging these visits when the study start date is uncertain. If they do go ahead they should be by teleconference. **c. Stop all monitoring visits unless in exceptional circumstances** e.g. a triggered monitoring visit for patient safety. **d. Prioritise all open studies using the criteria above.** Clinical Research Leads, Delivery Team Leads and Platform Leads/Managers to work with local investigators and research teams to review and prioritise all open studies. Spreadsheets will be distributed to teams for completion by 5pm on 18/03/20. **e. Review the protocol requirements of all open studies and assess the risk vs benefit for participants (and potential participants) in the context of the COVID-19 pandemic.** For example, studies where the intervention has the potential to immune-suppress, or where follow-up requires the patient to attend hospital frequently. PIs should undertake this risk assessment and liaise with the study sponsor and NJRO as necessary to try to minimise this risk. On a study-by-study basis, a PI may suspend recruitment if the risk assessment favours this action. Where there is a change to the protocol (e.g. change of follow-up visits from face-to-face to telephone) and the Trust are sponsor, please contact the NJRO to request the correct amendment is submitted. Nuth.nuthsponsorship@nhs.net	Effective 16/03/2020
2	**Suspend screening, recruitment and randomisation in Priority 3 studies.** Unless the risk assessment dictates otherwise, patients already enrolled should continue 'on study' including any amendments to study protocol from stage 1e.	Effective 18/03/2020
3	**Suspend screening, recruitment and randomisation in Priority 2 studies.** Unless the risk assessment dictates otherwise, patients already enrolled should continue 'on study' including any amendments to study protocol from stage 1e.	Effective 18/03/2020
4	**Suspend screening, recruitment and randomisation in Priority 1b studies.** Unless the risk assessment dictates otherwise, patients already enrolled should continue 'on study' including any amendments to study protocol from stage 1e.	Reviewed daily
5	**Suspend screening, recruitment and randomisation in Priority 1a studies.** Patients already enrolled should continue 'on study'.	Reviewed daily

Prioritisation criteria for clinical research studies in NUTH	
1a	Studies investigating COVID-19 including emergency public health studies.
1b	Studies where a patient's treatment depends on them being in the trial, e.g. early-phase cancer trials where the treatment is only available in the context of a trial and 'usual care' options are ineffective.
2	Studies where there is a safe and effective 'usual care' treatment option for patients not enrolled in the trial, e.g. a RCT of novel antihypertensive versus standard care, or a device study where an alternative device or treatment option exists.
3	Observational, tissue bio-bank, qualitative and other studies.