**EXAMPLE**

**COVID-19 R&D Clinical Trial Action Plan**

updated 30/03/2020

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| **Stage** | | **Action** |  |
| 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. | |
| 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 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 below.** 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.  **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 JRO 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 JRO to request the correct amendment is submitted. | |
| 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. | |
| 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. | |
| 4 | **Suspend all face-to-face follow up visits unless essential for patient safety or required for clinical care.** If patients are required to attend for safety reasons (e.g. blood tests for toxicity) or for the purposes of clinical care, then PIs should follow current Trust information and guidance, to minimise the risk to patients and staff. If the safety of a patient is at risk because they cannot complete key safety checks, then consideration to discontinuing that patient must be considered. | |
| 5 | **PIs should review the risk assessment for all open Priority 1a studies** in the light of the evolving pandemic, in particular Government advice on social distancing and current Trust advice and information. It is likely that on-going recruitment to some 1b studies is no longer feasible and should be paused. | |
| 6 | **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. | |
| 7 | **Suspend screening recruitment and randomisation to selected Priority 1a studies.** In the surge phase of the pandemic it may not be possible to support all Priority 1a studies. This process will most likely be coordinated by local ‘COVID-19 trial oversight group’. | |

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| **Prioritisation criteria for clinical research studies (example from one NHS Trust)** | |
| **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 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 drug versus standard care, or a device study where an alternative device or treatment option exists. |
| **3** | Observational, tissue bio-bank, qualitative and other studies. |