**Implications of COVID 19 on clinical research studies**

**Guidance for investigators and research staff**

This guidance relates to all clinical research studies taking place at St George’s University Hospitals NHS Foundation Trust and may be subject to change. The guidance complements guidance provided by the Trust to staff and patients regarding COVID 19.

**General advice for clinical research staff**

There may be a requirement for clinically trained research staff to support the provision of patient care during a serious outbreak. All clinically qualified research staff working on hospital premises should acquaint themselves with guidance issued within their clinical service.

**Categorisation of clinical research studies**

* The Trust delivers a wide range of patient research and it is not appropriate to issue blanket rules about which studies should continue and which should be suspended. In some cases, there will be an ongoing need to ensure patient treatments continue, for example patients enrolled in chemotherapy trials. Any studies specifically intended to maximise learning from this and similar infectious disease outbreaks should of course continue.
* Joint Research and Enterprise Services (JRES) has asked Principal and Chief Investigators and research teams of all research studies to review the circumstances of their research and to make a decision on which category each study falls into.
* There are five categories of clinical research study, and these are contained in the below table.

**Prioritisation of clinical research studies**

* Priority will be given to nationally-sponsored COVID-19 research studies, a key element of the Government’s overall response, and after this other pandemic studies. These are level 0 studies.
* For other studies (levels 1 to 4), the default situation is that all recruitment should be suspended and new studies should not commence. The Associate Medical Director (Research) will be reviewing studies on a case by case basis and JRES will contact Chief and Principal Investigators with exceptions.
* For other studies (levels 1 to 4), the default situation is that for existing patients recruited, all patient follow-up visits should be conducted remotely. The Associate Medical Director (Research) will be reviewing studies on a case by case basis and JRES will contact Chief and Principal Investigators with exceptions.
* For studies which are levels 1 and 2, Principal Investigators should contact the sponsor to determine and agree minimum safety requirements.
* Specific details for each level of study are in the below table, and should be followed with immediate effect.

**Categories of study and current actions**

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| **Level** | **Description**  | **Current action**  |
| **0** | Pandemic studies Studies highlighted by the Clinical Research Network as urgent health studies  | **Continue as usual****Follow Trust COVID 19 guidance on patient and visitor management**  |
| **1** | Studies delivering critical care for patientsClinical trials of investigational medicinal products (cTIMPs), where not seeing the patient would create a risk or safety risk for the patientsStudies delivering cancer treatment | **Recruitment should be suspended and no new studies should commence unless there is specific approval to continue recruitment/start the study from JRES.****Continue with studies for patients already recruited, but follow up visits should be carried out remotely unless either 1. an on-site visit is necessary to satisfy the minimum safety requirements of the sponsor (Principal Investigators should contact the sponsor to determine and agree this), or 2. if there is specific approval to continue these from JRES (assume no approval unless contacted).****Follow Trust COVID 19 guidance on patient and visitor management** |
| **2** | Studies where patient care could be compromised by not seeing the patient but this does not pose a risk to patient safety | **Recruitment should be suspended and no new studies should commence unless there is specific approval to continue recruitment/start the study from JRES.****Continue with studies for patients already recruited, but follow up visits should be carried out remotely unless either 1. an on-site visit is necessary to satisfy the minimum safety requirements of the sponsor (Principal Investigators should contact the sponsor to determine and agree this), or 2. if there is specific approval to continue these from JRES (assume no approval unless contacted).****Follow Trust COVID 19 guidance on patient and visitor management** |
| **3** | Studies that involve patient care but where patient care is not compromised if the study is suspended | **Recruitment should be suspended and no new studies should commence.****For patients already recruited, all patient visits should only be conducted remotely.**  |
| **4** | Studies that do not provide direct patient care  | **Recruitment should be suspended and no new studies should commence.** **For patients already recruited, all patient visits should only be conducted remotely.**  |

**Questions**

Questions on research patient visits should be addressed to Ade Adebiyi, Head of Research Nursing in the first instance - aderonke.adebiyi@stgeorges.nhs.uk

Questions on study categorisation should be address to Subhir Bedi, Head of Research Governance & Delivery in the first instance - sbedi@sgul.ac.uk