**DTVRA LOCAL RESTART PROFORMA FOR RESEARCH TRIALS PAUSED DUE TO COVID-19**

**GUIDANCE**

Please complete the proforma on pages 2&3, obtain relevant signatures and submit to stees.dtvra@nhs.net for review by your Trust R&D senior management team, following which you will be contacted regarding next steps.

When reviewing your study for feasibility to restart, please consider the following points and confirm in the proforma your responses to these issues.

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| **Viability** | **Only studies that are viable should restart.**Viability assessment for all paused studies to be ideally completed before 21st June 2020Have you had any correspondence from sponsor re: restarting and viability ? Provide some documentation of this discussion.Any protocol re-design/amendments from sponsor since pausing and can these be supported at our site ?Any site specific amendments needed by us to align with local practices/policies and will sponsor support these?Funding implications – are extensions needed and are these funded?Reductions in clinical service provision and throughput will impact on recruitment targets – have you had a discussion with sponsor re: reduction in target? Please advise R&D of new target – may impact on contracts |
| **Safety** | **Research should only restart/start if it is safe to do so.** Consider the following: Risk of exposure to COVID-19 for staff and patientsSpecial consideration needed for participants who are shielding – unlikely to be able to visit site for quite some timeOnly essential visits to research site for all patientsReview requirements for PPE – must be in line with Trust policy. If commercial study then sponsor should pay for thisAre additional tests required to confirm COVID status for participants (that are not routinely done) – if so discussion re: who pays for this.Are any protocol amendments needed to reduce risk locally (over and above any sponsor initiated ones) Does study comply with local policiesHow will you reduce patient concerns re: COVID in the research pathwayWhat remote working might be possibleEnsure that trial flexibilities put in place don’t impact on participant safety |
| **Capacity & Site readiness** | **The pace of restart should be commensurate with the capacity and readiness in the local Trust.**Impact on availability of research staff support for ongoing COVID-19 studiesDiscussion with Team Leads and research staff to ensure capacity exists - taking into account what the entire team is required to deliver (research team, PI etc)Confirm the clinical service provision is being restarted and be aware o how it’s being delivered and impact on the study / patient pathwayDo support departments have capacity to resume (Pathology, Pharmacy, Radiology) Are physical access arrangements OK for participants – social distancing, reduced public transport etc.Liaise with R&D team to formally re-confirm C&C with sponsor |
| **Prioritisation** | **To ensure we can prioritise which studies are opened please indicate the level of priority for your study.****Level 1** Essential study for providing evidence for pandemic management**Level 2** Studies where research protocol includes urgent treatment or intervention without which patients could come to harm**Level 3** All other studies (including other COVID studies not at Level 1)**N/A** for non NIHR funded studies |

If your study is sponsored by any DTVRA trust you will need to meet with the R&D department to undertake a more comprehensive risk assessment. Please contact joe.millar@nhs.net to arrange.

**RESTART proforma for completion:**

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| **Study Title** |  |
| **IRAS ID** |  |
| **Trust**  | Choose an item. |
| **PI** |  |
| **Lead Research Nurse** |  |
| **Research Team Lead** |  |
| **DTVRA / Trust Sponsored Study?** | Choose an item. |

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| Has the sponsor indicated they are able to consider restarting the study? | Choose an item. |
| Having discussed with the relevant research team lead, is there sufficient research nursing support available to restart this study? | Choose an item.  |
| Is there sufficient data management support available to restart this study? | Choose an item. |
| Have you discussed with your clinical service’s Manager to confirm the study is deliverable within the clinical service’s restart plans? | Choose an item. |
| **Does this Study require support department involvement?** *If no support departments are required please move on to next section.*  | Choose an item. |
| **Support Department** | **Select**  | **Confirmation of continued support provided by** | **Email** | **Date confirmed**  |
| Pharmacy |[ ]  Enter name of person. | Enter email address. | Click to enter date. |
| Radiology |[ ]  Enter name of person. | Enter email address. | Click to enter date. |
| Echocardiography |[ ]  Enter name of person. | Enter email address. | Click to enter date. |
| Pathology |[ ]  Enter name of person. | Enter email address. | Click to enter date. |
| OtherName of Department |[ ]  Enter name of person. | Enter email address. | Click to enter date. |
| **Please assess your study against the guidance notes on p1 and provide information in each category below** |
| **Viability** |  |
| **Safety** |  |
| **Capacity & Site readiness** |  |
| **Prioritisation** |  |

**PI Confirmation**

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| I confirm that the information provided above is accurate, the appropriate support departments and sponsor have been contacted providing confirmation that this study can restart. I confirm that careful consideration has been given to national guidance on social distancing ensuring patient and staff safety, with careful consideration to those patient groups who are considered extremely vulnerable to COVID-19 and are shielding. |
| **Principal Investigator** | Click here to enter text. | **Date:** | Click to enter date. |
| **Team Lead** | Click here to enter text. | **Date:** | Click to enter date. |

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| **FOR R&D USE ONLY:**  |
| **R&D Governance Manager Review**  | Click here to enter text. | **Date:** | Click to enter date. |
| **Clinical & Operations Manager Review** | Click here to enter text. |  | Click to enter date. |
| **Confirmation email sent by**  | Click here to enter text. | **Date:** | Click to enter date. |
| **Notes** |  |

Full details of the NIHR RESTART Framework can be found here: <https://www.nihr.ac.uk/documents/restart-framework/24886>