**Pandemic Site File Note**

# Instructions and Guidance

Please complete this Site File Note to document and inform the Research Governance Office of the outcome of your Pandemic Research Risk Assessment and the changes (if any) you will need to make to the management and conduct of your research during the pandemic.

If you have not already completed the Research Risk Assessment, please do so before completing your Site File Note.

Any and all changes to the management and conduct of your research requires an amendment to be submitted to the Research Governance Office.

In most cases, this Site File Note will act as your amendment documentation.

COMPLETION STEPS:

1. Identify amendment type

**If you think that your amendment(s) meet the criteria of an** [**Urgent Safety Measure**](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/) **please contact us immediately.**

1. Complete documentation: Please submit the completed Risk Assessment, Site File Note and any amended study documentation to Infonetica for processing.
	* Where you have multiple sites, please provide relevant details of any differences in the management and conduct of your research at those sites.
2. Sponsor Approval: We will review your Risk Assessment, Site File Note and any amended documentation before issuing Sponsor approval or requesting further information from you in order to complete your request for changes.
3. Continuous Review: You are expected to review the Risk Assessment and proposed changes in light of any new guidance that emerge, or and changes at your research sites. Update your documents and send these to us for processing. You only need to contact us if you wish to make additional changes to the management and conduct of your research.
4. Lifting Restrictions: Once research restrictions begin to lift, you can request Sponsor approval to reintroduce aspects of your research by completing the final section of this file note and emailing it to rgosponsor@le.ac.uk. An updated Risk Assessment may be requested.

**Please do not make any other amendments to your research without first discussing these with the Research Governance Office.**

**All correspondence associated with your Pandemic Research Planning should be retained for monitoring and auditing purposes within the Trial Master File.**

------------------------------------------------ SECTION ONE ------------------------------------------

|  |  |  |  |
| --- | --- | --- | --- |
| UoL Number: |   | IRAS Number: |  |
| Full Title: |  |
| Short Title: |  |
| Chief Investigator: | Please provide Name and Contact Details | Principal Investigator: | Please provide Name and Contact Details |
| Main Point of Contact (if different from Chief Investigator or Principal Investigator): | Please provide Name and Contact Details | Site(s): | Please list all participating sites |
| Access to Trial Master File:  | Please provide location, including room and building and Name and Contact Details of those with access. Please consider setting up an electronic TMF (eTMF) if you haven’t already | Access to Investigator Site File(s) (If applicable): | Please provide location, Name and Contact Details for all participating sites |

Based upon your Research Risk Assessment, please tick all of the following outcomes that apply:

|  |
| --- |
| Continuing recruiting (no change to research activity at all) |[ ]
| Completely on hold (no research activity at all)\* |[ ]
| Not actively recruiting/haven’t started yet |[ ]
| Delaying start up (PI decision) (i.e., SIVs conducted but no SGL to be issued)\* |[ ]
| Delaying start up (host organisation decision, please list per site) (i.e., SIVs conducted but no SGL to be issued)\* |[ ]
| Delaying start up (Sponsor decision) (i.e., SIVs conducted but no SGL to be issued)\* |[ ]
| Sponsor guidelines received; continue with caution |[ ]
| Recruitment of new participants paused but follow-ups continue (specify below)* Follow-ups continue as normal
* Follow-ups continue but adaptations made\*
* Follow-ups continue but changed to remote procedures\*
 | [ ] [ ] [ ] [ ]  |

**\*Please provide details of these changes in the summary box below.**

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| Summary of Changes to Management and Conduct of Research:Please use this space to provide a list of all of the changes you are requesting. |
| CI Oversight: | Provide confirmation that appropriate CI oversight will be maintained during this period and how this will be evidenced. |
| Amended Documents: | List in this space any documents that you are submitting as part of this amendment. |
| Samples: | List here all clinical and research samples that will continue to be taken, provide name and location of the labs used for processing and storage. |
| Completed by (Name & Role): |  | Date of completion: |  |

Type of Amendment Required:

|  |
| --- |
| Non-substantial Amendment that **does not** require HRA or REC approval, only Sponsor acknowledgement |[ ]
| Non-substantial Amendment that **does** require HRA or REC approval |[ ]
| Substantial Amendment |[ ]

For Research Governance Office use only:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **N/A** | **No** | **Yes** | **Date Completed** |
| COVID-19 Research Risk Assessment Reviewed |[ ] [ ] [ ]   |
| COVID-19 Site File Note Reviewed |[ ] [ ] [ ]   |
| Regulatory Approvals Required (ensure these are submitted accordingly via normal SOP) |[ ] [ ] [ ]   |
| Sponsor Approval Issued |[ ] [ ] [ ]   |
| EDGE Attribute Updated |[ ] [ ] [ ]   |

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| --- | --- | --- | --- |
| Completed by: |  | Date of completion: |  |

------------------------------------------------ SECTION TWO ------------------------------------------

**LIFTING RESTRICTIONS:**

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| Information to support lifting of restrictions: Please use this space to confirm which elements of the research will be re-starting and the timelines involved. If you have multiple sites please provide relevant information for each site. Confirm the date any specific amended study documentation will be superseded and removed from use |
| Completed by (Name & Role): |  | Date of completion: |  |

For Research Governance Office use only:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **N/A** | **No** | **Yes** | **Date Completed** |
| COVID-19 Site File Note Reviewed |[ ] [ ] [ ]   |
| Sponsor Approval Issued |[ ] [ ] [ ]   |
| EDGE Attribute Updated |[ ] [ ] [ ]   |

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| Completed by: |  | Date of completion: |  |