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| Form number | **51.021C** | Version | **1.0** |
| Title | **Sponsor Review of Amendment Checklist** | | |

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| Research study/trial name: |  |
| R&I reference: |  |
| Amendment Number/Type: |  |
| Date of receipt of Amendment: |  |
| Sponsor representative: |  |

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| A: Sponsor review | *Comments/date approved* | |
| Short summary of amendment |  | |
| Amendment tool checked and locked? | Select | |
| Is REC approval required? | Select | REC submission date: |
| Is HRA approval required? | Select | HRA submission date: |
| Is MHRA approval required? | Select | MHRA submission date: |
| Is Sponsor pharmacy review/input required? | Select | Pharmacy review received: |
| Is Monitoring review/input required? | Select | Monitoring review received: |
| Is Pharmacovigilance review/input required? | Select | Pharmacovigilance review received: |
| Will this have an impact on the eCRF? | Select | Confirmation of eCRF review received: |
| Is Finance review/input required? | Select | Finance review received: |
| Does the amendment have negative impact on the upcoming trial milestone (if applicable) | Select |  |
| Does this affect the agreements in place or a new agreement is required?  [add agreement type(s)] | Select |  |
| Is Imaging review/input required? | Select | Imaging review received: |
| Is Bio-repository review/input required? | Select | Bio-repository review received: |
| Does this require laboratory review? Will this have an impact on the Laboratory Manual (if applicable). If yes has the Lab Manual been updated? | Select | Lab review received: |
| Is statistical review required? | Select | Statistical review received: |
| Is amendment of Risk assessment required? | Select | RA amendment complete (include new version number and date): |
| Other: add comments as required |  | |
| Confirmation of amendment type (substantial or non-substantial) & category: |  | |
| Date of completion of Sponsor review and permission for REC/HRA and/or MHRA submissions |  | |

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| Documents reviewed by sponsor for REC/HRA and/or MHRA submission: | Version: | Date: |
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| B: Local requirements to implement amendment | *Comments/date approved* | |
| 1. Research co-ordinator agrees for this amendment to be locally approved (Yes/No; If No, provide pending requirements at Q2) | Select |  |
| Q2. What is required before “Local management approval remains valid” email confirmation can be issued?  (for e.g.   * Site pharmacy approval * finance approval * imaging approval * Confirmation of eCRF update, * Agreement (s) to be finalised. |  | |
| Once the above has been received, should “Local management approval remains valid” email confirmation be issued? Yes/No | Select |  |
| Research Administrator completed all relevant tasks including SReDA Checklist (Part C below) (name & date) | Select |  |

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| **C. SReDA Checklist** – to be completed by Senior Research Administrator in SReDA | Yes/No/NA/Comments | |
| Date of R&D Approval | Select |  |
| Date of HRA Approval | Select |  |
| Date of MHRA Approval | Select |  |
| Date of Ethics Approval | Select |  |
| Pharmacy notes: | Select |  |
| General notes: | Select |  |
| Co-ordinator review: required/not required | Select |  |
| Co-ordinator review: completed/not completed | Select |  |
| Pharmacy review: required/not required | Select |  |
| Pharmacy review: completed/not completed | Select |  |
| REC letter: required/not required | Select |  |
| REC letter received: date | Select |  |
| Documents checked against REC letter: initials & date (SRA) | Select |  |
| MHRA letter: required/not required | Select |  |
| MHRA letter received: date | Select |  |
| Research passport: required/not required/received | Select |  |
| Change to study team form: required/not required/received | Select |  |

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