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| Form number | **Form 51.020B** | Version | **1.0** |
| Title | **Sponsor Oversight Checklist For Issuing RGL** | | |

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| R&I Ref: |  |
| CI name: |  |
| Sponsor/Co-Sponsor |  |
| Project Manager/Trial Co-ordinator name: | / |
| NRSPCC Ref: (if applicable) |  |
| Funder Type:  (Eligible, Investigator led industry funded, etc) |  |

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| Regulatory Green Light | Wet ink signature and date  (*comments may be included*) |
| Sponsor Pharmacy RGL (Documents relating to this held by R&I Sponsor Pharmacy) |  |
| Sponsor RGL Letter issued by Sponsor Research Co-ordinator |  |

*Note: Once completed this form should be wet ink signed by Sponsor Pharmacy representative and Research co-ordinator*

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| Additional Comments section (*complete if applicable*) | |
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| Comments Added By:  Signature and date |  |

NOTE: All relevant documents to be stored in the TMF when signing off completion

Relevant Post RGL documentation is also stored in the TMF under corresponding indices (Appendix 1)

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| Sponsor Process: FUNDING APPLICATION (SOP 51.010) | Comments (if applicable) | Checked by (Initials) and date |
| Assessment of CI suitability  Review of CV and GCP training Actions *(if required; e.g. confirmation of mentoring for first time CIs)* |  |  |
| University of Glasgow Notification re insurance requirements  *(if applicable)*  Email confirmation if additional insurance not/required and estimate of costs:  Name :  Date :  Costs: |  |  |
| Sponsor Pharmacy Assessment (costs, feasibility)  Name :  Date : |  |  |
| Sponsor Trial Support Assessment  *(to be determined using Form 51.010E and Form 51.010A)*  *Date of confirmation email from all parties involved:*   1. Monitoring   Name :  Date :   1. PV   Name :  Date :   1. Statistician   Name :  Date :   1. Data management   Name :  Date :   1. SRC (if applicable)   Name :  Date :   1. Other (e.g. Biorepository, Imaging, labs) – include as applicable   Name :  Date :  Name :  Date :  Name :  Date : |  |  |

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| Sponsor finance review/costing completed:  Sole Sponsored:  NHSGGC Date:  Co-Sponsored:  NHSGGC Date:  UoG Date: |  |  |
| **Funding Application**  Name of funding body:  Date of submission:  Submitted by (name of organisation):  *(Ensure application submitted for successful application is in trial eFile)* |  |  |
| **Evidence of two peer reviews** *(for NEF trials only - Reviewers comments are captured on form 51.003A)*  Required  N/A |  |  |
| Funder Award letter/contract/ e-mail  Document Name:  Signature Date : |  |  |

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| Sponsor Process: PRE-REGULATORY SUBMISSON | Comments (if applicable) | Checked by (Initials) and date |
| Risk Assessment undertaken (SOP 51.004, Form 51.004A)  Date:  *Are there any outstanding Risk assessment actions required to be completed before RGL is issued?*  YES  NO  *If yes, the outstanding actions are captured at the last section of this form “Sponsor Process: REGULATORY GREEN LIGHT”)* |  |  |
| Insurance coverage appropriate  *(Required if CTIMP is co-sponsored with GU)*  YES  N/A |  |  |
| Registration on SRCTN (via HRA) or ClinicalTrials.gov  Data base:  Study reference number: |  |  |
| IRAS form - part of CWOW application (SOP 51.014)  Sponsor review date: |  |  |
| IRAS MHRA Clinical Trial Authorisation part of CWOW application (SOP 51.014)  Sponsor review date:  Pharmacy review date: |  |  |
| Final review of submissions to REC and MHRA:  For Co-Sponsored trials University of Glasgow Head of Research Regulation and Compliance and Research or equivalent should be notified by email that trial documentation is ready for submission  Date notification email sent:  Date of acknowledgement of email by University of Glasgow:  QC check of documentation (as per Notes below)  Name :  Date :  *Notes:*   * *Check IRAS, protocol and CTA documentation are aligned and contain the same information* * *Check ICH GCP is not in any of the documents (References to the principles of ICH GCP are acceptable) or contracts* |  |  |

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| Sponsor Process: CWOW – REC application - FINAL STUDY DOCUMENTS SUBMITTED (SOP 51.014) | Comments (if applicable) | Checked by (Initials) and date |
| IRAS form  IRAS code:  Application submitted by:  Date: |  |  |
| REC Covering Letter (with reference to all documents submitted)  Included in the application  Date: |  |  |
| Protocol  Submitted version:  Date:  List of stakeholders and signatories (reviews/comments received and relevant emails saved in trial eFolder):   1. Name (CI):   Date:   1. Name (Pharmacy):   Date:   1. Name (PV):   Date:   1. Name (Monitor):   Date:   1. Name (Statistician):   Date:   1. Name (Data Management)   Date:   1. Name (SRC):   Date: |  |  |
| Participant information sheet  Submitted version:  Date:  List of stakeholders and signatories (reviews/comments received and relevant emails saved in trial eFolder):   1. Name (CI):   Date:   1. Name (Pharmacy):   Date:   1. Name (SRC):   Date:   1. Name (Other as applicable):   Date: |  |  |

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| Consent form:  Submitted version:  Date:  List of stakeholders and signatories (reviews/comments received and relevant emails saved in trial eFolder):   1. Name (CI):   Date:   1. Name (Pharmacy):   Date:   1. Name (SRC):   Date:   1. Name (Other as applicable):   Date:  eConsent process approved by sponsor/co-sponsors *(if applicable)*:  YES  Date:  N/A |  |  |
| GP letter(s):  Submitted version:  Date:  SRC review  Name :  Date :  Other reviewers (if applicable)  Name :  Date : |  |  |
| Patient Alert Card:  Version:  Date :  Pharmacy Comments Received  Name :  Date : |  |  |
| Other study documents *(complete as appropriate)*  Document name:  Submitted version:  Date:  Document name:  Submitted version:  Date:  Document name:  Submitted version:  Date:  Document name:  Submitted version:  Date: |  |  |

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| REC Submission  REC Committee:  REC Reference:  **REC Opinion:**  Type of opinion provided\*:  Date of response to REC provided (if applicable):  Date of favourable opinion:  **HRA approval:**  Date:  \*NB if documents require to be changed at the request of REC please state new version and date in the comments column |  |  |

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| Sponsor Process: CWOW - MHRA application - FINAL STUDY DOCUMENTS SUBMITTED | Comments (if applicable) | Checked by (Initials) and date |
| Clinical Trial Authorisation application (and xml)  Sponsor signature date: IRAS code: |  |  |
| MHRA Covering Letter  Reviewed by Pharmacy  Included in the application  Date: |  |  |
| Protocol  Submitted version:  Date: |  |  |
| Label/justification for absence of label:  Version:  Date :  **OR**  Justification for absence provided in application |  |  |
| SmPC for clinical information: *(if applicable)*  Version:  Date: |  |  |
| IB (plus RSI): *(if applicable)*  Version:  Date: |  |  |
| Reference Safety Information  Version:  Date : |  |  |
| IMPD/simplified IMPD or Letter of Access: *(if applicable)*  Version:  Date : |  |  |
| NIMP Dossier: *(if applicable)*  Version:  Date: |  |  |
| **Manufacturer’s authorisation(s) or Importer’s authorisation for each EU, UK and ’Approved Country’ site and/or QP declaration on GMP for each non-EU manufacturing site and UK MIA(IMP) for UK QP oversight of any IMPs that are QP released from an Approved Country:** *(if applicable)*  Confirm inclusion: YES |  |  |
| **Scientific Advice**  **Not applicable**  **If applicable - Scientific Advice Letter:**  Date:  Confirm inclusion: YES |  |  |

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| MHRA Submission:  CTA Reference number:  **MHRA Authorisation:**  Date of response to MHRA if GNA/conditions (if applicable)\*:  Date of CTA:  \*NB if documents require to be changed at the request of MHRA please state new version and date in the comments column |  |  |

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| Sponsor Process: Contracts (SOP 52.004, SOP 51.011 and SOP 51.015) | Comments (if applicable) | Checked by (Initials) and date |
| 1. Contract type: ( *e.g. co-sponsor, collaboration, DPA, DSA, MTA, IMP provision, etc*)   Parties:  Purpose:  Fully executed date:   1. Contract type:   Parties:  Purpose:  Fully executed date:   1. Contract type:   Parties:  Purpose:  Fully executed date:  *(Repeat as necessary)* |  |  |
| Model Non-Commercial Agreement template  Completed draft date: |  |  |
| Vendor assessments (email evidence from Governance team)(e.g. trial support, laboratory analysis):  If not applicable please tick:  Vendor:  Vendor assessment approval date:  TMF Plan agreed and included in the contract - Confirm inclusion: YES  *(Repeat as necessary)* |  |  |
| IMP Vendor Assessment  If not applicable please tick:  Vendor:  Vendor assessment approval Date: |  |  |

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| Sponsor Process: Regulatory green light - FINAL STUDY DOCUMENTS | Comments (if applicable) | Checked by (Initials) and date |
| Protocol  Version:  Date: |  |  |
| Participant information sheet  Version:  Date:  Translated PIS *(if applicable)*  Languages:  Version:  Date: |  |  |
| Consent form:  Version:  Date:  Translated Consent form *(if applicable)*  Languages:  Version:  Date: |  |  |
| GP letter(s):  Version:  Date: |  |  |
| Patient Alert Card:  Version:  Date: |  |  |
| Other study documents *(complete as appropriate)*  Document name:  Version:  Date:  Document name:  Version:  Date:  Document name:  Version:  Date:  Document name:  Version:  Date: |  |  |
| Caldicott/PBPP approval; ARSAC assessment letter (if applicable)  Document name:  Version:  Date: |  |  |
| Label:  Version:  Date: |  |  |
| IMPD/simplified IMPD or Letter of Access:  Version:  Date: |  |  |
| Unblinding testing/process (if applicable):  If not applicable please tick:  Confirm process in place and testing completed: |  |  |
| User Acceptance Testing for IWRS  If not applicable please tick:  Confirm UAT testing completed: |  |  |
| Sponsor IMP Management documentation  Document name:  Version:  Date:  Document name:  Version:  Date:  Document name:  Version:  Date: |  |  |
| Case Report Forms (paper or electronic)   * Approved Version: * Confirm sponsor has provided crf/e-crf designer with UAT parameters * Confirm UAT is complete and approved by sponsor   Email confirmation received:  1) CI  Name:  Date:  2) Pharmacy  Name:  Date:  3) PV  Name:  Date:  4) Monitoring  Name:  Date:  5) Data Management  Name:  Date:  6) Investigator Team  Name:  Date:   * Confirm system validation is complete   (by email from Data manager)  Name:  Date:   * Confirm (by email from Data manager) that CRFs checked against protocol and CTA application are complete:   Name:  Date: |  |  |
| Laboratories  List laboratories and dates lab manuals approved by sponsor  (highlight any central laboratories)  Document name:  Version:  Date:  Document name:  Version:  Date:   * Lab Categorisation Form signed (if applicable)   Date:   * TMF Plan agreed and forms part of the contract (if applicable):   Date completed/signed: |  |  |

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| Sponsor Process: Regulatory green light– SITE FILE DOCUMENTS | Comments (if applicable) | Checked by (Initials) and date |
| PI Site file index *(Form 51.016C)*  Version:  Date: |  |  |
| IMP Management for sites  Pharmacy site file index  Version:  Date:  Document name:  Version:  Date:  Document name:  Version:  Date:  Document name:  Version:  Date:  Document name:  Version:  Date: |  |  |
| Sufficient supplies of IMP(s) QP released/available to support provision of Sponsor Green Light  Confirm for IMP: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  IMP supply: Via Sponsor  Site own stock  Confirm for IMP:  IMP supply: Via Sponsor  Site own stock  Confirm for IMP:  IMP supply: Via Sponsor  Site own stock |  |  |
| Delegation log template  Version:  Date: |  |  |
| Other log Template (if applicable)  Version:  Date: |  |  |
| Participant Enrolment Log template  Version:  Date: |  |  |
| File Note template  Version:  Date: |  |  |

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| Sponsor Process: Regulatory green light | Comments (if applicable) | Checked by (Initials) and date |
| Monitoring plan:  Monitor name:  Monitoring plan approved and signed by Governance Manager  Date: |  |  |
| PV Plan:  PV officer name:  PV plan approved and signed by Governance Manager:  Date: |  |  |
| Data Management Plan  DM provider name:  DM plan approved and signed by CI and DM:  Date: |  |  |
| IDMC Charter:  Charter members approved by funder (if applicable):  Honorary contracts in place for charter members (when trial is sole sponsored by NHSGGC):  Charter signed and accepted by all IDMC members: Date: |  |  |
| TSC Charter:  Charter members approved by funder (if applicable):  Honorary contracts in place for charter members (when trial is sole sponsored by NHSGGC):  Charter signed and accepted by all TSC members: Date: |  |  |
| Delegation of CI responsibilities (SOP 51.011):  List signed: Date: |  |  |
| Confirmation site tracker has been prepared by PM  Date:  N/A: |  |  |
| **Are there any outstanding Risk assessment actions required before RGL letter is issued?**  **NO:**  YES:  If Yes, list each action and date of completion  1. Action:  Completion date:  2. Action:  Completion date:  *(repeat as necessary)*  NB - If some actions were to be staggered during the lifetime of the trial please comment and indicate how they will be captured. |  |  |
| Regulatory Green Light letter issued  Research Co-ordinator Name:  Date: |  |  |

Appendix 1

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| **Post RGL Documentation** | Stored in the corresponding section of the TMF Index as per  Form 51.016A - Sponsor TMF Index and Form 51.016K - TMF Index Pages (TMF QC) |
| **Annual Progress Reports** | Section 4: REC/HRA/GTAC/ARSAC  4.2. Annual Reports |
| **IDMC Reports:** | Section 8: Pre/post RGL documents and relevant correspondence (SOP 51.023)  8.3. IDMC:  8.3.7. IDMC Reports |
| **Risk assessment reviews** | Section 8: Pre/post RGL documents and relevant correspondence (SOP 51.004)  8.5 Risk Assessment  8.5.1. Signed Risk Assessment (Form 51.004A (CTIMP) and/or Form 51.004D (CIMD) and relevant sponsor correspondence  8.5.2. Risk Assessment Amendments and correspondence (most recent at the top)  Also part of Form 51.021C (Sponsor review of amendment checklist) -  There is a question on RA impact of amendment “Is amendment of Risk assessment required?” |
| **TSC Reports:** | Section 8: Pre/post RGL documents and relevant correspondence (SOP 51.036)  8.2. TSC  8.2.7 TSC Reports |
| **End of trial procedures:** | Section 9: End of trial documentation (SOP 51.019)  9.1. End of trial declaration and acknowledgement REC  9.2. End of trial declaration and acknowledgement MHRA  9.3. Final Report  9.4. Other relevant email correspondence  9.5. File notes (if applicable) |
| **Final IMP Destruction:** | Pharmacy process: (SOP 22.011)  10.5. IMP Manufacture & Quality Documentation  o IMP Destruction by Manufacturer  10.7. IMP tracking  o Manufacturer IMP reconciliation and destruction documentation |
| **Duration of Archiving agreed:** | Section 8: Pre/post RGL documents and relevant correspondence  8.11. Archiving arrangements/destruction (Trial Archiving Oversight - Form 51.024E) |
| **Amendment Log Completed:** | Section 6: Amendments (SOP 51.021)  *Note: Use the trial amendment log as coversheet. Each amendment will be filed in reverse chronological order (most recent at the top) and the following documentation below will be filed under each amendment (i.e. Amendment 1 will include sections A, B, C etc.; Amendment 2 will include sections A, B, C etc.):*  Form 51.021B (Amendment log) along with Form 51.021C (Sponsor review of amendment checklist) |
| **Final Report submitted to funder:** | Section 2: Funding  2.4 Reports to Funding award body |

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