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| **Good Clinical Practice (GCP) Managers Checklist** | | | |
| **Prior to Sponsorship with conditions ( PART 1)** | | | |
| **Action** | | **Guidance** | **Procedure** |
|  | Chief Investigator confirmed as suitable (training, experience and capacity) | *Is the CI suitably qualified and experienced?* | *Review CV, qualifications and past experience running clinical trials.  Consider: - Does the CI have the correct qualifications for the trial type? - Have they acted as a chief investigator before? - Have they acted as a host site principal investigator before? - Have they managed multi-centre trials before? - Have they run MHRA regulated studies or Clinical Investigations before? - What risk categorisation did their previous projects have? - Are they supported by a CTU, research group or mentor?* |
|  | Conditions of sponsorship and delegation discussed and signed | *Has the sponsorship agreement been signed?* | *Sign sponsorship agreement and obtain signature from CI (and CTU if required).* |
|  | Statistician identified & Appropriate | *Please name*  *Is there are appropriate statistician?* | *The CI may not be the statistician for regulated trials.* |
|  | Protocol | *Is the protocol compliant with requirements? If not on a JRMO template insert justification and entered as waiver with Non-Compliance .* | *Ensure that the protocol is on the JRMO template or an appropriate alternative.  Ensure that the protocol has not deviated from standard wording.  Ensure that all template text has been answered and removed.* |
|  | Review of all documentation complete and reviewer satisfied | *Is the full document set present, compliant and of high quality?* | *Check that all required documents are present (per JRMO SOPs and review body requirements.)  Review the documents for quality and compliance to applicable regulations. Raise any queries with the CI.  Confirm that CI has answered all queries satisfactorily.* |
|  | Coordination resource agreed | *Are appropriate trial coordination arrangements in place?* | *Consider how the trial will be managed and which responsibilities will be delegated to which individuals or organisations. Pay careful attention to lone Investigator studies or small or inexperienced research teams.* |
|  | Monitoring plan agreed in principal | *What are the monitoring arrangements for this trial and are they appropriate?* | *Discuss the monitoring arrangements for the trial - who will conduct monitoring visits/ central monitoring and how frequent the visits will be.  The monitoring plan does not need to be written at this stage, but general arrangements must be agreed in principle.* |
|  | Pharmacovigilance arrangements agreed | *Are appropriate pharmacovigilance processes in place?* | *Consider:  -AE recording and reporting. -SAE reporting to sponsor. -SAE assessments. -SUSAR reporting to MHRA. -AESIs -Reporting exemptions. -DSURs* |
|  | Confirm insurance cover | *Are all activities insured?* | *= Confirm whether NHS Indemnity/ QMUL will cover all activities.  International sites may require additional insurance cover.  If external organisations are involved in the trial they will be required to insure their own activities.* |
|  | Funding contract fully executed | *Has the primary funding agreement been fully executed?* | *Confirm with costings and contracts team that the primary funding agreement has been fully executed.* |
|  | IMP supplier agreed in principle | *Is the proposed IMP supplier suitable?* | *Contract should normally be put in place at this stage and the suitability of the supplier should be assessed via vendor assessment. This activity should be performed in conjunction with the sponsor Pharmacy representative* |
|  | Database and CRF agreed | *Are the data management arrangements suitable?* | *Database / CRFs do not need to be designed at this stage, but the planned arrangements should be agreed. If an external provider is to be used then a vendor assessment should take place.* |
|  | All vendors identified and vendor assessments completed | *Are all vendors suitable?* | *Confirm the full list of vendors to be used for the trial. Check whether the vendors are known to the sponsor or preferred suppliers. For any unknown vendors, complete a vendor assessment. Make sure that the contact team are aware of the vendor so that they can put a contract in place.* |
|  | Risk assessment performed | *Has the sponsor risk assessment been completed?* | *Complete risk assessment as per SOP 23 and obtain CI signature.* |
|  | Provisional pharmacy agreement received | *Has provisional pharmacy agreement been issued?* | *I Receive approval from pharmacy.* |
|  | Equipment and devices assessed | *Have all equipment and devices to be used in the trial been approved by clinical physics, or are currently undergoing review?* | *All trial specific equipment and devices must be under review by clinical physics if they have not yet obtained approval.* |
|  | Kick-off meeting held | *All GCP team points covered as per agenda?* | *See SOP 11b AD 1* |
|  | Contract checklist completed and saved by C&C team | *Has the contract checklist been updated following the kick-off meeting?* | *Kick off section to be completed with all contracts needed prior to submission to regulatory bodies in place.*  *Obtain confirmation form the contract officer that the contract checklist has been updated following the kick-off meeting.* |
|  | Confirmation of GCP and regulatory compliance | *Does the trial comply with GCP and regulations?* | *Consider compliance with:  -ICH GCP -UK Policy Framework -The Medicines for Human Use (Clinical Trials) Regulations and amendments -The Medical Devices Regulations and amendments -Human Tissue Act -Data Protection Act -Mental Capacity Act  List is not exhaustive.* |
|  | Agreement in writing sent to Governance team to proceed |  | *Once all above steps have been completed, instruct governance lead to issue provisional sponsorship of the trial.  Please document here the name, number and version of the Sponsorship SOP that was followed for this stage or the approval* |

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| **Prior to Sponsorship with Conditions (Part 2)** | | | |
|  | Final Governance meeting held and documented as per meeting report | *Has the final governance meeting been held and documented?* | *Organise the final governance meeting. Minute the meeting using the final governance meeting report and send actions to all attendees.* |
|  | All final governance meeting actions completed |  |  |
|  | Database build in progress and on target | *Is the database build in progress?* | *Confirm with trial team.* |
|  | Monitoring plan in place | *Is the monitoring plan in place?* | *Create monitoring plan following SOP 28. Ensure plan agreed with and fully signed by all parties and .* |
|  | All contracts agreed and full executed (Signed checklist received) | *Is the contract checklist complete* | *Obtain signed contract checklist from the contract officer.* |
|  | Final pharmacy agreement received | *Has the sponsor pharmacist approved the trial?* | *Obtain final sponsor pharmacist approval email (ensuring it matches SOP 42b).* |
|  | Coordination Delegation Log signed |  |  |
|  | HRA Approval & conditions met | *Are any conditions present on the HRA approval? Have these been met?* | *Obtain HRA Approval letter, review to assess if conditions in place. Obtain written confirmation that the conditions have been met* |
|  | MHRA approval received & conditions met | *Are any conditions present on the MHRA, have these been met?* | *Obtain MHRA Approval letter, review to assess if conditions in place. Obtain written confirmation that the conditions have been met* |
|  | REC approval received & conditions met | *Are any conditions present on the REC, have these been met?* | *Obtain REC Approval letter, review to assess if conditions in place. Obtain written confirmation that the conditions have been met* |
|  | CI has capacity to begin trial | *Does the CI have capacity to run the trial?* | *Obtain confirmation from CI that they have capacity to commence the trial at the present time.* |
|  | Obtain confirmation from JRMO Clinical Trial Monitors to ensure ReDA, EDGE and files up to date | *Request confirmation* | *At this point the below attributes should be created and populated in Edge:*  *JRMO GCP Dataset*  *JRMO GCP Lead (sponsorship)*  *JRMO MHRA Risk Assessment Score*  *JRMO MHRA Sponsor Dossier Attribute set (Project)*  *The below fields should be set up in REDA:*   * *Short Title* * *Full Title* * *IRAS ID* * *ReDA No* * *REC no* * *European Union Drug Regulating Authorities Clinical Trials Database* * *Study Status* * *EDGE ID* * *CI* * *Sponsor*   *APR and DSUR reminders should be setup and active*  *Filing should be reviewed from GO and Sponsor oversight fields set up following SOP 27.* |
|  | Email Governance officer to confirm GCP ready and in support of issuing confirmation of Sponsorship | *Issue email.* | *Ensure all aspects of the checklist and final meeting actions are completed. Log any waivers or deviations from JRMO SOPs* |