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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 investigations and other clinical trials.  Consider:  - Does the CI have the correct qualifications for the trial type? - Have they acted as a chief investigator for a clinical investigation before?*  *- Have they acted as chief investigator for other MHRA- regulated clinical trials before?*  *-Has the CI worked on device trials? If yes are these Non-UKCA marked?* *- Have they acted as a host site principal investigator before?* *- Have they managed multi-centre trials before?*  *- What risk categorisation did their previous projects have?* *- Are they supported by a CTU, research group or mentor?*  *-Do they have ISO 14155 GCP training?* |
|  | 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.* |
|  | Clinical Investigation Plan (CIP) | *Is the CIP compliant with requirements? If not on a JRMO template, insert justification and entered as waiver with Non-Compliance.* | *Ensure that the CIP is on the JRMO template or an appropriate alternative.  Ensure that the CIP 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.* |
|  | Safety Reporting arrangements agreed | *Are appropriate safety reporting processes in place?* | *Consider the safety reporting requirements described in ISO 14155 GCP.*  *Where possible, safety reporting to the MHRA should be managed by the device manufacturer. -* |
|  | 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.* |
|  | Medical Device manufacturer contract fully executed? | *Is the device manufacturer suitable? Have they agreed to the sponsor’s requirements?* | *The investigational device manufacturer(s) must be listed on the IRAS form and must take responsibility for some aspects of the Clinical Investigation. Therefore, the contract between the manufacturer and the sponsor must be executed before sponsorship with conditions is awarded. The manufacturer should also agree with the sponsor’s requirements* |
|  | 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.* |
|  | Investigational medical device and any other medical devices assessed by Clinical Physics | *Agreement to proceed in place?* | *A representative from the Barts Health Clinical Physics department must be invited to the Kick-off meeting and must issue agreement for the trial to proceed to sponsorship.* |
|  | Kick-off meeting held and all actions completed? | *All GCP team points covered as per agenda?* | *See SOP 9 AD5* |
|  | 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:  -ISO14155 GCP -UK Policy Framework   -The Medical Devices Regulations 2002 and amendments -Human Tissue Act 2004 -Data Protection Act 2018 -Mental Capacity Act 2005  This 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 clinical investigation.  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 built and validated. | Is the database ready for use? | Review the database documentation to confirm that the database has been built and validated in accordance with SOP 38b and confirm that the database has gone live. |
|  | 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. |
|  | All contracts agreed and full executed (Signed checklist received) | Is the contract checklist complete | Obtain signed contract checklist from the contract officer to confirm that all required contracts have been executed. |
|  | Final Clinical Physics agreement received | Has the Clinical Physics department approved the trial? | Obtain final sponsor pharmacist approval email (ensuring it matches SOP 42b). |
|  | Device Manufacturer agreement to proceed | Is the investigational device manufacturer ready for the Clinical Investigation to begin? | An email or letter of confirmation is sufficient. |
|  | 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 (EUDRA-CT) * 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 |