The worksheet outlines the process of clinical trial feasibility and start-up undertaken at ACCTC by the following: Research Ethics, Governance and Integrity Unit (REGI), Manager (M), Primary Coordinator (PC), Principal Investigator (PI), Clinical Trials Administrator (CTA), Director of Research (DOR)

|  |  |
| --- | --- |
| Feasibility Received (dd/mmm/yyyy): |  |
| Protocol Number: |  |
| Protocol Name: |  |
| Sponsor: |  |
| PI: |  |
| Department: |  |
| Manager: |  |
| Primary Coordinator: |  |

|  |  |  |
| --- | --- | --- |
| **Feasibility Questionnaire** | | |
|  | **Yes** | **No** |
| **Study Design** | | |
| Is the study in an area of need? |  |  |
| Is the study of sound scientific merit? |  |  |
| Is the trial funded? How? |  |  |
| Do you think the study objective is feasible to achieve? |  |  |
| Do you think the study procedure is feasible? (Duration of study, Number of visits etc.) |  |  |
| Have the inclusion/ exclusion criteria been assessed appropriately (with supporting info / data)? |  |  |
| What Is the recruitment target? |  |  |
| Is this realistic for the population? |  |  |
| Are there any ongoing / competing trials? |  |  |
| Is hospitalisation required? |  |  |
| **Facilities** | | |
| Does the study require any specific support like imaging, optometry, laboratory service (fridge/freezer) etc. If yes, do you have access to it? |  |  |
| If specific laboratory tests are required, does ACL offer the laboratory tests needed for the trial? |  |  |
| Do you have space for storage of study related materials (lab kits etc...) |  |  |
| Do you have dedicated cupboard for study document storage. |  |  |
| Does the study team have a valid good clinical practice (GCP) training certificate? |  |  |
| Do you have sufficient staff FTE to conduct the study? |  |  |
| Does the IP need pharmacy involvement? (storage, Dispensing, and destruction) |  |  |
| **Regulatory** | | |
| Will the site be the lead site? If yes, who will do the ethics application? |  |  |
| Do you have a checklist for submission of the documents?  Eg:   * Protocol and amendments * Case Report Forms * Investigator's Brochure * ICF and ICF updates * Translation of ICF and Translation certificate (if needed) * Subject recruitment procedures (Advertisements) * Investigators current CV/FDA 1572/Financial Disclosure Forms * Any other documents required for submission please mention here. |  |  |
| **Costing and budget** | | |
| Is there any special site cost? If 'Yes' what is the amount? |  |  |
| Is the draft budget sufficient to run the study at Barwon Health? |  |  |

**FEASIBILITY**

☐ **M** – Initial feasibility received and distributed to PI and DOR

☐ **M** – Confidentiality agreement (CDA) signed off (if required)

☐ **M** – Protocol or synopsis received and distributed to PI and DOR

☐ **M** – Send out protocol or synopsis (if available) to Clinical Trials pharmacy and head of department to confirm feasibility

☐ **M and PI** – Feasibility questionnaire completed and sent to sponsor (if required)

☐ **PC** – Add trial to study tracker (if applicable)

**SITE SELECTION VISIT (SSV) PREPARATION**

☐ **M** – Provide site/unit/department profile, SOPs and reference ranges to sponsor representative

☐ **M** – Provide site qualification documents to sponsor representative (PI’s and SC’s CV and GCP, EMR Qualification Form, ACL Application)

☐ **M**– Review protocol and prepare SSV questions for sponsor (provide prior to SSV where possible)

**SITE SELECTION VISIT (SSV)**

☐ **M** – Facilities qualification tour (monitoring space, clinical space, pharmacy and office space as required)

30min discussion with PI

30min logistical review with D

☐ Participation confirmed and timelines set

**INTERNAL SUBMISSION PREPARATION**

☐ **M** – Send out budget assessment to PI and relevant departments (based on schema, lab assessments and eligibility criteria)

**SITE SELECTED**

☐ **M** – Obtain documents from sponsor (final protocol, customised PICFs, IBs, pharmacy manual and lab manual)

☐ **M** –Commence submission via ERM <https://au.forms.ethicalreviewmanager.com/Account/Login>

**HREC SUBMISSION and RGO PREPARATION**

☐ **M** – Create REGI Barwon Health number <https://www.barwonhealth.org.au/research/for-researchers/regi/how-to-prepare-an-application>

☐ **M** – Review and finalise budget assessment

☐ **M** – Commence ERM submission

☐ **M** – Review master PICFs and create site specific PICFs within 5 working days of receipt from sponsor, send to sponsor for approval once complete

☐ **M** – Update internal study tracker (if applicable) with submission details

☐ **M** - Handover all documents received to date to PC

**DOCUMENTS**

PC – Make contact with CRA/study team (in case of investigator initiated trials) to request templates once new contacts email is received. Documents should then be completed and filed within 10 days of receipt.

☐ **PC** – Request Investigator Site File (ISF) documents

☐ **PC** – Copy staff CVs and training certificates into ISF for all site staff

☐ **PC** – Provide signed Investigational Brochure (IB) signature page, protocol signature page, FDA 1572 (statement of investigator), Financial Disclosure Form (FDF) if applicable, and data privacy forms

☐ **PC** – Provide staff contact list, including role and required access (eCRF, IVRS, Imaging Portal etc.)

☐ **PC** – Review lab manual and central samples

☐ **PC** – Provide trial team documents to CRA/ study team (in case of investigator initiated trials):

* Delegation log
* Training log
* SOPs (again)
* Site/Unit/Department profile (again)

☐ **PC** – Request pharmacy folder

☐ **PC** – Prepare study specific worksheets for source data collection

☐ **PC** – Prepare patient documents (i.e. screening checklist, patient timetables, screening and eligibility worksheets)

**SITE INITIATION VISIT (SIV) PREPARATION**

☐ **PC** – Enquire who from the sponsor is attending and if a medical monitor will be present for the protocol and safety data component of the SIV (not CRA)

☐ **PC/CTA**– Book meeting room for 2 hour slot – send out agenda to CRA

☐ **PC/CTA** – Email ‘save the date’ Outlook invitation (PI, SubIs, Pharmacy, other SCs)

☐ **PC/CTA** – Update Outlook invitation once confirmed

☐ **CTA** – Catering

☐ **PC/CTA** – Email sponsor representative with meeting details (if being conducted online on a platform) or instructions of where to meet on site. If being held in hybrid mode, both details will need to be sent out.

☐ **PC/CTA** – Request required kits and any additional supplies – enter into SLOPE (or equivalent registry) once received

☐ **PC/CTA** – Request relevant equipment is compliant with the Australian Electrical Standard, supplied with a function, electrical safety and factory calibration test reports. No plug adapters. Needs to be tested and tagged prior to use

☐ **PC/CTA** – Provide BH privacy, confidentiality and security agreement to CRA to sign and return

☐ **PC** – Confirm Investigation Product (IP) availability, if applicable (is it in the country, when will it arrive?)

☐ **PC** – Print delegation log, SIV attendance log, training log

☐ **PC** – Resolve any outstanding queries and check all tasks are completed to enable activate post SIV

**PROJECT APPROVAL**

Ethics and governance approved

☐ **PC** – Review documents and approvals

☐ **PC** – File approval documents to ISF

**Site Initiation Visit (SIV)**

1 hour slot for Main SIV

1 hour slot with Study Team including site tour

1 hour slot with Pharmacy – CRA/study team to organise with pharmacy

☐ **PC** – Complete attendance record and file in ISF

☐ **PC** – Delegation log is signed by all attendees who will perform trial activities

☐ **PC** – Complete protocol training log and file in ISF

**POST SIV**

Sponsor confirms activation (if more than 1 week post SIV, escalate to PI and Director)

☐ **PC** – Provide trial description for BH Research website

☐ **PC/CTA**  – Request BH account for CRA in preparation for monitoring visits

First patient on study and registered on IPM