CORE SOPs FOR UKCRC REGISTERED CTUs

Notes:

- SOPs do not have to be named as below as long as all areas are covered by CTUs (or their Sponsor's) procedures and/or policies.
- SOP list is not exhaustive and CTUs will have additional SOPs in place.
- Many SOPs may need to refer to Trial Specific Procedures where applicable.
- All SOPs may need to cover requirements for international trials where necessary.
- Responsible personnel/roles must be identified in each area and the decision making process outlined (where applicable).

SOP area	**Typical content**
1. SOP on SOPs	SOP template/description of standard structure and content Responsibility for sign-off Document control Review process Circulation and dissemination Relevant regulatory references
2. Protocol development	Protocol template/Definition of content Responsibility for sign-off Protocol amendments Review
3. Monitoring	Risk assessment and development of monitoring plans (central & site) Procedures for site & central monitoring Internal & independent oversight arrangements
4. Trial Master File/Site Files (Investigator & Pharmacy)	Detail of contents Responsibilities and procedures for maintenance
5. Regulatory approvals	Submission Responsibility for sign-off of submission Submitting substantial amendments Maintaining approval
6. Trial Initiation and site set up	Site selection Details of site training Site activation process
7. Data management	Data handling processes Data transfer processes Data security CRF development & completion
8. Trials supplies	Trial supply management, including storage, drug accountability, drug distribution, recall procedures, labelling and incident reporting

9. Safety reporting/Pharmacovigilance (if CTIMPs)	Expedited reporting Annual safety reporting Definition of reporting responsibilities
10. Quality Management Systems	Description of internal audit and quality checks
11. Patient Information	Development of patient information, including Patient Information Sheet, Patient Consent Form, GP letter and any other documentation Implementation and dissemination (including approvals required) Process for managing revisions and document control
12. Training	Development, maintenance, and management of training plans and training records .
13. Registration/Randomisation (if run randomised trials)	Details of processes used by CTU e.g. web-based, phone-based Procedures involved including: Confirmation of treatment allocation/unique patient identifier for trial) Unblinding Procedures for emergency randomisation in event of system failure
14. Statistics	Responsibility for sign off of documentation Analysis plan, including interim analysis Statistical reports Sample size calculations Outcome data reports Statistical Quality Assurance Manipulation of data after export
15. IT/database	System and Data security Hardware management Software management Disaster recovery User support Network management Archiving System/Application development Training Acceptable Use Policy Regulatory Interpretation
16. Trial closure	Site closure Notification of end of trial to regulators Procedures for closing trial early
17. End of trial reporting	Dissemination of findings – investigators, patients, public and regulators

18. Archiving	Policy and procedure for data storage Security Process for access
19. **NEW** Deviations, Misconduct and serious breaches of GCP and/or the Protocol	Definition of circumstances Policy for addressing Notification to key stakeholders, e.g. regulators, Sponsor, employers
20. **NEW** Urgent safety measures	Definition of circumstances Procedures for notifying investigators, Sponsor, regulators, TSC & DMC Immediate measures to be taken
21. **NEW** Sponsorship, contracts/agreements and indemnity	Arrangements for financial disclosure Responsibilities at CTU (if applicable) Registration for sponsorship/communication between CTU and Sponsor Templates in use Negotiating, issuing & amending contracts/agreements Implementation of trial agreements with sites
22. **NEW** Data protection and confidentiality	Security measures to be taken Processes for dealing with breaches Defining sensitive data
23. **NEW** Document control	Version control Distribution control Archiving