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| **PROPOSAL & FUNDING**<br>Allow 7 days for Governance review | Governance review of funding application to identify costs e.g. regulatory fees, monitoring, drug and labelling, database, archiving.<br>CMVM Research Support Office usually coordinates applications. Find your Research Funding Specialist<br>For NHS costs contact r&dfinance@nhslothian.scot.nhs.uk |
| **SPONSOR REVIEW**<br>Allow a minimum of 10 working days for initial Sponsor review. The total duration to submissions will depend on the complexity of the study and quality of the documents e.g. build in 1-3 months depending on complexity^ | A lead Sponsor Rep will support you to develop documentation for submission to the relevant authorities. If your research is complex, a Research Facilitator will be assigned as Sponsor Rep. FACILITATION CHECKLIST<br>To begin the review process, send the following to resgov@accord.scot:<br>* Draft protocol<br>* Participant Information Sheet(s)<br>* Consent form<br>* Draft IRAS full project data set<br>* Draft Outline Organisation Information Document<br>* Schedule of Events<br>* Any other study documents e.g. recruitment materials, letters, CVs<br>Protocol and PIS/consent templates should be used, see CR007 Study Documents<br>Your Sponsor Rep will confirm single or co-sponsorship by UoE/NHS Lothian and confirm the approvals to be obtained e.g. ethics approval, R&D Management approval, MHRA approval.<br>All documents will be reviewed to ensure compliance with appropriate regulations, policies and SOPs. Your Sponsor Rep will work with you to address issues raised during the review. Once addressed, applications will be signed off by the Sponsor for submission. If your study is co-sponsored by UoE/NHS Lothian, submission to NHS Lothian R&D is still required for Management approval. |
| **COMBINED RISK ASSESSMENT**<br>Meeting is typically performed within 2-3 weeks of receipt of valid study documentation | All regulated drug and medical device trials undergo risk assessment. Higher risk or complex non-regulated trials may also be risk assessed. Your Sponsor Rep will advise.<br>Research Governance, QA, Monitoring, Pharmacovigilance and Pharmacy personnel review the trial design and documentation to identify any risks and ensure appropriate measures are in place to mitigate the risks. Other specialist input may be sought where necessary. RISK ASSESSMENT TOOL<br>You will be invited to attend the risk assessment meeting to provide input, expertise and to address any questions and comments raised by the Risk Assessment Committee. Your Sponsor Rep will also support you to implement any mitigations. |
| **SUBMISSIONS** | Timelines for different approvals vary. Generally, the following applies:<br>**NHS REC** within 60 calendar days of receipt of a valid application.<br>**NHS R&D** within 30 days of a valid application.<br>**MHRA** initial response within 30 days of a valid application. Amended requests within a total of 60 days from initial application. |
| **CONTRACTS**<br>Start contract preparation as early as possible | Your Sponsor Rep will identify any agreements that are required and will work with the Research Support Office Contracts team to discuss these. The Contracts team will arrange a "kick-off" meeting to discuss specific contracts. Contracts that may be required include:<br>* Funding Award Agreement<br>* Co-Sponsorship Agreement<br>* Site Agreement(s)<br>* Technical Agreement<br>* Service Level Agreement<br>* Data/Material Transfer Agreement<br>* Drug Supply Agreement<br>* Collaboration Agreement<br>* Others |
| **QUALITY ASSURANCE**<br>Ongoing activity | If a research study has been risk assessed, the ACCORD QA team will assess and approve any vendors (e.g. labs) or computer systems (e.g. database) involved in the study. This may include an audit of facilities. COMPUTER SYSTEMS VALIDATION CHECKLIST LAB QUALITY QUESTIONNAIRE |
| **APPROVALS** | When REC and MHRA approval, agreements and processes are in place, the Governance team will issue regulatory release to begin the trial where applicable. |
| **SPONSOR AUTHORISATION TO OPEN (SATO)** | If a research study has been risk assessed, the ACCORD Monitoring team will develop a monitoring plan adapted to the identified risks.<br>Once R&D approval and all other requirements of the SATO checklist have been met the site can open to recruitment. SATO CHECKLIST |
| **AMENDMENTS**<br>Allow a minimum of 10 working days for initial Sponsor review | Once your research has begun, proposed changes to the documentation and/or study design must be discussed with the Sponsor. Your Sponsor Rep will review, classify and authorise amendments to be submitted.<br>For studies sponsored by UoE and/or NHSL, proposed amendments should be sent to resgov@accord.scot<br>If a research study has been risk assessed, the assessment may be re-opened to review the amendment and evaluate any new risks. Any necessary changes to contracts will also be checked. |
| **MONITORING & AUDITING** | If a research study has a monitoring plan in place, an ACCORD Clinical Trials Monitor will make contact to the arrange monitoring visits. Research perceived to be high risk will be subject to more frequent and more intense monitoring than lower risk research.<br>Routine monitoring and close out visits will be performed. Triggered visits may be conducted if any issues arise during the study.<br>Study specific audit(s) may be performed based on the outcome of the risk assessment. |

^ Investigators should also consider building sufficient time in to provide responses to reviews, the risk assessment and submissions, and to make any necessary changes to documents.