**Vendor Questionnaire**

*To be completed for contract research organisations (CRO) / Clinical Trials Unit (CTU) providing services as part of research project.*

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| **COMPANY DETAILS** | |
| Name |  |
| Address |  |
| Contact Person (Job Title) |  |
| Telephone No. |  |
| Email |  |

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| **SERVICES COVERED** |
| *[Please state nature and purpose of services conducted as part of the trial]* |

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| **REQUIREMENTS** | |
| 1. **QUALITY SYSTEM** | |
| Does your organisation possess regulatory and GCP compliant SOPs? How often are SOPs reviewed?  (P*lease attach list / index of SOPs*). | ***Yes/No***  ***(delete as appropriate)*** |
| ***Details:*** | |
| Does your organisation have a self-inspection / internal audit programme? | ***Yes/No***  ***(delete as appropriate)*** |
| ***Details:*** | |
| Does your organisation have a documented training procedure? Are personal training records maintained? | ***Yes/No***  ***(delete as appropriate)*** |
| ***Details:*** | |
| Do you have adequate facilities and staff to handle project requirements? | ***Yes/No***  ***(delete as appropriate)*** |
| ***Details:*** | |
| Are all computerised systems used to capture, report, store clinical trial data developed and validated to ensure integrity and security of the data? | ***Yes/No***  ***(delete as appropriate)*** |
| ***Details:*** | |
| 1. **INSPECTION RECORD** | |
| Has the organisation been subject to a routine competent authority inspection? If so, what was the outcome?  ***Date(s):***  ***Details:*** | |
| Has the organisation been subject to any triggered inspections? If so, what was the outcome? | ***Yes/No***  ***(delete as appropriate)*** |
| ***Date(s):***  ***Details:*** | |
| Are all actions from the previous inspection closed? | ***Yes/No***  ***(delete as appropriate)*** |
| 1. **PREVIOUS EXPERIENCE** | |
| Number of CTIMP studies with current involvement: | |
| What experience do you have with similar projects?  *Please list what services were provided* | |

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| **AUTHORISATION**  *(To be completed by representative from organisation)* | | | |
| Authorising Individual |  | | |
| Signature |  | Date |  |

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| 1. **ORGANISATION’S ROLE**   (*To be completed by ACCORD QA Manager, or designee*) | |
| Are the roles and responsibilities allocated to the proposed organisation described in an agreement?  *Please refer to Combined Risk Assessment (GS002) for delegated services.* | ***Yes/No***  ***(delete as appropriate)*** |
| Does the agreement contain a GCP clause? | ***Yes/No***  ***(delete as appropriate)*** |
| Does the proposed organisation possess the necessary research governance infrastructure? | ***Yes/No***  ***(delete as appropriate)*** |

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| **OUTCOME**  (*To be completed by QA Manager, or designee*) | | | | |
| Vendor approved? | | | | ***Yes/No***  ***(delete as appropriate)*** |
| ***Comments:*** | | | | |
| ***If not approved, actions to be taken (e.g. pre-qualification audit, etc):*** | | | | |
| Signature: |  | Date: |  | |
| Name: |  | Job Title: |  | |