**Vendor Questionnaire**

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

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

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

|  |
| --- |
| **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* |

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

|  |
| --- |
| 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)*** |

|  |
| --- |
| **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: |  |