**DIVISION OF RESEARCH AND INNOVATION**

**Computer System Change Assessment**

**Section 1: System Details**

|  |  |
| --- | --- |
| Hardware name (if applicable) |  |
| Software name |  |
| System version number |  |
| Manufacturer / vendor |  |
| Area of use (specify the division, department, or study title and R&D number) |  |
| Outline of software use |  |
| Number of installations  |  |

**Section 2: What is the change?**

|  |  |  |
| --- | --- | --- |
| What is the change type? | Software (e.g. patch, update, configuration) | [ ]  Y [ ]  N |
|  | Hardware (e.g. upgrade or additional) | [ ]  Y [ ]  N |
|  | Regulatory risk (as per risk assessment)  | [ ]  Y [ ]  N |
|  | System requirements (as per validation plan) | [ ]  Y [ ]  N |
|  | System use | [ ]  Y [ ]  N |
| Change description |  |
| Reason for change |  |

**Section 3: Is revalidation/additional validation required?**

|  |  |
| --- | --- |
| Does the change impact any of the following? | Check Box |
| 1. Does the Risk Assessment require updating to demonstrate an increased risk?
 | [ ]  Y [ ]  N |
| 1. Have the system requirements become more stringent?
 | [ ]  Y [ ]  N |
| 1. Does the change impact/have the potential to impact any of the major functions listed in the validation plan?
 | [ ]  Y [ ]  N |
| 1. Will the change require migration of data?
 | [ ]  Y [ ]  N |
| Complete the appropriate box below according to the responses above:If any response is YES, revalidation/additional validation is required – validation plan and validation report must be completed (and risk assessment revised if applicable). If all responses are NO, revalidation/additional validation is not required – complete and sign off Validation Statement. |
| Revalidation/additional validation is NOT required: [ ]   | Revalidation/additional validation **IS** required:[ ]   |

|  |
| --- |
| **Validation Statement***Complete sections 1 - 3 of the Change Assessment before you complete the statement below.* |
| Sections 1 - 3 of this Change Assessment have been completed as required, and this change has been assessed as:  |
| HIGH significance | [ ]  | Revalidation of all functions is required.  |
| LOW significance | [ ]  | Revalidation/Additional validation of key functions is required.  |
| NO significance | [ ]  | No further action is required. |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Signature | DateDD-MMM-YY |
| System Owner |  |  |  |
| QA Representative/ Sponsor Representative |  |  |  |
| IT Representative (if applicable) |  |  |  |