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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Title:** |  | | | | | | |
|  | | | | | | | |
| **R&I Number** |  |  | **Protocol Version:** |  |  | **Sponsor(s):** |  |
|  |  |  |  |  |  |  |  |
| **Chief Investigator:** |  |  |  |  |  |  |  |
|  |  | | | |  |  |  |

*All Laboratory tests listed within the protocol must be listed below. (please use as many copies as needed and complete page numbering below).*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Lab Test:** |  |  |  |  |  |
| **Category 1, 2 or 3 Test**  **(Refer to SOP 51.028)** |  |  |  |  |  |
| Does this test a Primary Endpoint? | Yes/No | Yes/No | Yes/No | Yes/No | Yes/No |
| Does this test a Secondary Endpoint? | Yes/No | Yes/No | Yes/No | Yes/No | Yes/No |
| Does this test a Safety Endpoint? | Yes/No | Yes/No | Yes/No | Yes/No | Yes/No |
| Does this test Eligibility? | Yes/No | Yes/No | Yes/No | Yes/No | Yes/No |
| Is this test for another reason - please state? |  |  |  |  |  |
| Is the NHS GG&C Biorepository involved - state activity, e.g., central lab, aliquotting for courier, storage etc (this list is not exhaustive)? |  |  |  |  |  |
| Additional comments, e.g. blinded reporting required |  |  |  |  |  |
| Location of NHS Lab - state site and type of lab e.g Haem, Biochem, immunology, Pathology etc |  |  |  |  |  |
| Location of Lab external to NHS GG&C- state lead contact person |  |  |  |  |  |

Prepared by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_

Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_

Chief Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_