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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Title:** |  | | | | | | |
|  | | | | | | | |
| **R&D Number** |  |  | **Protocol Version:** |  |  | **Sponsor(s):** |  |
|  |  |  |  |  |  |  |  |
| **Chief Investigator:** |  |  | **EudraCT No:** |  |  |  |  |
|  |  | | | |  |  |  |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Imaging Test:** |  |  |  |  |  |
| **Category 1, 2 or 3 Test**  Category 1: Standard imaging protocol used by service  Category 2: Standard imaging protocol with specific requirements or  Category 3: Nonstandard imaging protocol specific to research study |  |  |  |  |  |
| 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? |  |  |  |  |  |
| Additional comments, e.g, blinded reporting required |  |  |  |  |  |
| Location of Imaging site |  |  |  |  |  |

|  |  |
| --- | --- |
| **Form Completed By:** | **Clinical Risk Assessment (B)** |

**Form Completed by:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** |  | **Signature** |  | **Date** |  |

**Approved on behalf of the Working Group:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** |  | **Signature** |  | **Date** |  |