**Active auditing form, October 2023, v2**

Research Ethics Committee

|  |  |  |
| --- | --- | --- |
| **Final Version** | **Reason for Amendment** | **Effective Date** |
| 2 | Updated and published for implementation | October 2023 |
|  | Administrative changes | March 2024 |

# GENERAL INFORMATION:

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **Protocol Number:** |  |
| **Principal Investigators:** |  |
|  |  |
|  |  |
| **Date of Audit:** |  |
| **Address of Site:** |  |
| **Name of Auditor:** |  |

# PROTOCOL:

**Comments:**

|  |  |
| --- | --- |
| **Is the correct version of the protocol approved by REC used** |  |
| **The protocol included all inclusion and exclusion criteria** |  |
| **Deviations and violations were recorded and justified** |  |
| **Amendments were approved by REC** |  |
| **Availability of investigators to confirm conduct of trial according to protocol and GCP** |  |

# INFORMED CONSENT:

**Comments:**

|  |  |
| --- | --- |
| **Site file was available** |  |
| **Patients were able to consent in a private location** |  |
| **Correct versions of Informed Consent Documents were signed** |  |
| **Contact details of Principal Investigator were given to participants** |  |

# GENERAL:

|  |  |
| --- | --- |
| **Randomization** |  |
| **Patients Enrolled** |  |
| **Patients Withdrawn** |  |
| **Patients Completing Study** |  |
| **Number of Serious Adverse Events** |  |
| **Number of Protocol Deviations, and were site staff retrained?**  **Corrective action?** |  |

# REMARKS:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_