***Template* -*– Include all inclusion and exclusion criteria directly from the IRB approved study protocol.***

**ELIGIBILITY CRITERIA –** Maintain all supporting documentation/original source for each answer and this document should be retained in the subject’s research file.

|  |  |  |  |
| --- | --- | --- | --- |
| **Inclusion Criteria** | **Comments (if applicable)** | **Yes** | **No** |
| **Example Only:**  Participant (or legal guardian) is able to understand and is willing to provide written informed consent for the trial | Date Consent Signed:\_\_\_\_\_\_\_\_\_ |  |  |
| Subject is at least 18 years of age | Date of Birth (DOB): |  |  |
| Diagnosed with type 2 diabetes mellitus ≥ 90 days prior to day of screening | Date of Diagnosis: |  |  |
| BP < 140/90 (screening visit) | Blood Pressure (BP): |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Exclusion Criteria** | **Comments (if applicable)** | **Yes** | **No** |
| Receipt of any investigational medicinal product within 90 days before screening | Exclusion confirmed by: |  |  |
| Subject has a history of:   * myocardial infarction (MI) * coronary bypass graft (CABG) * Stroke * Pancreatitis (acute or chronic) | Exclusion confirmed by: |  |  |
| * abnormal liver function tests (LFT)   (> 2 x upper limit of normal) | Date of LFT:  Result: |  |  |
| Pregnant or breastfeeding | Date of pregnancy test:  Result:  or LMP (last menstrual period) |  |  |
| History of substance abuse (within the last 6 mos.) | Exclusion confirmed by: |  |  |

**Eligibility Checklist Completed by:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
| **Signature of Research Staff Member** |  | **Date (MM/DD/YYYY)** |
|  |  |  |
|  |  |  |
| **Printed Name of Research Staff Member** |  |  |

**If any answers to inclusion criteria are ‘no’ or exclusion criteria ‘yes’, then participant is not eligible to be enrolled.**

**The subject is:**  **eligible** /  **ineligible** for participation in the above-named study based on the inclusion/exclusion criteria as verified by a qualified investigator.

**The PI or qualified investigator should sign below if the above signatory has not been delegated authority to review eligibility per the delegation of authority log, or if additional verification is required (e.g., medical monitor review, physician clearance, etc.)**

**Verified by:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
| **Signature of Investigator/Qualified Personnel** |  | **Date (MM/DD/YYYY)** |
|  |  |  |
|  |  |  |
| **Printed Name of Investigator/Qualified Personnel** |  |  |