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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Inclusion Criteria** | **Comments (if applicable)** | **Yes** | **No** |
| **Example Only:**  Subject is willing and able 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.

**Verified by:**

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