**ELIGIBILITY CRITERIA**

**Use source documents to capture data, and then use this checklist to confirm that each subject meets criteria for enrollment. This form must be signed by an Investigator.**

**Sections highlighted in yellow are sample text; use your protocol and/or iRIS application to fill in specific inclusion/exclusion criteria as appropriate.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Inclusion Criteria** | **Comments** | **Criterion Met?****All Must be “Yes”** | **Supporting Source documents?** |
| Subject is at least 18 years of age | Age: | ⁭Yes ⁭No | ⁭Yes ⁭No |
| Newly diagnosed with diabetes | Date of Diagnosis: | ⁭Yes ⁭No | ⁭Yes ⁭No |
| Prescribed oral medication for diabetes control | Name of Med/Dose: | ⁭Yes ⁭No | ⁭Yes ⁭No |
| Confirmed diagnosis of psychological disease, e.g., bi-polar, schizophrenia, depression | Diagnosis:Confirmed by: | ⁭Yes ⁭No | ⁭Yes ⁭No |
| BP < 140/90 | BP:  | ⁭Yes ⁭No | ⁭Yes ⁭No |

|  |  |  |  |
| --- | --- | --- | --- |
| **Exclusion Criteria** | **Criteria Met and Documented?**  | **Criterion Met?****All Must be “No”** | **Supporting Source documents?** |
| Subject has a history of:* myocardial infarction (MI)
* coronary bypass graft (CABG)
* heart failure
* stroke
* abnormal liver function tests

 (> 2 x upper limit of normal) | myocardial infarction (MI) coronary bypass graft (CABG)heart failurestrokeliver function tests results:  | ⁭Yes ⁭No | ⁭Yes ⁭No |
| Pregnant or breastfeeding | Date of pregnancy test:Result: or LMP (last menstrual period) | ⁭Yes ⁭No | ⁭Yes ⁭No |
| Exclusionary medications (list below) | Current Medications: | ⁭Yes ⁭No | ⁭Yes ⁭No |

**Participant is: Eligible Not Eligible**

**Completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Print Name Signature Date**

**Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name Signature Date**