**POST-IRB APPROVAL**

**ELIGIBILITY CRITERIA SELF-ASSESSMENT**

**Purpose**: This form is for researchers to use to conduct a self-assessment of their IRB approved study to ensure that the regulatory and institutional requirements for documenting eligibility criteria are met. Eligibility lists should be revised to reflect the specific criteria for your study. Please keep completed self-assessments with your study related records as documentation of on-going oversight of the study.

If you should have any questions or concerns regarding compliance for documenting eligibility criteria, contact the Office of Research Compliance Review at [orcr-deptemail@umich.edu](about:blank) .

Guidance regarding subject eligibility can be found at: [IRBMED ORIO Guidance](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting/other-reportable-information-or-occurrence-orio)

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| --- | --- |
| **STUDY INFORMATION** | |
| HUM # |  |
| Study Title |  |
| PI Name |  |
| Date Self-Assessment Completed |  |
| Person Completing Self-Assessment |  |

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| **ELIGIBILITY CRITERIA** | **SUBJECT ID**  **(Answer: Yes or No)** | | | | | | | | | | | |
| **#1** | **#2** | **#3** | **#4** | **#5** | **#6** | **#7** | **#8** | **#9** | **#10** | **#11** | **#12** |
| **INCLUSION CRITERIA (LIST)** |  |  |  |  |  |  |  |  |  |  |  |  |
| Subject at least 18 years of age *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| Newly diagnosed with diabetes *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| BP<140/90 *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| Prescribed oral medical for diabetes control *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| **EXCLUSION CRITERIA (LIST)** |  |  |  |  |  |  |  |  |  |  |  |  |
| History of myocardial infarction (MI) *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| Pregnant or breastfeeding *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| History of substance abuse *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| History of abnormal liver function test *[example]* |  |  |  |  |  |  |  |  |  |  |  |  |
| **ASSESSMENT** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Meet all inclusion criteria and no exclusion criteria?** (if no, describe below) |  |  |  |  |  |  |  |  |  |  |  |  |
| **Eligibility confirmed prior to implementing study procedure?** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Eligibility confirmed, signed, and dated by a qualified study team member’?** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Source doc for each criterion in participant’s study file?** (if no, describe below) |  |  |  |  |  |  |  |  |  |  |  |  |
| **Do all source documents meet ALCOAC\* standards?** (if no, describe below) |  |  |  |  |  |  |  |  |  |  |  |  |

\* *ALCOAC: documentation is Attributable, Legible, Contemporaneous, Original, Accurate, Complete*

**OBSERVATIONS AND FOLLOW-UP (describe any concerns noted above)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Subject ID** | **Observation** | **Follow-up actions** | **Date of IRB reporting** | **IRB response** | **Addt’l Notification**  ***(FDA, S-I, or Sponsor)*** |
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