**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 criteria should be revised to reflect the specific criteria for your study. Please keep completed self-assessments with your study related records as documentation of ongoing oversight of the study.

NOTE: Informed consent must be obtained and documented for each prospective research participant (or their legally authorized representative) for all non-exempt human research before they begin to participate in the research (including any related eligibility testing not conducted solely for clinical purposes), unless the appropriate IRB has approved a waiver or alteration of consent or waiver of documentation.

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.

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| **STUDY INFORMATION** |
| HUM # | Click or tap here to enter text. |
| Study Title | Click or tap here to enter text. |
| PI Name | Click or tap here to enter text. |
| Date Self-Assessment Completed | Click or tap here to enter text. |
| Person Completing Self-Assessment | Click or tap here to enter text. |

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| **ELIGIBILITY CRITERIA** | **PARTICIPANT ID****(Answer: Yes, No, or N/A)** |
| **#1** | **#2** | **#3** | **#4** | **#5** | **#6** | **#7** | **#8** | **#9** | **#10** | **#11** | **#12** |
| **INCLUSION CRITERIA (LIST) to meet eligibility criteria all inclusion criteria should be YES or N/A** |  |  |  |  |  |  |  |  |  |  |  |  |
| 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) to meet eligibility criteria all exclusion criteria should be NO or N/A** |  |  |  |  |  |  |  |  |  |  |  |  |
| 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)**

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| **Participant ID** | **Observation** | **Follow-up actions** | **Date Reported to IRB** | **Additional Notification, if applicable*****(FDA, Sponsor-Investigator, or Sponsor)*** |
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