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| **Study Stage:** Start-up, Conduct |

**Purpose:** The Eligibility Checklist documents and tracks a participant’s eligibility to take part in a study according to the criteria specified in the IRB approved protocol or research plan. The Eligibility Checklist serves to verify that no inclusion or exclusion criteria is missed. It makes determining eligibility easier and can provide assistance during an audit or monitoring visit. Strictly following both the inclusion and exclusion criteria is necessary to protect the safety of participants, the scientific integrity, and the reproducibility of the study.

*Note:* Eligibility Checklists can serve two purposes. 1.) To document in one place that source documentation exists elsewhere for each inclusion and exclusion criteria, e.g. in laboratory results. 2.) To serve as a source document for one or multiple inclusion or exclusion criteria which aren’t documented elsewhere; e.g. a study team member may inquire if a potential participant has the time and ability to come to appointments and carry out his or her tasks described in the protocol. When Checklists serve this additional function, columns for date, signature and initials should be added to the form next to each criteria for which the Checklist is serving as original proof so the person who obtains the information is contemporaneously attesting to having acquired that information. However, when no other source document exists for a given clinical inclusion or exclusion criteria, e.g. “Do you have pain now? How bad is the pain on a 0-10 scale?” best practice would normally be to create a separate case report form or source document for those criteria.

**Useful to:** Principal Investigators (PI), Co-investigators (Co-I), Study Coordinators,

**Instructions:**

* A sample template is provided below; customize the template by entering eligibility from your IRB approved protocol or research plan.
* Make sure to include the exact language of any inclusion or exclusion criteria as stated in the protocol or research plan as it was approved by the IRB.
* Each criterion should have a separate Checklist line.
* Create the Checklist prior to study start and update this Checklist when any eligibility criteria are amended and approved by the IRB.
* Have a second person review your Checklist for accuracy and completeness against the approved protocol.
* Remember, if the Checklist will serve as original proof for any eligibility criterion item listed, then columns for date and signature or initial should be added to the form next to each criteria for which the Checklist is serving as original proof. In this way the person who obtains the information is contemporaneously attesting to having acquired that information.
* To help facilitate audits and monitoring type visits it is helpful to note the location of source documentation in the comment section of the Checklist.
* If the inclusion or exclusion criteria are amended within the protocol, do not add any new inclusion or exclusion criteria until the amended protocol has been IRB approved.
* Once the Checklist is completed for a study participant, have an investigator or authorized designee sign the form and date it. This serves as confirmation that documentation exists that the participant meets the eligibility criteria that have been established in the IRB approved protocol.

**Best Practice Recommendations:**

* If your sponsor has provided you with an Eligibility Checklist, verify that it matches the protocol inclusion or exclusion criteria listed in the IRB approved protocol. If you find something that you believe is an error or discrepancy, contact the sponsor before using the Checklist.
* Use an Eligibility Checklist form for each patient screened for enrollment in your research study.
* All Eligibility Checklists should be signed and dated prior to randomization and/or treatment.
* For screen failures, file the Eligibility Checklist with study records to identify why the participant is not being enrolled to the study.
* Make certain that the person delegated to sign the Checklist is qualified to make clinical determinations of eligibility to enroll in the study and is designated on the delegation of authority log or other documentation.

**Template History:**

**Last Updated**:6/07/2022

**Version**: 2.3

**Reference(s):**

* **HRPP Operations Manual** <http://research-compliance.umich.edu/operations-manual-contents-page>
* **21CFR 312.60 General responsibilities of investigators**.

<http://www.ecfr.gov/cgi-bin/text-idx?SID=b324c0b1572feb38326b8926937f3479&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_160>

* **ICH –GCP 4.1.5** states the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

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| Study Name: | IRB HUM #: |
| Principal Investigator: |  |

**Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Consent Signed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**ELIGIBILITY CRITERIA**

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| **Inclusion Criteria** | **Comments (optional)** | **Yes** | **No** |
| **Example Only:**  Subject is at least 18 years of age | Date of Birth (DOB): |  |  |
| Newly diagnosed with diabetes (within the last 6 months) | Date of Diagnosis: |  |  |
| Prescribed oral medication for diabetes control | Name of Med/Dose: |  |  |
| BP < 140/90 (screening visit) | Blood Pressure (BP): |  |  |

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| **Exclusion Criteria** | **Comments (optional)** | **Yes** | **No** |
| Subject has a history of:   * myocardial infarction (MI) * coronary bypass graft (CABG) | Exclusion confirmed in: |  |  |
| * abnormal liver function tests (LFT)   (> 2 x upper limit of normal) | Date of LFT 1:  Date of LFT 2: |  |  |
| Pregnant or breastfeeding | Date of pregnancy test:  Result:  or LMP (last menstrual period) |  |  |
| History of substance abuse (within the last 6 mos.) | Exclusion confirmed in: |  |  |

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

**Subject is: Eligible Not Eligible**

**Confirmed by:**

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