

# Eligibility Criteria Errors

*What to do when a subject did not meet inclusion or exclusion criteria at enrollment*

## WHAT IS IT?

### Eligibility Criteria Error:

A subject is enrolled or continues in a study despite not meeting all inclusion criteria or meeting one or more exclusion criteria as defined in the protocol. This includes errors identified at screening, enrollment, or discovered later during the study.

## WHEN DOES THIS APPLY?

- A screening assessment reveals a subject does not meet inclusion criteria after enrollment
- A previously unidentified exclusionary condition or lab value is discovered post-enrollment
- A protocol amendment changes eligibility criteria affecting currently enrolled subjects
- A monitor or auditor identifies an eligibility discrepancy during a review

## PROCESS AT A GLANCE

### 1. Identify the Eligibility Issue

- Review the protocol inclusion and exclusion criteria carefully against the subject's screening and baseline data
- Confirm the eligibility deviation with supporting documentation (lab results, medical history, etc.)
- Do not take any action until the issue is confirmed

### 2. Notify the PI Immediately

- Inform the PI as soon as an eligibility issue is identified
- The PI must assess whether continued participation poses any risk to the subject
- Do not continue study procedures until the PI has evaluated the situation

### 3. Contact the Sponsor

- Notify the sponsor or medical monitor per the protocol reporting requirements
- The sponsor may issue a waiver, request protocol deviation documentation, or direct discontinuation
- Document all sponsor communications in the regulatory file

#### 4. Assess Subject Safety

- The PI must conduct a clinical assessment of the impact of the eligibility deviation on the subject
- If the subject is at increased risk, arrange appropriate medical evaluation and follow-up
- Document the safety assessment in the source record

#### 5. Complete a Protocol Deviation Report

- Initiate a Reportable New Information report (RNI) — eligibility errors are typically classified as major deviations [Reportable New Information](#)
- Include: subject ID, the specific criterion violated, when identified, how it occurred, and the safety impact
- Report to the IRB per institutional requirements

#### 6. Implement CAPA

- Identify the root cause: screening oversight, protocol misinterpretation, lab result delay, etc.
- Implement corrective actions: eligibility checklists, dual review of screening criteria, PI sign-off before enrollment
- Conduct a look-back review of other recently enrolled subjects

#### KEEP IN MIND

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**x Avoid:** Do not continue study procedures without PI and sponsor guidance. Do not alter screening records or eligibility checklists to conceal the deviation.

**✓ Best practice:** Notify the PI and sponsor immediately. Prioritize subject safety above all else. Document transparently and completely.

#### REFERENCES

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- ICH E6(R2) Good Clinical Practice Guidelines
- Applicable Study Protocol — Inclusion/Exclusion Criteria
- Reportable New Information <https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf>
- [Corrective and Preventative Action Plans v2025-06](#)