### Purpose
The purpose of this policy is to ensure that eligibility criteria for Lurie Cancer Center investigator-initiated trials (IITs) will be strictly adhered to and enforced.

### Scope
Applies to all studies that are monitored under the Robert H. Lurie Comprehensive Cancer Center Data and Safety Monitoring Plan.

### Applicable Regulations & Guidance
- ICH GCP; 4.5.2, 5.18.4i
- FDA 1572: Statement of the Investigator
- 21 CFR 312.66
- 21 CFR 312.50
- 21 CFR 312.30
- CTEP Policy on Protocol Waivers and Guidelines

### Detailed Policy
Eligibility waivers are not permitted under any circumstances. Subjects must meet all of the inclusion and exclusion criteria to be registered to the study. Study treatment may not begin until a subject is registered.

Screening deviations that do not affect safety or eligibility (e.g. out of window baseline procedures) are be considered by the voting members of the Data Monitoring Committee (DMC) on a case-by-case basis.