

## APPENDIX A: SITE QUALIFICATION REQUIREMENTS

A site must meet the following criteria to qualify for participation in the ISCHEMIA trial, as determined by site-reported data collected via the survey qualification process:

1. Access to a Stress Imaging Modality- Must be able to transmit images digitally
2. Access to a CT Scanner- Must be able to produce >64 slices and must perform 1 scan/week
3. PCI site and operator requirements are as follows:
  - a. PCI Site Criteria
    - i. Must be willing to establish an ISCHEMIA trial HEART TEAM of cardiovascular interventionalists and surgeons that can evaluate randomized patients on an ongoing basis in a collaborative, multidisciplinary fashion
    - ii. Average number of annual PCI cases over the last 3 years for the primary PCI location  $\geq 400$ /year
    - iii. EXCLUDING CASES WITH TOTAL OCCLUSION AND STEMI:
      1. Average procedural success rate over the last 3 years >95%):
      2. Average rate of emergency CABG over the last 3 years <0.6%):
      3. Average rate of in-hospital mortality over the last 3 years <1.5%)
  - b. PCI Operator Criteria
    - i. Average number of annual PCI cases for the operator over the last 3 years  $\geq 75$  cases/year). If the volume is <75 per year, total number of lifetime PCI cases must be >1500 cases):
4. CABG Site and Operator requirements are as follows:
  - a. CABG Site Criteria
    - i. Average annual total procedures with CABG over the last 3 years  $\geq 125$ /year
    - ii. Average annual cardiac surgical procedures (open heart) over the last 3 years  $\geq 300$ /year
    - iii. **AND** [either 1, 2 or 3]
      1. Non-risk adjusted in-hospital mortality for all isolated CABG procedures over the last 3 years  $\leq 3.0\%$ )
      2. Non-risk adjusted in-hospital mortality for isolated elective CABG procedures over the last 3 years  $\leq 2.0\%$ )
      3. **(For US Sites participating in STS Registry):** Risk adjusted operative mortality for isolated CABG procedures over the last 3 years  $\leq 2.7\%$
  - b. CABG Operator Criteria:
    - i. Average number of annual total procedures with CABG for the surgeon over the last 3 years  $\geq 75$  cases/year)
    - ii. Lifetime total procedures with CABG  $\geq 750$  cases)

Sites that do not meet these PCI and/or CABG criteria but are highly recommended by Country leaders may also be considered. The Country Leader recommendation is forwarded to the appropriate PCI/CABG committee for review and approval.