Massachusetts Department of Public Health
Division of Health Care Quality

**Guidelines for Development of an Agreement between a non-Surgery-on-Site (non-SOS) Hospital and a Surgery-on-Site (SOS) Hospital for Participation in the**

# MASS COMM Trial:

A Randomized Trial to Compare Percutaneous Coronary Intervention between Massachusetts Hospitals with Cardiac Surgery-On-Site and Community Hospitals without Cardiac Surgery-On-Site

A hospital without on-site cardiac surgery services (non-SOS Hospital) that proposes to participate in the MASS COMM Trial to provide elective angioplasty services must establish a written agreement with at least one hospital that provides cardiac surgery services on-site (SOS Hospital).

The agreement will establish the terms, for the purposes of the MASS COMM Trial participation, of the relationship between a non-SOS hospital and its partnering or corresponding SOS hospital.

The agreement at a minimum must:

- be *current* and *specific* to the community hospital's participation in the MASS COMM Trial and the services/support that the SOS hospital agrees to provide.

- be signed for each hospital by the Chief Executive Officer, the Chief of the Cardiology or Cardiovascular Services, as well as the Principal Investigator for the MASS COMM Trial at both the non-SOS hospital and the SOS hospital.

- for those non-SOS hospitals that do not provide primary angioplasty 24 hours per day, seven days a week, include terms specifying the plans for management of any elective angioplasty patient's complication(s) during the patient's non-SOS hospital stay.

- include specific provisions for the transport and/or efficient scheduling (in most cases on the same day as randomization, but no later than three days from randomization) of patients randomized to the SOS hospital for an elective angioplasty procedure.

- include provisions for the efficient and rapid transport for all elective angioplasty patients for whom a procedural complication warrants surgical intervention. This includes availability of ambulance transport at the non-SOS hospital within 30 minutes of a request by the cardiac catheterization service staff. Every effort must be made to ensure arrival of the patient at the partnering SOS hospital within 60 minutes of the decision to transport the patient.

- include provisions for the emergent and routine transfer of patients that delineate, at a minimum:

- Protocol specifying the responsibilities of each hospital's physician and nursing staffs in addressing any emergent situations.
- The SOS hospital's agreement to accept, without delay, any patient referred emergently. The SOS hospital's cardiac surgery staff and facilities shall be immediately available if needed.
- The pertinent patient information required and the method of transmission of this information to the SOS hospital in a timely manner. Information to accompany the patient during transfer should be identified.
- Which facility is responsible for arranging the safe and expeditious physical transfer of the patient and his/her personal belongings.
- Who shall accompany the patient during the transfer.

- include provisions to affirm that both hospitals will maintain a contract with Harvard Clinical Research Institute (HCRI) for the purposes of participation on the MASS COMM Trial and provide all patient information required by the MASS COMM Trial protocol and the Department in a timely manner.