**Device Significant Risk or Without 510k Approval**

**Monitoring and Oversight**

The sponsor investigator will be responsible for monitoring the trial per the trial monitoring plan, in addition to overseeing the safety and efficacy of the trial including any specimens collected, executing the data and safety monitoring (DSM) plan, and complying with all reporting requirements to local and federal authorities. This oversight will be accomplished through additional oversight from the Data and Safety Monitoring Committee (DSMC) at the University of Colorado Cancer Center (CU Cancer Center). The DSMC is responsible for ensuring data quality and study participant safety for all clinical studies at the CU Cancer Center, which is the coordinating institution of this trial. A summary of the DSMC’s activities is as follows:

• Conduct of internal audits

• Ongoing review of all unanticipated adverse device effects, serious adverse events (SAEs) and unanticipated problems (UAPs)

• May submit recommendations for corrective actions to the CU Cancer Center’s Executive Committee

Per the CU Cancer Center Institutional DSM Plan, SAEs and UAPs are reported to the DSMC, IRB and the sponsor investigator per protocol. All SAEs and UAPs including unanticipated adverse device effects are to be reported to the DSMC within 7 (for fatal or life-threatening events) or 15 (non-life-threatening events) calendar days of the sponsor investigator receiving notification of the occurrence.

Each subject’s treatment outcomes will be discussed by the site PI and appropriate staff at weekly meetings. Data regarding number of subjects, adverse device effects, treatment modifications and treatment responses will be discussed and documented in the meeting’s minutes.

The sponsor investigator will provide a DSM progress report to the CU Cancer Center DSMC on a recurring basis (either every six or twelve months based on DSMC vote). The DSM report will include a protocol summary, current enrollment numbers, summary of adverse device effects to include specific unanticipated adverse device effects, SAEs, UAPs and AEs, any treatment modifications, all protocol deviations, and protocol amendments. The DSM report submitted to the DSMC will also include, if applicable, the results of any efficacy data analysis conducted. Results and recommendations from the review of this progress report by the DSMC will then be provided to the sponsor investigator in a DSMC review letter. The sponsor investigator is then responsible for ensuring this letter is submitted to the site’s IRB of record at the time of IRB continuing review.

**\*\*Below section required if OCRST template monitoring language is not present elsewhere in the protocol\*\***

**Quality Control and Quality Assurance**

Site monitoring visits will be performed by the sponsor investigator’s authorized representative on a regular basis, pursuant to the Monitoring Plan. During these visits, information recorded on the CRFs will be verified against source documents. Additional computer programs that identify selected protocol deviations, out-of-range data, and other data errors within the electronic data entry may also be used to help monitor the study. As necessary, requests for data clarification or correction will be sent to the appropriate site PI. Independent auditors from the sponsor investigator’s authorized representative will be allowed by the site’s PI to audit. In addition, audits may be conducted at any time by appropriate regulatory authorities and/or the IRB.