The Radiosurgery Society® (RSS) Public Comment Invitation: Consensus Guidelines for the Design of Clinical Trials in Spatially Fractionated Radiation Therapy (SFRT) for Gynecologic Cancer

Consensus Guideline Development Process

This description provides a general overview of the process to develop consensus guidelines for the design of clinical trials in SFRT. The guidelines are developed according to the following structured process:

1. Literature review and development of initial criteria for clinical trial design through an expert group:
   A complete review of the literature is carried out, and an initial group of nationally/internationally recognized experts is convened to develop preliminary criteria for clinical trial design that address the general elements of clinical trials (e.g. eligibility, treatment, assessments).

2. First voting round: Rating of the appropriateness of clinical trial criteria:
   Based on the preliminary trial design criteria determined by the initial expert group, a voting survey is conducted among SFRT experts within the respective primary tumor disease site (e.g. gynecologic cancer).

3. Review and discussion by disease-specific SFRT Expert Panel:
   A disease-specific Expert Panel (e.g. for gynecologic cancer) of clinicians, a physicist and a basic scientist (biologist) with expertise in SFRT is convened. The aggregated anonymized results of the initial vote are reviewed and discussed by the disease-specific Expert Panel in iterative consensus calls/communications.

4. Iterative voting:
   Additional voting round(s), focused on areas where consensus is not achieved or for additional clinical trial design considerations, are held as decided upon by the disease-

specific Expert Panel. Voting results are reviewed and discussed by the Expert Panel as described in section 3.

5. Repeat literature review:
   The complete review described in section 1 is repeated to assess for interval publications. These are reviewed by the disease-specific Expert Panel.

6. Development of daft recommendations and review:
   Consensus recommendations are drafted and reviewed by disease-specific Expert Panel.

7. Posting for comment:
   Consensus recommendations for clinical trial design are posted for public comment. All comments are reviewed by the Expert Panel to inform the final guideline, and decisions on the specific content of the final consensus guidelines resides with the SFRT experts' review.