

VSSO Research Proposal Submission Format

- I. Title**
- II. VSSO member submitting the proposal, stating institutional affiliation.**
- III. Aims and objectives of the study**
- IV. Background and significance**
- V. Detail of pilot work or preliminary results**
- VI. Experimental Design**
 - a. Brief description
 - b. Patient eligibility
 - i. Disease criteria
 - 1. species
 - 2. histologic type
 - 3. grade
 - 4. stage
 - 5. other
 - ii. Health criteria
 - 1. cardiac function
 - 2. renal function
 - 3. blood counts
 - 4. other
 - c. Patient ineligibility criteria
 - i. intercurrent diseases
 - ii. pregnancy
 - iii. recurrent tumor
 - iv. previous treatments
 - 1. radiation therapy
 - 2. chemotherapy and/or immunotherapy
 - 3. other
 - d. Patient resources
 - i. Case accrual rate estimate
 - ii. Incentives/funding
 - e. Treatment schedule for any medications/chemotherapy or other.
 - f. Treatment endpoints
 - i. Local recurrence (histologically confirmed or imaging end point)
 - ii. Survival from date of excision to death
 - iii. Censoring indicators (lost to follow-up, death for other reasons that disease or treatment, onset of ineligibility criterion)
 - g. Anticipated toxicities
 - h. Criteria for stopping treatment

- i. Patient follow-up schedule and parameters to be measured at follow-up
- j. Duration of study
- k. Statistical design and power of the study