

Request For Use of Aggregate Data Form

Date of Submission (mm/dd/yy):	09/09/2019
Name of Organization:	St. Mary's Medical Center
Project Title:	1. An Examination of Clinical Outcomes Following SBRT for Metastases from Primary Head and Neck Cancers
Principal Investigator:	Sanjeev Sharma, M.D.
Co-Investigators:	Raj Singh, M.D. Hayden Ansinelli, M.D. Dana Sharma, B.S.
Corresponding Contact Name:	Sanjeev Sharma, M.D.
Contact Title:	Attending Radiation Oncologist, St. Mary's Medical Center Administrative Chair, Marshall University Joan C. Edwards School of Medicine
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Contact Address: City, State, Zip:	4 Windsor Drive Huntington, WV 25705

Project Description

Project Start Date (mm/dd/yy):	11/01/2019
Project End Date (mm/dd/yy):	05/01/2020
Type of Research Project:	<input type="checkbox"/> Prospective Study <input checked="" type="checkbox"/> Retrospective Analysis <input type="checkbox"/> Technical Study <input type="checkbox"/> Other
If "Other," please explain nature of project:	
What is the research question being asked?	How effective is SBRT at providing local control of metastases from primary head and neck cancer? What are the toxicities associated with treatment? Does dose escalation lead to improved local control or overall survival?
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	The role of SBRT in oligo-metastatic cancers is growing. However, seminal prospective studies have focused on carcinomas (i.e. lung, prostate, breast, colon) primaries with little data on the use of SBRT for metastatic head and neck cancers. We aim to address this gap through use of the RSS Registry
Patient Inclusion/Exclusion Criteria:	Inclusion: patients with initial primary head and neck cancers treated with SBRT with minimal survival data, treatment data, and follow-up data; all extra-cranial cases (including spine) Exclusion: exclude SRS/brain metastases cases;

Data Requested

Description of patient population to be analyzed:	All patients with primary head and neck cancers treated with SBRT to metastatic sites
Time frame to be studied:	From registry inception to present
List exact data variables requested (i.e. pathology, treatment planning information, outcome, reimbursement, etc.): If the request is not self-evident,	1. Treatment Planning (doses, fractions, number lesions, isodose lines, etc.) 2. Outcomes (survival, response, local control, KPS) 3. Side-effects/related toxicities 4. Patient Demographics

write a summary of the request and/or instructions on data output (e.g., table specifications, sample tables).	5. Pathology 6. Initial/primary site of origin 7. Prior and adjuvant treatments (particularly immunotherapy)
Deadline for receipt of data (mm/dd/yy):	10/01/2019

Data Use

Are these data for internal research purposes only? (yes/no)	no
If requesting party will seek to share data with persons not already listed on this request, list the organizations with which data would be shared and in what capacity? (e.g., FDA for a clinical trial, NIH for a grant proposal, consultant for project development)	
Peer-reviewed publications to which submission is anticipated (if any)	Am J Clin Oncol
National meetings at which abstract presentation is anticipated (if any)	Potentially ASTRO 2020

Additional Submission Requirements


Please attach each of the following:

- Copy of IRB approval letter for use of RSSearch® at your institution
- Curriculum vitae of the principal investigator

Requestor Certification

In making this request, I certify that:

- All information provided on this form and attachments is accurate and complete;
- I have all requisite institutional authority to submit this Request for Use of Collaborative Data

Signature	
Print Name	Sanjeev Sharma, M.D.
Title	Attending Radiation Oncologist, St. Mary's Medical Center Administrative Chair, Marshall University Joan C. Edwards School of Medicine
Date	09/09/2019

Please submit Request for Use of Collaborative Data to jjenkins@therss.org

For Internal Use Only:

Date application received:	
<i>RSSearch Registry Request #</i>	2019-0910