# RSSearch® Registry Protocol

# RSSearch Request Form for Use of Aggregate Data:

#### **Eligibility Criteria for Participating Centers**

 Enter > 50 patients into RSSearch annually (The RSS will not be held to this criterion)

#### **Submission Requirements**

Please attach each of the following with your Data Request Form:

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

### **General Information**

Submit the request for aggregate data to <a href="mailto:nbrown@therss.org">nbrown@therss.org</a>. You will receive confirmation and a response regarding the status of your request within 30 business days. Requested custom aggregate data report will require a minimum of 2 weeks to generate. Accepted applications are posted on the RSS website at <a href="https://www.therss.org">www.therss.org</a>.

Administrative Information

Date of Submission (mm/dd/yy):	11/30/2016	
Name of Organization:	Montefiore Medical Center/Albert Einstein College of Medicine	
Project Title:	Stereotactic Body Radiotherapy (SBRT) for Spine Metastases	
Principal Investigator:	Rafi Kabarriti, MD; Madhur Garg, MD	
Co-Investigators:	Shiv Desai, MD	
Corresponding Contact Name:	Rafi Kabarriti	
Contact Title:	MD	
Contact Telephone Number:	718-405-8550	
Contact E-mail Address:	rkabarri@montefiore.org	
Contact Address: City, State, Zip:	1625 Poplar St Suite 101 Bronx, NY 10461	

**Project Description** 

Project Start Date (mm/dd/yy):	11-30-2016
Project End Date (mm/dd/yy):	1-30-2016
Type of Research Project:	<ul> <li>□ Prospective Study</li> <li>☑ Retrospective Analysis</li> <li>□ Technical Study</li> <li>□ Other</li> </ul>

Version Date: 01/11/13 Version 1.1

If "Other," please explain nature of project:	
What is the research question being asked?	What are the outcomes and toxicities of SBRT or radiosurgery treatment for patients with vertebral metastases, in particular stratified by dose and spinal level and how does this compare to conventional radiotherapy?
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	SBRT has become an attractive treatment option for patients with vertebral metastases to achieve durable local control and symptom palliation. Severa institutional experiences have been reported and RTOG trials are ongoing. We seek to add to this body of knowledge by evaluating the RSSearch database
Patient Inclusion/Exclusion Criteria:	Patients with hepatocellular carcinoma treated with SBRT

**Data Requested** 

Data Nequested	
Description of patient population to be analyzed:	All patients with vertebral metastases in RSSearch database
Time frame to be studied:	From database inception until present
List exact data variables requested (i.e. pathology, treatment planning information, outcome, reimbursement, etc.): If the request is not self-evident, write a summary of the request and/or instructions on data output (e.g., table specifications, sample tables).	Patient characteristics including age, primary histology, co-morbidties, Tumor characteristics (if available) such as # of lesions, size, extent Imaging characteristics of tumors on MRI Treatment planning information (dose, fractionation, PTV size, technique Additional treatment (pre or post-SBRT surgery or vertebroplasty) Acute and chronic toxicities Outcome information (local control, pain palliation, and survival) Geographic location of treatment centers (state, urban/rural) Classification of treatment centers (academic/community)
Deadline for receipt of data (mm/dd/yy):	12/31/2016 if possible

#### Data Use

Data USC	
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)	Publication will be submitted to IJORBP or Radiotherapy & Oncology
National meetings at which abstract presentation is anticipated (if any)	Radiosurgery Society SRS/SBRT Annual Meeting or ASTRO Annual Meeting

## **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	Pafi KabanA
Print Name	Pali Kabarriti
Title	MP
Date	12/6//6

Please submit Request for Use of aggregate data to <a href="mailto:nbrown@therss.org">nbrown@therss.org</a>

For Internal Use Only:

Date application received:		
	2016-1130-08	
RSSearch Registry Request #		