

# RSSearch<sup>®</sup> 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 [nbrown@therss.org](mailto:nbrown@therss.org). 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 [www.therss.org](http://www.therss.org).

### Administrative Information

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

### Project Description

<b>Project Start Date (mm/dd/yy):</b>	11-30-2016
<b>Project End Date (mm/dd/yy):</b>	1-30-2016
<b>Type of Research Project:</b>	<input type="checkbox"/> Prospective Study <input checked="" type="checkbox"/> Retrospective Analysis <input type="checkbox"/> Technical Study <input type="checkbox"/> Other

<b>If "Other," please explain nature of project:</b>	
<b>What is the research question being asked?</b>	What are the outcomes and toxicities of SBRT or radiosurgery treatment for hepatocellular carcinoma (HCC) and how do these compare to other treatment modalities such as radiofrequency ablation (RFA), trans-arterial chemoembolization (TACE), and selective internal radiotherapy (SIRT)
<b>What is the background or rationale for the research question? (if needed, please attach as a separate page to application)</b>	SBRT as an adjunctive or initial treatment for patients with HCC is emerging as an attractive non-invasive treatment option for patients with solitary or multiple tumors of size amenable to SBRT treatment planning. There is limited published multi-institution experience with this treatment approach, we aim to add to this body of knowledge by evaluating the RSSearch database
<b>Patient Inclusion/Exclusion Criteria:</b>	Patients with hepatocellular carcinoma treated with SBRT

#### Data Requested

<b>Description of patient population to be analyzed:</b>	All patients with hepatocellular carcinoma in RSSearch database
<b>Time frame to be studied:</b>	From database inception until present
<b>List exact data variables requested (i.e. pathology, treatment planning information, outcome, reimbursement, etc.):</b> <i>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).</i>	Patient characteristics including age, stage (TNM and group), co-morbidities, Tumor characteristics (if available) such as # of lesions, size, pathology Imaging characteristics of tumors on MRI Treatment planning information (dose, fractionation, PTV size, gating) Additional treatment information (pre or post-SBRT TACE, RFA, or surgery) Acute and chronic toxicities Outcome information (local control and survival) Geographic location of treatment centers (state, urban/rural) Classification of treatment centers (academic/community)
<b>Deadline for receipt of data (mm/dd/yy):</b>	12/31/2016 if possible

#### Data Use

<b>Are these data for internal research purposes only? (yes/no)</b>	No
<b>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)</b>	
<b>Peer-reviewed publications to which submission is anticipated (if any)</b>	Radiosurgery Society SRS/SBRT Annual Meeting, ASTRO Annual Meeting Publication will be submitted to IJORBP or Radiotherapy & Oncology
<b>National meetings at which abstract presentation is anticipated (if any)</b>	As above, RSS SRS/SBRT Annual Meeting and ASTRO Annual Meeting

#### Additional Submission Requirements

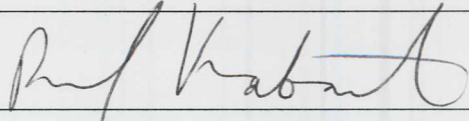
Please attach each of the following:

- 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	
Print Name	Rafi Kabarriti
Title	MD
Date	12/6/16

Please submit Request for Use of aggregate data to [nbrown@therss.org](mailto:nbrown@therss.org)

**For Internal Use Only:**

Date application received:	
<i>RSSearch Registry Request #</i>	2016-1130-03