

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 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.

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) Outcomes and Toxicity in Patients Treated with Immunomodulating Systemic Therapy
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:	<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?	What are the outcomes and toxicities for patients with metastatic cancer on treatment with immunomodulating systemic therapy who receive SBRT?
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	Immune-modulating drugs are now FDA approved for several cancer types. Durable disease control for patients responsive to therapy has encouraged widespread use of these agents. SBRT as an immune priming agent leading to potentially increased response or toxicity has been hypothesized but is underexplored to date. We seek to evaluate this question with RSSearch
Patient Inclusion/Exclusion Criteria:	Patients treated with SBRT and immune-modulating systemic therapy

Data Requested

Description of patient population to be analyzed:	All patients in treated with SBRT and immune-modulating systemic therapy (see attached list of drugs) in the 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.): <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, sex, co-morbidities Tumor characteristics # of lesions, grade, mutational status, PD-L1 status Imaging characteristics of tumors on CT, PET, or MRI Treatment planning information (dose, fractionation, PTV size, technique) Additional treatment (pre or post-SBRT systemic therapy) 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

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

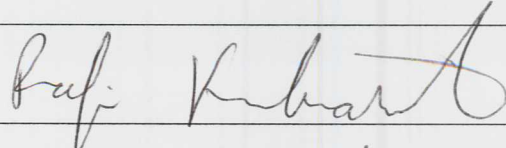
Please attach each of the following:

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

Please submit Request for Use of aggregate data to nbrown@therss.org

For Internal Use Only:

Date application received:	
<i>RSSearch Registry Request #</i>	2016-1130-09