

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 jjenkins@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):	4.16.18
Name of Organization:	Memorial Cancer Institute. Radiation oncology Department.
Project Title:	Clinical and radiographic control for patients with pituitary adenomas treated with hypo-fractionated CyberKnife radiosurgery
Principal Investigator:	Srinath Sundararaman
Co-Investigators:	Ana Botero, Michael Burdick, Ignacio Castellon, Maria Ciccica, Aaron Falchook, Yunkai Zhang
Corresponding Contact Name:	Nithay Sundararaman
Contact Title:	Director, Research Operations
Contact Telephone Number:	954.265.1846
Contact E-mail Address:	nsundararaman@mhs.net
Contact Address: City, State, Zip:	Office of Human Research 4411 Sheridan St. Hollywood, FL 33021

Project Description

Project Start Date (mm/dd/yy):	1/1/2000
Project End Date (mm/dd/yy):	12/31/2017
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?	We seek to assess and report clinical and radiographic control for patients with pituitary adenomas treated with hypo-fractionated CyberKnife Radiosurgery
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	We want to confirm more modify existing treatment algorithm based upon outcome data. Present fractionation scheme is 500 cGy x 5.
Patient Inclusion/Exclusion Criteria:	

Data Requested

Description of patient population to be analyzed:	review all patients diagnosed with pituitary adenomas treated with CyberKnife radiosurgery
Time frame to be studied:	1/1/2000 thru 12/31/2017
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—diagnoses with benign pituitary adenoma Tumor characteristics—secretory vs. not. (MHS path reviewed) Local control as defined by MRI, maybe CT. Biochemical control—need endocrinology data. May not be available. Toxicity—grossly evaluate vision stability versus symptomatology. Reimbursement—obtain average cost for total treatment. May provide for future cost-benefit analyses.
Deadline for receipt of data (mm/dd/yy):	

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)	N/A
Peer-reviewed publications to which submission is anticipated (if any)	PRO
National meetings at which abstract presentation is anticipated (if any)	ACRO

Additional Submission Requirements

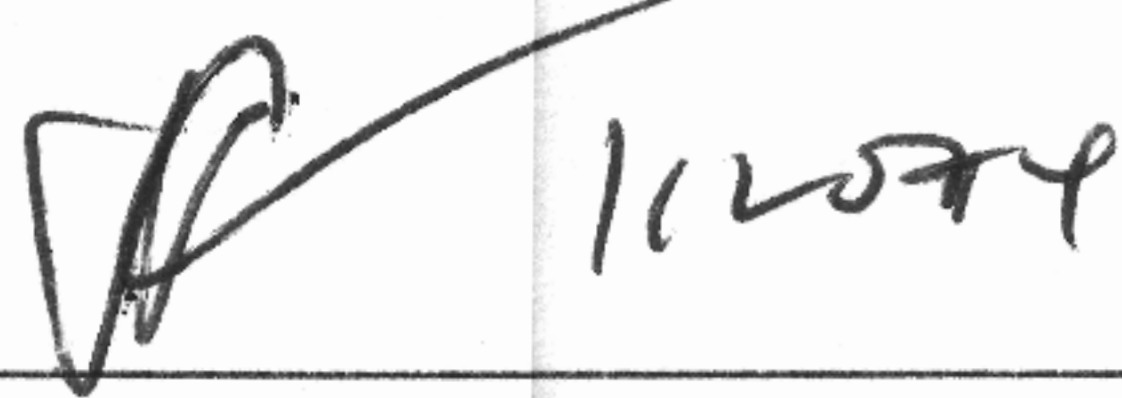
Please attach each of the following:

- 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	Srinath Sundararaman, MD, MS, FACRO
Title	Chief of Radiation Oncology Operations
Date	4/16/2018

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

For Internal Use Only:

Date application received:	04/16/18
<i>RS</i> Search Registry Request #	2018-0416