

Appendix D: Access to Data and Aggregate Reporting

RSSearch Request Form for Use of Aggregate Data:

Eligibility Criteria for Participating Centers

- Enter > 50 patients into RSSearch® annually
(The Radiosurgery Society 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

Submitted Data Request Forms (DRF) are posted on the RSS homepage under the Clinician Resource dropdown. Applications are reviewed twice/year (April & September). You will receive a letter from the RSSearch Registry Review Committee regarding the status of your request within 30 days. Accepted DRFs will be forwarded to Adverttek® by the RSS to generate the requested custom data report. Custom reports will require a minimum of 2 weeks to generate. Submit DRF to Nalani Brown at nbrown@therss.org. Applications are posted on the RSS website at www.therss.org.

Administrative Information

Date of Submission (mm/dd/yy):	Amendment submitted 7-9-2015
Name of Organization:	
Project Title:	Radiosurgery for Prostate Cancer
Principal Investigator:	David D'Ambrosio MD
Co-Investigators:	Joanne Davis PhD
Corresponding Contact Name:	David D'Ambrosio
Contact Title:	MD
Contact Telephone Number:	732-557-8148
Contact E-mail Address:	ddambrosio@barnabashealth.org
Contact Address:	99 highway 37 west
City, State, Zip:	Toms River NJ 08755

Project Description

Project Start Date (mm/dd/yy):	09/01/13; updated analysis 7-1-15
Project End Date (mm/dd/yy):	12/01/13; updated analysis 9-1-15
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 toxicities and outcomes of CK treatment for prostate cancer and how do they compare to standard external beam RT.
What is the background or rationale	There are limited published data on this and the

for the research question? (if needed, please attach as a separate page to application)	ReKord database will have the largest collection of patients regarding this.
Patient Inclusion/Exclusion Criteria:	Treated with SBRT with at least 6 months of follow up. Only include patients with date of consult before 1-1-15. Include early stage patients with low, intermediate and high risk disease. Exclude patients with (+) LN and/or metastatic disease.

Data Requested

Description of patient population to be analyzed:	All prostate patients
Time frame to be studied:	From inception to 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, acute and chronic toxicities, PSA levels, clinical outcome measures
Deadline for receipt of data (mm/dd/yy):	10/1/13; updated data 7-1-15

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)	First analysis was presented at the 2014 Radiosurgery Society SRS/SBRT meeting. An updated analysis will be submitted to Cureus for publication.
National meetings at which abstract presentation is anticipated (if any)	

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	Joanne Davis
Title	Executive Director
Date	7-9-15

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

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For Internal Use Only:

Date application received:	
<i>RSSearch Registry Request #</i>	2015-0719