Appendix D: Access to Data and Aggregate Reporting

ReCKord Request Form for Use of Aggregate Data:

Eligibility Criteria for Participating Centers

- Enter > 50 patients into ReCKord 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 ReCKord at your institution
- Curriculum vitae of the principal investigator.

General Information

Submitted Data Request Forms (DRF) are posted on the Radiosurgery Society homepage under the Clinician Resource dropdown. Applications are reviewed twice/year (April & September). You will receive a letter from the ReCKord Registry Review Committee regarding the status of your request within 30 days. Accepted DRFs will be forwarded to Advertek[sm] 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 Radiosurgery Society website at www.theradiosurgerysociety.org.

Administrative Information

Date of Submission (mm/dd/yy):	May 15, 2013
Name of Organization:	The Radiosurgery Society
Project Title:	The ReCKord Registry: Patterns of Care and Outcomes Research Through Multi-institutional User Database
Principal Investigator:	Anand Mahadevan MD
Co-Investigators:	Buddy Medbery MD, Joanne Davis PhD
Corresponding Contact Name:	Joanne Davis
Contact Title:	Consultant
Contact Telephone Number:	248-719-2998
Contact E-mail Address:	Davis.joanne@hotmail.com
Contact Address: **City, State, Zip:**	40791 Kingsley Lane Novi, MI 48377

Project Description

Project Start Date (mm/dd/yy):	February, 1 2013
Project End Date (mm/dd/yy):	June 1, 2013

Type of Research Project:	Prospective Study □ Retrospective Analysis □ Technical Study x Other
If "Other," please explain nature of project:	The purpose of this project is to describe the role and use of Multi-institutional prospective user databases to perform outcomes research. We describe the design, rationale, procedures for data collection, the clinical, treatment and outcome data variables that are tracked in The ReCKord Registry and present the patient demographics, tumor/lesion characteristics, SRS/SBRT treatment plan and delivery information of the first 11,457 patients enrolled in ReCKord database.
What is the research question being asked?	The objectives of the analysis are to describe the patient characteristics/demographics and lesion characteristics, and to determine the treatment patterns of SRS/SBRT in a clinical setting. The purpose of this project is to demonstrate that collective patterns of care and outcomes research can be performed from data entered prospectively by users in a common database.
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	Despite increased knowledge of stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) technology and clinical outcomes from single institutions, information on physician practice patterns of SRS and SBRT in the daily clinical practice is limited. A registry provides a systematic and inclusive database of information which can reveal and evaluate the effectiveness of management practices. In contrast to a clinical trial, where patient enrollment is defined by specific inclusion and exclusion criteria, treatment is dictated by protocol guidelines, and treatment evaluation is measured at specific follow-up time intervals, a registry documents actual care, representing a broad spectrum of patients where treatments are not specified by protocol guidelines and patient follow-up schedules are conducted in a real-life setting. A registry can provide information as to whether clinicians are adhering to practice guidelines, may complement randomized clinical trials and/or identify new clinical applications and treatment benefits. They would also generate powerful hypothesis to test in future clinical trials to advance the science of SRS/SBRT The ReCKord Registry was conceptualized and designed by a board of ReCKord Clinical Advisors in 2005. The ReCKord Clinical Advisory Committee is comprised of radiation oncologists, neurosurgeons, surgeons, medical oncologists, and medical physicists to create and oversee the scientific conduct of the registry. The goals and objectives of the registry are to provide a method to collect standardized data on the use of SRS/SBRT treatment practices and outcomes to help determine the most effective clinical use of SRS/SBRT in

	management of patients with life threatening tumors and other diseases. The purpose of this request is to analyze the aggregate screening and treatment data of the first 11,457 patients enrolled in ReCKord. By analyzing the aggregate data we intend to publish the value of such registries and also explore specific areas (e.g lung cancer, prostate cancer) of outcomes research.
Patient Inclusion/Exclusion Criteria:	All patients entered into ReCKord between January 2005 and February, 2013 will be included in the analysis.

Data Requested

Description of patient population to be analyzed:	All patients entered into ReCKord between January 2005 and February, 2013 will be included in the analysis.
Time frame to be studied:	January 2005 – February 2013
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).	All screening variables and treatment variables for all patients. Outcome and follow up data may also be explored for future projects.
Deadline for receipt of data (mm/dd/yy):	May, 2013

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)	All data to be included and reviewed for this study is anonymsed and HIPAA compliant. Other than the investigators listed, aggregate data may be shared with the scientific review committee of the Radiosurgery Society for scrutiny, monitoring and approval. The data may be made available for the IRB's of applicable investigators.
Peer-reviewed publications to which submission is anticipated (if any)	To be determined once analysis is complete.
National meetings at which abstract presentation is anticipated (if any)	RSS Meeting 2014, ASTRO 2014

Additional Submission Requirements

Please attach each of the following:

- Copy of IRB approval letter for use of ReCKord 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;

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)	All data to be included and reviewed for this study is anonymsed and HIPAA compliant. Other than the investigators listed, aggregate data may be shared with the scientific review committee of the Radiosurgery Society for scrutiny, monitoring and approval. The data may be made available for the IRB's of applicable investigators.
Peer-reviewed publications to which submission is anticipated (if any)	To be determined once analysis is complete.
National meetings at which abstract presentation is anticipated (if any)	RSS Meeting 2014, ASTRO 2014

Additional Submission Requirements
Please attach each of the following:

- Copy of IRB approval letter for use of ReCKord 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	Joanne Davis
Print Name	Joanne Davis, PhD
Title	Consultant
Date	5/25/13

Please submit Request for Use of Collaborative Data to nalani@theradiosurgerysociety.org

For Internal Use Only:

Date application received:	May 28, 2013
ReCKord Registry Request #	2013-0528