

## 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 Adverttek<sup>sm</sup> 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

<b>Date of Submission (mm/dd/yy):</b>	August 1, 2013
<b>Name of Organization:</b>	The Radiosurgery Society
<b>Project Title:</b>	
<b>Principal Investigator:</b>	Anand Mahadevan M.D.
<b>Co-Investigators:</b>	Clinton Medbery, M.D.
<b>Corresponding Contact Name:</b>	Joanne Davis
<b>Contact Title:</b>	Consultant
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<b>Contact Address: City, State, Zip:</b>	40791 Kingsley Lane Novi, MI 48377

#### Project Description

<b>Project Start Date (mm/dd/yy):</b>	August 1, 2013
<b>Project End Date (mm/dd/yy):</b>	November 1, 2013
<b>Type of Research Project:</b>	Prospective Study

	<input checked="" type="checkbox"/> Retrospective Analysis <input type="checkbox"/> Technical Study Other
<b>If "Other," please explain nature of project:</b>	
<b>What is the research question being asked?</b>	The purpose of this proposal is to investigate the treatment patterns, toxicity, and clinical outcomes of SBRT-treated liver lesions. We will also investigate associations between tumor characteristics, dose/fractionation and clinical outcomes.
<b>What is the background or rationale for the research question? (if needed, please attach as a separate page to application)</b>	<p>Currently, there is no consensus for the treatment of primary liver tumors and liver metastases with radiation. In 2012, the Liver Cancer Workgroup of the Third International Consensus on Metastases Workshop at the 2010 American Society for Radiation Oncology meeting published an international survey on the status of radiation therapy of liver metastases. The survey indicated there was a 54% increase in the average number of liver referrals over the past 5 years and the majority of referrals were for SBRT. No uniform SBRT treatment dose was identified and there was a wide variation of treatment regimens which were dependent on whether the treatment objective was curative or palliation. The group concluded there is a need for prospective studies and registries for comparison of treatment regimens and identification of parameters to optimize patient selection.</p> <p>The ReCKord Registry currently includes over 12,000 patients treated with SRS and/or SBRT. Preliminary analysis identified 174 patients with 204 liver metastases entered in ReCKord. The purpose of this proposal is to investigate the treatment patterns and clinical outcomes of liver lesions, including both primary and metastatic lesions, and conduct statistical analysis to identify any associating factors including lesion characteristics, dose/fraction scheme, BED, that correlate with clinical outcomes. Our goal is to compare SBRT treatment regimens for liver tumors and identify best treatment practices and patient characteristics that would best benefit from SBRT.</p>
<b>Patient Inclusion/Exclusion Criteria:</b>	All patients with primary liver lesions and liver metastases entered into ReCKord.

**Data Requested**

<b>Description of patient population to be analyzed:</b>	
<b>Time frame to be studied:</b>	All patients enrolled up to August 1, 2013.
<b>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).</b>	All screening, treatment and follow up variables for primary liver lesions and liver metastases.
<b>Deadline for receipt of data (mm/dd/yy):</b>	August 15, 2013

**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>	All data to be included and reviewed for this study is anonymized and HIPPA 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.
<b>Peer-reviewed publications to which submission is anticipated (if any)</b>	To be determined once analysis is complete.
<b>National meetings at which abstract presentation is anticipated (if any)</b>	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	<i>Joanne N. Davis</i>
Print Name	<i>Joanne N. Davis, Ph.D.</i>
Title	<i>Consultant</i>

Date	<i>August 14, 2013</i>
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Please submit Request for Use of Collaborative Data to [nalani@theradiosurgerysociety.org](mailto:nalani@theradiosurgerysociety.org)

**For Internal Use Only:**

Date application received:	August 14, 2013
<i>ReCKord Registry Request #</i>	2013-0814