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):	9-5-13
Name of Organization:	**Barnabas Health**
Project Title:	CyberKnife Stereotactic Body Radiotherapy for Early-Stage 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: **City, State, Zip:**	99 highway 37 west Toms River NJ 08755

Project Description

Project Start Date (mm/dd/yy):	09/01/13
Project End Date (mm/dd/yy):	12/01/13
Type of Research Project:	□ Prospective Study x Retrospective Analysis □ Technical Study □ Other
If "Other," please explain nature of project:	
What is the research question being asked?	The purpose of this proposal is to investigate the patient characteristics, treatment management practices, toxicities and biochemical disease free survival (bDFS) in patients with early-stage prostate

	cancer treated with CyberKnife SBRT in a clinical practice setting.
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	Prostate cancer is the most commonly diagnosed cancer (excluding skin cancer) in men in the US with an estimated 260,000 newly diagnosed cases in 2013. Localized prostate cancer represents 80% of newly diagnosed cases. There are several treatment options available for early-stage prostate cancer including surgery, radiation therapy, hormone therapy, and active surveillance. Studies have shown excellent clinical outcomes for each of these treatment options, none of which have proven to be superior to the other. There have been a few studies from a select group of institutions that have shown CyberKnife SBRT to also be a viable treatment option for early-stage prostate cancer. Initial five-year results have shown CyberKnife SBRT to achieve acceptable toxicity rates and excellent biochemical disease-free survival rates for early-stage prostate cancer (97% bDFS for low-risk and 91% bDFS for intermediate-risk), which are comparable to outcomes for surgery and radiation therapy. CyberKnife SBRT for the treatment of early-stage prostate cancer is a non-invasive, outpatient procedure typically completed in 4-5 treatment sessions, making it an attractive treatment option for patients who do not want to undergo surgery or complete 40 weeks of radiation therapy. CyberKnife SBRT for the treatment of prostate cancer has been adopted relatively quickly in many centers in the US. In 2011, Accuray, the manufacturer of the CyberKnife, reported a 24% increase in worldwide prostate treatments in one year. Because CyberKnife SBRT is a relatively new technology with a rapid adoption rate for the treatment of prostate cancer, it will be important to understand how physicians in a clinical practice are using the CyberKnife to treat prostate cancer and if the clinical outcomes (toxicities and bDFS) are comparable to initial published reports. The ReCKord Registry, a multi-center, ongoing patient registry, is an ideal resource for assessing CyberKnife SBRT practice patterns and outcomes for the treatment of prostate cancer in a clinical practice. Initial analysis of ReCKord indicated that there are over 1000 prostate cancer patients treated with CyberKnife SBRT. The purpose of this study is to investigate the patient characteristics, treatment management patterns and clinical outcomes of

	SBRT treatment for patients with early-stage prostate cancer. Patients will be stratified according to risk group (low, intermediate and high risk) to assess toxicities and bDFS following CyberKnife SBRT. We will also assess different dose and fractionation regimens, and if available, examine differences in toxicity and clinical outcomes for the two most commonly reported CyberKnife SBRT treatment regimen; homogeneous 5 fraction schedule vs heterogeneous 4 fraction. It will also be important to identify any factors that may be associated with differences in ReCKord clinical outcomes compared to initial published reports for CyberKnife SBRT.
Patient Inclusion/Exclusion Criteria:	Patients with prostate cancer as a primary malignancy treated with SBRT with a minimum 6 months of follow up.

Data Requested

Description of patient population to be analyzed:	All prostate cancer patients with early stage-prostate cancer treated with SBRT
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).	All screening variables (patient demographics, payer mix, PSA, Gleason score, VAS Pain score) All treatment variables All follow-up variables including toxicities and PSA levels
Deadline for receipt of data (mm/dd/yy):	10/1/13

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	The red journal

which submission is anticipated (if any)	
National meetings at which abstract presentation is anticipated (if any)	Abstract to be submitted to The RSS Scientific meeting

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	*David D'Ambrosio, MD*	
Print Name	David D'Ambrosio MD	
Title	Medical Director	
Date	Sept 5, 2013	

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

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For Internal Use Only:

Date application received:	Sept 5, 2013
ReCKord Registry Request #	2013-0905