



August 27, 2019

Rachelle Lanciano, MD
Radiation Oncology
30 Lawrence Road
Broomall, PA 19008

INSTITUTIONAL REVIEW BOARD
DELAWARE COUNTY MEMORIAL HOSPITAL
1ST FLOOR MOB

RE: 15-014
RSSearch Registry

Tel: 610.394.4722
Fax: 610.394.1849

(Principal Investigator : Dr. Lanciano)

501 NORTH LANSDOWNE AVE.
DREXEL HILL, PA. 19064

Date of Reapproval: August 17, 2019
Date Approval Expires: August 16, 2020

Dear Rachelle:

On August 17, 2019, the Crozer-Keystone Health System Institutional Review Board granted expedited reapproval for the RSSearch Registry. This approval expires on August 16, 2020. In compliance with federal and institutional regulations, no one involved in this study took part in this determination.

This approval includes use of consent form version 1.4 (dated November 28, 2016), which includes the HIPAA Authorization for this study, for prospective patients *and* for retrospective patients as they return to the Philadelphia Cyberknife facility for follow-up.

Please note that:

- All research studies done at or through Philadelphia Cyberknife using the RSSearch Registry must obtain prior approval by the CKHS IRB.
- You must obtain prior approval from the CKHS IRB if you wish to continue this registry beyond the expiration date or if you make changes in this registry.
- You must report to the CKHS IRB any significant violations of the Registry parameters as described in the project description approved by the CKHS IRB, within two working days of your knowledge of the event.

If you have any questions, you may contact me at (610) 619-7475, or you may contact Jackie DeFrancesco CKHS IRB Coordinator, at (610) 394-4722.

Sincerely,

A handwritten signature in black ink, appearing to read "Philip Gilman".

Philip Gilman, MD
CKHS IRB Chair

Request For Use of Aggregate Data Form

Date of Submission (mm/dd/yy):	10/21/19
Name of Organization:	Philadelphia Cyberknife / Virginia Commonwealth University
Project Title:	Stereotactic Radiosurgery (SRS) for Brain Metastases: Outcomes and Toxicity using the RSSearch Database
Principal Investigator:	Rachelle Lanciano, MD
Co-Investigators:	Anthony Ricco MD, Raj Singh MD
Corresponding Contact Name:	Anthony Ricco
Contact Title:	MS
Contact Telephone Number:	610-574-2322
Contact E-mail Address:	Anthony.Ricco@vcuhealth.org
Contact Address: City, State, Zip:	401 College Street Richmond, VA 23298

Project Description

Project Start Date (mm/dd/yy):	12/1/19
Project End Date (mm/dd/yy):	2/1/20
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 clinical outcomes and toxicities for patients treated with SRS?
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	Brain metastases are common sites of stereotactic radiation treatments. To our knowledge, authors have not previously reviewed the RSSearch database in this disease entity and reported outcome or toxicity data.
Patient Inclusion/Exclusion Criteria:	Patients with brain metastases treated with SRS in the RSSearch database

Data Requested

Description of patient population to be analyzed:	All patients in the RSSearch database with brain metastases.
Time frame to be studied:	From database creation until present
List exact data variables requested (i.e. pathology, treatment planning information, outcome, reimbursement,	Pt demographic information (age, sex, comorbidities) Tumor characteristics (histology) Imaging characteristics of tumors on CT or MRI

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).	Treatment planning information (PTV size, dose fractionation, number of mets treated) Acute or late toxicities (radionecrosis) Local control and overall survival information Location of treatment (academic vs private)
Deadline for receipt of data (mm/dd/yy):	12/1/19 if possible

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)	Radiation Oncology
National meetings at which abstract presentation is anticipated (if any)	ASTRO Annual Meeting

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	<i>Rachelle Lenciano MD</i>
Print Name	<i>Rachelle Lenciano MD</i>
Title	<i>Chief Department Radiation Oncology Philadelphia Cyberknife</i>
Date	<i>11/3/19</i>

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

For Internal Use Only:

Date application received:	11/04/2019
RSSearch Registry Request #	2019-1104