RSSearch® Patient Registry Protocol

Sponsor: the Radiosurgery Society®

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the Radiosurgery Society®

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RSSearch® Patient Registry Protocol

1 Registry Title

RSSearch® Patient Registry

The RSSearch® Patient Registry is an international, multi-center ongoing database designed to track utilization of all available stereotactic radiosurgery (SRS)/stereotactic body radiation therapy (SBRT) and Spatially Fractionated Radiation Therapy (SFRT – like GRID and LATTICE radiation) systems, treatment practices and outcomes to help determine, over time, the most effective use of the these systems in management of patients with life threatening tumors and other diseases.

The RSSearch® Patient Registry meets all Health Information Portability and Accountability Act (HIPAA) requirements regarding patient privacy and transmission of protected patient information.

Participant access to data entered into the RSSearch® Patient Registry will be limited as follows:

- Each clinical site will have full access to all data entered by that clinical site
- Each clinical site may have access to some reports using aggregate data, if created by the Radiosurgery Society® (RSS). Each clinical site may petition for access to aggregate data via the process outlined in Appendix D: Access to Data and Aggregate Reporting.

Sponsor

the Radiosurgery Society®

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2 Purpose

The RSSearch® Patient Registry is a database designed to standardize the collection of data on the use of SRS/SBRT/SFRT systems in everyday practice. Data to be recorded includes:

- Characteristics of patients who are selected for these treatments
- Treatment locations, disease diagnoses and lesion descriptions
- Treatment goals
- Treatment plans and delivery information
- Outcomes data
- Patient-reported quality of life questionnaires (if desired by the participating sites and approved by their Institutional Review Board (IRB)). See Appendix E for list of available health-related quality of life questionnaires.

The registry design including data collection forms were designed by a board of Clinical Advisors who are active users, including physicians, physicists, nurses and site administrators. The RSSearch® Patient Registry uses widely accepted standards for disease classification, treatment side effects and results and validated quality of life measures.

3 Objectives

Objectives of the RSSearch Registry include the following:

- Allow participants to record information about usage of the SRS/SBRT/SFRT systems in everyday practice, including patient characteristics and disease information, treatment plans and outcomes
- Allow participants to record information useful for their own SRS/SBRT/SFRT business reporting including utilization
- Provide participants with ready access to data for publication of their own SRS/SBRT/SFRT experience and as a tool for establishing collaborations with other participating sites
- Facilitate quality improvement efforts for individual treatment providers
- Provide participants the opportunity to collect quality of life data and other patient-reported outcomes
- Understand the effectiveness of different treatment plans for different types of lesions, diseases and treatments
- Provide comparative patient outcomes data to facilitate appropriate and successful use of the SRS/SBRT/SFRT system
- Collect information that may be useful for reimbursement

The RSSearch® Patient Registry is not a clinical trial or study. It is listed on www.clinicaltrials.gov and described as an observational patient registry (ClinicalTrials.gov Identifier: NCT01885299).

Information entered into RSSearch is already being collected as part of the medical record for patients at participating sites.

4 Duration

The RSSearch® Patient Registry will be an ongoing effort. This Registry began in 2005, as the ReCKord CyberKnife Registry and these CyberKnife patients remain embedded in RSSearch.

5 Participants

All clinical sites performing SRS/SBRT/SFRT treatment procedures of any kind will be invited and encouraged to participate in the Registry. Participation is voluntary, but Principal Investigators must be an active member of the Radiosurgery Society. There is no compensation for participation in the Registry, either to patients or to participating sites.

All sites participating in the Registry will be required to have a signed Data Use Agreement (DUA) or similar agreement with the Radiosurgery Society and submit this protocol to their Institutional Review Board (IRB) or Ethics Committee Review; this will expand the opportunities for collaboration and publication.

Sites will be required to comply with their own institution's IRB or Ethics Committee Review practices for ongoing review and approval.

Participating sites are responsible for sending the RSS Administrator documentation providing proof that they have received and/or have updated IRB or Ethics Committee Review approval.

6 Sponsorship

RSSearch resides under the auspices of the Radiosurgery Society and is funded partially through the membership fees of the RSS. An annual maintenance fee is required of all participants in RSSearch to cover costs for data storage, hosting fees, registry quality assurance (QA) and security checks.

The Radiosurgery Society® is a multidisciplinary non-profit organization aimed at advancing the science and clinical practice of radiosurgery. (See www.therss.org for additional information)

Objectives of the Radiosurgery Society® include:

- Improve results achieved in the field of Stereotactic Radiosurgery (SRS), Stereotactic Body Radiation Therapy (SBRT) and Spatially Fractionated Radiation Therapy (SFRT) by promoting scholarly exchange among the clinical users.
- Share detailed clinical information pertaining to SRS,SBRT and SFRT to promote protocol development.
- Encourage and enhance SRS, SBRT and SFRT techniques in the worldwide medical community and among healthcare providers and patients.

7 Patients

All patients of any age who are screened for potential SRS/SBRT/SFRT treatment are eligible to be entered into the RSSearch Registry. Some basic information including referral source, disease location etc., will be entered for any *patient who is screened* for SRS/SBRT/SFRT System treatment. Additional detailed demographic, diagnostic, treatment plan and follow up data will be entered on *patients who are selected* for one or more of these treatments. Patients who are selected and treated with SRS/SBRT/SFRT approaches will have data about their health status collected over the long-term, as long as they are considered candidates for follow-up.

There are no specific inclusion/exclusion criteria. The RSSearch® Patient Registry does not require specific tests or measures. Data that is collected in the normal course of a patient's treatment and follow up are entered into RSSearch.

There are no established endpoints for the RSSearch (as there are, for instance, for a Clinical Study); however, specific measures are recorded before and after treatment to determine outcomes of various SRS/SBRT/SFRT treatment approaches for different diseases.

All prospective patients must sign or have signed an informed consent form prior to their data being entered into the RSSearch® Patient Registry.

Initial entry of retrospective patient data may be considered under a Waiver of Authorization.
A Waiver of Authorization may be applicable for the following reasons:

- Risk to subject privacy is minimal
    - Procedure data is de-identified via the use of a unique identification number (ID) that will be created and known only to the participating site
    - Only four of the 18 variables considered protected health information (PHI) are necessary for use of RSSearch, specifically dates (admission, discharge, service dates, date of death), age (birthdates not collected), zip code and patient e-mail address (collected only if an individual site and their respective patients wish to use the Patient Portal feature of RSSearch, and then the email is visible only to the participating site).

    - The dates are important for understanding the data including, if and when:
        - Any adverse events occurred during and after the procedure
        - Key cancer outcomes including survival

    - If participating sites are using the Patient Portal feature, the patient e-mail will allow the patient to securely log-in to the Patient Portal and access and complete assigned quality of life questionnaires.

- Obtaining informed consent from patients who have already had a procedure and may not be returning for follow-up at a treating center performing the procedure may not be practical
- Obtaining informed consent may also inhibit a participating site's ability to completely characterize their patient population over time, practices associated with use of their SRS/SBRT/SFRT systems and long term outcomes

Retrospective data is marked as such in the database and can be separated for data analysis and publication purposes.

If Informed Consent is not obtained for initial data entry of retrospective patients and if the patient returns for follow-up or if follow-up data is otherwise obtained, Informed Consent can be obtained at follow-up.

If practical, obtaining Informed Consent from both retrospective and prospective patients is highly encouraged.

8 Forms

The RSSearch Registry includes the following forms and is available upon request:

- Screening Form
- Treatment Plan Form
- Follow-up Form
- Quality of Life Questionnaires

The registry contains both required and optional data fields, but it is highly recommended that all data fields, including required and optional fields be entered into RSSearch.

Screening Form

On the Screening Form, information is entered about any patient who is screened for treatment.

A new Screening Form is initiated and used for:

- New patients who have not previously been treated with SRS/SBRT/SFRT
- Existing patients who have previously been treated with SRS/SBRT/SFRT and
    - Have a recurrence or need for additional treatment at a previously treated target location, or
    - Have a new target treatment location or locations
- Existing patients who have previously been screened, but not treated by SRS/SBRT/SFRT
- Patients who are screened and not selected for SRS/SBRT/SFRT

If a patient has more than one target treatment location that will be treated during a single treatment period, details on these individual treatment locations will be recorded on the Screening Form.

If patients are screened and *not* selected for SRS/SBRT/SFRT, some basic information is entered including treatment location, referring physician and the reason why one of these systems was not selected for this patient at this time.

If patients are screened and selected for SRS/SBRT/SFRT treatment, the basic information mentioned above as well as the following additional information is entered; relevant patient characteristics and health status; detailed diagnostic information; and some information on reimbursement.

Treatment Plan Form

The Treatment Plan Form is filled out for every patient selected for SRS/SBRT/SFRT treatment. The design of the Treatment Plan Form follows typical treatment approaches, where a single treatment plan may be used to treat one or more lesions and multiple treatment plans may be used to treat a single target location. Clinicians will record one or more treatment plans and lesion details on a single Treatment Plan Form for any particular treatment period.

General Treatment Planning Systems (TPS) information can be digitally uploaded into RSSearch using an automated feature in VisionTree Optimal Care (VTOC) database platform (VisionTree, San Diego, CA, www.visiontree.com) the developer of the database platform used for RSSearch. This feature reduces the amount of duplicate data entry by participating sites while providing key information to meet the RSSearch Patient Registry objectives.

SRS/SBRT/SFRT systems not supported by system manufacturers may require manual entry of certain treatment planning information.

Treatment Plan Forms will be linked electronically within the database to patients, target treatment locations and lesions to assist with proper tracking for outcomes analysis.

Follow-Up Form

The Follow-Up Form is used to document the result of each treatment plan.

Follow-Up Forms are used at intervals determined appropriate by individual clinical sites. Data is recorded after patients attend regularly scheduled follow-up appointments. Patients are expected to be followed as long as they are deemed candidates for follow-up.

Follow-Up Forms will be linked electronically to patients and target treatment locations, lesions and treatment plans to assist with proper follow up and outcomes analysis.

Patient Quality of Life and other Patient-Reported Outcomes Forms

The patient quality of life questionnaires are optional and may be used if your institution wishes to collect these data. However, we are actively encouraging participants to collect quality of life data. The patient quality of life forms have been reviewed by the RSSearch Advisory Committee and are available and visible in the "Patient To Do's" Tab of the Registry. Many of the patient quality of life questionnaires are standard forms, validated and used to collect these kinds of data. A list of available quality of life and patient-reported outcomes forms are in Appendix E.

There are two approaches to reporting patient quality of life-data: 1) Via a secure VisionTree Patient Portal which automates the process by using the patient's email and your institution's selected forms of

interest. Patients will only be able to access their specifically assigned QOL forms. 2) Centers can manually enter patient-reported outcomes data through the Medical Team Portal. Forms can be printed from the VisionTree system, completed by the patient and then the medical team can enter the information directly into RSSearch.

9 Data Recording

The data recorded in the course of this registry will be documented on electronic case report forms (eCRFs) within a secure web-enabled software application. An independent medical software and web management company, VisionTree, San Diego, CA (www.visiontree.com), Inc. has designed and is managing the database and maintaining a HIPAA compliant system.

The system requires all information that is transmitted across the Internet be encrypted via Hyper Text Transfer Protocol Secure (HTTPS). To help avoid unauthorized usage, an automatic log-off feature is utilized after an extended period of user inactivity. A role-based security model is implemented to restrict access to various segments of the system (i.e. reports, screens, and site-specific data, along with other identified restricted information). In addition, the user interface and application components are stored behind an industry standard firewall with all outside communication closed except HTTP, HTTPS and Virtual Private Network (VPN) communication, while the database is only accessible via the internal network and VPN access. The system is physically housed within a HIPAA compliant facility including network redundancy for data availability, 24/7 network monitoring, multilevel access control requiring Badge/Photo ID and biometric access screening, internal and external video monitoring, fire protection, and disaster and environmental controls. The server and network updates are managed by VisionTree. The system data is backed up daily.

10 Patient Confidentiality

A unique patient identification number created and known only to your participating facility should be utilized in RSSearch and not a Medical Record Number. This data field is considered a “private” field and available only to the clinical site entering that data. The patient identification number will be used only as required for registry operations, specifically:

- To assist in enabling the digital import of treatment plan data from various Treatment Planning Systems, automatically and accurately linking the data
- To assist in enabling the digital import of data currently being collected in electronic form by participating clinical sites
- To make it easier for individuals at participating clinical sites to find a specific patient to enter additional data, to modify previously entered data and to record follow up data

As an additional security measure, a randomly generated patient ID is generated by VisionTree and linked to the unique patient ID created by the individual sites. This randomly generated ID can be used by VisionTree and the RSS to communicate with you if necessary, about specific patients. See Section 9 above to see how the limited PHI entered into RSSearch will be managed and protected by the software application and services provided by VisionTree.

Some payer and payment information is being collected to help gain insight into reimbursement of SRS/SBRT/SFRT treatment for different diagnoses by different health plans. Individual patient health plan numbers are *not* included in the database.

Patient email addresses may be collected by individual sites to allow patients to access the Patient Portal in order to view and complete select Quality of Life forms. If email addresses are collected for this purpose, these emails are only visible to the individual site and will be protected by the software application processes put in place by VisionTree.

All patient data will be de-identified prior to use for research and analysis. If and when comparisons of aggregate data are made, no specifically identified patient-to-patient, physician-to-physician or geographic comparisons of data will be performed.

11 Security

Participants will be required to enter a unique username and password to access the RSSearch Patient Registry. No sharing of usernames and passwords will be allowed.

If a clinical site determines they need written copies of RSSearch Data Collection Forms, these should be managed in accordance with data protection regulations by that clinical site.

12 Reporting

Participants may routinely access reports of their own individual center's data and are free to publish their own data at any time. The particular research and methods must be evaluated for scientific merit and ethical propriety by their own institutions. Publications or presentations that result from the RSSearch Registry should be acknowledged accordingly.

The RSSearch Registry Review Committee (RRRC) composed of SRS/SBRT/SFRT users may review and release de-identified aggregate data as deemed appropriate for publication. Any individual participating site may choose to have their data included or excluded in the released aggregate data, but because aggregate data will not contain any identifiers, either patient, physician or site, all participating sites will be encouraged to include their data to increase the value for educational purposes. Participating sites/clinicians and the RSS may submit requests for aggregate data for publication to the expert review panel. Please see Appendix D for details on aggregate reporting.

13 IRB/Ethics Review Committee Approval

IRB or Ethics Review Committee review and approval is required to participate in the RSSearch Registry (see Appendix A for review considerations).

Patient Informed Consent

Obtaining Patient Informed Consent for prospective patients being entered into the database is required and is highly suggested for retrospective patients; since increasingly, peer reviewed publications require Informed Consent for submitted research. A sample Patient Consent Form is attached in Appendix B. For institutions that require a patient research authorization to collect patient data prospectively, a sample Patient Authorization Form is attached in Appendix C.

14 Risks/Benefits

There are no specific risks to patients of having limited patient information collected in a central database. Information entered into RSSearch is currently being collected as a standard part of patient care and follow up.

The benefits may include improved follow up for individual patients by participating sites and improved understanding of the use and results of SRS/SBRT/SFRT treatment for all patients.

15 Reporting of Adverse Events

The RSSearch® Patient Registry provides a means on the Follow-Up Form for participating sites to indicate if the patient is experiencing any unexpected side effects or adverse events (AE) that can be attributable to SRS/SBRT/SFRT treatment. Reported adverse events will be graded on a scale of 1-5 as defined by the published standard Common Terminology Criteria for Adverse Events (CTCAE) v5.

Participation in RSSearch with its AE system does not in any way replace the responsibilities of clinicians or sites in reporting adverse events related to any treatment in accordance with all applicable laws and regulations including notifying the manufacturer of the associated SRS/SBRT/SFRT device, or medical complaints associated with SRS/SBRT/SFRT treatment as soon as possible.

16 Appendix A: Institutional Review Board (IRB) and Ethics Review Committee Considerations

Aspects to consider in determining what type of review (expedited or full board) application to use include:

1. The RSSearch® Patient Registry is not a clinical trial or study, and no investigational device exemption (IDE) is required for use of the various SRS/SBRT/SFRT Systems.
2. Data entered into RSSearch are observational outcomes data, which are already collected as part of the medical records for patients undergoing SRS/SBRT/SFRT treatment.
3. A unique patient identification number (not medical record number) is recorded at the site level, is only available to the respective site, and is used for the following purposes:
    a. To match the various Treatment Planning System data
    b. To assist in long term follow up at the participating site
    c. For registry operations
4. Physician-specific data will only be available to the respective site.
5. The RSSearch® Patient Registry is being managed in a secure environment by VisionTree®, San Diego, CA, an independent developer of web-based registries.

17 Appendix B: Sample Text for Patient Consent Form

A registry is a databank of information about people who have something in common. The RSSearch Patient Registry is keeping track of information on patients who have been considered for or have undergone treatment by various Stereotactic Radiosurgery (SRS), Stereotactic Body Radiation Therapy (SBRT), and Spatially Fractionated Radiation Therapy (SFRT – like GRID and LATTICE) methods.

Who is operating the Registry?

- The study is being sponsored and managed by the Radiosurgery Society (RSS), a non-profit organization of surgeons, radiation oncologists, physicists, and allied professionals, who are dedicated to advancing the science and clinical practice of SRS, SBRT and SFRT. Originally formed in 2002 and becoming a non-profit (501c6) in 2008, the RSS today represents clinician members who perform SRS,SBRT and SFRT in hospitals and freestanding centers throughout the world. (See www.therss.org for additional information).
- The registry database is being managed by an independent medical database company, VisionTree®, San Diego, CA.

What is being asked of you?

As you and your physician or health care provider at the treatment centers are having a discussion about whether SRS/SBRT/SFRT may be used to treat your particular condition, you are being asked to enroll in the registry. If you agree,

- Your physician will record information about you and your care into the registry
- Information about your care will be recorded at significant follow ups and over time
- Your physician and medical team may wish to collect information directly from you about your experience with the procedure and health-related qualify of life. Your medical team may ask you to complete a paper quality of life survey that will be maintained with your medical records and then the medical team will enter the data into the registry.
- Your physician may offer you the option to access these quality of life surveys directly online via a secure website. If you agree to directly access the website, you will need to provide an email address in order to login to the secure website. You will be sent reminders periodically from VisionTree to login, access and fill out your quality of life surveys in the Registry database managed by VisionTree®.
    - If after discussing this with your physician, you choose not to participate in the quality of life surveys, your email address will not be collected, and you won't receive any email reminders to fill out your surveys online.

What are the possible risks from participating?

There are no known health risks to participating in this registry.

Your confidential information will be protected as much as possible within the law. Any Protected Health Information recorded in the registry (i.e. zip code, treatment dates, email, etc.) will be encrypted (secure against hackers and other unauthorized uses). This special coding will secure access of your Protected Health Information to authorized parties only, like your physician, physician practice and the registry. The registry will not include personally identifiable information such as name, medical record number, address, or date of birth. However, for those physicians and patients who choose to access the Patient Portal to complete quality of life surveys, your email will be required.

Your email is visible only to your physician and physician's practice and like the other confidential information will be encrypted to help make sure that unauthorized access to this information does not occur.

As a function of managing the registry, a registry monitor may be exposed to certain personally identifiable information through interaction with your physician's practice; however, such information will only be used for quality control purposes and not be collected or used in any other way by the registry.

Aggregated and de-identified information from the patients participating will be used for analysis, publications, and reports.

Are there any possible benefits from participating?
You may not obtain a direct benefit from being in this registry. However, patients in the future may benefit from the information obtained from this research.

Financial considerations:
- There are no costs to participate in the registry.
- There will be no impact on the costs of your care.
- You will not be provided payment for participating in this registry.

Who can I talk to if I have questions?
Your first choice should be to talk with your physician who is a study investigator. He or she should be able to discuss the study, your participation, and your rights as a subject. If you have any other questions that you don't wish to talk about with your physician, you may call the independent review board that reviewed this study. They are this institution's review board.

AGREEMENT and CONSENT
If you agree to be in this registry, please sign this form.
- Your decision to be in this registry is voluntary.
- You will not be penalized or lose benefits if you decide not to participate or decide to stop participating.
- You may cancel your permission to participate in this research at any

You will receive a copy of this form signed by both of us.

	Participant	Investigator or designee
	Having read the above, I agree to participate	I have discussed this with this person
Signature		
Printed Name		
Date/Time		

18 Appendix C: Sample Registry Authorization form

USE AND DISCLOSURE OF YOUR
INFORMATION ENTERED INTO THE REGISTRY

Principal Investigator: <name of principle investigator, MD>
Title: RSSearch® Patient Registry

This form is called an Authorization and relates to use and disclosure of your health information in this research project which is an observational database. You also have been given a Consent form that tells you about the research and any activities or procedures that are part of the project. By signing this form, you agree that health information that identifies you may be used as necessary for the registry.

1. What information about you may be used or given out for the Registry?

Information that identifies you and might relate to your health or medical condition may be used in this registry. Information that identifies you can include your personal health information (PHI) consisting of dates and zip code. Information that relates to your medical condition includes:

- Information that you share with us, including information about your health history
- Information obtained during the normal course of treatment, such as what treatment is prescribed and delivered to you, how you respond to treatment(s) and/or procedure(s), information we learn in study visits, phone calls, surveys, physical examinations, x-rays and other tests and any other medical information we learn from you while conducting this registry.
- Your email address only if you are accessing the VisionTree Patient Portal to complete online quality of life questionnaires.

2. What information about you may not be used or given out for the Registry?

- Your name, Social Security number, medical record number, face photo/images, or unique identifying number/codes, except the unique code assigned by the investigator to code the data, will not be recorded in the Registry.

3. Who may use and give out information about you?

Your physician and other health care providers may provide the physical health and treatment information required for this registry. These include the researcher and the research staff, <name of the Treatment Center> and other physician practices and/or hospitals where you might be seen during your course of treatment by and follow up of SRS/SBRT/SFRT treatment.

4. Who may see your information?

Certain individuals/departments may see your health information to conduct the registry and to make sure it is being done as it should. These include:

- The Institutional Review Board (IRB)
- People who are responsible for research and HIPAA oversight at the institution(s) where the research is conducted

- Health care providers who may provide treatment to you during your participation in the registry
- People involved in ongoing management of registry operations

5. How will this information be used?

- To track treatment over time.
- To determine how care is being delivered.
- Your information will be used as part of research purposes.

6. Is your health information protected after it has been given to others?

Your specific identified health information will never be shared with an entity not covered by these policies and laws. This includes the registry sponsor, and other entities with whom the sponsor contracts to work on the registry.

7. What if you decide not to give your permission to use and give out your health information?

You do not have to give your permission to use or give out your health information. Your treatment will not be affected in any way if you refuse your permission.

8. May you withdraw or cancel your permission?

You may cancel your agreement to allow your health information to be used or given out at any time by completing a written Revocation Form and forwarding it to the_____. A Revocation Form may be obtained from your physician. If you have any questions, call _____. If you revoke your authorization, you are leaving the registry. If you leave the Registry, no new health information about you will be gathered after that date. However, information gathered before that date may be used for the registry or any follow-up for the registry**.**

9. Does this authorization have an end date?

There is no expiration date for this research authorization.

10. Have you given up any legal rights by signing this form?

By signing this authorization form, you have not waived any of the legal rights you would have were you not in the registry.

FOR ADULTS CAPABLE OF GIVING AUTHORIZATION:

_____

Subject's Signature Date Signed

_____

Printed Name

NOTE: THE PRINCIPAL INVESTIGATOR MUST:

- PROVIDE A COPY OF THE SIGNED AUTHORIZATION TO THE SUBJECT
- RETAIN THE ORIGINAL SIGNED AUTHORIZATION IN THE RESEARCH RECORD

- PLACE A COPY OF THE SIGNED AUTHORIZATION IN THE SUBJECT'S MEDICAL RECORD

19 Appendix D: Access to Data and Aggregate Reporting

Overview
This guideline provides information on the specific and accepted professional use of data and database-derived information of the RSSearch® Patient Registry.

Use of Data
Participants: RSSearch® Patient Registry "Participants" may consist solely of one or more physicians, physicists, nurses and site administrators, plus their hospital or center, at the physician's election, who engage in the process of collecting clinical practice data and utilization of data-base derived information.

Participants may routinely access reports of their own individual center's data and are free to publish their own data at any time. The particular research and methods must be evaluated for scientific merit and ethical propriety by their own Institutional Review Board or Ethic Review Committee.

Any individual participating site may choose to have their data included or excluded in the released aggregate data, but because aggregate raw data will not contain any identifiers, either patient, physician or site, all participating sites will be encouraged to include their data to increase the value for educational purposes. Participating sites/clinicians and the RSS may submit requests for aggregate data for publication for expert review panel.

Registry Administrator: The RSSearch® Patient Registry Administrators are the RSS employees, who are responsible for managing the development and maintenance of the registry. The responsibilities of the Administrators include:

- Oversee the management, development and maintenance of the database
- Providing participants with the most recent updated registry protocol, sample consent form and supporting materials for IRB, Ethics Review Committee or regulatory agency equivalent submission
- Acting as a liaison between the participants and the database vendor
- Creating and editing Data Collection Forms
- Notifying the database vendor of new participants or changes user access
- Coordinating database training
- Create and distribute timely reports of limited aggregate data under advisement of the RRRC
- Review and process applications for access to aggregate data
- May create, distribute and report on aggregate data and Quality Assurance and Performance Improvement studies with prior approval by the RSSearch® Patient Registry Review Committee (RRRC)

The Administrator will have read only access to de-identified registry data. All physician and specific patient identifying information will be restricted and not visible to the Administrator.

Aggregate Data Reporting: The RSSearch® Registry Review Committee (RRRC) will periodically review opportunities for presenting topline aggregate data to all participants via the Registry.

Access to data for publication and presentation: Data entered into the registry is available for research and publications. Clinical research on aggregated data may be used to produce one or more of the following forms of reporting and dissemination of information: abstract, scientific meeting presentation,

manuscript for publication in the medical literature. Patient identifying information will remain confidential.

All publications will include reference to all participating RSSearch® sites. Researchers will be provided assistance in getting permission to be named in a publication by the RSSearch Administrator.

RSSearch® Registry Review Committee (RRRC):
The RRRC consists of clinicians with extensive SRS and SBRT experience that have been selected by RSS Board of Directors. The RRRC evaluates the proposals based on originality, interest and benefit to the entire SRS and SBRT community and feasibility (as defined by availability of data in the aggregate database).

All persons interested in publishing RSSearch® aggregate data must submit their proposal for publication and request for data analyses to the RRRC using the RSSearch® Request For Use of Aggregate Data Form (see Attachment D.1). **The Radiosurgery Society®** will submit requests for aggregate data for publication to the RRRC. The RRRC will review individual applications for aggregate data release. There is no fee to submit an application for RRRC.

As indicated above and throughout the document, no physician, patient, or site identifying information is available or will be made available in granted requests for aggregate data. Site identifying information will be provided to the Radiosurgery Society for purposes of aggregate study requests and for conducting quality assurance of the database.

RSSearch® Data Request Form for Use of Aggregate Data:

Eligibility Criteria for Participating Centers
(The RSS will not be held to below criteria)

- Enter > 50 patients into RSSearch® annually
- Principal Investigator must be an RSS member
- The RSS will not be held to this criterion

Submission Requirements
Please attach each of the following with your RSSearch® Request For Use of Aggregate Data Form:

- Copy of IRB approval letter for use of RSSearch® at your institution
- Curriculum vitae of the principal investigator
- The RSS will not be held to this criterion

General Information
Submit Appendix D: Access to Data and Aggregate Reporting to the RSS RSSearch Administrator at jdavis@therss.org You will receive a letter regarding the status of your request within 30 business days. Requested custom aggregate data report will require a minimum of 2 weeks to generate. .

Request For Use of Aggregate Data Form

Date of Submission (mm/dd/yy):	
Name of Organization:	
Project Title:	
Principal Investigator:	
Co-Investigators:	
Corresponding Contact Name:	
Contact Title:	
Contact Telephone Number:	
Contact E-mail Address:	
Contact Address: **City, State, Zip:**	

Project Description

Project Start Date (mm/dd/yy):	
Project End Date (mm/dd/yy):	
Type of Research Project:	□ Prospective Study □ Retrospective Analysis □ Technical Study □ Other
If "Other," please explain nature of project:	
What is the research question being asked?	
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	
Patient Inclusion/Exclusion Criteria:	

Data Requested

Description of patient population to be analyzed:	
Time frame to be studied:	
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).	
Deadline for receipt of data (mm/dd/yy):	

Data Use

Are these data for internal research purposes only? (yes/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)	
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	
Title	
Date	

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

For Internal Use Only:

Date application received:	

RSSearch Registry Request #	

20 Appendix E: Health-Related Quality of Life Questionnaires

Form Name	Reference	GoogleDoc URL
Actual Life Changes in Epilepsy	Rose Trial for Radiosurgery or Open Surgery for Epilepsy http://www.igkrf.org/uploads/6/6/3/7/66377631/13-01.pdf	https://drive.google.com/file/d/0B_Fo8tKvsaUyTUJyZFNvbFZud3M/view?usp=sharing
BCPT - Everyday Problems During The Past 4 Weeks	Life After Breast Cancer: Understanding Women's Health-Related Quality of Life and Sexual Functioning By Patricia A. Ganz, Julia H. Rowland, Katherine Desmond, Beth E. Meyerowitz, and Gail E. Wyatt J Clin Oncol 16:501-514. © 1998 by American Society of Clinical Oncology http://ascopubs.org/doi/pdf/10.1200/jco.1998.16.2.501	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyTzBKVE1VZW1Jd1k/view?usp=sharing
Beck Anxiety Inventory	Beck, A. T.,Epstein, N.,Brown, G.,Steer, R. A. (1988). An inventory for measuring clinical anxiety: Psychometric properties.Journal of Consulting and Clinical Psychology, 56,893-897.	https://drive.google.com/file/d/0B_Fo8tKvsaUyalhHU1lla3RvNzQ/view?usp=sharing
Bladder Cancer Index (BCI)	Development and Validation of the Bladder Cancer Index: Scott M. Gilbert, Rodney L. Dunn, Brent K. Hollenbeck,* James E. Montie, Cheryl T. Lee,† David P. Wood‡ and John T. Wei§. A Comprehensive, Disease Specific Measure of Health Related Quality of Life in Patients With Localized Bladder Cancer. Journal of Urology Vol. 183, 1764-1770, May 2010.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyZ3c2VmFybkIyNjQ/view?usp=sharing
Breast Cancer Treatment Outcomes Scale	BCTOS in measuring HR-QOL after breast conserving therapy: Chen et al. The Breast Journal, Volume 17, Number 4, 2011 443l Feb 2014 https://www.researchgate.net/publication/51488510_BCTOS_in_measuring_HR-QoL_after_breast-conserving_therapy	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyeFdFOWlFN2JGUUE/view?usp=sharing
Breast Symptom Survey	Modifed from and used by UCLA Breast Registry: The BCPT Symptom Scales: A Measure Symptoms for Women Diagnosed With or at Risk for Breast Cancer. Stanton et al. JNCI Accepted January 18 2005 http://apntoolkit.mcmaster.ca/index.php?option=com_content&view=article&id=137:breast-cancer-prevention-trial-bcpt-symptom-checklist&Itemid=58	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyczZxekZzd3dSbnM/view?usp=sharing

Brief COPE Informant	Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the Brief COPE. *International Journal of Behavioral Medicine*, 4, 92-100.	https://drive.google.com/file/d/0B_Fo8tKvsaUyYVZmU1FjQzhXanc/view?usp=sharing
Brief COPE Patient	Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the Brief COPE. *International Journal of Behavioral Medicine*, 4, 92-100.	https://drive.google.com/file/d/0B_Fo8tKvsaUyZmVlWm5OaWJJak0/view?usp=sharing
Caregiver Reaction Assessment Scale	Given CW, Given B, Stommel M, et al. The caregiver reaction assessment (CRA) for caregivers to persons with chronic physical and mental impairments. Research in Nursing & Health. 1992; 15: 271-283.	https://drive.google.com/file/d/0B_Fo8tKvsaUyb25nTlhrbDFhSEk/view?usp=sharing
CESD Depression Inventory	Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Applied Psychological Measurement. 1977;1:385-401.	https://drive.google.com/file/d/0B_Fo8tKvsaUyZU5HbWpMMFRpcms/view?usp=sharing
Coping Strategy Indicator (CSI) Scale (Patinet and Spouse/Partner)	Amirkhan, J. H. (1990). A factor analytically derived measure of coping: The Coping Strategy Indicator. Journal of Personality and Social Psychology, 59, 1066-1075.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyMlFReGw5MG9VLXM/view?usp=sharing
EORTC QLQ- BR23	Sprangers MA, Groenvold M, Arraras JI, Franklin J, te Velde A, Muller M, Franzini L, Williams A, de Haes HC, Hopwood P, Cull A, Aaronson NK. The European Organization for research and treatment of cancer breast cancer-specific quality-of-life questionnaire module: first results from a three-country field study. J Clin Oncol. 1996;14:2756–2768.	
EORTC QLQ H&N35	Sherman AC1, Simonton S, Adams DC, Vural E, Owens B, Hanna E. Assessing quality of life in patients with head and neck cancer: cross-validation of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Head and Neck module (QLQ-H&N35). Arch Otolaryngol Head Neck Surg. 2000 Apr;126(4):459-67	
EORTC QLQ-C30 (version 3)	Aaronson N.K., Ahmedzai S., Bullinger M. et al: The EORTC core quality of life questionnaire: Interim results of an international field study. In: Osoba D. ed. Effect of Cancer on Quality of Life. Boca Raton, FL: CRC Press 1991: 185-203	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyd2hGMTNIOURtaU0/view?usp=sharing
EORTC-QLQ-BN20	Taphoorn MJ1, Claassens L, Aaronson NK, Coens C, Mauer M, Osoba D, Stupp R, Mirimanoff RO, van den Bent MJ, Bottomley A; EORTC Quality of Life Group, and Brain Cancer, NCIC and Radiotherapy Groups. An international validation study of the EORTC brain cancer module (EORTC QLQ-BN20) for assessing health-related quality of life and symptoms in brain cancer patients. Eur J Cancer. 2010 Apr;46(6):1033-40	https://drive.google.com/file/d/0B_Fo8tKvsaUySTJ5YkwxSXJla2M/view?usp=sharing
EPIC (Expanded Prostate Cancer	Development and Validation of the Expanded Prostate Cancer Index Composite (EPIC) for Comprehensive Assessment of Health-Related	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyeVhFUHRLWXhveXc/view?usp=sharing

Index Composite)	Quality of Life in Men with Prostate Cancer", Urology. 56: 899-905, 2000.	
EPIC-26 (Expanded Prostate Cancer Index Composite)	https://medicine.umich.edu/sites/default/files/content/downloads/epic26web.pdf	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyOWJZVjJoRUQ2cEk/view?usp=sharing
Erectile Score Questionaire	Used by the FROG group—derived from other standard measurement tools	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyclJ6bDEzYl83T2c/view?usp=sharing
Everyday Cognition Scale	Sarah Tomaszewski Farias, Dan Mungas, Bruce R. Reed, Deborah Cahn-Weiner, Kathleen Baynes, Charles DeCarli. The Measurement of Everyday Cognition (ECog): Scale Development and Psychometric Properties. Neuropsychology. 2008 Jul; 22(4): 531–544.	https://drive.google.com/file/d/0B_Fo8tKvsaUydzdnMGItZEVZWVU/view?usp=sharing
FACT E	Darling et al. Validation of the Functional Assessment of Cancer Therapy Esophageal Cancer Subscale, Cancer 2006;107:854–63.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyUldRUjEyeng3ZXM/view?usp=sharing
FACT En	Hopp EE1, Osborne JL2, Schneider DK3, Bojar CJ4, Uyar DS4. A prospective pilot study on the incidence of post-operative lymphedema in women with endometrial cancer. Gynecol Oncol Rep. 2015 Dec 24;15:25-8	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyVHJCMWpfZUNzeGM/view?usp=sharing
FACT Ga	Garland SN1, Pelletier G, Lawe A, Biagioni BJ, Easaw J, Eliasziw M, Cella D, Bathe OF. Prospective evaluation of the reliability, validity, and minimally important difference of the functional assessment of cancer therapy-gastric (FACT-Ga) quality-of-life instrument. Cancer. 2011 Mar 15;117(6):1302-12	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUycFBGZ0R2anM2eWc/view?usp=sharing
FACT Hep	Cella D, Butt Z, Kindler HL, Fuchs CS, Bray S, Barlev A, Oglesby A. Validity of the FACT Hepatobiliary (FACT-Hep) questionnaire for assessing disease-related symptoms and health-related quality of life in patients with metastatic pancreatic cancer. Qual Life Res. 2013 Jun;22(5):1105-12	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUydVpEQUp0SENTVWs/view?usp=sharing
FACT-BR v4	Thavarajah N, Bedard G, Zhang L, Cella D, Beaumont JL, Tsao M, Barnes E, Danjoux C, Sahgal A, Soliman H, Chow E. Psychometric validation of the functional assessment of cancer therapy--brain (FACT-Br) for assessing quality of life in patients with brain metastases. Support Care Cancer. 2014 Apr;22(4):1017-28.	https://drive.google.com/file/d/0B_Fo8tKvsaUyanF3dl9CNktOVTA/view?usp=sharing
FACT-Cog (v3)	Vardy J1, Wong K, Yi QL, Park A, Maruff P, Wagner L, Tannock IF. Assessing cognitive function in cancer patients. Support Care Cancer. 2006 Nov;14(11):1111-8	https://drive.google.com/file/d/0B_Fo8tKvsaUyT2NTc2hFRnlHQjA/view?usp=sharing
FACT-Cx (English w/ Spanish drop-down option)	McQuellon R, Thaler H, Cella D, Moore DH. Quality of life (QOL) outcomes from a randomized trial of cisplatin versus cisplatin plus paclitaxel in advanced cervical cancer: a Gynecologic Oncology Group study. Gynecol Oncol. 2006;101:296–304	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyelkxaEhsZy0yU0U/view?usp=sharing
FACT-G	Luckett, T.; King, M. T.; Butow, P. N.; Oguchi, M.; Rankin, N.; Price, M. A.; Hackl, N. A.; Heading, G.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyOGprOHBTUm1fblU/view?usp=sharing

	(2011-02-21). "Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations". Annals of Oncology: mdq721. doi:10.1093/annonc/mdq721. ISSN 0923-7534. PMID 21339384	
FACT-H&N (Version 4)	List MA, D'Antonio LL, Cella DF, et al. The Performance Status Scale for Head and Neck Cancer Patients and the Functional Assessment of Cancer Therapy-Head and Neck Scale. A study of utility and validity. Cancer. 1996;77:2294–2301	https://drive.google.com/file/d/0B_Fo8tKvsaUyT0dxYWtYMVRtT1k/view?usp=sharing
FACT-Trial Outcome Index (TOI) for Lung Cancer	Cella, D.F., Bonomi, A.E., Lloyd, S.R. et al. Reliability and validity of the FACT-L quality of life instrument. Lung Cancer 12(3): 199-220, 1995.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyMllBQVpRN3NfUzA/view?usp=sharing
Fear of Cancer Recurrence Inventory - Baseline	Simard S1, Savard J. Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence. Support Care Cancer. 2009 Mar;17(3):241-51	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyMVRLeXAxOUFqYVk/view?usp=sharing
Female Pelvis Symptom Survey	Modified and used by UCLA Radiation Oncology Group	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyX21UWXNqWlA4Sms/view?usp=sharing
FSS (Fatigue Severity Scale)	Krupp LB. The fatigue severity scale. Application to patients with multiple sclerosis and systemic lupus erythematosus. Arch Neurol. 1989;46:1121–3.	https://drive.google.com/file/d/0B_Fo8tKvsaUyUUVEUmkzX0QzbW8/view?usp=sharing
Global Health Scale - Baseline	2008-2012 PROMIS Health Organization and PROMIS Cooperative Group	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyVXRINzNIejBkVEU/view?usp=sharing
Head and Neck Symptom Survey	Modified and used by UCLA Radiation Oncology Group	https://drive.google.com/file/d/0B_Fo8tKvsaUyZm9jRlZiVHRVMWs/view?usp=sharing
IIEF (Not Sexually Active)	Rosen RC, Cappelleri JC, Smith MD, et al. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. Int J Impot Res. 1999 Dec;11(6):319-26	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyZ0NPNW9PNmxuUjA/view?usp=sharing
IIEF (Sexually Active)	Rosen RC, Cappelleri JC, Smith MD, et al. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. Int J Impot Res. 1999 Dec;11(6):319-26	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyaDdKR3FMYWlRUE0/view?usp=sharing
IPSS (Pre-Treatment)	Barry MJ, Fowler FJ Jr, O'Leary MP, Bruskewitz RC, Holtgrewe HL, Mebust WK, Cockett AT. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. J Urol 1992 Nov;148(5):1549-57.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyVzNzQzNKTHhqX2c/view?usp=sharing
M.D. Anderson	Cleeland CS[1], Mendoza TR, Wang XS, Chou C, Harle MT, Morrissey M, Engstrom MC. Assessing	https://drive.google.com/file/d/0B_Fo8tKvsaUydlgta2ZFd1pYVHc/view?usp=sharing

Symptom Inventory (MDASI) Core Items	symptom distress in cancer patients: the M.D. Anderson Symptom Inventory. Cancer. 2000 Oct 1;89(7):1634-46	
Male Pelvis Symptom Survey	Modified and Used by UCLA Radiation Oncology Group	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyY2FQa0E3TlYyRms/view?usp=sharing
MDADI (dysphagia)	Chen AY, Frankowski R, Bishop-Leone J, et al. The development and validation of a dysphagia-specific quality-of-life questionnaire for patients with head and neck cancer: the M. D. Anderson dysphagia inventory. Arch Otolaryngol Head Neck Surg 2001;127:870-6.	https://drive.google.com/file/d/0B_Fo8tKvsaUyYmpheGpKNlRWZ0k/view?usp=sharing
MDASI-HN	Rosenthal DI, Mendoza TR, Chambers MS, et al. Measuring head and neck cancer symptom burden: The development and validation of the M. D. Anderson Symptom Inventory, head and neck module. Head Neck 29(10): 923-931, 2007.	https://drive.google.com/file/d/0B_Fo8tKvsaUydndHWURycFJNZW8/view?usp=sharing
Modified Functional J.O.A. (Japanese Orthopedic Association) Scale	Benzel EC, Lancon J, Kesterson L, Hadden T. Cervical laminectomy and dentate ligament section for cervical spondylotic myelopathy. J Spinal Disord. 1991;4:286–95	https://drive.google.com/file/d/0B_Fo8tKvsaUyeklYMENmRkpHM0k/view?usp=sharing
Modified PROLO Scale (Spine)	Prolo D, Oklund SA, Butcher M (1986) Toward uniformity in evaluating results of lumbar spine operations. A paradigm applied to posterior lumbar interbody fusions. Spine 11(6):601–606.	https://drive.google.com/file/d/0B_Fo8tKvsaUyYlhleEphaUtHQXc/view?usp=sharing
Movement Disorder Society - Unified Parkinson's Disorder Rating System	http://www.movementdisorders.org/MDS/Education/Rating-Scales.htm	https://drive.google.com/file/d/0B_Fo8tKvsaUyRTdRSno4TVdIRm8/view?usp=sharing
Neck Disability Index (NDI)	Vernon, H. & Mior, S. (1991). The Neck Disability Index: A study of reliability and validity. Journal of Manipulative and Physiological Therapeutics. 14, 409-415	https://drive.google.com/file/d/0B_Fo8tKvsaUyTVdKSC03ZG56Wlk/view?usp=sharing
Oswestry v2	Fairbank J.C., Pynsent P.B. The Oswestry Disability Index. Spine. 2000;25(22):2940–2952. [discussion 52]	https://drive.google.com/file/d/0B_Fo8tKvsaUyVlNUcTZNcXhpMTA/view?usp=sharing
Patient Health Questionnaire (PHQ-9)	Kroenke K, Spitzer R, Williams W. The PHQ-9: Validity of a brief depression severity measure. JGIM, 2001, 16:606-616	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyTGNUb2xsbk9lb2M/view?usp=sharing
PDQ-39 Questionnaire (Parkinson's)	Peto V, Jenkinson C, Fitzpatrick R. PDQ-39: A review of the development, validation and application of a Parkinson's disease quality of life questionnaire and its associated measures. J Neurology, 1998; 245: Suppl 1 S10-4.	https://drive.google.com/file/d/0B_Fo8tKvsaUyX3VoMEpGZVBzaTA/view?usp=sharing
Quality of Life - Meningioma	Modified and adapted by UCSF Neurological Surgery: Reference below: FACT-MNG: tumor site specific web-based outcome instrument for meningioma patients D.	https://drive.google.com/file/d/0B_Fo8tKvsaUyYnBUY3ZRRm9DdFE/view?usp=sharing

	Zlotnick • S. N. Kalkanis • A. Quinones-Hinojosa • K. Chung • M. E. Linskey • R. L. Jensen • F. DeMonte • F. G. Barker • C. A. Racine • M. S. Berger • P. M. Black • M. Cusimano • L. N. Sekhar • A. Parsa • M. Aghi • Michael W. McDermott Journal of Neuroncology August 2010 http://www.visiontree.com/assets/files/pdf/studies-and-abstracts/vtoc_usedfor_meningioma_outcomes_research.pdf	
RAND 36 (SF-36)	http://www.rand.org/health/surveys_tools/mos/36-item-short-form.html	https://drive.google.com/file/d/0B_Fo8tKvsaUyN0ctRWNFdUZkSDA/view?usp=sharing
RAND 36 (SF-36)	http://www.rand.org/health/surveys_tools/mos/36-item-short-form.html	https://drive.google.com/file/d/0B_Fo8tKvsaUyN0ctRWNFdUZkSDA/view?usp=sharing
Sexual Health Inventory for Men (SHIM)	Cappelleri JC *et al.*. Relationship between patient self-assessment of erectile function and the Sexual Health Inventory for Men. *Clin Ther* 2001; 23: 1707-1719.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyTUlPUVBhSi0tQ00/view?usp=sharing
SOSG Self-Assessment Questionnaire	Validation of the Spine Oncology Study Group—Outcomes Questionnaire to assess quality of life in patients with metastatic spine disease Stein J. Janssen, MDa, Teun Teunis, MDa , Eva van Dijk, BSca , Marco L. Ferrone, MDb , John H. Shin, MDc , Francis Hornicek, MD, MS, PhDa , Joseph H. Schwab, MD, MSa a Department of Orthopaedic Surgery, Orthopaedic Oncology Service, Massachusetts General Hospital—Harvard Medical School, 55 Fruit St, Boston, MA 02114, USA b Department of Orthopaedic Surgery, Spine Service, Brigham and Women's Hospital—Harvard Medical School The Spine Journal 9 February 2015; revised 22 May 2015; accepted 23 July 2015 file:///C:/Users/MK/Downloads/2015%20janssen%20sosg%20validation.pdf	https://drive.google.com/file/d/0B_Fo8tKvsaUybUZURkp1d051Tzg/view?usp=sharing
TESS - Lower Extremity	A. M. Davis, R. S. Bell, E. M. Badley, K. Yoshida, and J. I. Williams, "Evaluating functional outcome in patients with lower extremity sarcoma," Clinical Orthopaedics and Related Research, no. 358, pp. 90–100, 1999.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyT2R0dlpKSzczNEU/view?usp=sharing
TESS - Upper Extremity	A. M. Davis, J. G. Wright, J. I. Williams, C. Bombardier, A. Griffin, and R. S. Bell, "Development of a measure of physical function for patients with bone and soft tissue sarcoma," Quality of Life Research, vol. 5, no. 5, pp. 508–516, 1996.	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyRVRhd3NRMGVwRTA/view?usp=sharing
Testicular Cancer Patient Diary Card	Used by the UCLA Radiation Oncology Group	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUybmVkck42S1J5eDA/view?usp=sharing
University of Michigan Xerostomia Quality of	Hensen, B.S., Inglehart, M.R., Eisbruch, A., Ship, J.A. (2001). Preserved salivary output and xerostomia-related quality of life in head and neck cancer patients receiving parotid-sparing radiotherapy. Oral	https://drive.google.com/a/visiontree.com/file/d/0B_Fo8tKvsaUyUV9QaXdOWW8yT1k/view?usp=sharing https://drive.google.com/file/d/0B_Fo8tKvsaUyVmxPbUR4b3I3VW8/view?usp=sharing

Life Survey (Xe-QOLS)	Oncology, 37(1): 84-93.; Lin, A., Kim, H.M., Terrell, J.E., Dawson, L.A., Ship, J.A., Eisbruch, A., (2003) Quality of life after parotid-sparing IMRT for head and neck cancer: A prospective longitudinal study. Int J Radiat Oncol Biol Phys, 57(1):61-70.	
WHO-5	Staehr Johansen K: The use of well-being measures in primary health care - the DepCare project; in World Health Organization, Regional Office for Europe: Well-Being Measures in Primary Health Care - the DepCare Project. Geneva, World Health Organization, 1998, target 12, E60246.; The WHO-5 Well-Being Index: A Systematic Review of the Literature, Psychother Psychosom 2015;84:167-176 (DOI:10.1159/000376585)	https://drive.google.com/file/d/0B_Fo8tKvsaUyZTJzTHVvVWhwUG8/view?usp=sharing