RSSearch® Registry Protocol

RSSearch Request Form for Use of Aggregate Data:

Eligibility Criteria for Participating Centers

- Enter > 50 patients into RSSearch annually
  (The RSS 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 RSSearch at your institution
- Curriculum vitae of the principal investigator.

General Information

Submit the request for aggregate data to nbrown@therss.org. You will receive confirmation and a response regarding the status of your request within 30 business days. Requested custom aggregate data report will require a minimum of 2 weeks to generate. Accepted applications are posted on the RSS website at www.therss.org.

Administrative Information

Date of Submission (mm/dd/yy):	11/30/2016
Name of Organization:	Montefiore Medical Center/Albert Einstein College of Medicine
Project Title:	Stereotactic Body Radiotherapy (SBRT) Outcomes and Toxicity in Patients Treated with Targeted Systemic Therapy
Principal Investigator:	Rafi Kabarriti, MD; Madhur Garg, MD
Co-Investigators:	Shiv Desai, MD
Corresponding Contact Name:	Rafi Kabarriti
Contact Title:	MD
Contact Telephone Number:	718-405-8550
Contact E-mail Address:	rkabarri@montefiore.org
Contact Address: **City, State, Zip:**	1625 Poplar St Suite 101 Bronx, NY 10461

Project Description

Project Start Date (mm/dd/yy):	11-30-2016
Project End Date (mm/dd/yy):	1-30-2016
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 are the outcomes and toxicities for patients with metastatic cancer under treatment with targeted systemic therapy who also receive SBRT?
What is the background or rationale for the research question? (if needed, please attach as a separate page to application)	Many patients with metastatic cancer are eligible for treatment with newer systemic agents targeting cancer specific mutations or cell cycle aberrations. These patients can receive SBRT for palliation or control of "escape clones" The safety, SBRT timing, and dosing of targeted therapy with this approach is not well established. We aim to evaluate this with the RSSearch database
Patient Inclusion/Exclusion Criteria:	Patients treated with SBRT and targeted systemic therapy

Data Requested

Description of patient population to be analyzed:	All patients treated with SBRT and targeted systemic therapy (see attached list of drugs) in the RSSearch database
Time frame to be studied:	From database inception until 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).*	Patient characteristics including age, sex, co-morbidties Tumor characteristics # of lesions, grade, mutational status Imaging characteristics of tumors on CT, PET, or MRI Treatment planning information (dose, fractionation, PTV size, technique) Additional treatment (pre or post-SBRT systemic therapy) Acute and chronic toxicities Outcome information (local control, pain palliation, and survival) Geographic location of treatment centers (state, urban/rural) Classification of treatment centers (academic/community)
Deadline for receipt of data (mm/dd/yy):	12/31/2016 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)	Publication will be submitted to IJORBP or Radiotherapy & Oncology
National meetings at which abstract presentation is anticipated (if any)	Radiosurgery Society SRS/SBRT Annual Meeting or 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	Rafi Kabarniti
Print Name	Rafi Kabarniti
Title	MD
Date	12/6/16

Please submit Request for Use of aggregate data to nbrown@therss.org

For Internal Use Only:

Date application received:	
RSSearch Registry Request #	2016-1130-10

Targeted Therapy

Most Commonly Used Agents:

EGFR-Cetuximab; erlotinib, gefitinib, panitumumab, Osimertinib, Afatinib
TKI-Sorafenib; Sunitinib; Nilotinib; Lapatinib; Imatinib;
Alk- Crizotinib; ceritinib
ERBB2- Ado-trastuzumab emtansine ; Lapatinib; Pertuzumab; Trastuzumab
BRAF V600e: Vemurafenib; Dabrafenib; trametinib
BRAF nonV600: Trametinib
RET: Vandetanib
PARP inhibitor: olaparib, Veliparib
PIK3Ca/mTOR- Everolimus, Temsirolimus; Taselisib
NF1 mut: Trametinib
GNAQ/GNA11: Trametinib
SMO/PTCH1: Vismodegib
NF2 loss: Defactinib
cKIT mut: Sunitinib
FGFR1/2/3: AZD 4547
DDR2 mut: Dasatinib
AKT1 mut: AZD 5363
NRAS mut: Binimetinib
CDK 4/6 inhibitor: Palbociclib
MEK: Trametinib, Cobimetinib
KIT, PDGFRβ: Axitinib, Olaratumab
FLT3: Cabozantinib

Full list of targeted agents:

Agent	Target(s)
Ado-trastuzumab emtansine (Kadcyla)	HER2 (ERBB2/neu)
Afatinib (Gilotrif)	EGFR (HER1/ERBB1), HER2 (ERBB2/neu)
Aldesleukin (Proleukin)	
Alectinib (Alecensa)	ALK
Alemtuzumab (Campath)	CD52
Atezolizumab (Tecentriq)	PD-L1
Axitinib (Inlyta)	KIT, PDGFRβ, VEGFR1/2/3
Belimumab (Benlysta)	BAFF
Belinostat (Beleodaq)	HDAC
Bevacizumab (Avastin)	VEGF ligand
Bortezomib (Velcade)	Proteasome
Bosutinib (Bosulif)	ABL
Brentuximab vedotin (Adcetris)	CD30
Cabozantinib (Cabometyx [tablet], Cometriq [capsule])	FLT3, KIT, MET, RET, VEGFR2
Canakinumab (Ilaris)	IL-1β
Carfilzomib (Kyprolis)	Proteasome
Ceritinib (Zykadia)	ALK
Cetuximab (Erbitux)	EGFR (HER1/ERBB1)
Cobimetinib (Cotellic)	MEK
Crizotinib (Xalkori)	ALK, MET, ROS1
Dabrafenib (Tafinlar)	BRAF
Daratumumab (Darzalex)	CD38
Dasatinib (Sprycel)	ABL
Denosumab (Xgeva)	RANKL

Dinutuximab (Unituxin)	B4GALNT1 (GD2)
Elotuzumab (Empliciti)	SLAMF7 (CS1/CD319/CRACC)
Erlotinib (Tarceva)	EGFR (HER1/ERBB1)
Everolimus (Afinitor)	mTOR
Gefitinib (Iressa)	EGFR (HER1/ERBB1)
Ibritumomab tiuxetan (Zevalin)	CD20
Ibrutinib (Imbruvica)	BTK
Idelalisib (Zydelig)	PI3Kδ
Imatinib (Gleevec)	KIT, PDGFR, ABL
Ipilimumab (Yervoy)	CTLA-4
Ixazomib (Ninlaro)	Proteasome
Lapatinib (Tykerb)	HER2 (ERBB2/neu), EGFR (HER1/ERBB1)
Lenvatinib (Lenvima)	VEGFR2
Necitumumab (Portrazza)	EGFR (HER1/ERBB1)
Nilotinib (Tasigna)	ABL
Nivolumab (Opdivo)	PD-1
Obinutuzumab (Gazyva)	CD20
Ofatumumab (Arzerra, HuMax-CD20)	CD20
Olaparib (Lynparza)	PARP
Olaratumab (Lartruvo)	PDGFRα
Osimertinib (Tagrisso)	EGFR
Palbociclib (Ibrance)	CDK4, CDK6
Panitumumab (Vectibix)	EGFR (HER1/ERBB1)
Panobinostat (Farydak)	HDAC
Pazopanib (Votrient)	VEGFR, PDGFR, KIT
Pembrolizumab (Keytruda)	PD-1

Pertuzumab (Perjeta)	HER2 (ERBB2/neu)
Ponatinib (Iclusig)	ABL, FGFR1-3, FLT3, VEGFR2
Ramucirumab (Cyramza)	VEGFR2
Regorafenib (Stivarga)	KIT, PDGFRβ, RAF, RET, VEGFR1/2/3
Rituximab (Rituxan, Mabthera)	CD20
Romidepsin (Istodax)	HDAC
Ruxolitinib (Jakafi)	JAK1/2
Siltuximab (Sylvant)	IL-6
Sonidegib (Odomzo)	Smoothened
Sorafenib (Nexavar)	VEGFR, PDGFR, KIT, RAF
Temsirolimus (Torisel)	mTOR
Tocilizumab (Actemra)	IL-6R
Tofacitinib (Xeljanz)	JAK3
Tositumomab (Bexxar)	CD20
Trametinib (Mekinist)	MEK
Trastuzumab (Herceptin)	HER2 (ERBB2/neu)
Vandetanib (Caprelsa)	EGFR (HER1/ERBB1), RET, VEGFR2
Vemurafenib (Zelboraf)	BRAF
Venetoclax (Venclexta)	BCL2
Vismodegib (Erivedge)	PTCH, Smoothened
Vorinostat (Zolinza)	HDAC
Ziv-aflibercept (Zaltrap)	PIGF, VEGFA/B