



SCRI Oncology Research Consortium

Site Profile

The SCRI ORC will review applications and contact sites regarding selection.

Please send all documents to:
SCRI Oncology Research Consortium
Attn: Amy Perez
Sarah Cannon Research Institute
3322 West End Avenue, Suite 900
Nashville, TN 37203
(615) 329-7493

This questionnaire must be completed in its entirety and returned to the SCRI Oncology Research Consortium

Greetings,

We are thrilled you are interested in becoming a SCRI Oncology Research Consortium member. In 1995, our research network was started with the intention of providing innovative and clinically relevant new treatment options to practicing oncologist in our community. Since that time, our network has accrued thousands of patients to clinical trials, resulting in numerous peer-reviewed publications and presentations at regional and national scientific meetings. More importantly, our network has been the first to explore several innovations in cancer therapy that have now become established components of standard treatment.

In order for the SCRI Oncology Research Consortium to consider your interest, we ask that you complete the SCRI Oncology Research Consortium Site Profile and provide the required documents requested on the form.

Upon receipt of your completed profile and required documents, we will contact you with follow up information pertaining to your potential membership in the Consortium. Should you have any questions please fee to contact Amy Perez in Administrative Operations at anytime at (615) 329-7493 or via email, amy.perez@scresearch.net.

With warm regards,

Patricia S. Graham
Senior Director,
SCRI Research Consortiums

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**SCRI ORC Site Profile
Site/Investigator Information**

Provide the legal name and address of the institution or corporation responsible for conducting research.

Name of Research Facility/Practice: _____

Address: _____

Address (con't): _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____

Internet Address: _____

Responsible Investigator: _____

Phone: _____ Mobile: _____ Email: _____

Lead Site Coordinator: _____

Phone: _____ Fax: _____ Email: _____

Investigational Drug Contact (list the name of the person responsible for study drug):

Address to ship investigational drug: _____

Phone: _____ Fax: _____ Email: _____

*** Please provide a copy of your research facilities drug destruction policy.**

Radiation Oncologist: _____

Phone: _____ Fax: _____ Email: _____

***Please provide a list of all Sub-Investigators including specialties and email addresses as an attachment in format below.**

Name	Address	Phone	Fax	Email	Specialty
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SCRI ORC Site Profile
Research Facility Information

Describe your facility:

- Hospital Clinic Research Facility Private Practice Public Health Clinic
 Other _____

What are your days and hours of operation? _____

Hospital Affiliation Name: _____ Phone: _____

Additional Hospital Affiliation Name: _____

Tax ID#: _____

Are there satellite offices for this practice: No Yes *(please provide a list of satellite locations as an attachment)

Nearest airport: _____

Distance from Site: _____

Does your site have an electronic records system? Yes No

If yes, what system _____

Is the system compliant with the electronic records regulations 21 CFR Part 11? Yes No

If no please explain: _____

Research History

How long has your site been conducting research?

- < 1yr. 1-5 yrs. Over 5 yrs.

What type of research has your site participated in?

- Industry Cooperative Group Investigator Initiated Other

If other, please explain: _____

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SCRI ORC Site Profile Research Facility Information

Which type studies are your investigators interested in participating in?

Phase I	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Phase II	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Phase III	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Phase IV	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Placebo-controlled	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Patterns of care/Outcomes	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

Patient Populations/Demographics

Pediatric	_____ %	Caucasian	_____ %	Male	_____ %
Adolescent	_____ %	African American	_____ %	Female	_____ %
Adult	_____ %	Hispanic	_____ %	Outpatient	_____ %
Geriatric	_____ %	Asian	_____ %	Inpatient	_____ %
		Other	_____ %		

Total clinic visits per day: _____

Total number of patients in practice database: _____

Investigator/Sub-Investigator Information

Have any of the investigators at this site ever been charged or sanctioned by any state medical board, i.e., has a license to practice medicine ever been suspended, revoked or restricted? Yes No

Are there any current medical board charges or criminal charges pending against any of the investigators? Yes No

Have any of the Investigators ever had privileges at any hospital revoked or restricted? Yes No

Have any of the Investigator ever been charged with a misdemeanor or felony that, in any way, relates to the practice of medicine? Yes No

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**SCRI ORC Site Profile
Regulatory/IRB Information**

Regulatory Coordinator: _____ Address: _____

Phone: _____ Fax: _____ Email: _____

Which type of IRB does your site utilize?

Local Central IRB, Specify _____

If local, what is the name of your IRB of record? _____

If applicable, how often does Local IRB meet? _____

Have you ever had an IRB terminate or suspend its approval of a study at your site? Yes No

(If yes please explain in detail on a separate page)

Have you ever had an IRB impose restrictions or sanctions on your site's ability to conduct a study?

Yes No *(If yes please explain in detail on a separate page)*

Have you ever had an IRB refuse to review a protocol for any investigator at your site? Yes No

(If yes, please explain in detail on a separate page)

Will your site be enrolling non-English speaking patients? Yes No

If yes, what secondary languages are prevalent in your patient population? _____

Do you have staff available at your site fluent in these secondary languages Yes No

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SCRI ORC Site Profile

FDA Information

Has your site and/or any Investigator(s) at your site ever been audited?

Yes No

If yes, check all that apply: Site audited by FDA Investigator audited by FDA

Was the date(s) of the FDA audit(s): _____

Please attach all audit related correspondence including but not limited to the Form 483, the Establishment Inspection Report (EIR), and the site's/Investigator's response, if any, to the FDA audit findings.

Have you ever had any subject seek compensation for injury as a result of their participation in a clinical research study?

Yes No

Has the FDA or NIH ever terminated a study at your site?

Yes No

Has the FDA or NIH ever issued a Warning Letter regarding a study at your site?

Yes No

Has the FDA or NIH ever sanctioned any principal, co-, or sub-investigator at your site?

Yes No

**IF YES, TO ANY OF THE ABOVE PLEASE PROVIDE A DETAILED EXPLANATION
ON A SEPARATE PAGE DESCRIBING HOW THIS ISSUE WAS RESOLVED.**

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**SCRI ORC Site Profile
Research Interest**

Please indicate your practice's interest in the following specialty specific questions.

Cancer Research	Interest
Bladder Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Bone Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Breast Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Brain Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Cervical Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Colon Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Endometrial Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Gastrointestinal Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Genitourinary Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Head and Neck Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Hematological Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Kaposi Sarcoma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Kidney Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Leukemia	<input type="checkbox"/> Yes <input type="checkbox"/> No
Liver Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Lung Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Lymphoma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Melanoma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Multiple Myeloma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Non-Hodgkins Lymphoma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Ovarian Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pancreatic Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Prostate Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Radiation-Related	<input type="checkbox"/> Yes <input type="checkbox"/> No
Soft Tissue Sarcoma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Solid Tumors	<input type="checkbox"/> Yes <input type="checkbox"/> No
Outcomes/Registry	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other (specify):	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other (specify):	<input type="checkbox"/> Yes <input type="checkbox"/> No

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SCRI ORC Site Profile Required Documents

Before returning site profile please make sure the following information is included:

Checklist

- CV's and Medical Licenses for any Physicians, Physicians Assistants, Nurse Practitioners and Pharmacist (CV's must be current, show affiliation with site, and be signed and dated)
- Lab Credentials (CLIA, CAP/COLA) with lab normal values
- Comprehensive contact list of your site's personnel (Please include full name, address, phone/fax number, and email address, and specialty)
- All audit related correspondence including but not limited to the Form 483, the Establishment Inspection Report (EIR), and the site's/Investigator's response, if any, to the FDA audit findings.
- List of all satellite offices (Please include name of facility, address, phone/fax, and email address for personnel)
- Copy of your research facilities drug destruction policies.
- Other (any additional documents you wish to provide)

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