



SARAH CANNON RESEARCH INSTITUTE

SCRI ONCOLOGY RESEARCH CONSORTIUM MEMBERSHIP APPLICATION

GENERAL INFORMATION

Date:

Name of Applicant Institution:

Mailing Address:

City:

State:

ZIP Code:

Telephone Number:

Fax Number:

Name of Applicant's Responsible Investigator:

Responsible Investigator (RI) E-Mail Address:

Address:

City:

State:

ZIP Code:

Hours of operation :

Do you have a 24/7 contact available for patients? Yes No

If yes, please specify:

Are you currently affiliated with an SMO (Site Management Organization)? Yes No

If yes, please specify SMO:

Are you currently a member of any Cooperative Groups? Yes No

If "Yes" please specify which Co-Op groups:

Indicate the characteristics of the site where patients will be enrolled into clinical trials and treated per the protocol: (Check all that apply)

- Inpatient Hospital – University
- Inpatient Hospital – Community
- Outpatient Clinic – Hospital based
- Outpatient – Private Practice
- HMO
- Multiple Specialty Group Practice

- Single Specialty Group Practice
- Single Physician Practice
- Group Physician Practice
- Hospital Based Practice
- Other (please describe):

Please complete application in its entirety and return to: Amy Perez, amy.perez@scresearch.net or fax to (615) 329-7593. If you have any question please contact me at (615) 329-7493

CLINICAL RESEARCH EXPERIENCE

Number of new cancer patients seen last year (approximate):

Inpatient:

Outpatient:

Number of new cancer patients seen each month:

Inpatient:

Outpatient:

How many years has the site been involved with clinical research trials:

How many clinical research studies are you currently conducting:

How many clinical research studies have you conducted in the past three years:

Please provide a separate comprehensive list of clinical research studies your site has conducted in the past three years

What percentage of your Institution's current studies are:

Industry Sponsored

Cooperative Group

Investigator Initiated

Other

What percentage of your Institution's historical studies are (past three years):

Industry Sponsored

Cooperative Group

Investigator Initiated

Other

Protocol Type Experience

Treatment Disease Management (Questionnaire, diagnostic/screening, etc)

Supportive Care Other, please state type:

Please describe the methods you have in place for patient recruitment:

INVESTIGATOR INFORMATION

How many Physicians do you have at your institution:

How many Medical Oncologists do you have at your institution:

How many Physicians at your institution are currently Investigators on clinical research studies:

What percentage of your Investigator's work time will be devoted to clinical research:

What human subject's protection (HSP) and good clinical practice (GCP) training and certifications have your Investigators received:

Please list above or provide a comprehensive list of completed training and certifications on a separate attachment

How many sub investigators do you have at your institution:

Have any of the investigators at your institution 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

If yes, please explain:

Are there any current medical board charges or criminal charges pending against any of the investigators at your institution?

Yes
 No

If yes, please explain:

Have any of the investigators at your institution ever had privileges at any hospital revoked or restricted?

Yes
 No

If yes, please explain:

Note- The following are required for each Investigator prior to contract execution

- Current signed and dated CV
- Copy of Medical License

CLINICAL RESEARCH STAFF/ADMINISTRATION

Does your institution have a dedicated study/site coordinator (SC) in place to conduct clinical research?

Yes
 No

Study/Site Coordinator Name:

Mailing address of (SC) if different from above:

City:

State:

ZIP code:

Telephone:

Fax:

Email Address:

Mobile:

Work Hours:

What human subjects protect (HSP) and good clinical practice (GCP) training and certification has your (SC) received:

Please list above or provide a comprehensive list of completed training and certifications on a separate attachment

What percentage of work time can your (SC) devote to clinical Research:

How many years/months of clinical research experience does your (SC) have:

How many years/months has your (SC) been employed at your institution:

Please provide any additional information related to your (SC) experience in clinical research:

Administrative official at institution with authority to commit institutional contracts:

Name:

Title:

Email:

Phone:

Address:

City:

State:

Zip Code:

Note The following are required for each research staff member prior to contract execution

- Current signed and dated CV
- Copy of Medical License

CLINICAL RESEARCH STAFF/ADMINISTRATION (cont.)

How many research nurses does your site/dept have:

How many research nurses will be involved in clinical research:

Does your Research Nurse/Support Staff have experience/access to the following:

RECIST criteria/tumor assessment
 NCI CTCAE toxicity grading
 Electronic Data Capture (EDC)– *Please Specify:* _____

Interactive Voice/Web Response System (IVWRS)
 Internet
 Electronic Medical Records (EMR) – *Please Specify:* _____

Which type of source documents are regularly utilized at your site? Paper Electronic Both

If electronic source documents are utilized, will the monitor have access to these documents? Yes No

If using hard copy (paper) CRFs will your site create shadow charts for research files? Yes No

Preference for Monitoring visits (if necessitated)

Days:

Time:

The following are required for each research staff member prior to contract execution

- Current signed and dated CV
- Copy of Medical License

RESEARCH PROCESS

Does this institution have research policies and procedures for the following:

Research Administration process for reviewing new studies Yes No

Protocol regulatory preparation and submission Yes No

Patient recruitment, consent and enrollment Yes No

Patient assessments (eligibility, toxicity and response) Yes No

Current IRB reporting system (w/timeframe for IRB acknowledgement) Yes No

Data collection and submission Yes No

COPIES OF YOUR INSTITUTIONS POLICIES/PROCEDURES MAY BE REQUESTED BY SCRI ORC PERIODICALLY

REGULATORY

Regulatory Contact:

Mailing address of (SC) if different from above:

City:		State:		ZIP code:	
Telephone:		Fax:		Email Address:	

Will your site/dept utilize the Central IRB selected by SCRI? (SCRI ORC utilizes WIRB)

Yes
 No

If "No" does site have access to a properly constituted IRB in compliance with FDA requirements and ICH guidelines?

Yes
 No

If "Yes" name of Local IRB:

Please specify or provide separately the Local IRB meeting schedule and submission deadlines:

Are there any approvals required prior to IRB submission?

Yes
 No

If "Yes" please provide details:

What is the average number of weeks from receipt of regulatory packet to IRB approval:

Has your site/Investigator been inspected by the FDA or similar regulatory agency in the past five years?

Yes
 No

If "Yes" please provide the following information in separate documentation:

Outcome of investigation Copy of 483 or equivalent document

Has your site/department ever had an IRB terminate or suspend its approval of a study?

Yes
 No

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

Yes
 No

Have you ever had an IRB refuse to review a protocol for any Investigator at your site?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will you be enrolling non-English speaking patients?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" what secondary languages are prevalent in your population:	
Do you have staff available at your site fluent in these second languages?	<input type="checkbox"/> Yes <input type="checkbox"/> No

FACILITIES

SATELLITE SITES

Will your site utilize satellite sites?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If yes, please provide drug shipment requirements (e.g. can drug be shipped to one central location or to each site)

PLEASE PROVIDE NAME AND ADDRESS OF ALL SATELLITE SITES IN A SEPARATE DOCUMENT

LABORATORY

Can you use a central laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you have a local laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

If "Yes" please list name and address of local laboratory:

Lab Director:

Address:		City:		State:	
Phone:		Fax:			

- The following are required for each laboratory used for research procedures prior to contract execution
- Laboratory Medical Director CV and License
 - CLIA and CAP Certificates
 - Normal Lab Values

LABORATORY (cont.)

Freezer temperature ranges:

Fridge temperature ranges:

If needed, will dry ice be available?

-
- Yes
-
-
- No

Do you have a refrigerated centrifuge?

-
- Yes
-
-
- No

Does your facility have a -80 centigrade freezer?

-
- Yes
-
-
- No

ASK
SARAH

1-877-MY-1-SCRI

asksarah@scresearch.net

dedicated service for research sites
and patients**PHARMACY**

Do you have a Pharmacist to prepare study drug?

-
- Yes
-
-
- No

If "No" please indicate who will be responsible for investigational drug:

Pharmacy Contact:

Central Drug Shipment Address:

City:

State:

Zip Code:

Telephone:

Fax:

Email Address:

Does the site have a handling area and storage facility for biological samples?

-
- Yes
-
-
- No

Does the site have adequate investigational product dispensing areas and secure storage facilities?

-
- Yes
-
-
- No

Does the site have adequate storage facilities for all study-related records and materials?

-
- Yes
-
-
- No

Will the main door of the pharmacy remained locked?

-
- Yes
-
-
- No

Does the site have a refrigerator for investigational product only?

-
- Yes
-
-
- No

If "Yes" is temperature monitored electronically?

-
- Yes
-
-
- No

Do you have a temperature alarm system?

-
- Yes
-
-
- No

Do you have a backup generator?

-
- Yes
-
-
- No

Do you have a freezer for investigational product only?

-
- Yes
-
-
- No

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CHEMOTHERAPY/EXAM ROOMS

How many exam rooms does your Institution have:

Does your Institution have dedicated chemotherapy suites:

If "Yes", how many chairs/beds:

Chairs:

Beds:

Please list any other amenities offered in your chemotherapy suites:

PATIENT POPULATION/DEMOGRAPHICS

Please specify the approximate demographic breakdown in percentages for the total patient population

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

Please indicate which type of studies are of interest to your Investigators

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
Outcomes/QOL	<input type="checkbox"/> Yes <input type="checkbox"/> No

PLEASE INDICATE YOUR PRACTICE'S INTEREST IN THE FOLLOWING SPECIALTIES

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 Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Melanoma Cancer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Multiple Myeloma	<input type="checkbox"/> Yes <input type="checkbox"/> No
Non-Hodgkin's 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 (please specify):	<input type="checkbox"/> Yes <input type="checkbox"/> No

CHECKLIST

BEFORE RETURNING SITE PROFILE, PLEASE MAKE SURE THE FOLLOWING INFORMATION IS INCLUDED

<input checked="" type="checkbox"/>	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)
<input checked="" type="checkbox"/>	Lab Credentials (CLIA, CAP/COLA) with lab normal values
<input checked="" type="checkbox"/>	Comprehensive contact list of your site's personnel (Please include full name, address, phone/fax number, email address and specialty)
<input checked="" type="checkbox"/>	All audit related correspondence including but not limited to; Form 483, Establishment Inspection Report (EIR) and the site's/Investigator's response, if any, to the FDA audit finding.
<input checked="" type="checkbox"/>	List of all satellite offices (Please include name of facility, address, phone/fax number and email addresses for personnel)
<input checked="" type="checkbox"/>	Copy of your research facilities drug destruction policy
<input checked="" type="checkbox"/>	Other (any additional documents you wish to provide)

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