Site Network Questionnaire (PDF)

Legal Name of Entity / Institution

Address 1

Address 2

City

States

Zip code

Point of Contact

First Name

Last Name

Title/Role

Degree(s)

Email

Phone

Address 1

Address 2

City

State

Zip Code

Physician Site Champion

First Name

Last Name

Title/Role

Degree(s)

Email

Phone

Fax

Address 1

Address 2

Address 3

City

State

Zip Code

Please identify who is completing this form

First Name

Last Name:

Email

Phone

Fax

Section 1: General Information

1a. Number of pediatric inpatient beds at your Institute

1b. Number of pediatric inpatient psychiatric beds at your institute

1c. Number of pediatric outpatient visits

2. Please identify any and all pediatric subspecialties you HAVE at your institute. Please add any additional areas not listed in the "other" text boxes below.

- ☐ Adolescent Medicine
- ☐ Ambulatory Pediatrics
- ☐ Behavioral Pediatrics
- ☐ Child Abuse
- ☐ Community Based Urgent Care
- ☐ Dermatology
- ☐ Endocrinology
- ☐ Genetics
- ☐ Infectious Disease
- ☐ Nephrology
- ☐ Orthopedics
- ☐ Pathology
- ☐ Psychiatry
- ☐ Pulmonary
- ☐ Rheumatology
- ☐ Surgery
- ☐ Other 2
- ☐ Allergy / Immunology
- ☐ Anesthesiology
- ☐ Cardiology
- ☐ Community Based Pediatric Offices
- ☐ Critical Care
- ☐ Emergency Medicine
- ☐ Gastroenterology
- ☐ Hematology/Oncology
- ☐ Neonatology (NICU)
- ☐ Neurology
- ☐ Pain Management
- ☐ Pharmacology / Toxicology
- ☐ Psychology
- ☐ Radiology
- ☐ Sports Medicine
- ☐ Other 1

Other 1

Other 2

3. Do any of your sub-specialty areas have access to a Clinical Research Center (CRC) / Clinical Trials Unit (CTU)?

- ○ Yes
- ○ No

4. Number of States in your catchment area?

5. What percentage of each racial background best composes your center's population of care (amounts in the boxes should sum to 100%):

a. American Indian or Alaskan Native

b. Asian American

c. Black or African American

d. Native Hawaiian or Pacific Islander

e. White or Caucasian American

6. What percentage of Non Hispanic/Latino ethnic background best composes your center's population of care (amounts in the boxes should sum to 100%):

a. Hispanic of Latino

b. Not Hispanic of Latino

7. For International Sites please complete (describe the background of your population served below):

8. Are you a birthing hospital / facility?

- ○ Yes
- ○ No, but affiliated with/access to a birthing facility
- ○ No

9. Is your Institution part of a Clinical and Translational Science Award (CTSA) or Clinical and Translational Science Institute (CTSI)?

- ○ Yes
- ○ No

9a. If yes, do you utilize any of the core services?

- ○ Yes
- ○ No

10. Which phases of clinical trials are your research teams capable of participating in?

- ☐ Phase 1
- ☐ Phase 2
- ☐ Phase 3
- ☐ Phase 4

11. Please check the consortium/pediatric research groups your institution is currently working with (if any):

- ☐ Childhood Arthritis and Rheumatology Research Alliance (CARRA)
- ☐ Childhood Liver Disease Research Network (ChiLDREN)
- ☐ Childrens Oncology Group (COG)
- ☐ COG Developmental Therapeutics Consortium
- ☐ Cystic Fibrosis Therapeutic Development Network (TDN)
- ☐ ImproveCareNow
- ☐ International Study Group of Pediatric Pancreatitis (INSPPIRE)
- ☐ Midwest Pediatric Nephrology Consortium
- ☐ National Experimental Therapeutics Consortium (NEXT Consortium)
- ☐ North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS)
- ☐ A National Pediatric Learning Health System (PEDSnet)
- ☐ Pediatric Acute Lung Injury & Sepsis Investigators (PALISI)
- ☐ Pediatric Blood and Marrow Transplant Consortium (PBMTC)
- ☐ Pediatric Critical Care Blood Research Network (BloodNet)
- ☐ Pediatric Heart Network (PHN)
- ☐ Pediatric Inflammatory Bowel Disease (PIBD) Collaborative Research Group
- ☐ Pediatric Neuro-Oncology Consortium (PNOC)
- ☐ Pediatric Rheumatology Collaborative Study Group (PRCSG)
- ☐ Pediatric Trials Network
- ☐ TrialNet
- ☐ Pediatric Diabetes Consortium (PDC)
- ☐ Other 1
- ☐ Other 2

Other 1

Other 2

12. Does your site have an established parent/child advocacy or engagement group with knowledge or experience in pediatric clinical trials?

- ○ Yes
- ○ No
- ○ It is a work in progress

Section 2: Satellite Site Information

1. Does your Institution have satellite sites where clinical trials are being conducted?

- ○ Yes
- ○ No

If yes, how many satellite sites?

2. What is the relationship between the Institution and the Satellite?

- ☐ Stand-alone Satellite
- ☐ Reliance on main hospital
- ☐ General affiliation with main hospital
- ☐ Other

3. What clinical services are available at the satellites?

- ☐ Outpatient Clinical Rooms
- ☐ Laboratory
- ☐ Pharmacy Services
- ☐ Radiology
- ☐ If no pharmacy service, able to transport investigational product to satellite
- ☐ Pediatric inpatient beds
- ☐ Long term care beds
- ☐ NICU beds
- ☐ Other

4. Are the satellites equipped and capable to enroll, screen, and treat subjects on pediatric clinical trials?

- ○ Yes
- ○ No

Section 3: Contact, IRB & Other Review Information

1. Does your site currently use Master Clinical Trial Agreements (MCTAs)?

- ○ Yes
- ○ No, but we would be willing to engage in this type of agreement
- ○ No

1a. Please indicate the sponsors with which you have MCTAs:

- ☐ Bayer
- ☐ Chiesi
- ☐ Eli Lilly
- ☐ Janssen
- ☐ Novartis
- ☐ Sanofi
- ☐ Amgen
- ☐ Roche
- ☐ Biogen
- ☐ Genetech
- ☐ Pfizer
- ☐ Other

2. Does your site currently use Master Confidentiality Disclosure Agreements (MCDAs)?

- ○ Yes
- ○ No, but we would be willing to engage in this type of agreement
- ○ No (skip to question 4)

2a. Please indicate the sponsors in which you have MCDAs:

- ☐ Bayer
- ☐ Chiesi
- ☐ Eli Lilly
- ☐ Janssen
- ☐ Novartis
- ☐ Sanofi
- ☐ Amgen
- ☐ Roche
- ☐ Biogen
- ☐ Genetech
- ☐ Pfizer
- ☐ Other

3. Does your institution require a fully executed contract prior to IRB submission?

- ○ Yes
- ○ No

4. What type of IRB does your site use?

- ◉ Institutional IRB ONLY
- ○ Central IRB ONLY
- ○ Local and Central IRB

5. If you answered 'Institutional IRB Only' would your institution be willing to use a Central IRB for studies conducted through I-ACT for Children?

- ○ Yes
- ○ No

6. If you use a Central IRB please note with which IRBs your site holds reliance agreements?

- [ ] Advarra (Chesapeake IRB, Quorum IRB, Schulman IRB)
- [ ] Sterling IRB
- [ ] Western Copernicus Group (Aspire IRB, Copernicus Group IRB, Hummingbird IRB, Midlands IRB, New England IRB, Western IRB)
- [ ] Other

6a. If Other, please provide detail:

7. IRB Review Timeline, please provide the following information:

- [ ] Meeting frequency per week
- [ ] Average number of business days from date of submission to final IRB approval
- [ ] Average number of business days from date of submission to "ready to enroll" first subject

7a. How many meetings per week?

7b. Provide # of days from 'submission date' to 'final IRB approval'

7c. Provide # of days from 'submission date' to 'ready to enroll' first subject

8. Does your Institution have a Scientific Review Committee?

- ○ Yes
- ○ No
- ○ For select types of protocols, please specify

8a. Please specify type of protocols

9. What is the average turnaround time for the Scientific Review Committee?

- ○ 1 week
- ○ 2 weeks
- ○ greater than 2 weeks
- ○ greater than 1 Month
- ○ greater than 6 Months
- ○ greater than 1 Year

10. If your Institution has other committees that must review industry sponsored clinical trials before they can be approved by the IRB, what is the average turnaround time?

- ○ 1 week
- ○ 2 weeks
- ○ greater than 2 weeks
- ○ greater than 1 Month
- ○ greater than 6 Months
- ○ greater than 1 Year
- ○ No other committees needed

Section 4: Clinical Trial Experience Information

Step 1: Please identify any and all areas in which your site conducts clinical trials by checking the box to the left, next to the sub-specialty.

1. Please place a check mark next to all that apply

- ☐ Acne
- ☐ Allergy/Immunology
- ☐ Antibiotic/Infections
- ☐ Asthma
- ☐ Cardiology
- ☐ Community Pediatric Offices
- ☐ Crohns Disease
- ☐ Device Research
- ☐ Eczema
- ☐ Epilepsy
- ☐ Genetics
- ☐ Hypertension
- ☐ JRA
- ☐ Multiple Sclerosis
- ☐ Nephrotic Syndrome
- ☐ Osteogenesis Imperfecta
- ☐ PK/PD Studies
- ☐ Psychiatry
- ☐ Pulmonary Hypertension
- ☐ RSV
- ☐ Substance Abuse
- ☐ Type 2 Diabetes
- ☐ Other 2
- ☐ ADHD/ODD
- ☐ Ambulatory Pediatrics
- ☐ Anti-Viral/Anti-Fungal
- ☐ Behavioral Pediatrics
- ☐ Celiac Disease
- ☐ Community Urgent Care
- ☐ Cystic Fibrosis
- ☐ Downs Syndrome
- ☐ Emergency Medicine
- ☐ Feeding Disorders
- ☐ Growth Hormone Def.
- ☐ Infectious Disease
- ☐ Migraines
- ☐ Neonatology (NICU)
- ☐ Neurology
- ☐ Pathology
- ☐ Post Op Pain Management
- ☐ Psychology
- ☐ Radiology
- ☐ Schizophrenia
- ☐ Surgery
- ☐ Vaccine
- ☐ Adolescent Medicine
- ☐ Anesthesiology
- ☐ Anxiety Disorders
- ☐ Birth Control
- ☐ Child Abuse
- ☐ Critical Care
- ☐ Dermatology
- ☐ Eating Disorders
- ☐ Endocrinology
- ☐ Gastroenterology
- ☐ Hematology/Oncology
- ☐ Irritable Bowel Syndrome
- ☐ Mood Disorders
- ☐ Nephrology
- ☐ Neuromuscular Disorders
- ☐ Pharmacology/Toxicology
- ☐ Prematurity
- ☐ Pulmonary
- ☐ Rheumatology
- ☐ Sports Medicine
- ☐ Type 1 Diabetes
- ☐ Other 1

Step 2: Please indicate the Top 5 Therapeutic Areas (from the list above) in which your site highly performs, has highly engaged principal investigators and research staff, achieves enrollment targets in most projects, etc.

We would like to obtain performance data about the 5 key areas you identified as your site's research strengths. Would you please provide the following:

Sub-specialty 1

Specialty Area / Question 1

a. In the past year, how many studies were conducted in this area

b. # of Investigator Initiated Studies- not sponsored funded

c. # of Investigator Initiated Studies- sponsored funded

d. # of Investigator Initiated Device Studies- not sponsor funded

e. # of Investigator Initiated Device Studies- sponsor funded

f. # of Industry Sponsored Trials

g. # of Industry Sponsored Device Trials

h. Was your site able to reach its enrollment for this sub-specialty?

- ○ Yes
- ○ No

If No, please provide a brief explanation

Sub-specialty 2

Specialty Area / Question 2:

a. In the past year, how many studies were conducted in this area

b. # of Investigator Initiated Studies- not sponsored funded

c. # of Investigator Initiated Studies- sponsored funded

d. # of Investigator Initiated Device Studies- not sponsor funded

e. # of Investigator Initiated Device Studies- sponsor funded

f. # of Industry Sponsored Trials

g. # of Industry Sponsored Device Trials

h. Was your site able to reach its enrollment for this sub-specialty?

- Yes
- No

If No, please provide a brief explanation

Sub-specialty 3

Specialty Area / Question 3

a. In the past year, how many studies were conducted in this sub-specialty?

b. # of Investigator Initiated Studies- not sponsored funded

c. # of Investigator Initiated Studies- sponsored funded

d. # of Investigator Initiated Device Studies- not sponsor funded

e. # of Investigator Initiated Device Studies- sponsor funded

f. # of Industry Sponsored Trials

g. # of Industry Sponsored Device Trials

h. Was your site able to reach its enrollment for this sub-specialty?

- Yes
- No

If No, please provide a brief explanation

Sub-specialty 4

Specialty Area / Question 4

a. In the past year, how many studies were conducted in this sub-specialty?

b. # of Investigator Initiated Studies- not sponsored funded

c. # of Investigator Initiated Studies- sponsored funded

d. # of Investigator Initiated Device Studies- not sponsor funded

e. # of Investigator Initiated Device Studies- sponsor funded

f. # of Industry Sponsored Trials

g. # of Industry Sponsored Device Trials

h. Was your site able to reach its enrollment for this sub-specialty?

- ○ Yes
- ○ No

If No, please provide a brief description

Sub-specialty 5

Specialty Area / Question 5

a. In the past year, how many studies were conducted in this sub-specialty?

b. # of Investigator Initiated Studies- not sponsored funded

c. # of Investigator Initiated Studies- sponsored funded

d. # of Investigator Initiated Device Studies- not sponsor funded

e. # of Investigator Initiated Device Studies- sponsor funded

f. # of Industry Sponsored Trials

g. # of Industry Sponsored Device Trials

h. Was your site able to reach its enrollment for this sub-specialty?

- Yes
- No

If No, please provide a brief description

Section 5: Research Team Information

1. Please check below all the members of your research team:

- [ ] Medical Director
- [ ] Principal Investigator
- [ ] Site Administrator / Director
- [ ] Business Development
- [ ] Budget Manager
- [ ] Legal / Contracts Coordinator
- [ ] Research Nurse / Study Nurse / Clinical Trials Nurse / Nurse Coordinator (LPN, RN, BSN, etc.)
- [ ] Research Coordinator / Study Coordinator (no nursing degree - not a nurse)
- [ ] Regulatory or IRB Coordinator
- [ ] Data Coordinator / Data Manager
- [ ] Laboratory Coordinator or Technician
- [ ] Training / Compliance Coordinator
- [ ] Research Pharmacist
- [ ] Feasibility Coordinator
- [ ] Other 1
- [ ] Other 2

Other 1

Other 2

2. For the core clinical research team please indicate the number of staff:

a. Research Nurse / Study Nurse / Clinical Trials Nurse

- ○ less than 5
- ○ greater than 5

b. Research Coordinator / Study Coordinator (non-nurse)

- ○ less than 5
- ○ greater than 5

c. Regulatory or IRB Coordinator

- ○ less than 5
- ○ greater than 5
- ○ none

d. Data Coordinator / Data Manager

- ○ less than 5
- ○ greater than 5
- ○ none

e. Research Pharmacist

- ○ less than 5
- ○ greater than 5
- ○ none

f. Laboratory Coordinator or Technician

- ○ less than 5
- ○ greater than 5
- ○ none

3. Is your research team part of a centralized clinical research infrastructure?

- ○ Centralized infrastructure
- ○ Decentralized infrastructure
- ○ Hybrid infrastructure (both Centralized and Decentralized infrastructure

4. How many clinical trials on average are you managing per year?

5. Of those clinical trials noted in Question 4, how many are the following:

(amounts in boxes should sum to 100%)

a. Percent of Industry sponsored under an IND

b. Percent of Investigator Initiated Drug Trials

c. Percent of Industry Sponsored Device Trials

d. Percent of Consortium Trials

e. Percent of Registry Trials

f. Percent Other, provide brief description

6. Are any members of the site research team certified through ACRP or SoCRA?

- ○ Yes
- ○ No

6a. How many?

7. Does your Institution encourage research certification?

- ○ Yes, it is encouraged and they cover ALL the associated costs
- ○ Yes, it is encouraged and they pay for a PORTION of the cost
- ○ Yes, it is encouraged but they do not pay for any of the associated costs
- ◉ No, it is not encouraged

8. How is specimen collection and processing handled at your site? (Please check all that apply)

- ☐ Study nurse collects specimens, processes them and ships them
- ☐ Study nurse collects specimens, study coordinator / study team processes them and ships them
- ☐ Subjects are sent to lab where samples are drawn, then study team processes and ships specimens
- ☐ Subjects are sent to lab where samples are drawn, processed and shipped
- ☐ Other

9. Please describe how your team approaches developing a recruitment plan for clinical trials? (Please check all that apply)

- ☐ Discussions with PI and research staff
- ☐ Discussions with Inpatient Staff
- ☐ Discussions with Outpatient Clinical Staff
- ☐ Discussions with Satellite Clinical Staff
- ☐ Discussions with all staff in which the protocol may interface
- ☐ Discussions with the Clinical Trials Office
- ☐ Electronic Medical Record Query of Potential Patients
- ☐ Telehealth System
- ☐ Use of your own Research Website
- ☐ Other

10. Please describe how your team approaches maximizing retention for clinical trials? (Please check all that apply)

- ☐ Coordinator to subject phone calls throughout the study
- ☐ Subject stipends
- ☐ Mailings
- ☐ Automated emails
- ☐ Clinical Trial Management System
- ☐ Text Communication
- ☐ Parent Reimbursement for time off from work
- ☐ Travel Expenses Covered - mileage, parking, overnight stays
- ☐ Provide patient specific study calendars and information
- ☐ Other Methods

Section 6: Research Team Training

1. Please describe the clinical research training the research team has completed. (Please check all that apply)

- [ ] Human Subjects Protection- OTHER
- [ ] Human Subjects Protection - CITI
- [ ] Institution developed clinical research training
- [ ] Good Clinical Practice - Investigational Drugs/Devices- CITI
- [ ] Good Clinical Practice - Investigational Drugs/Devices- OTHER

1a. Human Subjects Protection 'Other', please describe

1b. CGP Investigational Drugs/Devices 'Other', please describe

2. If training is listed in Question 1, is this training required or suggested?

- ○ Required
- ○ Suggested

3. If training listed in Question 1 is required, does it apply to all members of the study team or select members?

- ○ All
- ○ Select

3a. Please indicate the select groups

4. Does your Institution support or fund continuing education opportunities for staff to educational conferences that relate to clinical research?

- ○ Yes, but does not fund
- ○ Yes, Institution does fund
- ○ No

Section 7: Research Compliance Information

1. Does your Institution / site have Clinical Research Standard Operating Procedures (SOPs) in place?

- ○ Yes
- ○ No

2. Has the Institution, site or principal investigator at the Institution been audited by a regulatory agency (FDA, OIG, OHRP) in the past 2 years?

- ○ Yes
- ○ No

3. Which agency conducted the audit (please check all that apply)?

- ☐ FDA
- ☐ OIG
- ☐ OHRP

4. What was the reason for the audit (please check all that apply)?

- ☐ For cause
- ☐ Routine
- ☐ Re-audit
- ☐ Investigator
- ☐ IRB

5. What was the outcome of the audit?

- ○ No Action Indicated
- ○ Voluntary Action Indicated
- ○ Official Action Indicated

Section 8: Research Facility Information

Do you have the following facilities / equipment / resources available on site?

- [ ] Dedicated research space to conduct study visits
- [ ] Adequate space to conduct study visits
- [ ] Overnight research space greater less than 24 hours
- [ ] Overnight research space greater than 24 hours
- [ ] Satellite sites used for subject recruitment
- [ ] Satellite sites used for clinical trial conduct
- [ ] Blood Pressure Monitors
- [ ] Scale
- [ ] Wheelchair accessible scale
- [ ] Stadiometer
- [ ] Height and Head circumference (length) measure
- [ ] 12 lead ECG machine
- [ ] Local laboratory for analysis of safety labs
- [ ] Adequate space to process and ship specimens
- [ ] Adequate space to store specimens
- [ ] Centrifuge
- [ ] Refrigerated Centrifuge
- [ ] Specimen Refrigerator
- [ ] Specimen Freezer (-20°C)
- [ ] Specimen Freezer (-80°C)
- [ ] Research Pharmacy
- [ ] Psychological Assessments (IQ, Behavior, Achievement, Developmental, etc.)
- [ ] Ability to record / videotape study visit assessments
- [ ] Experience with electronic data capture
- [ ] Experience with electronic diaries, surveys, etc.
- [ ] Experience with pediatric PK/PD studies
- [ ] High speed internet access
- [ ] International fax / telephone line
- [ ] Monitoring Space
- [ ] Secure, climate-controlled, long term record archival facility
- [ ] On-site record archival
- [ ] Off-site record archival
- [ ] Electronic Health Records
- [ ] Tracking system for laptop use for research
- [ ] Tracking system for tablet use for research
- [ ] Tracking system for smartphone use

Provide any comments or additional facilities / equipment / resources not noted in the chart above

Section 9: Investigational Drug / Product Information

1. Does your site employ a research pharmacist?

- ○ Yes, we have research dedicated staff
- ○ Yes, we have research dedicated staff as part of the hospital pharmacy services
- ○ No, we use hospital provided pharmacy services
- ○ Other

2. If your site has a research pharmacist(s), how many full-time equivalents (FTEs) do you have?

3. Is all investigational product stored separately from non-investigational medications?

- ○ Yes
- ○ Most (please explain)
- ○ No (please specify where it is stored)

3a. If Most, Please briefly explain

3b. If No, Please specify where it is stored

4. Does the Institution/site require Good Clinical Practice (GCP) training for personnel managing investigational products?

- ○ Yes
- ○ No

5. Does the Institution/site have Standard Operating Procedures (SOPs) for investigational drug receipt, management, temperature monitoring and closeout?

- ○ Yes
- ○ No

Other: Any other information that you would like to share regarding your site that is unique to conducting pediatric clinical trials?

Required Files

When submitting this questionnaire, please also provide the following attachments:

CV of Physician Site Champion

Prepare to Attach Document in Web-based Online Submission

Maximum upload size: 134.22MB

Organizational Chart for your clinical research team

Prepare to Attach Document in Web-based Online Submission

Maximum upload size: 134.22MB

Copies of any 483s in the past 2 years (if applicable)

Prepare to Attach Document in Web-based Online Submission

Maximum upload size: 134.22MB

Submit

Contact Info

Phone (301) 605 - 7571

Email info@iactc.org (mailto:info@iactc.org)

Address 9211 Corporate Blvd, Suite 260 Rockville, MD 20850