Toolkit for Site Readiness for Performing Clinical Trials in Pediatric Nephrology

I. Overview

Implementation and conduct of a clinical study is a complex process that involves a team from various departments and multiple steps that are inter-dependent. The TDC and RC of the ASPN has developed this checklist to help sites or investigators prepare for the rigors of conducting research that involves children with kidney disease as human subjects. **The questions were adapted from feasibility checklists used by industry sponsors and CROs (clinical research organizations), to facilitate ASPN members to advocate for / build the necessary resources within their institution. Comments are included to provide the purpose for these questions when asked by sponsors or CROs.** The purpose of this toolkit is to help identify the issues that we feel are necessary for your division to be successful in industry sponsored trials and registries.

II. Site Information

Legal/official institutional name	
Type of institution:	Hospital Public ❑ Clinical - Group Practice ❑ Hospital – Private ❑ Clinical – Solo Practice ❑ Charitable ❑ Other ❑ Specify:
Principal Investigator (PI)	Name: Credentials: Address: Office phone: Cell: Office Fax: Email:
Sub-investigators (sub-I)	Name: Credentials: Address: Office phone: Cell: Office Fax: Email:
Does your institution have a central or departmental research coordinator:	

If yes, specify contact: If no central research coordinator is available, who will serve as research coordinator:	Department name: Contact person: Address: Office phone: Office Fax: Email:
What is the hourly fee for research coordinators:	
Number of providers at your site/in division:	
Do you know how to find the number of active patients with condition X at your site:	
Number of active clinical research studies at your site:	
In the last 3 years, were enrollment targets for studies met:	Yes ❑ No ❑
Number of active clinical research studies involving condition X:	
Are any other providers in your department willing to support your clinical trial:	 Yes ❑ No ❑

III. Laboratory

Does your institutional laboratory perform test the following: If yes, provide the cost of each:	Hematology Yes ❑ No ❑ Cost _____ Pathology Yes ❑ No ❑ Cost _____ Histopathology Yes ❑ No ❑ Cost _____ Serology Yes ❑ No ❑ Cost _____ Immunology Yes ❑ No ❑ Cost _____ X-ray Yes ❑ No ❑ Cost _____ MRI Yes ❑ No ❑ Cost _____ CT Yes ❑ No ❑ Cost _____ Other _____
Lab head and study lab coordinators:	Name: Role: Address: Office phone: Office Fax: Email: Preferred contact method and time:
Does your lab have any accreditations: If yes, specify (CLIA, APA etc):	Yes ❑ No ❑
Where do study subjects go for phlebotomy/sample collection: Where can you find rates for phlebotomy/sample collection:	Department name: Location:
Is there a charge for lab collection if not done with standard of care testing:	Yes ❑ No ❑
Who provides sample collection materials:	Collection site ❑ PI ❑ Other_____
Is your laboratory working as a referral laboratory:	Yes ❑ No ❑
Name of lab for any outsourced labs or procedures:	Name: Lab/procedure: Contact person: Address: Office phone: Office Fax: Email:
What is the turn-around time for standard and stats assays:	Standard: _____ Stat:_____

IV. Protocol-related Facilities and Equipment

Where will subjects be seen: Please list addresses for each site where research subjects will be recruited and where study visits will occur:	Address: Distance from main site	
Where will research samples be processed:		
Does each site have a dedicated 4°C refrigerator for clinical research with temperature monitor:	Yes ❑	No ❑
Does each site have a dedicated -20°C freezer with temperature monitor for specimen storage:	Yes ❑	No ❑
Does each site have a dedicated -70°C freezer with temperature monitor for specimen storage:	Yes ❑	No ❑
Does each site have a refrigerated and non-refrigerated centrifuge:	Yes ❑	No ❑
Does the site have access to dry ice for shipping: If yes, specify designated trainee with appropriate certification (e.g. IATA certification)	Yes ❑	No ❑
Does the site have locked storage for storage of study documents:	Yes ❑	No ❑
Does the site have adequate storage space for study materials (test kits, tubes, supplies etc):	Yes ❑	No ❑

V. Pharmacy

Does your institution have an Investigational Pharmacy: If yes, specify contact:	Yes ❑ Name: Address: Office phone: Office Fax: Email:	No ❑
Is there a start-up fee for a new study with the Investigational Drug Pharmacy: What is that fee?	Yes ❑	No ❑
Does the site have a dedicated Drug storage cabinet / fridge / freezer with temperature and humidity monitor:	Yes ❑	No ❑
How will your institution dispense study drug:		

VI. Regulatory and Legal Requirements 

Do you know where to find your institutions standard operating procedures (SOP) for participation in clinical trials:	Yes ❑	No ❑
Does your institution permit central IRBs: If yes, central IRB contact:	Yes ❑ Name: Address: Office phone: Office Fax: Email:	No ❑
Do you know where to find the list of reliance IRBs:	Yes ❑	No ❑
If your institution requires local IRB review and approval:		
Does your institution require a specific format for a new IRB submissions:	Yes ❑	No ❑
When does the IRB review committee meet:		
How soon before IRB committee meeting do documents need to be submitted:		
How long does it typically take to approve IRB (from submission of IRB proposal to receipt of approval letter):		
How long between IRB approval and site initiation visit:		
Is contract and budget completion required prior to IRB submission/approval:	Yes ❑	No ❑
What are your IRB fees for industry sponsored grants:		

Who is your business office contact to help develop budget:	Name: Address: Office phone: Office Fax: Email:
What are your institutional indirect costs: If company sponsored research does not support indirect costs, does your business office know how to prepare budget:	Yes ❑ No ❑
Are there additional approval or review committees at your institution (e.g. CRC): If yes, contact and turn-around time?	Yes ❑ No ❑ Name: Address: Office phone: Office Fax: Email: Submission and approval timeline:
Does your institution have dedicated recruitment specialists:	Yes ❑ No ❑
Who is your contact for execution of Data Use Agreements (DUA) Material Transfer Agreements (MTA): 	Name: Address: Office phone: Office Fax: Email:
Are you authorized to sign a confidential disclosure agreement (CDA): If no, who is legal designee:	Yes ❑ No ❑
Is there a legal person to review the Clinical Trial Agreement (CTA): If yes, what is the timeline for this review:	Name: Address: Office phone: Office Fax: Email:
What is the average time for contract execution (i.e. including budget review, start to finish):	

VII. Data, Quality, and Safety Management

What EHR do you use: Will clinical study monitor have access: If not, what is the procedure for source document verification:	 	Yes ❑	No ❑
Can your patient database OR EHR be searched for screening purposes based on study requirements and eligibility:		Yes ❑	No ❑
Do you have any experience with RedCap: If no, do you have any local resource for training and support:		Yes ❑ Yes ❑	No ❑ No ❑
Does your IT department provide dedicated server space for secure clinical trial documents:		Yes ❑	No ❑
Does your operating system support specialty software required to participate in study:		Yes ❑	No ❑
Does your institution have any specific requirements for the transmission of data from devices or other monitoring equipment:		Yes ❑	No ❑