American Society of Pediatric Nephrology

SURVEY ON SITE READINESS FOR CLINICAL TRIALS IN PEDIATRIC NEPHROLOGY

The goal of this survey is to assess the interest and the needs of the Pediatric Nephrology community for involvement in prospective clinical research. The survey is supported by ASPN Council, the ASPN Research Committee (RC) and the ASPN Therapeutics Development and Research Committee (TDC). The survey is now open, and responses will be collected thru January 31, 2020.

The ASPN is interested in improving access to clinical research trials for all of our patients, and the TDC and RC have together declared 2019 to be "The ASPN Year of Clinical Trial Site Readiness" as part of their educational mission. Survey results will be used to design the workshop to be held at the 2020 ASPN meeting in Philadelphia, "Secrets to Developing (and Sustaining) a Clinical Research Program that Every Institution Wants."

Many of these questions will require some research so would recommend printing out the attached PDF version of this survey and completing as a division / section *(We recommend completing this at a division meeting). Please answer questions with respect to your institution or practice (as opposed to you personally as an individual). If your division includes individuals who practice internal medicine, answers would apply only to the pediatric nephrology part of the practice*

The Therapeutics Development Committee has developed a Toolkit to help sites improve their readiness for participation in clinical trials. This Toolkit is available online in the members-only section of the ASPN website. We recommend reviewing and referring to the Toolkit in preparation for completing this survey.

Aggregate anonymized survey results will be made available on the members-only section of the ASPN website, and may be shared with ASPN's industry partners, and hopefully will be published. Individual responses will NOT be shared outside of the ASPN's TDC and RC, and will be held strictly confidential.

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1. What is your division/section's current level of participation (or future interest for participation) in clinical research? (select all that apply)

    a. Sponsored prospective interventional studies (drugs and devices)
    b. Sponsored prospective observational studies (registries, epidemiology, and outcomes research)
    c. Unsponsored research including registries and retrospective studies
    d. No interest

2. Is the primary appointment for pediatric nephrologists within a dedicated division/section? Y/N

3. Which term best describes your practice?

    a. Academic/University
    b. Private practice
    c. Other: _____

4. "Please consider providing the full name for the center for which your survey responses apply (optional, but encouraged):" _____

The following questions specifically relate to interventional clinical trials.

5. How many pediatric nephrology providers (who see patients independently, including NPs, PAs that would enroll subjects) in your practice would participate (i.e. enroll subjects) in a clinical study?

   - 0
   - 1
   - 2-3
   - 4-5
   - 6-10
   - > 10

6. How many distinct **investigator initiated** interventional trials (*includes trials that were initiated at your site or another site and were not organized by a pharmaceutical company. They could be NIH-funded, etc. or sponsored by a pharmaceutical company, but designed and organized by an academic physician*) has your site participated in over past 3 years?

   - 0
   - 1
   - 2 - 3
   - 4 - 5
   - 6 - 10
   - > 10

7. Over the past 3 years, how many distinct **industry sponsored** interventional trials (*drug or device organized by a pharmaceutical company/industry*) have you participated in as a site?

   - 0
   - 1
   - 2 - 3
   - 4 - 5
   - 6 - 10
   - > 10

8. Of the **sponsored** interventional trials that have been active at your site over the past 3 years, how many have **NOT** reached your enrollment target?

   - 0
   - 1
   - 2 - 3
   - 4 - 5
   - 6 - 10
   - >10

Research Support Personnel

9. To whom do your available research study staff (coordinators) report?

    a. your Pediatric Nephrology section / division
    b. a centralized group in your Pediatrics Department outside the section / division
    c. a centralized office outside the Pediatrics department but within the institution
    d. we contract with a separate clinical studies group outside of the institution
    e. I don't know
    f. We do not have any available research study staff

    - *If a, go to Q#10*
    - *If b-c, go to Q#11*
    - *If d-f, go to Q#12*

10. Do your available research coordinator(s) also have clinical responsibilities? Y/N

11. Do(es) the same individual(s) perform research coordination (consent, data entry, etc.) and regulatory roles (contracts, IRB, etc.)? Y/N

    - *If Y, go to Q#13*

12. To whom do your available regulatory coordinator(s) report?

    a. within your Pediatric Nephrology section / division
    b. within a centralized group in your Pediatrics Department outside the section / division
    c. within a centralized office outside the Pediatrics department but within the institution
    d. we contract with a separate clinical studies group outside of the institution
    e. I don't know

13. Who in your practice interacts on behalf of principal investigators with legal, regulatory and study management offices at your institution?

    a. Research administrator in your Pediatric Nephrology division/section
    b. Research administrator in your Pediatrics Department outside the section / division
    c. Research administrator outside your Pediatrics Department, but within the institution
    d. Clinical administrators in your Division/Section and/or Department
    e. I don't know

IRB / Available facilities / Equipment / Study resources

14. Does your institution accept external (commercial or academic) IRBs (in lieu of internal review) for at least some prospective clinical trials? Y/N/?

15. From receipt of full protocol, assuming no delays by the study sponsor, what is your institution's mean time for contract execution in months?

    - < 2 months
    - 2 - 4 months
    - 5 - 9 months
    - > 10 months
    - I don't know

16. Where are subjects for clinical trials seen for research visits?

    a. In your clinic (dedicated rooms)
    b. In your clinic (same rooms as routine clinical care)
    c. In a dedicated clinical research unit such as a CTSA or Clinical Research Center (CRC) or equivalent (not allowed to use same rooms as routine clinical care)
    d. In clinic or CTSA / CRC (study dependent / visit dependent)
    e. I don't know

17. Do you have access to the following equipment/resources for use in clinical trials? Answer "Y" if free, "$" if for cost, "?" if unknown, or "N" if unavailable

Locked cabinet for confidential study documents	Y/N/$/?
Research pharmacy with controlled access to investigational product	Y/N/$/?
Refrigerated Centrifuge (in division or core facility)	Y/N/$/?
Refrigerator (in division or core facility)	Y/N/$/?
Freezer (-20) (in division or core facility)	Y/N/$/?
Freezer (-80) (in division or core facility)	Y/N/$/?
Dry ice for shipping (with certification) (in division or core facility)	Y/N/$/?
Sample processing core facility (either within or outside section / division)	Y/N/$/?

Survey ends, "*thank you for completing the survey*"

Disclosures:

For questions or concerns about this survey, please feel free to reach out to any of the members of the Working Group for Site Readiness for Clinical Trials in Pediatric Nephrology:

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