

## TABLE OF CONTENTS

The section titles and sub-sections below are hyperlinks to its corresponding page within this document.

<b>1. Overview</b>	<b>2</b>
<b>2. Criteria</b>	<b>2-3</b>
2.1 General Criteria	2
2.2 Additional Factors that Should be Considered	3
<b>3. Approval</b>	<b>3</b>
<b>4. Types of Research Opportunities</b>	<b>3-9</b>
4.1 PKIDS Member-Initiated	3-4
4.2 Outside Investigator-Initiated	4-6
4.3 Industry-Initiated	6-8
4.4 Collaborations with Other Research Networks	8-9

## 1. Overview

As a large research network and the only one dedicated to the generation and application of knowledge to improve care for pediatric patients with kidney stone disease, the Pediatric KIDney Stone (PKIDS) Care Improvement Network is an ideal platform to conduct impactful comparative effectiveness and health services research, clinical trials of therapeutics, evaluation of medical devices, and evaluation of the epidemiology of stone disease. The purpose of this statement is to provide guidelines for how new research proposals will be considered in PKIDS.

## 2. Criteria

### 2.1 General Criteria

- **Absolute:** All research proposals that would be considered must meet the following criteria
  - Advance the PKIDS Mission: To improve care for and the lives of children with kidney stone disease through collaborative patient-centered research
  - Offer an opportunity to grow the reach and/or impact of PKIDS
  - PKIDS sites should have the opportunity to participate at a level determined by and consistent with their interest, resource structure, and capacity
  - Have clearly defined objectives and hypotheses that are supported by a research plan
  - Ethical soundness and ability to be approvable by IRB
  - Be proposed by or sponsored by a PKIDS member in “good standing”, which is determined by active regulatory approval and meeting prior commitments/deadlines.
    - PI of proposal has not had any significant delays in meeting prior PKIDS academic deadlines (i.e. production of previously promised manuscript, delayed responses in research committee feedback, etc.).
    - Site from which proposal is emanating will be in good regulatory standing for PKIDS with both their internal IRB and the CHOP IRB.

## 2. Criteria

### 2.2 Additional Factors that Should be Considered

- Burden on PKIDS investigators and staff
- Financial support provided
  - For research procedures
  - For investigators
  - For staff
- Value the contributions of PKIDS members

## 3. Approval

1. Approval by a majority of the PKIDS Publications and Study Initiation Committee
  - a. A quorum of four voting members must be present at the time of the Committee vote
  - b. In the instance in which the proposing individual is a member of the PSIC, the individual will recuse her/himself from the Committee vote
  - c. In the event of a tie vote, the Associate Director of PKIDS will review the proposal in question and provide a deciding vote
2. Consent by the PKIDS site PI for their site to participate

## 4. Types of Research Opportunities

### 4.1 PKIDS Member-Initiated

#### a. Types

- i. **Secondary analysis:** A PKIDS Member (Investigator, manager, or coordinator) or nested group of PKIDS members (e.g. investigators at PEDSnet sites) proposes a study that would use data already collected as part of ongoing research.
- ii. **New investigation:** A PKIDS Member (Investigator, manager, or coordinator) or nested group of PKIDS members (e.g. investigators at PEDSnet sites) proposes a new study that requires a new protocol or amendment to an existing protocol.

## 4. Types of Research Opportunities

### 4.1 PKIDS Member-Initiated (continued)

#### b. Requirements

- i. Research plan, including statistical analysis plan
- ii. Timeline for completion
- iii. Demonstration of appropriate resources to implement plan
- iv. Resources provided by PKIDS Required if increases effort by PKIDS investigators and/or staff
- v. Not required if the collaboration does not increase burden on PKIDS members or detract from PKIDS-initiated studies
- vi. If site-level IRB review is required, IRB fees for participating sites must be covered by study funds, if unable to be absorbed/waived at the site level
- vii. In instances of industry involvement, negotiation of a budget for the work to be performed may be required. The DCC can assist with formulation of said budget

#### c. Authorship

##### i. Requirements

1. Per Publications Guidelines
2. PKIDS and external research network investigators must meet all ICMJE requirements for authorship

##### ii. Expectations

1. All PKIDS investigators and other members who meet ICMJE requirements for authorship will be included

### 4.2 Outside Investigator-Initiated

#### a. Types

- i. **Secondary analysis:** An outside investigator proposes a study that would use data already collected as part of ongoing PKIDS research.
- ii. **New investigation:** An outside investigator proposes a new study that requires a new protocol or amendment to an existing protocol.

## 4. Types of Research Opportunities

### 4.2 Outside Investigator-Initiated (continued)

#### b. Requirements

- i. Research plan, including statistical analysis plan
- ii. Timeline for completion
- iii. Demonstration of appropriate resources to implement plan

#### c. Resources provided by PKIDS

- i. Access to data
- ii. Submitting amendment to existing protocol or new protocol  
(NB- the protocol would be written by the outside investigator)
  1. The DCC will submit the proposal to the CHOP IRB for review and approval. If necessary, site-level submissions are the responsibility of each participating center

#### d. Deliverables

- i. 300-word abstract describing research findings (to be used for progress reports and internal tracking)
- ii. Work product including, but not limited to
  1. Abstract to meeting
  2. Presentation
  3. Manuscript

#### e. Funding

- i. Required if increases effort by PKIDS investigators and/or staff
- ii. Not required if the collaboration does not increase burden on PKIDS members or detract from PKIDS-initiated studies
- iii. If site-level IRB review is required, IRB fees for participating sites must be covered by study funds, if unable to be absorbed/waived at the site level

## 4. Types of Research Opportunities

### 4.2 Outside Investigator-Initiated (continued)

#### f. Authorship

##### i. Requirements

1. Per Publications Guidelines
2. PKIDS and external research network investigators must meet all ICMJE requirements for authorship

##### ii. Expectations

1. All PKIDS investigators and other members who meet ICMJE requirements for authorship will be included

### 4.3 Industry-Initiated

#### a. Types

- i. **Secondary analysis:** Industry, with or without collaboration with PKIDS investigator, proposes a study that would use data already collected as part of ongoing PKIDS research.
- ii. **New investigation:** Industry, with or without collaboration with PKIDS investigator, proposes a new study that requires a new protocol or amendment to an existing protocol.

#### b. Requirements

- i. Research plan, including statistical analysis plan
- ii. Timeline for completion
- iii. PKIDS Investigator partner(s)

#### c. Resources provided by PKIDS

- i. Access to data and/or patient population
- ii. Partnership in developing and revising research question and plan
- iii. Submitting amendment to existing protocol or new protocol

1. The DCC will submit the proposal to the CHOP IRB for review and approval. If necessary, site-level submissions are the responsibility of each participating center.

## 4. Types of Research Opportunities

### 4.3 Industry-Initiated (continued)

- iv. Implementation of research plan
- v. Statistical analysis (if required)
- d. Deliverables
  - i. 300-word abstract describing research findings
    - 1. to be used for progress reports and internal tracking
    - 2. to be written by PKIDS investigator
  - ii. Work product written by PKIDS investigator(s) and or Industry partner(s) including, but not limited to:
    - 1. Abstract to meeting
    - 2. Presentation
    - 3. Manuscript
  - iii. Additional documentation requested by Industry partner
- e. Funding: required (approval needed by all PKIDS members/sites involved in proposed study)
  - i. Salary support
  - ii. Research support
  - iii. IRB fees per participating institution requirements
  - iv. Indirects per CHOP/participating institution requirements
- f. Conflicts of Interest
  - i. Disclosure of financial interests per sponsor and institution policies.
  - ii. Documentation of management plan for potential conflicts, per institution policy.
- g. Authorship
  - i. Requirements
    - 1. Per Publications Guidelines
    - 2. PKIDS and external research network investigators must meet all ICMJE requirements for authorship

## 4. Types of Research Opportunities

### 4.3 Industry-Initiated (continued)

#### ii. Expectations

1. All PKIDS investigators and other members who meet ICMJE requirements for authorship will be included

### 4.4 Collaborations with Other Research Networks

a. Definition: Collaboration with existing research networks to compare findings in new populations or access new populations

#### b. Requirements

- i. Research plan, including purpose and means of accessing PKIDS populations
- ii. PKIDS Investigator partner(s)

#### c. Resources provided by PKIDS

- i. Access to data and/or patient population
- ii. Submitting amendment to existing protocol or new protocol
  1. The DCC will submit the proposal to the CHOP IRB for review and approval. If necessary, site-level submissions are the responsibility of each participating center.

#### iii. Implementation of research plan

#### d. Deliverables

- i. 300-word abstract describing research findings (to be used for progress reports and internal tracking). To be written by PKIDS investigator or collaborative partner
- ii. Work product written by PKIDS investigator(s) and or Industry partner(s) including, but not limited to:
  1. Abstract to meeting
  2. Presentation
  3. Manuscript



## 4. Types of Research Opportunities

### 4.4 Collaborations with Other Research Networks (continued)

#### e. Funding:

- i. Required if increases effort by PKIDS investigators and/or staff
- ii. Not required if the collaboration does not increase burden on PKIDS members or detract from PKIDS-initiated studies
- iii. If site-level IRB review is required, IRB fees for participating sites must be covered by study funds, if unable to be absorbed/waived at the site level

#### f. Authorship

##### i. Requirements

1. Per Publications Guidelines
2. PKIDS and external research network investigators must meet all ICMJE requirements for authorship

##### ii. Expectations

1. All PKIDS investigators and other members who meet ICMJE requirements for authorship will be included.