

# NephCure Kidney Network Research Committee Standard Operating Procedure

*Approved:*

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## Contents

Purpose ..... 2

Scope..... 2

Committee Operations ..... 2

    Member Composition and Terms ..... 2

    Member Expectations..... 3

    Voting Procedures..... 3

Procedure..... 3

    1. Feasibility and Burden Initial Review by Project Team ..... 3

    2. Research Committee Review ..... 4

    3. Steering Committee Review ..... 4

    4. Letter of Support..... 4

Review Criteria ..... 5

    Feasibility and Burden..... 5

    Research Committee Criteria..... 5

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## Purpose

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The NephCure Kidney Network (NKN) is an innovative initiative led by NephCure Kidney International (NKI) and Arbor Research Collaborative for Health (Arbor Research) to establish a patient-powered research network (PPRN) for Nephrotic Syndrome (NS) patients. The goal of the NKN is to facilitate the conduct of timely, accurate, and efficient research related to NS that will provide information about the best available evidence to help patients and providers make more informed decisions.

The NKN allows important clinical and patient-reported data to be contributed, under patient control, to a centralized repository, facilitating rapid development and execution of research studies. The establishment of a research network with readily available clinical and patient-reported data, an organizational structure that includes patients in the governance process, and direct partnership with patients who are seeking opportunities to be a part of the solution to better health will facilitate much-needed advances for patients with this rare and devastating condition.

The NKN Steering Committee (SC) serves as the primary governance locus for the network. The NKN Research Committee (RC), a subset of the SC, will ensure that all research conducted by the NKN or utilizing NKN non-data resources involves patients as partners in every step of the research process and matches the research priorities of the NKN patient Community.

## Scope

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As part of the NKN's goal to facilitate the conduct of timely, accurate, and efficient research related to NS, the NKN accepts requests from researchers ("the investigator") to conduct research that utilizes the NKN research infrastructure. The RC was convened in order to assess these requests and ensure alignment with the NKN mission.

The NKN RC will oversee all research requests that:

- List or seek to list the NKN as a collaborating entity;
- Seek to recruit NKN patient registrants for research study participation;
- Are proposed by the NKN Project Team (NKI and Arbor Research employees who participate in NKN operational activities) and utilize NKN resources;
- Involve any NKN Project Team members participating on a research project specifically in connection with their role as an NKN team member.

The NKN RC will not oversee any decisions regarding access to the NKN's patient-reported data repository. For all data access requests, please refer to the *NKN Data Access Committee Standard Operating Procedure*.

## Committee Operations

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### Member Composition and Terms

The NKN RC will be comprised of five (5) or seven (7) people, with no fewer than three (3) or four (4), respectively, members being either NS patients or caregivers. The remainder of the members are required to have experience in research and be able to speak to the scientific validity of any proposal.

Nominations for new RC members may be made by RC, NKN Project Team, or SC members at any time. Nominations for RC members must be approved by the NKN SC and such approval will not normally be withheld.

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The RC may have one Chair or two Co-Chairs. The initial Chair of the RC was appointed by the NKN Project Team. Each RC Chair is elected annually by a majority vote of the NKN SC on a date as close as practical to the date of expiration of their term of service, or as necessitated by a vacancy. Nominations of existing RC members for RC Chair will be sought for a period of two (2) weeks beginning one (1) month prior to the expiration of the term of the Chair, or as soon as practical after the occurrence of a vacancy. RC Chairs may serve multiple one-year terms, consecutive or non-consecutive.

## Member Expectations

As an extension of the NKN SC, RC members will be expected to adhere to the general philosophy and behavioral guidelines as outlined in the *NKN SC Charter*, including Conflict of Interest (COI) disclosures. In order to avoid COIs, if a member of the RC submits a research request, that member must recuse themselves from the discussion and voting process and identify an alternate from the NKN SC with a similar stakeholder perspective (e.g. a patient must identify another patient or patient caregiver, a researcher should identify another researcher).

Due to the rapid turnaround often required in research collaborations, RC members are expected to be responsive to calls for comment, invitations to RC teleconferences, and votes. As such, if an RC member does not participate in RC activities encompassing three (3) consecutive votes and/or calls, the RC will have the right to appoint a replacement member.

## Voting Procedures

Decisions of the RC will be reached by a simple majority vote, although the RC will strive for consensus on all decisions. Votes may be held at meetings of the RC or by e-mail. Members have the right to request additional discussion, either electronically or via teleconference, before voting.

RC-External subject matter experts may be invited to advise the RC, either electronically or by teleconference. However, they will not be invited to vote on any requests.

Time periods outlined below will serve as a general guideline. However, they may be shortened if a request has an accelerated timeline, and the burden of review is light.

## Procedure

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### 1. Feasibility and Burden Initial Review by Project Team

Upon receipt of a request to conduct research, the NKN Project Team (NKI and Arbor Research employees who participate in NKN operational activities) will conduct an initial assessment of the project's overall feasibility and burden on the NKN's resources, including review of the project budget and Statement of Work (SOW; if applicable). This initial review shall take no longer than five (5) business upon receipt of the research request, unless otherwise communicated to the investigator.

Once this initial assessment is completed, the NKN Project Team will deem the project either **Feasible** or **Not Feasible**.

If **Not Feasible**, the investigator will be notified of the decision and will be permitted to revise the request accordingly.

If **Feasible**, within two (2) business days after the decision is made, a member of the NKN Project Team will notify the investigator of the decision and alert the RC Chair(s) of the request, forwarding all pertinent documentation. This will include a brief summary of the request, and feasibility assessment.

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If the proposal is being led by a member of the NKN Project Team, then the investigator will recuse themselves from the Feasibility and Burden review. However, if the proposal is being led by a majority of the Project Team, then the proposal shall automatically require both RC and full SC approval.

## 2. Research Committee Review

Upon receipt of the forwarded request, the RC Chair(s) will send the request to the full RC, copying the NKN Registry Manager, within one (1) business day upon receiving the request. This will open a period for open comment lasting fourteen (14) days. At any time during this period, if an RC member requests a call to discuss the request further, either the RC Chair(s) or the Registry Manager will alert the Project Team, who will work with the RC to schedule a call. Once the call is held, a new open comment period will be reopened.

At the end of the open comment period, the RC Chair(s) will call for a vote, opening a voting period of one (1) business day. All RC members will vote either: **Yes**, **No**, **Revisions Needed** or **Requires Full SC Approval**. Upon closure of the voting period, the RC Chair(s) will immediately inform the Project Team of the decision. The Project Team will then inform the investigator of the decision.

If the RC votes **Revisions Needed**, the RC will allow the investigator to revise and resubmit their request.

If the RC votes **Requires Full SC Approval**, the RC Chair(s) will forward the request to the NKN SC co-chairs for full SC review. (See Section 3 for details.)

## 3. Steering Committee Review

Once the RC has completed their review, the NKN Project Team will notify the full NKN SC of the decision. Included in this notification will be a bulleted summary of the project, the Project Team's initial review, and the RC's review. This will open a period for open comment lasting ten (10) business days.

For RC approved projects, if the open comment period expires with no comment or only comments of support, the request will be considered fully approved.

If any objections are raised by NKN SC members during this period, or if the RC has recommended a full NKN SC review, the NKN Project Team will initiate a voting period lasting five (5) business days. The NKN SC will then review the request using the same criteria as the RC. NKN SC members will vote either: **Yes**, **No**, or **Revisions Needed** and the decision will be based on a simple majority electronic vote (e-vote). Upon closure of the voting period, the NKN Project Team will immediately inform the investigator of the decision.

If **Approved**, the request will be sent back to the NKN Project Team for next steps, and is no longer under the purview of this policy. If **Revisions Needed**, the investigator will be allowed to revise the request and resubmit to the RC.

## 4. Letter of Support

If the request is approved and requires a Letter of Support, a Letter of Support will be drafted and signed by the NKN Principal Investigators and at least one Chair from both the NKN SC and RC.

## Review Criteria

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### Feasibility and Burden

The NKN Project Team will perform the Feasibility and Burden review of the proposal and its associated Budget and SOW (if applicable) using the following criteria:

1. **Will the proposal strengthen the mission of the NKN?**
2. **Is the proposal feasible within the NKN?**
3. **Will the proposal impose any undue burden on NKN participants or the core NKN infrastructure?**
4. **Are the proper precautions taken to assure high quality of generated data?**
5. **Will the proposal detract from core NKN activities?**

### Research Committee Criteria

The NKN RC will review the proposal using the following criteria:

1. **Is the proposal scientifically valid?\***
2. **Are patients partners in the research process?**
3. **Does the research question align with the NKN Community's research priorities?\***
4. **Does this research relate specifically to NS, or otherwise benefit NS patients?\***
5. **Will at least one NKN Community member participate as a patient-leader in a decision-making role and receive compensation for that role?**
6. **Does the proposal include accountability reporting on study progress and results back to the full SC and larger NKN Community?\***

If a request fulfills none of these criteria, the request will be denied. If a request fulfills *some* of these criteria, the request will either be returned for revisions, or will be forwarded to the full NKN SC for review.

Note that proposals seeking only to recruit NKN registrants for research study participation, without additional involvement of the NKN in other study activities, need only to meet the criteria noted with an asterisk(\*) above.

**Requests for patient contact information to recruit patients for a study will not be approved under any circumstances.** In accordance with the NKN Patient Registry informed consent and Institutional Review Board (IRB)-approved protocol, the NKN will notify potentially eligible registrants to decide if they want to opt-in and actively participate in any approved research opportunities. It is incumbent upon the registrant to contact the study's Principal Investigator or Study Coordinator. This allows NKN registrants to maintain control over their personal information.