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This policy is intended to outline the approved use and review process for Kidney Research Network (KRN) Patient Registry and Trials Network data (Network Data).

Network Data are derived from completed clinical studies/trials and the medical records of participants enrolled in the Kidney Research Network Patient Registry. Data identifiers are masked to preserve confidentiality within the Network Data Warehouse.

Network Data files approved for sharing will be either fully de-identified or a limited data set.

Network Data Use will be governed by the KRN Steering Committee and affiliated human subjects research regulatory body (IRB).

### **Use of Network Data**

- A. Network data will be retained and used by the Kidney Research Network.
- B. The Network will use the Network Data for Network oversight, approved research and approved quality and maintenance of certification initiatives.
- C. Network sites (investigators and trainees under the mentorship of the site principal investigator) may
  - 1) use the Network data for Steering Committee approved network research projects
  - 2) use limited local site only data for local site initiatives without Steering Committee approval
- D. Extramural (academic and industry) investigators may request collaborative analysis of Network data in the following settings:
  - 1) Extramural investigators must partner with a Network investigator for the project and provide necessary resources.
  - 2) KRN Steering Committee approves the project prior to initiation.
  - 3) Data may be analyzed in the KRN data analysis team or within the Network Site Investigator team as outlined in C above
  - 4) Copies of data may not be shared.

### **Proposal Review and Approval Process**

Network investigators may submit proposals using the KRN Ancillary Study Proposal Form found at <https://www.kidneyresearchnetwork.org/krn-ancillary-proposal>. The proposal forms will be reviewed by the Steering Committee. Approval is required prior to project initiation.

### **Conditions of Approval**

- 1) Changes in the project aims or analysis plan should be submitted to the Network Steering Committee for approval.
- 2) Regulatory approval will be documented prior to data sharing or study initiation.

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- 3) Following completion of the analysis, share the analysis programming code and results/manuscript draft with the Network Steering Committee for review and approval.
  - 4) Presentations and publications must follow the KRN Publication Policy.