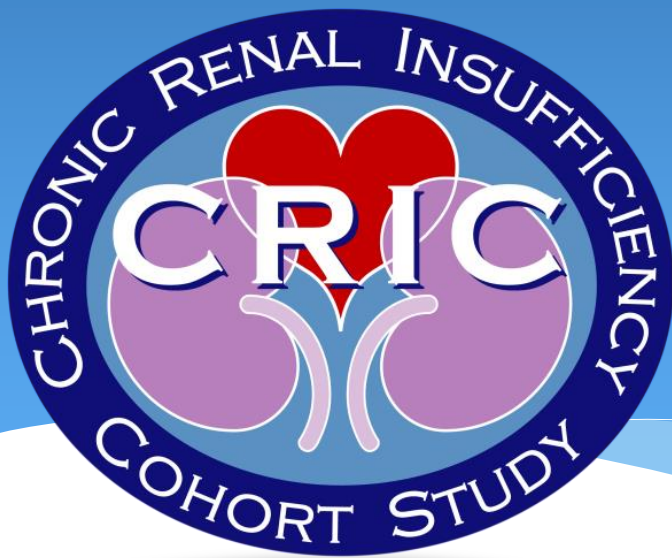


# The CRIC Study

## Ancillary Studies Process Overview

(Co-chairs: R Townsend and J Fink)



# CRIC Ancillary Studies Committee proposing an ancillary study

- \* **Develop an idea that uses the CRIC Study as a platform to advance your scientific ideas**
- \* **Start the process 3-4 months in advance of planned grant submission deadline**
- \* **Submit a proposal to CRIC Scientific and Data Coordinating Center (SDCC) using ancillary submission template on CRIC website ([www.cristudy.org](http://www.cristudy.org))**
- \* **CRIC policies protect the aims of approved ancillary investigators by avoiding overlap among applications**
  - \* **Website includes list of funded ancillaries**
  - \* **Approved but not yet funded proposals are not shared publicly**
  - \* **Consider discussing your idea with Ancillary Studies Committee chairs (Fink or Townsend) to consider the feasibility or possibility of overlap with other proposals**

# CRIC Ancillary Study Proposals

## elements of submission

- \* Does the proposed project involve analyses of existing data or samples, or new data collection from participants?
  - \* Select an appropriate RFA for the work that you propose to do
  - \* If proposing prospective data collection, consider whether project will include all CRIC participants (11 clinical sites) or smaller subset. Subcontracts with participating sites may be needed.
- \* Will the project use an expendable and fixed resource (e.g, biological specimens)? If so, from which study visit(s): baseline or Yr X?
- \* Quality assurance plan required for new data that will be generated (e.g., new lab measure)
- \* Plan to engage the SDCC to develop a subcontract for data analysis, data set creation, laboratory costs, etc.
- \* Ancillary Studies and Steering Committees make great effort to accommodate K-award applications

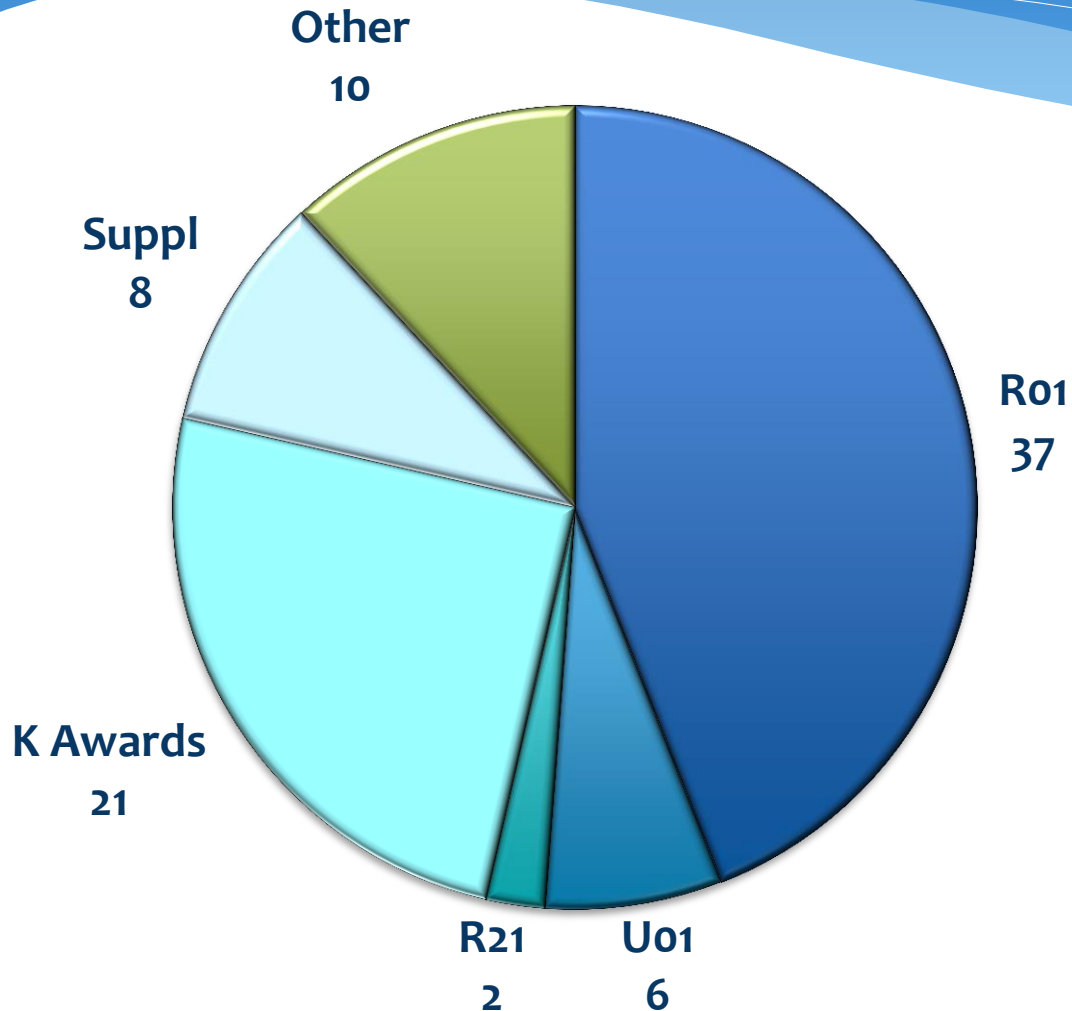
# CRIC Ancillary Studies Committee review process

- \* **Submit proposal to the SDCC**
  - \* Pre-discussion with a co-chair or Coordinating Center encouraged
- \* **Proposal reviewed by two independent reviewers**
  - \* Reviewers consider overlap, feasibility, capabilities of study team, burden to participants and sites, request for limited resources (biospecimens) and merit
- \* **Feedback will be sent to submitting investigator with request for additional information or revisions if necessary**
- \* **Final proposal is then sent to CRIC Steering Committee for vote**
- \* **Reminder: proposals should be submitted 3-4 months before grant submission deadline to permit revisions as needed and sub-contract negotiations as needed**

# Potential Funding Sources

- \* **NIH is most commonly used funding agency for ancillary studies in CRIC**
- \* **Other sources include AHA, ASN, Foundation, VA, and Industry where appropriate**
- \* **NIDDK PA 16-034 Ancillary Studies to Major Ongoing Clinical Research Studies to Advance Areas of Scientific Interest within the Mission of the NIDDK (R01)**  
*All proposed studies must involve additional collection of new data, outcomes and/or biological samples, and all questions being addressed must be within the scientific mission of the NIDDK*

# Award Types of Funded Ancillary Studies



**84**

**Funded Ancillary  
Studies**