# UT RocKs K Club
# K Award Application: What About All That Other Stuff?

THE UNIVERSITY of TENNESSEE HEALTH SCIENCE CENTER

Children's Foundation Research Institute

Le Bonheur Children's Hospital
Methodist Healthcare Family

# Other Stuff

- Major focus on Career Development Plan and Scientific Content
- Other stuff is important, too!
  - Budget and justification-will cover in another session
  - Biosketches
  - Resources, equipment and environment
  - Statements/Letters-Mentor, Co-Mentors, Collaborators, Consultants
  - Institutional commitment
  - Protection of human subjects
  - Vertebrate animals
  - Resource sharing plan
  - Appendix

# Biosketches

- PI and all key personnel
- “New” NIH format (5 pages)
- Requires a bit of work and thought
- Generally more useful to reviewers
- Scientific Editor, Amanda Preston, PhD

# Resources, Equipment and Environment

- Make sure this description includes everything you need to do the proposed research
- Lab and office space
- Individual and shared equipment
- Animal and human research facilities
- Core resources and services
  - Genomics, proteomics, metabolomics, bioinformatics, biostatistics, etc.
- Use “boilerplate” judiciously

## Statements/Letters-Mentor, Co-Mentors, Collaborators, Consultants

- Important! If you mention a collaborator or consultant needed for your project, you must have a letter!
- Letter should be succinct and describe precisely what the contribution to the project will be.
- Briefly describe the qualifications/experience for the contribution, as well as any previous interaction/collaboration you have had.

# Institutional Commitment

- Extremely important!
- Usually letter from Chair or Program Director
- Describes commitments made to you, including faculty appointment, space, equipment, start-up funds, protected time and expected career trajectory
- Your value to the department and institution
- Ideally, expresses commitment/support even if this grant is not funded.

# Protection of Human Subjects

- Federal-Wide Assurance (FWA)
- Human subjects involvement and characteristics
- Source of research material
- Risks and safeguards
- Adverse reactions and discontinuation from the study
- Confidentiality/HIPAA
- Recruitment and informed consent

# Protection of Human Subjects

- Data and safety monitoring plan
- Other information (compensation, etc.)
- Potential benefits of proposed research
- Importance of knowledge to be gained
- ClinicalTrials.gov requirements
- Inclusion of women and minorities
- Inclusion of children (under 21 yoa)
- Planned enrollment table

# Targeted/Planned Enrollment Table

**This report format should NOT be used for data collection from study participants.**

**Study Title:** Ursodeoxycholic acid in pediatric primary sclerosing cholangitis

**Total Planned Enrollment:** 50

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| **Ethnic Category** | **Sex/Gender** | | |
| | **Females** | **Males** | **Total** |
| Hispanic or Latino | 1 | 1 | 2 |
| Not Hispanic or Latino | 19 | 29 | 48 |
| **Ethnic Category: Total of All Subjects *** | 20 | 30 | 50 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | 0 | 0 | 0 |
| Asian | 1 | 1 | 2 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 3 | 4 | 7 |
| White | 16 | 25 | 41 |
| **Racial Categories: Total of All Subjects *** | 20 | 30 | 50 |

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

# Vertebrate Animals

- Animals to be used
- Justify the use and number of animals
- Veterinary care
- Procedures to limit pain and discomfort
- Methods of Euthanasia

# Resource Sharing Plan

- All cell lines and protocols created and published as a part of this project will be available to other investigators. Any transfer of such materials will be made in accordance with the policies of the University of Tennessee and are consistent with the Uniform Biological Materials Transfer Agreement.

# Appendix

- Do NOT use the appendix to circumvent page limits in the application
- Manuscripts and/or abstracts accepted for publication but not yet published
- Published manuscripts and/or abstracts **only** when a free, online, publicly available journal link is not available.
- Patent materials directly relevant to the project
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents
- Paper PHS398 applications **only** may include full-sized glossy photographs, such as electron micrographs or gels; however, the image (reduced in size but readily legible) must also be included within the page limitations of the Research Plan.

# CFRI Access

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