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| KPRI Established and New InvestigatorPilot and Feasibility Grant Application 2025***Applications should be sent to Mary Aiken at:*** ***mary.tubbs@childrensal.org*** |
| 1. **TITLE OF PROJECT** *(Do not exceed 81 characters, including spaces and punctuation.)* |
| **2. PRINCIPAL INVESTIGATOR** | **New Investigator [ ]  *OR* Established Investigator [ ]**  |
| 2a. NAME *(Last, first, middle)* | 2b.DEGREE(S) |
| 2c. POSITION TITLE | 2d.TELEPHONE |
| 2e.DIVISION | 2f. E-MAIL ADDRESS |
| 2g.DEPARTMENT/INSTITUTE |
| 3. HUMAN SUBJECTS RESEARCH | 3a.Research Exempt? | If “Yes,” Exemption No:  |
| [ ]  No [ ]  Yes If ”Yes”, IRB Approval Date:  | [ ]  No [ ]  Yes |
| 3b. Federal-Wide Assurance No.  | 3c. Clinical Trial? | 3d. NIH-defined Phase III Clinical Trial? |
|  FWA00005960 | [ ]  No [ ]  Yes | [ ]  No [ ]  Yes |
| 4. Vertebrate Animals [ ]  No [ ]  Yes | 4a. If “Yes,” IACUC Approval Date:  | 4b. Animal Welfare Assurance No. A3255-01 |
| 5. Institutional Biosafety Committee Protocol? [ ]  No [ ]  Yes | 5a. If “Yes,” Approval Date: | 5b. Approval Number: |
| 6. Dates of proposed period of support *(month, day, year—MM/DD/YY)* | 7a. Direct Costs, Initial Budget Period: | $  |
| From | Through | Direct Costs, Entire Budget Period: | $  |
| 02/01/25 | 1/31/27 |
| 10. The undersigned reviewed this application for a KPRI research award and is familiar with the policies, terms, and conditions of the KPRI concerning research support and accept the obligation to comply with all such policies, terms, and conditions. |
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| Signature of Primary Applicant | Date | Signature of Division Chief/Dept Chair/Institute Director of Primary Applicant | Date |

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| PROJECT SUMMARY: Using scientific language, briefly describe the research design and rationale for achieving the stated goals (150 word limit).. |
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| LAY PROJECT SUMMARY and RELEVANCE: Briefly, describe the proposal including the relevance of this research to public health, in terms that a lay person would understand. |
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| Please provide names and contact information for three potential Peer Reviewers (internal to UAB, COA but not in your own division or external to UAB) for this application): |
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| KEY PERSONNEL: *Use continuation pages as needed* to provide the required information in the format shown below.Start with Principal Investigator. List all other key personnel in alphabetical order, last name first. |
| Name | Organization | Role on Project |
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| KPRI Pilot and Feasibility Grant Application |
| TABLE OF CONTENTS |
|  | ***Page numbers*** |
| Face Page  |  | 1 |
| Project Summary, Relevance, Suggested Reviewers, Key Personnel  |  | 2 |
| Table of Contents  |  | 3 |
| Detailed One Year Budget  |  | 4 |
| Budget Justification  |  | 5 |
| Biographical Sketch – Principal Investigator (*Not to exceed five pages – use current NIH format page*)  |  | 6 |
| Other Biographical Sketches *(If applicable)*  |  |  |
| Research Plan  |  |  |
| A. Specific Aims *A and B not to exceed 5 pages* |  |  |
| B. Research Strategy……………………………………………………………………………… |  |  |
| C. Human Subjects  |  |  |
| * Protection of Human Subjects (Required if Item 3 on the Face Page is marked “Yes”)
 |  |  |
| * Data and Safety Monitoring Plan (Required if Item 3c on the Face Page is marked “Yes” Clinical Trial)
 |  |  |
| D. Vertebrate Animals  |  |  |
| E. Literature Cited  |  |  |
| F. Long term goals of the research project……………………………………………………….. |  |  |
| G. Pediatric Research Office *(resources used)* ………………………………………..……………. |  |  |
| H. Letters of Support (New Investigators must provide a letter from mentor including mentoring plan; other letters may include collaborators, consultants, etc.) |  |
| Appendix *–* Optional *(No page numbering necessary for Appendix.)* | **Check if Appendix is Included**[ ]  |

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| DETAILED BUDGET FOR INITIAL BUDGET PERIODDIRECT COSTS ONLY (FIRST YEAR ONLY) | FROM | THROUGH |
| 2/01/\_\_ | 1/31/\_\_ |
| PERSONNEL *(Applicant organization only)* | Months Devoted to Project |  | DOLLAR AMOUNT REQUESTED *(omit cents)* |
| NAME | ROLE ONPROJECT | Cal.Mnths | Acad.Mnths | SummerMnths | INST.BASESALARY | SALARYREQUESTED | FRINGEBENEFITS | TOTAL |
|  | PrincipalInvestigator |  |  |  |  | 0 | 0 | 0 |
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| SUBTOTALS |  |  |  |
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| CONSULTANT COSTS |  |
| EQUIPMENT *(Itemize)* |  |
| SUPPLIES *(Itemize by category)* |  |
| TRAVEL |  |
| PATIENT CARE COSTS | INPATIENT |  |  |
| OUTPATIENT |  |  |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)* |  |
| OTHER EXPENSES *(Itemize by category)* |  |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7, Face Page)* | $ |  |

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| Budget JUSTIFICATION.  |

**Follow the instructions below for the content of the application. Continue the header and footer information (Name, page numbering) throughout.**

**A-B. Research Plan.** Follow length guidelines. Sections A-B should not exceed 5 pages:

A. **Specific Aims (1/2 page):** *Remember, this is a 1-2 year pilot project.*

B. **Research Strategy (4½ pages).** Organize the Research Strategy into three sections - *Significance*, *Innovation* and *Approach* using the instructions provided below. Include a thorough, but concise description of the work leading up to your current hypothesis (applicants are not required to have extensive preliminary data since this is a pilot project).

* + - * **Significance**: Explain how the proposal will address an important problem or a critical barrier in the field. Also, indicate how this proposal will generate significant preliminary data needed for an NIH grant application.
			* **Innovation**: Explain how the proposal challenges existing paradigms or clinical practice; address an innovative hypothesis or critical barrier in the field.
			* **Approach**: Describe the overall strategy, methodology, and analyses used to accomplish the specific aims of the project. Include preliminary data, a rationale for experimental design and discuss any potential problems and solutions.

**C. Human Subjects.**If you answered “Yes” to the question “Are human subjects involved?” in Item 3 on the face page, applicants should include the following information on the involvement of human subjects and the proposed protections from research risk relating to their participation.  Organize as follows: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For additional information on writing the Human Subjects section, please refer to the [NIH Human Subjects Research](https://grants.nih.gov/policy/humansubjects/research.htm) pages on its Grants Policy website as well as the UAB IRB [Guidebook](https://www.uab.edu/research/administration/offices/IRB/guidebook/Pages/default.aspx).   The application should also include plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on the Inclusion section, please refer to the [NIH Inclusion](https://grants.nih.gov/policy/inclusion.htm) section as well as UAB IRB Guidance.

If the answer is “No” to the question “Are human subjects involved?” in Item 3 on the face page, but your proposed research involves human specimens and/or data from subjects, provide a justification in this section for your claim that no human subjects are involved.

**D. Vertebrate Animals.** If you answered “Yes” to vertebrate animals in block 4 on the face page, use the NIH [Vertebrate Animals Section Checklist](http://grants.nih.gov/grants/olaw/vaschecklist.pdf) to complete this section.

**E. Literature Cited.**

**F. Brief description of long-term goals of the research project you plan to develop.**

What are the plans for future funding if the line of investigation is successful?

**G. Pediatric Research Office (PRO)**

The [PRO](http://www.uab.edu/peds/pro) is available to assist with project design, including statistical evaluation, and administrative questions. Please indicate how you have used the PRO or will use the PRO for this project.

**H. Other Letters/Documentation**

 **a. Letter(s) from collaborators (Established investigators only)**

 **b. Letter from mentor (New investigators only)**

New Investigators should provide a letter from a mentor which describes his/her commitment to you and this project and indicates a mentoring plan.

 **c. Letter of commitment for use of Children’s of Alabama (COA) resources**

If you will need IT resources from COA, please obtain a letter of commitment from Eric Brown (eric.brown@childrensal.org). To obtain this letter, you must consult with Eric Brown by September 16, 2024. If you will need other resources from COA (not IT-related), please obtain a letter of commitment from Nancy Corona (nancy.corona@childrensal.org) by September 16, 2024. To obtain this letter, you must consult with Nancy Corona by September 16, 2024.