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| --- |
| Digestive Health Center Pilot and Feasibility Grant Application 2023***Applications should be sent to Cynthia Wetzel, PhD DHC Manager at*** ***cynthia.wetzel@cchmc.org******.*** |
| 1. TITLE OF PROJECT *(Do not exceed 200 characters, including spaces and punctuation.)*      |
| **2. PRINCIPAL INVESTIGATOR** | **New Digestive Diseases Investigator [ ]  No [ ]  Yes** |
| 2a. NAME *(Last, first, middle)*      | 2b. DEGREE(S) |  |
|       |       |       |  |
| 2c. POSITION TITLE      | 2d. TELEPHONE      |
| 2e. DIVISION      | 2f. E-MAIL ADDRESS      |
| 2g. DEPARTMENT/INSTITUE      |  |
| 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 |
| 00002988 | [ ]  No [ ]  Yes |  [ ]  No [ ]  Yes |
| 4. Vertebrate Animals [ ]  No [ ]  Yes | 4a. If “Yes,” IACUC Approval Date       | 5b. Animal Welfare Assurance No. A 3108-01 |
| 5. IBC Protocol [ ]  No [ ]  Yes | 5a. If “Yes,” Approval Date:       | 5b. Approval Number:       |
| 6. DATES OF PROPOSED PERIOD OF  SUPPORT *(month, day, year—MM/DD/YY)* | 7. COSTS REQUESTEDDirect Costs ($)      |  |
| From | Through |  |  |
| 06/01/24 | 5/31/25 |
| 10. The undersigned reviewed this application for a CCHMC DHC research award and are familiar with the policies, terms, and conditions of CCHMC concerning research support and accept the obligation to comply with all such policies, terms, and conditions. |
| Principal Investigator:  | Division Chief/Dept Chair/Institute Director of Primary Applicant:  |
| Signature of Primary Applicant | Date | Signature of Division Chief/Dept Chair/Institute Director of Primary Applicant | Date |

 Face Page **Form Page**

|  |  |
| --- | --- |
| Program Director/Principal Investigator (Last, First, Middle): |       |
|  |
| PROJECT SUMMARY: Using technical language, briefly describe the research design and rationale for achieving the stated goals. |
|       |
| PROJECT NARRATIVE: Using no more than two or three sentences, describe the relevance of this research to public health. |
|       |
| DIVISION, DEPARTMENT OR INSTITUTE |
| 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 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Human Embryonic Stem Cells | [ ]  No | [ ]  Yes |
| **If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list:** <http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp>. *Use continuation pages as needed.*If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used. |
| **Cell Line** |
|       |       |       |

 Page 2 **Form Page 2**

|  |  |
| --- | --- |
| Principal Investigator/Program Director (Last, First, Middle): |       |
| DHC Pilot and Feasibility Grant Application |
| TABLE OF CONTENTS |
|  | *Page Numbers* |
| Face Page  |  | 1 |  |
| Project Summary, Relevance, Performance sites, Key Personnel  |  | 2 |  |
| Table of Contents  |  | 3 |  |
| Detailed Budget  |  | 4 |  |
| Budget Justification  |  | 5 |  |
| Biographical Sketch – Principal Investigator  |  | 6 |  |
| Other Biographical Sketches  |  |       |  |
| Other Support of Principal Investigator ONLY  |  |       |  |
| Research Plan  |  |       |  |
| A. Specific Aims  |  |       |  |
| B. Research Strategy…………...……………………………………………………………………. A-B: not to exceed 5 pages  |  |       |  |
| C. Literature Cited  |  |       |  |
| D. Human Subjects  |  |       |  |
| E. Vertebrate Animals  |  |       |  |
| F. Select Agent Research |  |       |  |
| G. Resource Sharing Plan  |  |       |  |
| H. Authentication of Key Biological and/or Chemical Resources  |  |       |  |
| I. Long term goals of the research project |  |       |  |
| J. Description of DHC Cores you will be utilizing |  |       |  |
| K. Letter from Division Director  |       |
| L. Letters of Support (e.g., Consultants) |       |
|  |  |

Please provide the information below about yourself which will be used for aggregate statistical reporting only. This information will help the Digestive Health Center Leaders ensure equitability for all applicants.

**Gender:**

[ ] Female [ ] Male[ ] Transgender or non-binary

[ ] Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Prefer not to answer

**Race:**

[ ] American Indian or Alaska Native [ ] Asian [ ] Black or African American

[ ] Native Hawaiian or Other Pacific Islander [ ] White [ ] Prefer not to answer

**Ethnicity:**

[ ] Hispanic/Latino [ ] Non-Hispanic[ ] Prefer not to answer

 Page 3 **Form Page 3**

|  |  |  |
| --- | --- | --- |
| DETAILED BUDGET FOR INITIAL BUDGET PERIODDIRECT COSTS ONLY | FROM | THROUGH |
| 6/01/24 | 5/31/25 |
| 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 |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
| SUBTOTALS |       |       |       |
|  |
| MATERIALS AND SUPPLIES *(Itemize by category)*      |       |
| PUBLICATION COSTS      |       |
| PATIENT CARE COSTS | INPATIENT |       |       |
| OUTPATIENT |       |       |
| OTHER EXPENSES *(Itemize by category i.e. expenses at DHC Supported Research Cores)*      |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7, Face Page)* | $ |       |

 Page 4 **Form Page 4**

|  |  |
| --- | --- |
| Principal Investigator/Program Director (Last, First, Middle): |       |
|  |
| JUSTIFICATION.       |

 Page 5 **Form Page 5**

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE*(if applicable)* | Completion DateMM/YYYY | FIELD OF STUDY |
| --- | --- | --- | --- |
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**NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.**

**A. Personal Statement**

Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields, including ongoing and completed research projects from the past three years that you want to draw attention to (previously captured under Section D. Research Support).

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware. Use of hyperlinks and URLs to cite these items is not allowed.

Note the following additional instructions:

* If there are factors affecting your past productivity that you wish to explain, such as family care responsibilities, illness, disability, or military service, you may address them in your personal statement.
* Indicate if you have published or created research products under another name.
* You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this biosketch or the application.
* Figures, tables and graphics are not allowed.

**B. Positions, Scientific Appointments, and Honors**

List in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

List any relevant academic and professional achievements and honors. In particular:

* Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
* Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.present position.

**C. Contribution to Science**

Briefly describe **up to** **five** of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations.

**Content:**

For each contribution, indicate the following:

* the historical background that frames the scientific problem;
* the central finding(s);
* the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and
* your specific role in the described work.
* Figures, tables, or graphics are not allowed.

You may cite up to four papers accepted for publication or research products that are relevant to the contribution.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using [My Bibliography](http://www.ncbi.nlm.nih.gov/books/NBK53595/). Providing a URL to a list of published work is not required, and reviewers are not required to look at the list.

**PHS 398 OTHER SUPPORT**

**Complete ONLY for PI of application**

Name of Individual:

Commons ID:

**Other Support – Project/Proposal**

ACTIVE

\*Title:

Major Goals:

\*Status of Support:

Project Number:

Name of PD/PI:

\*Source of Support:

\*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

\* Total Award Amount (including Indirect Costs):

\* Person Months (Calendar/Academic/Summer) per budget period.

| Year (YYYY) | Person Months (##.##) |
| --- | --- |
| 1. [enter year 1]  |  |
| 2. [enter year 2]  |  |
| 3. [enter year 3] |  |
| 4. [enter year 4] |  |
| 5. [enter year 5] |  |

PENDING

\*Title:

Major Goals:

\*Status of Support:

Project Number:

Name of PD/PI:

\*Source of Support:

\*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

\* Total Award Amount (including Indirect Costs):

\* Person Months (Calendar/Academic/Summer) per budget period.

| Year (YYYY) | Person Months (##.##) |
| --- | --- |
| 1. [enter year 1]  |  |
| 2. [enter year 2]  |  |
| 3. [enter year 3] |  |
| 4. [enter year 4] |  |
| 5. [enter year 5] |  |

**IN-KIND**

\*Summary of In-Kind Contribution:

\*Status of Support:

\*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

\*Person Months (Calendar/Academic/Summer) per budget period:

\*Estimated Dollar Value of In-Kind Information:

**Pre-Submission Approval**. **Established digestive disease researcher** wishing to explore innovative new ideas that represent a significant departure from their ongoing, funded projects **MUST** obtain pre-submission approval. Using new technology or methodology does not represent a significant departure from current projects.

Send your specific aims page including an explanation of how the proposed work differs from your current research focus to **Cynthia Wetzel, PhD** (DHC Manager) cynthia.wetzel@cchmc.org.

The DHC leadership will review to determine if you are eligible to submit an application.

If applicable Response to Previous Review **(1 page)**

**A-B. Research Plan.** Follow the below length guidelines for the 5 pages. Based on current NIH format.

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

B. **Research Strategy (4 ½ 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**: Describe the scientific premise and rigor of the prior data for the proposed project as well as explain how the proposal will address an important problem or a critical barrier in the digestive disease 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 digestive disease field.
* **Approach**: Describe and provide the rational for the overall research strategy, experimental design, and methodology used to accomplish the specific aims of the project. Provide the justification for sample sizes and the feasibility of obtaining the sample(s). Include a statistical analysis plan that addresses the study hypotheses and aims, as well as specifying the primary and secondary study outcomes. Include preliminary data as appropriate. Discuss any potential problems and solutions. In keeping with current NIH guidelines, describe plans to address weakness in the rigor of prior research that serves as support for the proposed project, methods to ensure robustness and unbiased results, validation of key biological resources and explain how relevant biological variables (i.e. sex) are factored into the research design and analysis for studies involving vertebrate animals or humans.

[See NIH for more information regarding rigor and transparency](https://grants.nih.gov/policy/reproducibility/guidance.htm)

[See NIH Scientific Rigor Examples](https://grants.nih.gov/policy/reproducibility/resources.htm)

 **Applying for 2nd Year Funding.** If applicable clearly describe: 1) the progress toward the original aims during the first year of funding, 2) how the work proposed for the second year relates to the original aims, 3) publication(s) and outcome of extramural grant applications related to the first year of funding.

**C. Literature Cited.**

**D. Human Subjects.** Include Inclusion of Individuals Across the Lifespan, Inclusion of Women and Minorities,

 Recruitment and Retention Plan, Study Timeline, Planned Enrollment Report, Protection of Human

 Subjects, and Data Safety and Monitoring Plan required for a NIH application. If your application is selected

 for funding, you will need to submit all sections required for a NIH application.

 [See PHS Human Subjects and Clinical Trials instructions for more information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.500-phs-human-subjects-and-clinical-trials-information.htm)

**E. Vertebrate Animals.** Include 4-point narrative required for a NIH application.
 [See NIH instructions for more information](https://olaw.nih.gov/guidance/vertebrate-animal-section.htm)

**F. Select Agent Research.** [See Section 6 of NIH instructions for more information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.400-phs-398-research-plan-form.htm)

**G. Resource Sharing Plan.** [See Section 10 of NIH instructions for more information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.400-phs-398-research-plan-form.htm)

**H. Data Management and Sharing Plan.** If your application is selected for funding, you will need to submit a Data Management and Sharing Plan. See [NIH Writing a Data and Management Plan for more information](https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after).

**I. Authentication of Key Biological and/or Chemical Resources.**

[See Section 12 of NIH instructions for more information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.400-phs-398-research-plan-form.htm)

**J. 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? Describe how the project is
 related to [one of the themes of the DHC](https://www.cincinnatichildrens.org/research/divisions/d/dhc/research-focus-areas):

1) Mechanisms of Liver Disease

2) Digestive Disease and Immunity

3) Stem Cell and Organoid Modeling of Digestive Disease

**K. Brief description of the proposed** [**DHC Supported Research Cores**](https://www.cincinnatichildrens.org/research/divisions/d/dhc/cores) **you will be utilizing.** Click on links

 below for descriptions of the core services.

1) [Gene Analysis Core](https://www.cincinnatichildrens.org/research/divisions/d/dhc/cores/gene-analysis)

2) [Integrative Morphology Core](https://www.cincinnatichildrens.org/research/divisions/d/dhc/cores/integrative-morphology)

3) [Stem Cell/Organoid and Genome Editing (SCOGE) Core](https://www.cincinnatichildrens.org/research/divisions/d/dhc/cores/pluripotent-stem-cell)

4) [Clinical Component- Data Management/Analysis and Biobank](https://www.cincinnatichildrens.org/research/divisions/d/dhc/cores/clinical)

**L. Letter of support from your division director.**

**M. Letter(s) of support from any consultants.**