FORMAT OF THE APPLICATION

The body of the grant must be no more than five (5) single-spaced pages (for **new** applicants; see items #7 and #8 below for **second year** and/or **resubmissions**) with standard type size of 11 to 12 points (no more than 15 characters per inch) and margins of 1 inch. The applications should follow the general format of NIH research project applications (R01) and be submitted on current NIH forms. One additional summary sheet page is for the DDC only (see below). Each application must contain the following items:

1. Summary sheet (DDC form attached) (1 page). This will be given to all reviewers.
2. Table of Contents (NIH form page 3).
3. Detailed budget for the application on a NIH R01 budget page, with justification for each major item. Pilot projects should plan on taking advantage of DDC core facilities; specific plans to use the cores and funds to pay core fee-for-service charges should be included in the budget. **In general, PI salary and travel should not be included, and strong justification will be required for any piece of equipment.** (Maximum, 1 page for budget justification).

   ***DO NOT SUBMIT A MODULAR BUDGET*.** **Indirect costs will not be paid.**

4. NIH-5 page biosketch of the applicant with a list of recent publications and previous projects.
5. Sources and amounts of funds currently available to support research on this or related subjects by the applicant and/or by a senior investigator with whom the applicant is associated. If such funds exist, the applicant should state clearly why DDC P/F funds are needed. List any pending applications at granting agencies with potential budgetary overlap.
6. Body of application for **NEW** applications (maximum of 5 pages) on NIH continuation pages:

a) Specific aims (Approximately half-page, single-spaced.
   - List numerically and make them brief and to the point.
   - The aims should address specific hypotheses rather than just gathering data or doing a "fishing expedition". List the hypotheses your aims address.

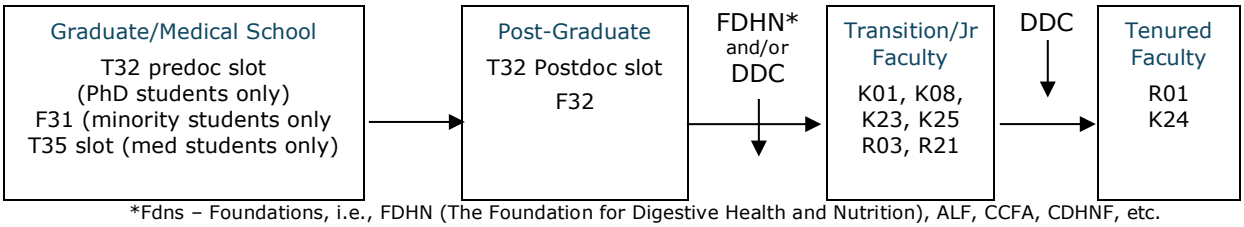
b) Significance and Innovation (1-2 pages maximum):
   - Briefly describe why this work is important and how it addresses a critical problem or scientific question in the field.
   - How does this work challenge existing paradigms with novel approaches or methods?
   - Make a synthesis from your literature review rather than just a listing of a string of facts.
   - Be concise in your review of the literature and make judicious use of subheadings/bold font. Only list the key literature has led to your hypothesis.

c) Preliminary Studies (No more than 1 page, single-spaced):
   - Preliminary data is not required in the grant, since this is a pilot/feasibility grant.

- If you have relevant preliminary results, these should be included and indicate whether it was done by you or someone else. If there is key preliminary data to show feasibility of your idea this should be included within this section of the application. You can put additional supporting figures/tables etc. in the Appendix, but do not put critical information in the Appendix to subvert the page limits.

d) Research approach (Study design, methodology, data analysis and any problem areas anticipated) (1-3 pages, single-spaced):
   - In format, this should parallel that of your Specific Aims section, e.g., if you have two specific aims, you will have two subheadings in this section where you describe the design of experiments related to each specific aim. If there are general methods that apply to all specific aims, identify them as such under a separate heading.
   - Explain your rationale for your experimental design and for choosing one particular approach over another.
   - There is no need (or space) to give minute details of common methods such as enzyme assays, RNA preparation, Northern blots, etc. Instead, state briefly the type of method that will be used and indicate what results will be expected.
   - Describe how you will analyze your results and address the potential pitfalls and potential problems you may encounter. Applicants are strongly advised to seek consultation with the DDC Study Design Core during the application-writing phase to assist with study design, power analysis and statistical analysis. Applications should also consider elements of rigor and reproducibility. Contact Fasiha Kanwal, MD, MSHS, Core Director, at kanwal@bcm.edu for more information.

7. Body of application for a **second year of funding** (maximum of 6 pages):
   Applications for a second year of funding must include a brief progress report (1 page) In addition to following the instructions outlined above for new applications.
8. Body of application for **resubmitted** applications (maximum of 5 ½ pages):
   Include a brief description of (half page), which addresses previous critiques for all resubmitted applications, in addition to following the instructions outlined above for new applications.
9. Literature cited:
   - Give full details of all references used, including authors and titles of articles.
   - List numerically, either in order of citation in the text or alphabetically.
10. **Long term goals and mentoring plan**: Briefly describe the long-term goals of the research project that you hope to develop, if the pilot project is successful. Provide a short rationale for the proposed pilot project and planned research program, based on past experience of the applicant (maximum, 1 page). Indicate your plans for future grant submissions to the NIH or other national organizations. If you have not previously had an extramural grant, you should identify a mentor and outline a mentoring plan. The diagram below outlines a common pathway for funding for GI researchers. Also, describe how you plan to become more involved in DDC and/or BCM Pediatric GI training program activities, such as GI Forum, Pediatric GI workshop, Pediatric GI Journal Club.



*Fdns – Foundations, i.e., FDHN (The Foundation for Digestive Health and Nutrition), ALF, CCFA, CDHNF, etc.

11. **Important: Describe how this project relates to the theme of the DDC: GI infection, injury, and metabolism.** GI is defined as the gastrointestinal tract, liver and pancreas. *Injury* is defined as drug, genetic, ischemic, inflammatory, surgical, nutritional, or stress-induced injury to the gastrointestinal tract. *Injury* also includes gastrointestinal adaptation and stem cells. *Metabolism* including diseases associated with obesity and the gut-brain axis.
12. **Provide a timeline of your project.** Explain how you will carry out your project over the course of funding and add any anticipated milestones that can be addressed in your annual progress report.
13. **Briefly describe the use of the DDC cores for your project**. Specifically, outline how the cores will facilitate this research. Describe how you plan to participate and become involved in the activities of the DDC, such as attending the GI Forum regularly, attending Pediatric GI Workshops and monthly Journal Clubs, and trainee lectures.
14. Appendix material (optional; maximum of 2 pages).
15. Protocols using human subjects, animals, radioisotopes or biohazardous materials must have appropriate review and approval before DDC funds can be expended. It is not necessary to obtain these approvals or a Routing Sheet before the application is reviewed. **If an application is approved, all of the relevant approvals must be obtained prior to final funding.**
16. For any project involving human subjects, you will be required to submit a **planned enrollment table and data sharing plan** for all nonexempt Human Subjects research. These items must be submitted before funding can be finalized.
17. **Applications require the signature of the chair of the applicant's academic unit (on the Summary Sheet)**. This signature will confirm that all clinicians who are PI's will have 50% protected time to perform the research. It is not necessary to obtain institutional signatures from the Office of Research.