# CAMEO Ancillary Study Proposal Form

Section 1: Basic Study Information and Projected Impact on CAMEO

1. Project Title:
2. Initiating investigator(s) (name, address, phone and fax numbers, e-mail address):
3. CAMEO sponsor and all other collaborators:
4. Timeline and Funding
5. Proposed starting and ending dates:
6. Estimated cost by year:
7. Source of funding and anticipated date of submission:
8. Does this study involve the support or collaboration of a for-profit corporation, or do you intend to use the data to patent any process, aspect or outcome of the analysis?
9. CAMEO involvement:

If this proposal poses any burden to the participants, the sites, or the central laboratory, please provide specifics about the expected burden as requested below.

5a) Participants: Yes [ ]  No [ ]  If yes,

1. Explicitly state the size and any special characteristics of the participant sample.
2. Will participants be contacted, interviewed, or examined? If so, describe participant involvement and estimate the time required of each participant.

5b) Biological Specimens: Yes [ ]  No [ ]  If yes, describe biological specimens to be used.

1. Is Genomic DNA to be used?
2. Specify amount of DNA:
3. Are plasma, stool, or mucosal RNA and/or DNA to be used?
4. Time points for which the samples were collected:
5. Sample type (e.g., plasma, stool, mucosal RNA and/or DNA):
6. Specify sample volumes or sizes:
7. Where will the lab work be conducted?
8. Projected timeline for:
9. pulling samples and shipping:
10. sample analysis:
11. return of samples to Lab:

Investigators are encouraged to contact the CAMEO Central Laboratory to discuss these considerations before submitting their proposals.

5c) CAMEO Clinical Centers: Yes [ ]  No [ ]  If yes,

Indicate which Clinical Centers have agreed to participate and describe the effort and estimated time required of CAMEO staff at each participating Center.

5d) CAMEO UNC Data Coordinating Center: Yes [ ]  No [ ]  If yes,

Describe the effort and estimated time required of CAMEO DCC staff. Specifically:

1. Will the following work be done at the DCC? (please check all that apply)
2. [ ]  Case report form development and/or collection using CDART
3. [ ]  Sample selection
4. [ ]  Data set preparation
5. [ ]  Consultation
6. [ ]  Statistical analysis
7. How many manuscripts do you estimate will be written from the ancillary study?
8. Will the DCC be involved in data collection?
9. State the data from the CAMEO main study needed for the ancillary study:

Clinical data recorded in DMS Yes [ ]  No [ ]

Endoscopy review consensus data Yes [ ]  No [ ]

Imaging review consensus data Yes [ ]  No [ ]

Fecal calprotectin Yes [ ]  No [ ]

Plasma immune proteins Yes [ ]  No [ ]

IBD Serology Yes [ ]  No [ ]

Mucosal RNA Seq and/or 16S Seq Yes [ ]  No [ ]

Participant genotyping Yes [ ]  No [ ]

Fecal metagenomics Yes [ ]  No [ ]

Other: Yes [ ]  No [ ]

7) Genetic information (defined as any data from a participant’s DNA):

7a) Does your proposal contain the use of genetic data? (please check one)

 [ ]  No (go to question 8) [ ]  Yes (see questions 7 b-c)

7b) Name the gene(s) to be investigated:

7c) Should genetic results be reported to patients’ physicians?

The CAMEO IRB protocol states that: Incidental findings with real or potential clinical implications will not be shared with patients/parents or the site.

8) Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.

9) Advantage(s) of conducting the study within the CAMEO cohort:      **Section 2: Description of the Proposed Ancillary Study**

Please provide a brief (maximum 4 pages not including citations) description of the proposed study. Include the following:

1. Abstract

Summarize background information and literature, and state how they lead to the question(s) of interest. Include a concise justification and explanation of the research question(s) to be addressed. End by stating the aim of the ancillary study and summarizing the method(s) that will be used to address the questions.

2. Background and Rationale

Explain in detail the background information summarized in the Abstract paragraph. Explain why this information is lacking regarding the ancillary study question(s) of interest, and how the proposed study will address that gap. Finally, explain how the methods and/or information from CAMEO will address the ancillary study question(s). Acknowledge any limitations or concerns related to the proposed methods and explain how they have been or will be dealt with.

3. Specific Aims

Detail the research questions or hypotheses to be addressed by the ancillary study

4. Methods

1. Study Population

Describe the sample of interest (the entire CAMEO cohort or certain subgroups). Include the anticipated time frame of participant involvement (if any).

1. Data Collection

Describe information to be collected and any methods or equipment to be used. Include detailed explanations and protocols for each method in the ancillary study. Explain how the information from the method or equipment will address the question(s) of the study. Attach copies of any study instruments (questionnaires and forms) that CAMEO participants or administrators will be expected to complete. Include an estimate of the time necessary to complete them. Describe the data needed from the CAMEO main study (including outcomes/events).

1. Statistical Analysis

Explain how each study hypothesis (from section 3 - Specific Aims) will be analyzed. Include any current hypotheses or information that might influence the approach to the analysis or the question itself.

5. Sample Size Calculations

6. Literature References

Please return the completed ancillary study proposal form by e-mail to the CAMEO Project Manager, Dena Hopkins (*CAMEO\_CCC@connecticutchildrens.org*)