

Proposal to be submitted to CCRC

(\*sample proposals for reference can be found in the attached document )



CCRC-subcommittee to review the proposal

Input on data feasibility & overlapping projects from DMIC & Steering committee



Feedback by CCRC to the submitting investigator



Proposal  
returned



Proposal accepted  
(pending requested changes)



Final presentation of the amended proposal  
(including milestones & time frames) to Steering Committee



**CCRC -Supports and monitors progression of proposal**

Type of study	Select sections that best describes your study by adding comments
THERAPY	
PREVENTION	
DIAGNOSIS	
ETIOLOGY	
COST ANALYSIS	

COMPONENTS OF PICO	YOUR QUESTION?
P- patient or population	
I –intervention , exposure , prognostic factor	
C-comparison ( standard therapy , gold standard)	
O-outcomes and variables of interest (reduced morbidity, accuracy etc.)	
The well-built clinical question should include PICO format, (please see examples below)	

Some examples to consider:

### ***THERAPY***

In children with IBD (P), what is the effect of anti-TNF's (I) on CS free sustained remission and mucosal healing rates (O) compared with IL12/23 inhibitors (C) within 2 years of diagnosis (T)?

### ***PREVENTION***

For children with UC (P) does the use of ASA co-therapy with anti-TNF therapy (I) reduce the future risk of relapse (O) compared with anti-TNF monotherapy (C)?

### ***DIAGNOSIS/PROGNOSIS***

Does early use of anti-TNF (I) influence development of complicating Crohn's disease and surgical resection (O) in patients who have inflammatory Crohn's disease at diagnosis (P) over 5 years (T)?

In children with ileal vs. colonic CD (P), how does early anti-TNF agent (I) compared to late anti-TNF use (C) influence development of complicating CD (O) over 5 years (T)?

### ***ETIOLOGY***

Are children (P) who have celiac disease in addition to IBD (I) compared with those IBD without celiac disease (C) at risk for/of poor response to anti-TNF therapy (O) over 5 years(T)?