Weill Cornell Medicine

Institutional Review Board

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October 26, 2017

Neera Gupta, MD

Submission Type:	Continuing Review Response to Issues
Protocol Number:	1501015826R001
Protocol Title:	Growth, Nutrition, Natural History and Outcomes in Pediatric IBD Patients
Status of IRB Protocol:	Open, data analysis only
Risk Level:	Minimal Risk
Expedited CR Category:	5

Dear Dr. Gupta:

The Institutional Review Board has conducted a review of your response to the modifications required letter issued on **09/25/2017** regarding the above mentioned protocol. The renewal for the abovementioned protocol was approved by a member of the IRB via expedited review procedures as per 45CFR46.110.

The protocol and its relevant documents stand approved for the following period:

Approved: 10/25/2017 **Expires**: 10/24/2018

Please do not hesitate to contact the IRB office staff if you have any questions or need assistance in complying with the terms of this approval.

Sincerely,

Alavy Sos, M.S.
Director, Institutional Review Board

Please note the following important information about this approval:

- No investigators on this study, who also serve as members of the Weill Cornell Medicine IRB, participated in the review, discussion or vote of this submission.
- Billing Compliance: This approval is contingent upon continued adherence with institutional billing compliance policies.
- Immediate Reporting: Investigators must follow the Immediate Reporting Policy at http://weill.cornell.edu/research/research_integrity/institutional_review_board/irb_adv.html
- Failure to comply with IRB directives within specified time frames may result in federally mandated penalties, up to and including suspension or termination of IRB approval and mandatory reporting to the Federal government.

- Human Gene Transfer: If this is a human gene transfer protocol, it is a term and condition of IRB approval that the principal investigator obtains Institutional Biosafety Committee (IBC) approval of all amendments prior to initiation, reportable adverse events as per WCMC policy, and annual reports as per M-I-C-3 of the NIH Guidelines for Research Involving Recombinant DNA Molecules. View the IBC website at http://weill.cornell.edu/research/research_integrity/ibc.html or contact ibc@med.cornell.edu if you require assistance in complying with these requirements.
- Other reporting: The reporting requirements of various regulatory bodies may differ with regard to both what must be reported and when. You are responsible for acquainting yourself with and abiding by all applicable federal and state regulatory reporting requirements.
- Changes to this protocol: If you want to change this research in any way or if any unanticipated hazardous conditions emerge affecting the rights or welfare of the human subjects involved in it, you must submit an amendment detailing these changes to the IRB for review and approval prior to implementing those changes. If the CTSC is used, the changes must also be submitted to the Translational Research Advisory Committee (TRAC). It is your responsibility to obtain approval for any such changes prior to initiating them.
- Continuing approval: You will receive a reminder via email for continuing review of this protocol in advance of the expiration date. The continuing review forms must be filed with the IRB sufficiently early to permit timely review and approval if the project is to continue beyond the period for which it was approved. Please note, no study related activities can continue beyond the WCMC IRB expiration date, including subject recruitment, enrollment, intervention and data analysis.
- If your research study involves human tissues: In addition to IRB approval, Section 4.4 of the hospital By-Laws "**Specimens Removed During Resective Surgery"** requires that all specimens removed during surgical diagnostic procedures that will be used for research must be approved by Pathology Service. Information about Pathology review can be found online at http://www.med.cornell.edu/research/for_pol/forms/Pathology_Review_Instructions.pdf
- If the IRB is requiring that you obtain informed consent from subjects: The signed IRB approved consent forms must be kept in the subject's hospital chart. If the subject has no New York Presbyterian Hospital chart, you are responsible for retaining such signed forms in your research files.
- Information about the WCMC IRBs: The Weill Cornell Medical College (WCMC) Institutional Review Board (IRB) is constituted as required by the Federal Office for Human Research Protections (OHRP). WCMC holds a Federalwide Assurance (FWA) with OHRP. The FWA number is FWA00000093. The WCMC IRB is registered on that FWA. The registration number for the IRB is: General IRB #1 IRB00009417, General IRB #2 IRB00009418, Cancer IRB#1 IRB00009420, Cancer IRB#2 IRB00009421 and Expedited IRB IRB00009419. Should you need additional information about the terms of the WCMC FWA or the WCMC IRBs, please refer to http://weill.cornell.edu/research/research_integrity/institutional_review_board/index.html.
- Note that new federal legislation took effect April 7, 2008, (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html), requiring that all peer-reviewed journal articles resulting from NIH supported research be deposited in PubMed Central, the NIH free digital archive of biomedical and life sciences journal literature, and be made publicly available within twelve months of publication. The Library and RASP have prepared general information which you can see at: http://library.med.cornell.edu/FacPub/nihpolicy.html
- **ClinicalTrials.gov: To comply with applicable requirements (HHS, NIH, and/or ICMJE), you must register prior to the first subject enrollment for studies that meet the following criteria:**
    - Interventional investigator-initiated NIH-funded WCM studies
    - Interventional investigator-initiated WCM studies evaluating at least one FDA-regulated drug, biological, or device product (except for phase 1 and small device feasibility studies)
    - Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes

  Updating of the record is required every 6 months, with results reporting required for some studies 12 months after study completion. Email registerclinicaltrials@med.cornell.edu with full name, CWID and phone number to set up a ClinicalTrials.gov account. More information is available at http://researchintegrity.weill.cornell.edu/clinicaltrialsdotgov.html.