



Office of Clinical Investigation  
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**Principal Investigator** Yamini Sharma, MD  
**Protocol Number** IRB-P00012640  
**Protocol Title** Clinical predictors of long term outcome in children with mild crohn's disease controlled with minimal therapy  
**Date:** November 12, 2014

### **NOTICE OF EXPEDITED APPROVAL**

**IRB Approval Date:** 11/7/2014

**IRB Activation/Release Date:** 11/7/2014

**IRB Expiration Date:** 11/6/2015

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The Committee on Clinical Investigation has approved the above referenced protocol through expedited review procedures as permitted under 45 CFR 46.110, category 5.

Risks were determined to be minimal with no potential for direct benefit.

The Committee has determined that you have met the regulatory requirements necessary in order to obtain a waiver of informed consent/authorization.

The occurrence of unanticipated problems should promptly be reported to this office. Any revisions, amendments, or changes to the protocol require prior Committee approval. The Committee has asked this office to notify investigators that clinical investigation protocol files are subject to audits at some future time.

Sincerely,

A handwritten signature in black ink, appearing to read "Anna M. Mitchell".

Anna Mitchell, IRB Administrator  
For the Committee on Clinical Investigation

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