



Boston Children's Hospital

Institutional Review Board (IRB)

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Principal Investigator Laurie Fishman, MD

Protocol Number IRB-P00021554

Protocol Title The impact of pediatric inflammatory bowel disease on physical activity, exercise and sports participation: patient and caregiver perspectives

Date: March 22, 2016

NOTICE OF EXPEDITED APPROVAL

IRB Approval Date: 3/22/2016

IRB Activation/Release Date: 3/22/2016

IRB Expiration Date: 3/21/2017

The Institutional Review Board has approved the above referenced protocol through expedited review procedures. We are now able to release this approval to you since you have adequately responded to the IRB's questions and concerns.

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

The IRB has determined that only one parent/guardian is required to provide permission for their child to participate

The IRB has determined that you have met the regulatory requirements necessary in order to obtain informed consent through a method other than a written consent document. It is the IRB's understanding that families will receive an introductory letter that will explain the survey, its rationale and information about how end results can be obtained at study completion. Completion of the survey will signify consent, assent, and parental permission.

Assent is required from those subjects capable of understanding the research and its ramifications.

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

Sincerely,

Matthew Stafford, Assistant IRB Director
For the Institutional Review Board

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