

Institutional Review Board (IRB)

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Principal Investigator Paul Rufo, MD
Protocol Number IRB-P00024515
Protocol Title Active Management of Iron Deficiency Anemia in Patients with IBD
Date: June 15, 2017

NOTICE OF EXPEDITED APPROVAL

IRB Approval Date: 5/20/2017
IRB Activation/Release Date: 5/20/2017
IRB Expiration Date: 5/19/2018

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 in this study.

Assent is required from those subjects capable of understanding the research and its ramifications. If you determine a particular child is not capable of providing assent, you will need to provide justification on the informed consent after the parental signatures.

The approved consent form is available on-line through the BCH Informed Consent Library. To obtain the consent form, please go to <http://chbcfapps/research/consents>. The ICLibrary should be accessed each time you need a consent form to ensure that the current version of the consent is always used. Do not store the consent forms on your computer or make copies for future use. Note that the activation/expiration date on the consent form can only be changed or modified by the IRB Office staff. Children and adolescents are required to sign the consent form in addition to the parent(s)/guardian(s). If you determine a particular child is not capable, you will need to provide the rationale on the informed consent after the parental signatures. Please also note that subjects cannot be enrolled in a study if the consent form has expired. A copy of the signed consent should be kept in your files. It is our understanding that consent forms will be stored in the medical record/research record. The subject/family must also be given a signed copy.

Use of the short form is permitted for this protocol per the conditions and procedures outlined in the IRB's policy.

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,

A handwritten signature in black ink that reads "Anna M. Mitchell". The signature is written in a cursive style with a large initial 'A'.

Anna Mitchell, IRB Administrator
For the Institutional Review Board

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