



Office of Clinical Investigation
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Principal Investigator Dascha Weir, MD
Protocol Number IRB-P00015951
Protocol Title Nonresponsive Celiac Disease in Children
Date: January 2, 2015

NOTICE OF EXPEDITED APPROVAL

<u>IRB Approval Date:</u>	<u>12/30/2014</u>
<u>IRB Activation/Release Date:</u>	<u>12/30/2014</u>
<u>IRB Expiration Date:</u>	<u>12/29/2015</u>

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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