

Geisinger Institutional Review Board
M.C. 30-69
100 North Academy Avenue
Danville, PA 17822
570 271 8663 Tel
570 214 7031 Fax

Approval Notice - Expedited Review

October 21, 2014

Jeffrey Wild
GWV - General Surgery

IRB #: 2014-0533 (Hemotx mgmt), entitled **Management of occult hemothorax**

RE: Submission Response for Initial Review Submission Form (only used with new study submission), 10/14/2014 08:56:58 AM EDT

Dear Jeffrey Wild:

Members of Institutional Review Board (IRB) reviewed and approved your research protocol under [45 CFR 46.110(b)(1) and/or 21 CFR 56.110(b)(1)] expedited review **Category 5**: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis) on 10/20/2014.

PLEASE NOTE: In addition to IRB approval, per Legal Policy 01.500, Contract Development and Administration, any contracts, agreements, and consent form reconciliations must be completed prior to initiating any research activities.

Please note the following information about your IRB approval:

Approval Date: 10/20/2014

Expiration Date: 10/19/2015

Risk Assigned: Minimal Risk

Approved Subject Enrollment: 1,500

Approved PHI Elements: Name (first, last, initials), Dates (all elements), Medical record numbers

Retrospective Date Range: 09/01/2007 - 09/01/2014

Consent/Authorization Process:

- HIPAA Authorization for research approved under 45 CFR 164.508 (a) (1)
- Waiver of HIPAA Authorization for Research approved under 45 CFR 164.512 (i) (2) (ii)
- Waiver/alteration approved 46.116(c) or (d)

Sponsor: Internal

Study Specific Information:

<i>Submission Components</i>			
<i>Study Document</i>			
Title	Version Number	Version Date	Outcome
protocol 1.1	Version 1.1	10/13/2014	Approved

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the Human Research Protection Program at (570) 271-8663.

Sincerely,
Thomas D Challman, MD
IRB Chair
Institutional Review Board

CC: Marie A Hunsinger, R.N.