



Science at the heart of medicine

Institutional Review Board

Albert Einstein College of Medicine
FWA #00023382

Montefiore Medical Center
FWA #00002558

North Bronx Healthcare Network
FWA #00009807

Yeshiva University
FWA #00000140

East Campus IRB
Jack and Pearl Resnick Campus
1300 Morris Park Ave., Belfer 1002
Bronx, NY 10461
718.430.2237 fax 718.430.8817

West Campus IRB
Montefiore Medical Center
3308 Rochambeau Avenue
Bronx, NY 10467
718.798.0406 fax 718.798.5657

<http://www.einstein.yu.edu/irb>

Notification of Exempt Determination

Date: September 23, 2016

Principal Investigator: Yanan Fang

Study Title: Evaluation of different methods for detection of Helicobacter pylori.
IRB #: 2016-6957 Reference #: 022254
Type of Submission: Submission Response for Initial Review Submission form

Determination Date: 09/22/2016

Exempt 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The waiver of HIPAA authorization was approved.

Re-review by the IRB will be required if any substantive change is made in the protocol during the course of the study, to determine whether or not the study still qualifies as Exempt Research.

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

Reviewed Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.