Washington University in St. Louis

Human Research Protection Office

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

IRB ID #: 201106051

To: Akwi Asombang

From: The Washington University in St. Louis Institutional Review Board,
WUSTL DHHS Federalwide Assurance #FWA00002284
BJH DHHS Federalwide Assurance #FWA00002281
SLCH DHHS Federalwide Assurance #FWA00002282

Re: Urinary Isoprostanes as a Marker of Oxidative Stress in Gastric and Esophageal Cancer

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Approval Date: 07/27/11

Next IRB Approval Due Before: 07/25/12

Type of Application:

- ☐ New Project
- ☒ Continuing Review
- ☐ Modification

Type of Application Review:

- ☒ Full Board:
  Meeting Date: 07/27/11
- ☐ Expedited
- ☐ Exempt
- ☐ Facilitated

Approved for Populations:

- ☐ Children
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, Neonates
- ☐ Wards of State
- ☐ Decisionally Impaired

Source of Support: DHHS, National Institutes of Health

MATERIALS APPROVED

Protocol:

Protocol Number:	10-0757
Protocol Version:	not available
Protocol Date:	1/20/2010

Amendment Number/Date(s): 1 - 01/04/2011

Consent/Assent Materials:

Consent & Assent Forms

CLEAN_USA_IRB_GAstric_CA_Study_Consent_form_.rtf

Questionnaires:

Subject Data Collection Instruments

Final FFQ draft with seasonal variation June 2011.doc

Relative/Proxy Data Collection Instruments

Gastric Esophageal Ca History physical initial Interview June 2011.doc

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This approval has been electronically signed by IRB Chair/Designee:
Linda Van zandt, CIP, BS
08/10/11 1446

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are available in *my*IRB. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.)

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at midnight on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project by that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however you will receive reminder notice prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any unexpected adverse experience, as defined in the IRB/HRPO policies and procedures, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of seven (7) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application, if that is longer than seven years.

Additional Information: Complete information regarding research involving human subjects at Washington University is available in the "Washington University Institutional Review Board Policies and Procedures." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. This document and other important information is available on the HRPO website http://hrpohome.wustl.edu/.