NOTICE OF INSTITUTIONAL REVIEW BOARD APPROVAL

Date: August 27, 2012
To: Fink, Melissa, Office of Research Integrity
IRB3, Guest, Admin, SP3
From: Kisselov, Oleg, Chairperson, Associate Professor, Full Board #1
Protocol Number: 22459
Protocol Title: Bio Full Test Protocol
Sponsor Protocol and Version Date: As supplied by Investigator in protocol

The above-listed protocol was reviewed and approved by the Saint Louis University Institutional Review Board.
Assurance No: FWA00005304

Below are specifics of approval:
Form Type: NEW
Level of Review: FULLBOARD
Form Approval Date: August 21, 2012
Protocol Expiry Date: August 31, 2012
HIPAA Compliance: Not Applicable
Waiver of Consent: Consent


Approved Study Documents Include: ASSENT.docx, ATTACHMENT1.docx, ATTACHMENT4.pdf, CONSENT1.docx, CONSENT2.docx

Items attached to the main protocol appear here. NOTE: Items categorized as “Archived Consent Materials” in the Attachments Section do not appear. Documents attached to Report Forms, SAE Forms, and Final Report Forms do not appear here unless the Investigator also uploads those items on the Attachments Page of the protocol in an Amendment or Continuing Review.

HIPAA MATERIAL (from above):
Category names of items uploaded to the HIPAA section of the protocol will appear here. For example, “HIPAA Authorization” (only appears once even if multiple documents), “Waiver of Authorization” if waived, could say “Code Access Agreement”, “Data Use Agreement”, or “HIPAA De Identification Certification”, if applicable. “Not Applicable” will appear if no PHI.

CONSENT MATERIAL (from above):
Category names of items uploaded to the Consent section of the protocol will appear here. For example, “Consent” will appear once if consent documents have been uploaded (even if multiple). Category names: “Alteration of Consent”, “Waiver of Consent”, “Waiver of Written Consent”, or “Additional Recruitment Statements” could also appear if applicable to the protocol.