



SAINT LOUIS UNIVERSITY

Approval Letter

The Full Approval Letter is used for New Protocols, Amendment Forms, and Continuing Review Forms ONLY.

Institutional Review Board
3556 Caroline Street, Room C110
St. Louis, MO 63104
TEL: 314 977 7744
FAX: 314 977 7730
www.slu.edu

NOTICE OF INSTITUTIONAL REVIEW BOARD APPROVAL

Date: August 27, 2012 — **Date letter generated**

To: Fink, Melissa, Office of Research Integrity — **Principal Investigator (PI), Dept.**
IRB3, Guest3, Admin SPS — **Department Chair**

From: Kisselev, Oleg, Chairperson, Associate Professor, Full Board #1 — **Panel Chair, Reviewing Panel**

Protocol Number: 22459 — **Panel = Board**

Protocol Title: Bio Full Test Protocol

Sponsor Protocol Version Number and Version Date: 1 - 08/10/2012 — **As supplied by Investigator in protocol**
In Funding section

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 — **Fullboard, Expedited/Exempt with categories listed**

Level of Review: FULLBOARD — **Date submission was approved**

Form Approval Date: August 27, 2012 — **Date protocol will expire**

Protocol Expiry Date: August 31, 2012

HIPAA Compliance: Not Applicable — **Associated HIPAA material (see below)**

Waiver of Consent: Consent, — **Associated consent material (see below)**

The Saint Louis University Institutional Review Board complies with the regulations outlined in 45 CFR 46, 45 CFR 164, 21 CFR 50 and 21 CFR 56.

Approved Study Documents include: ASSENT.docx; ATTACHMENT 1.docx; ATTACHMENT 4.pdf; CONSENT1.docx; CONSENT2.docx

Items attached to the main protocol appear here. NOTE: Some archived document categories may 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):

The type of material uploaded to the HIPAA section of the protocol will appear here. Each type will only appear once, regardless of the number of documents uploaded.

For example, "HIPAA Authorization"; "Waiver of Authorization"; "Code Access Agreement", etc.

"Not Applicable" will appear if no PHI.

CONSENT MATERIAL (from above):

The type of material uploaded to the Consent section of the protocol will appear here. Each type will only appear once, regardless of the number of documents uploaded.

For example, "Consent"; "Waiver of Consent"; "Additional Recruitment Statements", etc.