BioMed•IRB

IRB Meeting Date: February 5, 2013 **Expiration Date:** February 5, 2014

BIOMED IRB REINSTATEMENT APPROVAL NOTIFICATION

Study Title: Blood Collection for Non-therapeutic Research

Sponsor: [redacted]

Protocol Number: 601-01

Protocol Date: January 24, 2011

Principal Investigator: [redacted]

Approved Facilities:

BioMed IRB has approved the above referenced study as having satisfied the criteria for continuing research at the February 5, 2013 meeting.

The IRB committee has determined that the risk assessment for this study is Minimal. The IRB has determined that continuing review of this study will occur annually.

Approximately thirty days before the end of the reinstated approval cycle on February 5, 2014, you will be required to complete a Continuing Review Report Form. Any future approvals beyond the reinstatement period will require a normal continual review cycle. Continual review is the responsibility of the Principal Investigator. If you do not receive this form, please contact the IRB office immediately. The Continual Review Report Form must be received by the due date to allow ample time for ongoing review before the study's expiration date.

IRB approval is granted conditional on your adherence to the following requirements:

- The information submitted to the IRB is true and correct.
- Research will be conducted in accordance with the approved protocol.
- All materials used to recruit study subjects must be pre-approved by the IRB.
- Additional safeguards will be followed when vulnerable subjects, such as children or minors, are participants in the study.

The investigator agrees to report the following information to the IRB:

- Serious Adverse Events occurring at your site should be reported within ten (10) calendar days from the date of discovery by the investigator.

- Serious Adverse Events (IND Safety Reports) occurring at other sites should be reported no later than thirty (30) days from the date of discovery.
- Any changes in the research activity (i.e. changes in study staff, facility etc.) should be reported promptly. In addition, the investigator will not make any changes in the research without the IRB's approval, except when necessary to eliminate apparent immediate hazards to study subjects.
- Any other unanticipated problems involving risks to study subjects.

As you know, your approval from BioMed IRB for protocol 601-01 under Principal Investigator [redacted] was set to expire on December 07, 2012 but a continual review report was not received until February 05, 2013.

Due to the late submittal of the continual review, BioMed IRB board members have requested that a CAPA be submitted to the IRB on or before the expiration date of February 5, 2014.

BioMed IRB is comprised of a diverse group of individuals in accordance with the Federal Regulations and the International Conference on Harmonization, Global Harmonization or other appropriate guidance for Good Clinical Practice. BioMed IRB follows written procedures for performing review, documenting meeting minutes, disclosure of member conflict of interest prior to deliberation or voting, as well as the retention of all records containing research materials as required by the Code of Federal Regulations (21CFR parts 50 and 56; and 45 CFR part 46).

On behalf of the BioMed IRB, I certify that the information contained in this letter is true and correct as verified by the minutes and records of the BioMed IRB.

Please keep a copy of the reinstatement letter in your files for future reference. Should you have questions or concerns, please do not hesitate to contact this office.

Sincerely,

Authorized Signature	Chairman Emeritus Title
Fred Fox Printed Name	February 5, 2013 Date