Alpha IRB
1001 Avenida Pico, Suite C # 497, San Clemente, CA 92673
T: 949-542-3882 F: 949-940-0134 www.alphairb.com

NOTICE OF RENEWAL APPROVAL

To:
Site: LeukoLab, A Clinical Division of AllCells
1301 Harbor Bay Parkway
Suite 200
Alameda, CA 94502
Attention: Sheila Smith, RN, BSN
Sponsor: LeukoLab, A Clinical Division of AllCells
Re: 7000-SOP-078
Study Title: Bone Marrow and/or Peripheral Blood Collection From Disease-Specific Donors for the Research Market
Date: February 8, 2016

This is to inform you that on February 8, 2016 Alpha IRB has renewed its approval for the above research site.

The approval period is from February 8, 2016 **to** February 7, 2017. **Please be sure to reference the protocol number in any correspondence with Alpha IRB.**

All conditions for continued approval during the prior approval period remain in effect.

- **Renewal of your study** - Please submit to Alpha IRB the **Continuing Review Report** within 60 days before the expiration of the approval period. The study cannot continue until re-approved by Alpha IRB.
- **Continuing education** - Investigators and members of their research teams should complete continuing education at least every two years after Initial IRB approval for as long as they are involved in human subjects research. Please see the *Sponsor/Investigator IRB Requirements and Guidebook* for a list of acceptable forms of training or contact Alpha IRB. We request you submit evidence of any continuing education you have completed within the past approval period at the time of continuing review.
- **Completion, Termination, or if not Renewing** - send **Close-out Report** upon completion of the study.
- Alpha IRB Reporting Forms and the Sponsor/Investigator IRB Requirements and Guidebook are located on our website at: www.alphairb.com.

Alpha Independent Review Board (Alpha IRB) operates in compliance with applicable laws and regulations including, but not limited to, federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as other pertinent regulations and guidelines, such as the Good Clinical Practice (GCP) Guideline (E6) of the International Conference on Harmonization, as applicable. Alpha IRB is registered with OHRP/FDA; our registration number is IRB00006205, or you may refer to OHRP's Web site at http://www.hhs.gov/ohrp/. Alpha IRB is also fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Alpha IRB consists of members of the clinical and scientific communities, non-scientists, as well as members of the community as required by Federal regulations to assure a fair and thorough review process.

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Please contact Alpha IRB at: **949-542-3882** if you have any questions about the terms of this approval.

Elizabeth Stefani
Study Management Specialist

This is a representation of an electronic record that was signed electronically as part of 21 CFR Part 11. Information herein is true and correct as reflected in the records of Alpha Independent Review Board.

February 8, 2016