

# Request for Information Email, February 18, 2011 - Laviv

**From:** Tull, Lori  
**Sent:** Friday, February 18, 2011 12:19 PM  
**To:** 'Jeanne Novak'  
**Cc:** 'Dana Weinberger'; Kevin Hennegan  
**Subject:** Request for information

Hi Jeanne,

Dr. Zhu would like to request the following information regarding subject --(b)(6)- who had SAE of leukocytoclastic vasculitis in Study IT-H-001.

- (1) full admission history & physical and discharge summary of the July 4 admission;
- (2) rheumatological and/or dermatological consultation write-ups;
- (3) skin biopsy report on the admission;
- (4) routine blood work, lab tests, and rheumatological markers during this admission: such as CBC, CMP, UA C&S, CRP, ESR, ANA, ANCA, etc;
- (5) clinical follow-up and update on this patient, including any blood work such as CRP/ESR (whether it is normalized)

Thank you,  
Lori

Lori A. Tull, RAC  
Regulatory Project Manager  
Office of Cellular, Tissue, and Gene Therapies  
Center for Biologics Evaluation and Research  
(301) 827-5359

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

Page Last Updated: 09/24/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العبرית](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [عربى](#) | [English](#)