Appendix 2

PATIENT/CAREGIVER INFORMATION LETTER

Title of Study: Clinical Trial of Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen (INTERCEPT Fibrinogen Complex) in Patients with Bleeding to Expedite Blood Product Availability in Perioperative Bleeding

Principal Investigator (PI): Melissa Cushing, MD

A research study is currently underway at Weill Cornell Medicine to compare a new blood product that has been treated to remove any infectious organisms to the traditional product that is not treated, in cardiothoracic and liver transplant patients. The study is being led by Dr. Melissa Cushing. You were provided this letter because based on your treatment during surgery you are eligible for this study. The purpose of this letter is to give you and/or your caregivers information about the study and to tell you how we will be using your information.

WHY IS THIS RESEARCH BEING DONE?

Our hospital is interested in comparing a newer blood product (called INTERCEPT Fibrinogen Complex) used to replace fibrinogen, to a traditionally used blood product used to replace fibrinogen, called cryoprecipitate. Fibrinogen is an important protein that makes your blood clot and can help prevent bleeding. Both blood products are already in use and are FDA approved, but the traditional product must be stored in a frozen state in the blood bank and the new product can be kept in a liquid state making it immediately available when a patient bleeds.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to determine whether one of the FDA-approved products to replace fibrinogen can reduce a patient's need for additional blood products during surgery because it is immediately available. The results of this study will be used to identify the better blood product to treat surgical patients.

WHAT DOES THIS MEAN FOR YOU?

One of the two blood products described above is chosen randomly every month in the blood bank laboratory and that product is given to all patients who require fibrinogen replacement during that month. If you are receiving this letter, this means that you have received one of the products during or after your surgery, based on the decision your surgeon or anesthesiologists made to replace fibrinogen. The choice to transfuse a blood product to replace fibrinogen is completely up to your surgeon/doctor and your consent to receive blood, not the study.

WHAT ARE THE POSSIBLE RISKS?

The risk to participants is thought to be very low, but whenever patient information is included in a study there is always a very low risk that a patient's privacy may be breached. There is no known difference is safety risks between the two blood products being studied.

WHAT ARE THE POTENTIAL BENEFITS?

The study results will help us better understand which blood product is best to decrease blood product use and decrease time to transfuse blood for surgical patients, so that we can help other patients undergoing cardiothoracic or liver transplant surgery in the future. It will also evaluate which product is associated with less blood product wastage to conserve this precious resource.

WHAT INFORMATION IS BEING COLLECTED?

We will review your medical chart, collect information, and analyze your hospital stay while you are in hospital from before, during and after surgery. The information collected will include your medical history, medications, blood products received, and laboratory results.

- You will not be contacted by or need to meet with research personnel.
- No additional testing or involvement by you is required for your participation in this research study.

HOW WILL THE INFORMATION BE USED?

After obtaining the information, we will remove details that can identify patients personally (deidentify). Study results will be reported in aggregate form only, so that no individuals can be identified. Information will be stored in a secure location (password-protected file on a secure server) to protect patient privacy.

CAN YOU REQUEST TO HAVE YOUR INFORMATION REMOVED FROM THE STUDY?

You can request to have your information removed from the study. This request can be made to the Principal Investigator or Study Coordinator listed below. We will not be able to remove your information once it has been linked to our database, approximately 1 month following your procedure. Requesting your information to be removed will not affect your care.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions about the research now or later or would like your information removed from the study, please contact the Principal Investigator Dr. Melissa Cushing at Weill Cornell Medicine at [redacted] or mec2013@med.cornell.edu or study coordinator at [redacted].

Dr. Melissa Cushing, the principal investigator, serves as a paid scientific board member for Cerus Corporation, the study sponsor. If you have any questions about the financial interests listed in this paragraph, you can discuss this matter with the Office of Research Integrity at [redacted], if you have any questions or complaints, you may contact a person not on the research team at the Biomedical Research Alliance of New York Institutional Review Board at [redacted] or at www.branyirb.com/concerns-about-research.