May 8, 2019

Investigational Review Board

RE: Letter of Intent for Research Use of Blood Products To whom it may concern:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is requesting approval for the use of human blood products, namely packed Red Blood Cells, plasma and whole blood purchased from commercial sources for in vitro testing in its research and development program. The blood is intended to be used in testing for the Development of the \_\_\_\_\_\_\_\_\_\_\_\_\_ porous polymer bead filters for the express purpose of removing excess potassium, antibodies and cellular decomposition products. \_\_\_\_\_\_\_\_\_ warrants the following:

1. All donor data will be de-identified
2. \_\_\_\_\_\_\_\_\_ has no contact with the blood donor or access to identifying information
3. There is no genetic analysis of the material
4. \_\_\_\_\_\_\_\_\_\_\_\_ maintains annual training in handling and preventative measures associated with blood borne pathogens
5. \_\_\_\_\_\_\_\_\_\_\_\_ has contracted with a licensed medical waste disposal company for proper disposal of all medical waste

As the Chief Operating Officer of \_\_\_\_\_\_\_\_\_\_ I have responsibility and the authority to ensure compliance of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ research program with these claims. We believe the use of these human blood products a necessary step in the development of the \_\_\_\_\_\_\_\_\_ filter.

Please do not hesitate to contact me if there are any further questions. Sincerely,

coo