Fairfax Cryobank

Contract Establishment Agreement

Facility Name:_____

Facility Address:_____

City, State Zip Code:_____

This agreement is to document facilities which Facility Name:_____ contracts with in the processing, production, handling, testing, transport, or storage of HCT/Ps.

Establishment Name: Fairfax Cryobank, Inc.

Address: 3015 Williams Drive, Suite 110

Address: Fairfax, VA 22031

Phone: 703-698-3976

Fax: 703-698-3933

This facility: ■ **Is not required to hold a CLIA license**

☐ **Holds a current CLIA license**

☐ **This facility is not registered with the FDA as a HCT/P establishment**

■ **This facility is currently registered with the FDA as a HCT/P establishment**

Registration Number: 3004731690

FDA establishment registration functions include:

■ **Recover** ■ **Screen** ☐ **Test *** ■ **Package** ■ **Store** ■ **Label** ■ **Distribute**

I agree Fairfax Cryobank, Inc. (hereafter referred to as "Cryobank") will maintain FDA registration for HCT/Ps as required. In addition, Cryobank will remain compliant with all regulations governing the manufacture of HCT/Ps.

Facility Name:_____ agrees to notify Cryobank within 48 hours of any finding from an audit or inspection which effects HCT/Ps distributed by Cryobank.

* While Cryobank does not directly perform "testing" we do contract with a FDA registered, CLIA licensed testing facility using only FDA approved screening tests for donor testing. Tests are conducted and interpreted as per manufacture recommendations.

I agree to notify *Facility Name*:_____ within 5 business days of any change in our status.

Responsible Person Printed Name:_____

Responsible Person Signature: _____Date:_____