
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:** _____
