



CONTRACT ESTABLISHMENT AGREEMENT

FACILITY NAME:

FACILITY ADDRESS:

CITY, STATE AND ZIP CODE:

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

Establishment Name: **Fairfax EggBank, Inc.**
Address: **3015 Williams Drive, Fairfax, VA 22031**
Phone: **888-352-5577**

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: 3003140045

FDA establishment registration functions include:

Recover Screen Test* Package Store Label Distribute

* While Fairfax EggBank does not directly perform "testing" we do contract with an FDA-registered, CLIA-licensed testing facility that uses only FDA-approved screening tests for donor testing. Tests are conducted and interpreted as per manufacturer recommendations.

FACILITY NAME: _____ agrees to notify Fairfax EggBank within 48 hours of any finding from an audit or inspection involving HCT/Ps distributed by Fairfax EggBank.

I agree Fairfax EggBank will maintain FDA registration for HCT/Ps as required, will remain compliant with all regulations governing the manufacture of HCT/Ps and will notify **FACILITY NAME:** _____ within 5 business days of any changes in our status.

Responsible Person Printed Name: _____

Responsible Person Signature: _____ **Date:** _____