## Background

If a client is banking for future use with a sexually intimate partner recipient, the client typically will be categorized for banking purposes as a Client Depositor (sometimes referred to as a "CD").

The Food and Drug Administration ("FDA") does not currently require additional testing and screening for CDs.

If a client is banking for future use with a recipient with whom they are **not sexually intimate**, such as a gestational carrier or surrogate, the client typically will be categorized for banking purposes as a Directed Donor.

- The FDA regulates the use of certain reproductive tissue use, including the use of sperm banked for use by recipients with whom the donor is not sexually intimate. The FDA requires a Physical Exam by a contracted physician, a set of Infectious Disease testing, and additional "donor screening" questions.
- If the samples will be used in New York State, some genetic screening is also required by the NY Department of Health.
- Samples produced outside of 7 days of the testing and screening must remain in quarantine for a minimum of 180 days and the Directed Donor must have repeat infectious disease testing to release the vials for use.



## **Gender Affirming Hormone Therapy Client Depositor Program**

Fairfax Cryobank offers this program for individuals who are pursuing Gender Affirming Hormone Therapy ("GAHT") but are not yet sure how their reproductive samples will be used in the future.

## Why We Created the Enhanced GAHT Client Depositor Program

We understand that transitioning individuals are sometimes unsure of who they will partner with in the future and therefore do not know if the recipient of the reproductive samples will be their sexually intimate partner (cis-female or non-binary individual who can provide an egg and carry a pregnancy) or a recipient with whom they are not sexually intimate (such as a gestational carrier or surrogate). Our Enhanced GAHT CD Program incorporates some elements of the Directed Donor Requirements to make it easier to qualify the samples for use later if the client decides to use the samples with a non-sexually intimate partner recipient.

- Participants in this program should have a physical exam around the time of banking the reproductive samples
  - o Ideally this would occur within 7 days of the sample collection
- Participants will also complete a panel of infectious disease testing with the Cryobank and fill out screening documents that will be kept in their file for later use

Then, when the client is ready to use samples banked as an Enhanced GAHT CD:

- With a sexually intimate partner: simply call the Cryobank to ship the samples or prepare the samples for client pickup
  - o Samples can be used with no additional testing or screening
- With a gestational carrier or surrogate
  - The client will need to work with a medical provider who will advise on an additional testing and screening that is necessary
  - The Cryobank will release the samples to the medical provider accompanied by the original screening and testing results
    - Note the shipping documentation will state the samples are for autologous use only, meaning with a sexually intimate partner
- Once received at the clinic, the provider will complete the steps for eligibility determination and use with the gestational carrier/surrogate

The Enhanced GAHT CD Program is designed to give clients the flexibility in how they use their banked samples in the future while making the process as easy as possible now.

Please speak with a member of our team if you have any questions about whether this program is right for you.