cryobio

Additional Agreement to Use Donor PC 101-A

We, _____ (Recipient), and _____ (Partner, if applicable), specifically request and accept frozen semen from Cryobio donor PC 101-A. We understand that this Additional Agreement is an additional part of the Sperm Use Agreement specific to donor PC 101-A. We reviewed the genetic test results on this sperm donor, and we understand that donor PC 101-A has been found to be a carrier of the following recessive genetic condition:

Alpha-Thalassemia

Alpha-Thalassemia (HBA1 and HBA2 genes): Alpha-thalassemia is an autosomal recessive condition that affects the red blood cells. It can affect people of any ethnicity, but is more common in people who can trace their ancestry to Southeast Asia, India, equatorial Africa, the Mediterranean, or the Arabian Peninsula. Typically, individuals have 4 alpha (HBA) genes and are neither carriers nor are they affected with the disease. Individuals who are carriers have 2 or 3 working HBA genes and do not typically have symptoms of the disease, however, some carriers may have mild anemia. The two major and severe forms of alpha-thalassemia are hemoglobin Bart syndrome and alpha-thalassemia (also known as HbH disease). Hemoglobin Bart syndrome is caused by a loss of all 4 alpha-globin genes. It is very severe, and fetuses are either stillborn or die shortly after birth. Alpha-thalassemia (HbH disease) is caused by a loss of 3 alpha-globin genes. It results in anemia, an enlarged spleen, and mild jaundice. Most individuals are mildly disabled by this disease. Some people with more severe disease require frequent blood transfusions. The type of disease as well as the severity of symptoms can be predicted based on the genetic variants detected.

PC 101-A is a silent carrier of Alpha-Thalassemia: PC 101-A has a ***deletion*** of one of the alpha-globin genes, and therefore carries a total of 3 (instead of 4) copies of the alpha-globin gene. This does not cause any problems for him, as he is just a silent carrier. However, as a result of his silent carrier status, any offspring would be at an increased risk to have a more severe form of alpha-thalassemia depending on the recipient's (or egg source's) carrier status.

Carrier status frequency:
Carrier status frequency is the chance of an individual being a carrier for a genetic condition based on their ethnicity alone prior to any genetic screening. If an individual tests negative as a carrier for a condition or conditions, then the chance of being a carrier is significantly decreased. This remaining risk is known as residual risk, meaning what is the risk of being a carrier even after negative genetic testing. Residual risk data is available directly through sema4's website, sema4.com, or can be requested from Cryobio.

Alpha-thalassemia (HBA1 and HBA2 genes) carrier status frequency in different ethnicities, from Sema4's website:

Caucasian	1 in 500
African American	1 in 30

Asian	1 in 20
Worldwide	1 in 25

Recommendation: Both Sema4 and Cryobio recommend that the recipient, or the egg source, if different than recipient, be tested for alpha-thalassemia carrier status and consider genetic counseling. Please refer to Sema4's website, sema4.com, for more information and contact Cryobio with any questions or to arrange genetic counseling. Because the donor was tested by Sema4, Cryobio recommends that the recipient or the egg source be tested by Sema4 as well. We also strongly recommend that you discuss the donor's genetic carrier status results with your health care provider. Finally, we recommend that any future child be notified of this donor's carrier status once they are of reproductive age, as even if they do not have a recessive disease, they could be a carrier and their carrier status could be important to identify risks related to their own reproductive future.

Cryobio has advised us of the following:	**Please initial to show your understanding and agreement:**
The donor we have chosen has positive results from genetic testing. These results indicate that the donor is a carrier for alpha-thalassemia.	**Initials: _____ Initials: _____**
This genetic condition is inherited as a recessive trait. This means that if both the egg source and the sperm source are carriers for the same gene/condition, there is a significantly higher chance of the resulting child having that genetic condition.	**Initials: _____ Initials: _____**
By the donor testing positive for alpha-thalassemia, the risk to a resulting child would now be higher than that of the general population.	**Initials: _____ Initials: _____**
Both the risk of being a carrier and the sensitivity of the genetic testing can vary depending on an individual's ethnicity. When an individual tests negative for carrier status, it ***does not completely eliminate*** their chance of being a carrier for that disease. Instead, their remaining (residual) risk of being a carrier is determined by their ethnic background. While a negative result decreases the likelihood that an individual is a carrier, how much that risk is reduced can vary significantly. For more detailed information regarding the sensitivity of testing and remaining risk after negative screening, please see Sema4's website.	**Initials: _____ Initials: _____**
Genetic testing looking at a large panel of genes, including the gene/condition that the donor has tested positive for, is available.	**Initials: _____ Initials: _____**

Genetic testing is ***strongly recommended*** for me, (or the egg source, if different), to see if I am a carrier for alpha-thalassemia.	**Initials: _____ Initials: _____**
A negative genetic test result in me, (or the egg source, if different) significantly reduces the likelihood that the resulting child could be affected with this condition. However, we fully understand that the risk cannot completely eliminated.	**Initials: _____ Initials: _____**
While genetic testing can lower the likelihood for certain genetic diseases, no amount of genetic testing can guarantee that a child will be healthy or free of genetic disease.	**Initials: _____ Initials: _____**
Genetic counseling is available to us, either through Cryobio or Sema4, if we have additional questions regarding these test results and potential risks.	**Initials: _____ Initials: _____**
Both the donor's carrier status and whether the donor is acceptable for my use should be discussed with my health care provider.	**Initials: _____ Initials: _____**

We have read the above material and assume the risk of using donor sperm from a donor who has been found to be a carrier of a genetic disorder. We are making the choice to use donor sperm from donor PC 101-A willingly and agree to release any legal claims, including negligence, that may arise from or are related to insemination or assisted reproduction using donor sperm from donor PC 101-A.

We have had the chance to read and ask questions, and we understand and agree to the terms of this Additional Agreement to use donor PC 101-A.

_____
Recipient

_____
Date

_____
Partner, if applicable

_____
Date

William C. Baird, PhD.
Cryobio

10-18-2020
Date