cryobio

Additional Agreement to Use Donor WL 4002

We, _____ (Recipient), and _____ (Partner, if applicable), specifically request and accept frozen semen from Cryobio donor WL 4002. We understand that this Additional Agreement is an additional part of the Sperm Use Agreement specific to donor WL 4002. We reviewed the genetic test results on this sperm donor, and we understand that donor WL 4002 has been found to be a carrier of the following recessive genetic condition:

Non-Syndromic Hearing Loss (GJB2-related)

Non-syndromic hearing loss (GJB2-related) (GJB2/GJB6 gene):
Non-syndromic hearing loss (*GJB2/GJB6*-related) is an autosomal recessive disorder that is caused by pathogenic variants primarily in the gene *GJB2 and also, although more rare, mutations in the gene GJB6*. Most commonly this hearing loss is caused by a mutation in both of an individual's GJB2 genes. However, there have been reports of individuals with one mutation in GJB2 and one mutation (specifically deletions) in GJB6 that resulted in this hearing loss. It is found in individuals of many different ethnicities, but it more prevalent in individuals of Ashkenazi Jewish descent, as well as Caucasians and Asians. Patients with this form of hearing loss do not experience any other disease manifestations. Hearing loss is usually present from birth and does not progress in severity over time. The level of hearing loss can vary between patients from mild to profound. Patients with two inactivating variants are more likely to have profound hearing loss, whereas patients with two non-inactivating variants are more likely to have mild hearing loss. However, the variability that exists between patients means that it may not be possible to predict the severity of an individual's hearing loss based on their genotype. Life expectancy is not reduced.

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.

Non-syndromic hearing loss (GJB2-related) carrier status frequency in different ethnicities, from Sema4's website:

African	1 in 56
Ashkenazi Jewish	1 in 13
East Asian	1 in 5
Finnish	1 in 16
Caucasian	1 in 18
Latino	1 in 28
South Asian	1 in 55
Worldwide	1 in 18

Recommendation: Both Sema4 and Cryobio recommend that the recipient, or egg source, if different than recipient, be tested for non-syndromic hearing loss GJB2 and GJB6 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 egg source should 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 had positive results from genetic testing. These results indicate that the donor is a carrier for non-syndromic hearing loss (*GJB2/GJB6*-related).	**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 condition, there is a significantly higher chance of the resulting child having that genetic condition.	**Initials:** _____ **Initials:** _____
By the donor testing positive for carrier status for non-syndromic hearing loss (*GJB2/GJB6*-related), 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 and could be done.	**Initials:** _____ **Initials:** _____
Genetic testing is ***strongly recommended*** for me (or the egg source, if different) to see if I am a carrier for non-syndromic hearing loss (*GJB2 and GJB6 genes*).	**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 be 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 WL 4002 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 WL 4002.

We have read, had the chance to ask questions, understand, and agree to the terms of this Additional Agreement to use donor WL 4002.

_____
Recipient

_____
Date

_____
Partner, if applicable

_____
Date

William C. Baird, PhD
_____
Cryobio

10-18-2020
_____
Date