



Department
of Health &
Social Care

Annex

Gamete (Egg and Sperm) and Embryo Storage Limits: Consequential Impacts. Consultation Reply

1 October 2021

Questions

Section 1: Third-Party Donations

Question 1

Should the maximum statutory storage limit of 55 years apply equally to all third-party donated gametes and embryos?

- Yes

If you answered Yes to Question 1, please go to Question 8. If you answered No, please go to Question 2.

Question 2

Should third-party donated gametes, and embryos created using third-party gametes, have the same maximum statutory storage limit as each other?

- Yes
- No

If you answered Yes to Question 2, please go to Question 3. If you answered No, please go to Question 4.

Question 3

If yes, what should the new limit be for third-party donated gametes and embryos created using third-party donated gametes? Please select from the list below.

- 10 years
- 20 years
- 30 years
- 40 years
- 50 years

If you answered Yes to Question 2 and answered Question 3, please go to Question 8 next.

Question 4

Should there be a different maximum time-limit applied to third-party donated gametes, rather than the new statutory storage limit of a maximum of 55 years?

- Yes
- No

If you answered Yes to Question 4, please go to Question 5. If you answered No, please go to Question 6.

Question 5

If yes, what should the new limit be for third-party donated gametes? Please select from the list below.

- 10 years
- 20 years
- 30 years
- 40 years
- 50 years

Please go to Question 6 next.

Question 6

Should there be a different maximum time-limit applied to embryos created using third-party donated gametes, rather than the new statutory storage limit of a maximum of 55 years?

- Yes
- No

If you answered Yes to Question 6, please go to Question 7. If you answered No, please go to Question 8.

Question 7

If yes, what should the new limit be for embryos created using third-party donated gametes? Please select from the list below.

- 10 years
- 20 years
- 30 years
- 40 years
- 50 years

Please to go to Question 8 next.

Question 8

The Government intends that in cases where a couple use their own gametes, and one or both individuals previously stored their gametes, to create an embryo that is then also entered into storage, the embryo's 55 year limit will start from the date when the last person gave consent.

For example, person A had eggs in storage for 10 years and person B had sperm in storage for 6 years and subsequently they create embryos which also enter storage. The embryos have 49 years of storage time remaining because person B was the latest person to give consent. If person B provided fresh gametes that were not in storage, the embryo would have 55 years storage time as their consent would be considered the latest.

Taking the above in account, please consider the below options in the case of third-party donated materials and select either option a) or b).

a) two different periods, such as a set number of years for donor gametes and then an additional set number of years for any embryos created using the donated gametes

Please go to Question 9 next.

Question 9

Please explain the reasoning behind your answers in this section of questions.

We would recommend having two distinct storage periods for donor gametes and embryos from date first stored. We recommend a maximum statutory storage period of 55 years for donor gametes and a maximum statutory period of 55 years for donor embryos, **from the date first stored as embryos**. This is in keeping with limits for gametes and embryos

designated as 'own' gametes and embryos. We see no overwhelming reason why donor gametes and embryos should be treated differently to 'own'.

Such a policy would support the following key policy tests mentioned in the consultation document -

a. **ensuring equity** for all patients including same-sex couples and single women who benefit specially from stored donor gametes and embryos derived from these.

b. **facilitating greater reproductive choice.** With advances in freezing technique such as rapid vitrification, there is a likelihood that going forward, more donor eggs will be frozen for future allocation without a named recipient. This is already the case with donor sperm. Hence having a maximum storage period of 55 years will offer more choice to all potential recipients, including future recipients.

and

c. **reducing administrative burden** for clinics and the regulator. This policy will ensure that storage limit requirements are kept simple, consistent and easy to enforce. This will remove the need for complex calculations derived from remaining storage periods of historically stored gametes, reducing the risk of error, and avoiding confusion for clinics and recipients

Donors should be given the choice for informed consent at the time of donating their gametes and/ or embryos to store for the two separate maximum statutory periods for gametes and embryos without the need to renew every 10 years, or have an option to consent for being contacted to renew every 10 years.

We acknowledge the importance of donor-conceived persons being able to access identifying and contact information about the donor. However, we note that a differential limit on storage terms for donor gametes and/or embryos could be seen as discriminatory, and there is no certainty that contact with a donor will be possible in any event.

Section 2: Known or Family Donations

Please answer all questions in this section.

Question 10

Should the new approach of 10-year renewable storage periods with a maximum time-limit of 55 years, be applied to known family donations of gametes and embryos?

- Yes

Question 11

If not, what should the new limit be? Please select from the list below.

- 10 years
- 20 years
- 30 years
- 40 years
- 50 years

Question 12

Please explain the reasoning behind your answers in this section of questions.

There is no reason to treat 'known' donation differently to 'anonymous' donation in this respect. Consistency with the two types of donations will reduce the risk of errors in clinics and ensure fairness. Our comments in response to Question 9 apply equally here.

Section 3: Surrogacy

Please answer all questions in this section.

Question 13

Should the definition of 'own use' be extended to embryos destined for surrogacy created using both the intended parents' gametes, even though the person undergoing fertility treatment will be the surrogate?

- Yes

Question 14

Embryos that enter storage and that were created using third-party donor gametes destined for surrogacy should be treated the same way as embryos created using a third-party donor in a non-surrogacy arrangement. Do you agree?

- Yes

Question 15

Please explain the reasoning behind your answers in this section of questions or offer any other views you may have on this issue.

Embryos created for surrogacy should be for 'own use' as they are intended for the intended parent to have a baby. The surrogate carries the pregnancy but does not intend to be the parent.

We are not convinced of the value of a distinction between 'own-use' and other gametes and embryos. We are anxious that such a distinction would unfairly and disproportionately affect individuals who need surrogacy for clinical conditions, for instance hysterectomy due to cancer.

Section 4: Posthumous Use

Please answer all questions in this section.

Question 16

Should there be an additional period applied to cases when, having consented to their gamete or embryo being used posthumously, a person then dies, before being able to renew their storage period for another 10 years?

- Yes

Question 17

If yes, how long should the extension be? Please select from the list below.

- 10 years

Question 18

Please explain the reasoning behind your answers in this section of questions.

We believe that this should be 10 years **at a minimum**, and consideration should be given to making it longer. This would give patients able to use these gametes or embryos more reproductive choice. They may wish to have more than one child, and may not be in a position to start fertility treatment immediately after a bereavement.

Section 5: Research Use

Please answer all questions in this section.

Question 19

When consent has been given, should there be an extension to the 10-year consent period, following completion, to allow gametes and embryos to be kept for research purposes?

- Yes

Question 20

If yes, how long should the extension be?

- 2 years
- 5 years
- 10 years

NONE OF THE ABOVE – 55 years

Question 21

Please explain the reasoning behind your answers in this section of questions.

There is an important difference between consent to storage for use in treatment, when the clinic is under a duty to store the embryos for the time specified in the agreement with the patient, and consent to research, which instead enables the researchers to use the stored material in a project of research, if it is useful for them to do so. Researchers are not under a duty to use the stored material, and nor are they under a duty to store it for the maximum period of time allowed: consent to research enables the material to be used, it doesn't mandate its use or storage.

When people donate their embryos or gametes for use in research, they consider this to be a one-off consent, and the end of the matter, rather than the start of an ongoing relationship with the researchers. Particularly in the case of embryos, where people are donating what could have been a sibling for their existing children, it would be upsetting and cruel to keep going back to the donors to ask for extensions to their consent for research.

It would therefore be in the interests of patients, as well as in the interests of simplicity and clinics/researchers, for consent to donation to research to take the form of a one-off consent, for the maximum permitted period of time, while being clear with researchers that they are not mandated to use or keep the material if it is no longer useful to them. Patients could

withdraw their consent to the use of their gametes or embryos in research at any point during this period.

ADDITIONAL POINT NOT ADDRESSED IN THE CONSULTATION

The BFS is anxious to avoid the administrative and regulatory confusion that has attended previous revisions of the statutory storage period, which required clinics to take into account when gametes or embryos were first stored and the complex regulations and requirements that prevailed then. This has led to several legal cases and a significant burden on clinics and patients, due to the complexity of, and interaction between, different sets of storage regulations. We would strongly urge consideration of transitional provisions similar to those applied in the wake of the Coronavirus pandemic in 2020. The new regulations should apply across the board from the date they come into force, and cover all gametes and embryos in storage on that date.

Your completed consultation response should now be returned to storagelimit@dhsc.gov.uk by 31 October 2021.