Policy for the Provision of NHS funded Gamete Retrieval and Cryopreservation for the Preservation of Fertility
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Restricted

1. Gamete Retrieval and Cryopreservation.

This policy lays out the CCG commissioning intentions regarding the retrieval and storage of gametes for patients in certain clinical circumstances as outlined below.

Gametes are sex cells. The male gametes are the sperm, and the female gametes are the eggs. Conception (getting pregnant) happens when a man's sperm fertilises a woman's egg.

In certain circumstances, a man or a woman’s fertility may be compromised for a number of reasons:
- Certain types of treatment (e.g. cytotoxic therapy) which permanently prevents the individual producing gametes (eggs/sperm) or
- Certain types of treatment (e.g. cytotoxic therapy) which permanently causes genetic abnormalities in the eggs/sperm.
- The ovaries or testes may, in certain clinically required circumstances, (e.g. to prevent the spread of disease) need to be surgically removed which results in infertility.
- The patient has premature ovarian failure.

Gamete Retrieval is the extraction of gametes (by surgical or non-surgical methods) which can then be stored for future use.

Cryopreservation is the process of storing biological material at extreme temperatures; most common -196 °C/-321 °F in nitrogen (N₂) vapour. At these low temperatures, all biological activity stops, including the biochemical reactions that lead to cell death and DNA degradation.

Patients undergoing treatments such as chemotherapy for cancer or radical surgery may be made sterile by such treatments. Where there is a significant likelihood of making a patient permanently infertile as an unwanted side-effect of NHS funded treatment, including gender reassignment, those patients will be eligible, under the CCG commissioned pathway, for gamete retrieval and cryopreservation to preserve fertility. Patients may also experience infertility through chromosomal abnormalities, e.g. Turner’s syndrome or through premature ovarian Insufficiency, which is defined for the purposes of this policy as: a woman below the age of 40 years; with an absence of external factors / pathology which has caused the ovarian failure, where cessation of ovulation has occurred and ovarian failure is confirmed by measurement of the ovarian reserve). In such cases it may be possible to store some eggs before the ovaries stop functioning completely.

Patients undergoing such treatments may be made sterile by such treatments. Where there is a significant likelihood of making a patient permanently infertile as an unwanted side-effect of NHS funded treatment, including gender reassignment, those patients will be eligible, under the CCG commissioned pathway, for gamete retrieval and cryopreservation to preserve fertility.
2. Eligibility Criteria:

2.1 The patient must be permanently registered with a Birmingham and Solihull CCG GP practice or a Sandwell & West Birmingham GP practice.

AND

2.2 The patient must have no living children.

The aim of this criterion is to give priority to individuals with no existing living children. An adopted child has the same status as an individual’s biological child. However, self-funding for gamete retrieval and storage is still possible.

AND

2.3 Age.

2.3.a Upper age restrictions for both men and women will be in line with those patients funded for fertility services under the Assisted Conception policy in place at the time of the funding request.

2.3.b At the time the Policy for the Provision of NHS funded Gamete Retrieval and Cryopreservation for the Preservation of Fertility 2018 was commissioned these limits were as follows:

- A woman must be under the age of 40
- A man must be under the age of 55 years.

There is clinical evidence which demonstrates that a women’s fertility falls with age, significantly dropping by the age of 40 years. Chromosomal abnormality increases with age in men and increases significantly after the age of 55 years. Gamete retrieval (surgical or non-surgical) will be offered to all women aged 39 or younger and all men aged 55 years or younger at the date of the procedure, when the patient also meets the other eligibility criteria set out in this policy.

There is no lower age limit applied in this policy however all patients including those aged under 16 years must be able to understand the procedure being carried out and considered competent to give informed consent.

AND

2.4 The patient must meet ONE of the following clinical criteria:

2.4.a The patient must be undergoing NHS funded treatment which is likely to render the patient permanently infertile e.g. cytotoxic therapy

OR

2.4.b The patient is at immediate risk of premature ovarian failure.
For the purposes of this policy premature ovarian failure is defined as:

- a woman below the age of 35 years;

AND

- with an absence of external factors / pathology which have impacted on fertility, the patient is experiencing a cessation of ovulation and menstruation

AND

- ovarian failure is confirmed by measurement of the ovarian reserve

OR

2.4.c The patient has a diagnosed chromosomal abnormality which is likely to render the patient permanently infertile.

e.g. Turner's syndrome which carries a high risk of premature ovarian failure

OR

2.4.d The patient's ovaries/testes are going to be removed as part of NHS funded treatment.

e.g. to prevent the spread of disease in a cancer diagnosis or the patient is undergoing gender reassignment.

AND

2.5. The funding application must be supported by the NHS consultant providing their care.

AND

2.6. The patient has NOT undergone a previous sterilisation and/or reversal of sterilisation procedure.

Gamete retrieval and cryopreservation will not be funded where the patient has previously undergone elective sterilisation (vasectomy or the fallopian tubes are blocked or sealed to prevent the eggs from reaching the sperm and becoming fertilised).
2.7 Previous Assisted Conception

Access to NHS funded Cryopreservation will not be affected by previous attempts at Assisted Conception. However, funding for further assisted conception attempts will be subject to the criteria stated in the currently commissioned Assisted Conception Policy at the time of any funding application.

3 Timescales for NHS Funding for Storage of Gametes

Where the eligibility criteria (Section 2) are met, NHS funding will be available as set out below from the date of the retrieval of the patient’s gametes.

The funding parameters set out below in Section 3.1 are ONLY for patients who have been assessed as eligible under the terms of Section 2 above, for the specific storage of eggs or sperm for the preservation of fertility and NOT as part of fertility treatment. Funding parameters for those patients undergoing fertility treatment are set out in Section 3.2.

3.1.a. The patient will give written consent for an initial storage term of 10 years if the gametes are to be stored for longer than the initial 10 years for which consent was given, the patient’s consent must be reviewed and reacquired from the patient and the patient must continue to meet the medical criteria for premature infertility.

AND

3.1.b. i. If gamete storage is to be funded under the terms of this policy, the CCG will fund gamete storage for up to 5 years or until the patient’s 30th birthday, whichever arrives later.

OR

3.1.b. ii. If storage is to be funded under the terms of this policy, the CCG will fund gamete storage for up to 5 years or until the patient’s 39th birthday (female) or 55th birthday (male) whichever arrives sooner.

AND

3.1.c. The patient must have a valid written storage agreement with the provider in place.

AND

3.1.d. Beyond the above timescales for CCG funded storage, as long as the patient continues to meet the criteria for storage, i.e. medically confirmed infertility, if the patient wishes for cryopreservation of his/her gametes, then the patient will be solely responsible for the annual storage fee.
3.2. Patients having CCG funded fertility treatment - IVF or ICSI - Cryopreservation of Embryos.

3.2.a. Embryos which are not used during the CCG funded fresh transfer cycle should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use.

3.2.b. Cryopreservation and storage of any suitable surplus embryos following a completed CCG funded cycle is for a period of 12 months, in line with Human Fertilisation and Embryology Authority (HFEA) guidelines and is funded by the specialist tertiary treatment provider.

3.2.c. The consent to storage completed by patients is for ten years.

3.2.d. Patients must use the embryos within the legally consented storage period, at the end of this time if the storage consent agreement is not renewed then the embryos will be removed from storage and will perish.

3.2.e. Funding - the CCG does not fund for storage of embryos resulting from IVF / ICSI. The clinic will offer storage for the first year free of charge. After the first year, if any embryos remain in storage, the patient will be sent a reminder letter detailing that gametes remain in storage, and if they wish to keep the gametes stored they will be invoiced the agreed annual fee to continue storage. They will pay this annually until used, or perished or up to ten years. No storage is allowed beyond ten years at present.

3.2.f. If the patient has undergone unsuccessful IVF/ICSI treatment and has stored embryos and then experiences a loss of fertility, and meets the eligibility criteria set out in section 2, then the CCG will fund cryopreservation of the embryos with the consent of both partners for 5 years or until the female partner’s 39th birthday, whichever comes sooner

ALL funding renewals for gamete storage will be considered in line with the ages specified in the Assisted Conception Policy in place at the time of application.

Patients may choose to self-fund storage once NHS funding ceases within the terms of the Human Fertility and Embryology Act 1990.
**Human Embryo and Fertility Act 1990**

Cryopreservation of gametes or embryo’s must meet the current legislative standards.

The provider of the service must ensure the patient receives appropriate counselling and provides full consent.

In the case of embryo preservation, both partners must be made aware of the legal position regarding embryos which have been cryopreserved, should one partner remove consent to their ongoing storage or use.

Patients must also be aware of legal issues on posthumous use of gametes and embryos should they wish a partner to be able to use these should their treatment not be successful.

The provider of the service should contact patients annually to confirm that they wish to continue storage. The patient will be responsible for ensuring the storage provider has up to date contact details.

The provider must ensure that material is only stored where there is valid consent in place.
## Appendix 1

### Definitions

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<tr>
<th>Item</th>
<th>Definition</th>
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<tr>
<td>Assisted Conception</td>
<td>The collective name for all techniques used artificially to assist conception and pregnancy, including In vitro fertilisation (IVF), Intra-cytoplasmic sperm injection (ICSI), Intrauterine insemination (IUI) and donor insemination (DI). These techniques are referred to as Infertility Treatment.</td>
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| Female/Partner/ Couple | Any reference to a female/partner/couple could relate to any of the following:  
  - Heterosexual couple; a male and a female in a relationship; same sex female couple; A single female  
  - Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs  
  - Transgender female, biologically born as a male, gender reassigned to female, retention of male reproductive organs. |
| Infertility        | A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment (FSH & progesterone levels) and investigation along with her partner (semen analysis). Following the first year and clinical investigation:  
  - Where the cause of infertility is known, the couple should be referred to secondary care services without |
| **further delay for further investigation and treatment as clinically required.** |
| - In the absence of any known cause of infertility, and where the woman is below 38 years of age, the couple should be referred to secondary care services for further investigations and treatment after a further 1 year of regular unprotected vaginal sexual intercourse |
| A female who has a known cause of infertility, e.g. Turner Syndrome should be immediately referred for specialist assessment and where clinically indicated infertility treatment without delay. |
| In circumstances where the above definition cannot be applied, for example females in a same sex relationship, a single female, or a transgender male, infertility is identified where the female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a Human Fertilisation and Embryology Authority (HFEA) registered clinic, in the absence of any known medical cause of infertility. |

| **One cycle of fertility treatment** | A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy. |

<p>| <strong>Reproductive Pathology</strong> | Diagnosis of a recognised condition that renders a patient infertile or reduces fertility, including confirmed diagnosis of: |
| - Polycystic Ovarian Syndrome (PCOS, including amenorrhea and oligomenorrhea) |
| - Early onset of menopause |
| - Complete amenorrhea |
| - Endometriosis which has previously been surgically treated |</p>
<table>
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<tr>
<th>Condition</th>
<th>Description</th>
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<tr>
<td>Clinically significant fibroids</td>
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<td>Pelvic Inflammatory Disease</td>
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<td>Ovarian Failure including Turner syndrome and other genetic abnormalities</td>
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<td>Azoospermia</td>
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<td>Undescended testes</td>
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<td>Tubal disorders and/or damage as a result of disease or trauma (e.g. blocked fallopian tubes, blocked seminal tubes); this does not include patients who have chosen to receive sterilisation surgery.</td>
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<td>A physical disability preventing vaginal sexual intercourse</td>
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<td>Planned/received treatment that has resulted in infertility eg. cancer treatment</td>
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<tr>
<td>Oligozoospermia / Asthenozoospermia / Teraotozoospermia, or any combination of these.</td>
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<td>Chronic Anovulation</td>
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</table>

**One cycle of fertility treatment**

A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.

**In vitro Maturation (IVM)**

In the IVM process, eggs are removed from your ovaries when they are still immature. They are then matured in the laboratory before being fertilised.

**Sperm washing**

Sperm washing has been developed for couples who wish to have a child where the male partner is HIV positive but the female is HIV negative (referred to as HIV discordant status). The aim is to reduce the risk of HIV transmission by attempting to achieve pregnancy.
through insemination of sperm washed free of HIV rather than through unprotected intercourse.

The technique used to do this is called **sperm washing** and rests on the observation that HIV infective material is carried in the fluid around the sperm (seminal fluid) rather than by sperm itself. The technique involves separating the HIV infected seminal fluid from the sperm by centrifugation and ‘washing’. The ‘washed’ sperm is then combined with nutritional fluid, tested for HIV using a sensitive test called a ‘PCR’ assay and, provided this is negative, inseminated into the female partner when she is ovulating and most likely to become pregnant. In couples with fertility problems washed sperm can be used in other fertility treatments such as IVF.
## Appendix 2 – Eligibility Criteria

| 1a. | Age of Female Partner wishing to conceive | In females aged under 40 years, offer NHS infertility treatment. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. | The age of the female partner at the time of treatment must be under 40 years of age.  
- If infertility is clinically identified in a female from the age of 18 years old - NHS infertility treatment should be offered without delay.  
- Where the woman is aged 38 - 39 years of age, the couple should be offered referral to specialist NHS infertility centre for assessment without further delay.  
Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday. | Consistent with NICE Guideline. Fall off in treatment success with increasing maternal age. Increased maternal and child complication rate. Prevention of delays in treatment where appropriate. Whilst NICE recommend an extension of the female age to 42 where specific criteria are met, the success rates for this cohort of patients is relatively low. For females aged under 34, success rates are 41%; in females aged 40-42, this drops down to 21%. [HFEA Trends and Figures 2011]. |
| 1b | Age of Male Partner | Both female fertility and (to a lesser extent) male fertility decline with age. [CG 1.2.1] | The age of the male partner at the time of treatment must be under 55 years of age. | HFEA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor’s age on assisted conception success is considered on a case by case basis. |
There is limited evidence that IVF success decreases in men over the age of the 40. Men aged over 40 are half as likely to conceive with IVF compared to 30-year-old men when their female partner is aged 35-39 years (de La Rochebrochard et al, 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998).

In light of some evidence that male age does impact on infertility, and may have an impact on IVF outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.

<p>| 2. | Childlessness | n/a | Resource Allocation: The priority of infertility treatment for childless couples. | NHS infertility treatment will NOT be funded if either partner has living children of any age; this includes an adopted child or a child (biological or adopted) from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple / individual will no longer be considered childless and will not be eligible for NHS funded treatment. |</p>
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<th></th>
<th>Previous Infertility Treatment</th>
<th>n/a</th>
<th>NHS infertility treatment will not be offered to people where either partner within the couple has already undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded.</th>
<th>The ability of the commissioner to provide infertility treatment to the optimal number of couples.</th>
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<td>4.</td>
<td>Sterilisation</td>
<td>n/a</td>
<td>NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.</td>
<td>Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this.</td>
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<td>5.</td>
<td>Body Mass Index</td>
<td>Females who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive.</td>
<td>The female wishing to conceive must have a BMI of &lt;30 kg/m² at the time of referral and commencement of treatment. Females wishing to conceive must be informed of this criterion at the earliest opportunity and offered the support of local NHS services to optimise their BMI.</td>
<td>Consistent with NICE Guideline.</td>
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<td>6.</td>
<td>Smoking / Vaping Status</td>
<td>Females who smoke/vape should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking.</td>
<td>Only non-smoking females/couples will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral for infertility treatment.</td>
<td>Maternal and paternal smoking can adversely affect the success of infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Females should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and...</td>
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smoking / vaping, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke / vape should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking/vaping will improve their general health.

| smoking / vaping, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke / vape should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking/vaping will improve their general health. | reduced semen quality. The impact of vaping on conception, pregnancy and the passive impact of vaping is uncertain and without further evidence of the safety of vaping in conception / pregnancy / childhood, this cannot be currently recommended as an alternative to smoking. |