NHS
Surrey Heartlands

CLIN 5

Assisted Conception Policy (including Operating Procedures for managing Assisted Conception applications)

Policy number	CLIN05
Version	1.1
Approved by	Integrated Care Board (ICB) following recommendation from CCG Audit Committee
Name of originator/ author	Dr Ruchika Gupta, IFR Clinical Lead Andrea Golding, ECI Manager
Owner (director)	Clare Stone, ICS Director of Multi-Professional Leadership and Chief Nursing Officer
Date of last approval	December 2021 (Health & Care Professionals Committee)
Next approval due	December 2024

Version control sheet

Version	Date	Author	Status	Comments / changes since last version
1	01.04.2008	Working Group: Niki Bartrop/ Abigail Groves/ Marion Heron/ Anna Raleigh/ Sue Waters	Draft	Out for consultation
1	01.7.2008	Working Group: Commissioning	Final	Approved ay Board
2	01.07.2009	Niki Baier/ Avril Imison	Draft	Reviewed and agreed as part of specialist commissioning group for South East Coast
2	01.08.2009	Niki Baier/ Avril Imison	Final	Approved at Risk and Clinical Governance Committee
3	01.02.2010	Kelly Morris	Draft	Reviewed to include SEC policy recommendation re: cancer treatment and sperm retrieval
3	01.12.2011	Amelia Whittaker/ Michael Baker	Draft	Reviewed and now includes: • Paragraph on armed forces covenant added • Oocyte vitrification included and time limit for storage confirmed as 10 years • Smoking: details of referral to Surrey Stop Smoking Service now included • BMI changed to reflect NICE classification of a healthy weight • Confirmation that the lower age limit (23 years) will not apply to patients that are accessing Assisted Reproductive Techniques for Fertilisation Preservation • Update to current service providers • Clarification of NHS provision for self-funding patients • Gamete/Embryo Storage guidelines • FSH/AMH levels reviewed by clinicians • Single Embryo transfer-HFEA guidelines added • Guidance regarding women in same sex individuals and women not in a partnership

				• HFEA code of ethics added to criterion • Individuals to take up funding offer within 6 months
4	01.02.2012	Amelia Whitaker/ Michael Baker	Final	Approved by Quality and Performance Committee
4.1	01.12.2012	Amelia Whitaker/ Michael Baker	Final	Extended until conclusion of NHS Surrey
5	01.04.2013	Working Group	Draft	For approval by Executive Committee
5	01.07.2013	Working Group	Final	Approved by Governing Body
6	01.05.2016	Dr Liz Saunders/ Cyril Haessig	Final	Approved by Governing Body
7	01.10.2016	Dr Ruchika Gupta	Draft	For approval by each CCG
7	01.11.2016	Dr Ruchika Gupta	Final	Approved by Governing Body
8	01.07.2017	Dr Ruchika Gupta/ Andrea Golding	Final	• Changed wording from “couple” to “individuals” • Inclusion of details relating to immigration health surcharge under “Introduction”
9	01.08.2017	Dr Ruchika Gupta/ Andrea Golding	Final	• In light of inclusion of details relating to immigration health surcharge • Completed new EQIA on the policy • Review date extended by 6 months until August 2018 to enable Public Health to conduct an evidence review
9.1	01.06.2018	Surrey Priorities Committee	Draft	Statement inserted in relation to Cryopreservation of eggs and sperm for young patients
9.1	01.07.2018	Surrey Priorities Committee	Final	Approved by Governing Body
9.2	01.10.2018	Surrey Priorities Committee	Draft	Review conducted by Public Health team, no new or additional evidence available – SPC agreed to review in 3 years’ time
9.2	01.12.2018	Surrey Priorities Committee	Final	Approved by Governing Body
9.3	07.05.2021	Surrey Priorities Committee	Final	• Addendum added to policy to take into consideration patients that do not meet the age-related criteria due to the global pandemic • Amended Woking Nuffield Hospital to Care Fertility, Woking to reflect the change in provider name

9.4	16.08.2021	Andrea Golding	Draft	• Review period for all thresholds increased from 3 to 5 years, in line with NICE guidance • Amended policy review date to December 2022 to allow for the publication of new NICE guidance • Operating process for dealing with Assisted Conception applications included as an appendix within this policy
9.4	02.11.2021	Andrea Golding	Draft	• Approved by the Health and Care Professional Executive
10	15.12.2021	Andrea Golding	Final	Ratified by Quality & Performance Assurance Board: • Version amended to 10 from 9.4 on the advice of the Surrey Heartlands CCG Governance Team • Revised addendum in relation to COVID vaccine recommendation for pregnant women
CCG Abolished – ICB Established July 2022				
1.0	July 2022	Andrea Golding	Final	Approved by Health & Care Professionals Committee (HCPC)
1.1	September 2022	Andrea Golding	Draft	Extension applied to the review date to allow for the upcoming NICE guidelines, which has been delayed until 2024.
1.1	September 2022	Andrea Golding	Final	Approved by Health & Care Professionals Committee (HCPC)

Addendum to the Policy – December 2021

Eligibility Criteria:

1. The Policy's key eligibility thresholds with regards to age and the maximum number of cycles remain in place. The eligibility for IVF in respect of age will be determined at the point of referral to an Assisted Conception Unit (ACU). Up to 2 full cycles of IVF, with or without ICSI, will be funded in eligible women who are aged not more than 39 years and zero days at the time of referral to the ACU. If the woman reaches the age of 40 during treatment, then the current full cycle will be funded but no further full cycles will be funded. However,
2. For women whose referral to an ACU has been made before the age cut-off point set out in the Policy - but have not yet started their fertility treatment due to COVID-19 - and now find themselves over the 39 years and zero-day threshold, treatment should still carry on as originally planned.
3. If a cycle is cancelled because of COVID-19 the cancelled cycle should not count as an NHS funded cycle and a further cycle should be offered as soon as it is safely feasible.
4. For clarity the definition of a "full cycle" in Surrey Heartlands ICB policy is defined as a full IVF treatment, which should include 1 episode of ovarian stimulation and the transfer of 1 set of fresh and 1 set of frozen embryos, if available.

COVID-19 Vaccination, Assisted Conception and Pregnancy:

The following advice is correct as of 8th October 2021. However, we would advise health professionals and patients to check for the latest information on GOV.UK as scientific evidence on Covid is regularly updated.

The Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe. The coronavirus (COVID-19) vaccines available in the UK have been shown to be effective and to have a good safety profile. These vaccines do not contain live coronavirus and cannot infect a pregnant woman or her unborn baby in the womb.

The JCVI explains that Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age who are coming for their first dose. Anyone who has already started vaccination and is offered a second dose whilst pregnant, should have a second dose with the same vaccine unless they had a serious side effect after the first dose".

More information can be accessed on https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a-pregnancy-or-breastfeeding

Duration:

This addendum is temporary and will be kept under review as the COVID-19 situation changes.

Equality statement

Surrey Heartlands Integrated Care Board (ICB) is committed to promoting equality and diversity in all its activities and to promoting inclusive processes, practices and culture.

- We will strive to work to eliminate any unlawful or unfair discrimination including direct or indirect discrimination, discrimination by association, discrimination linked to a perceived characteristic, harassment and victimisation.
- We will remain proactive in taking steps to ensure inclusion and engagement for all the people who work for and with us.
- We will continue to strive towards a culture that is diverse and inclusive that recognises and develops the potential of all staff and service users.
- We recognise the business benefits and opportunities of having a diverse community of staff who value one another and realising the contribution they can make to achieving the ICB's vision.

This includes promoting equality and diversity for all irrespective of:

- age*
- disability*
- ethnic group*
- sex*
- gender reassignment*
- religion or belief*
- sexual orientation*
- marriage and civil partnership*
- pregnancy and maternity*

*Under the Equality Act (2010) these are known as "protected characteristics".

In addition, it includes promoting equality and diversity for carers, people with diverse communication needs and veterans.

The ICB aims to meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. We take into account the Human Rights Act 1998 and promote equal opportunities for all. We embrace the seven staff pledges in the NHS Constitution that represent a commitment by the NHS to provide high-quality working environments for staff. This policy is consistent with these pledges.

This document has been assessed to ensure that no employee or member of the public receives less favourable treatment based on their protected characteristics.

Members of staff, volunteers or members of the public are invited to request assistance with this policy if they have particular needs. If the member of staff has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

Equality analysis

This policy has been subject to an Equality Analysis, the outcome of which is recorded below.

		Yes/No	Comments
1.	Does the document/guidance affect one group less or more favourably than another on the basis of:		
	Age Where this is referred to, it refers to a person belonging to a particular age (e.g., 32-year-olds) or range of ages (e.g. 18 - 30 year olds).	No	The lower age limit in the original policy has been removed which will give greater equality in relation to age. There is evidence that fertility declines with age in both men and women. The upper age limit in this policy for women accessing treatment remains at 39 which is based on the most favourable outcome based clinical evidence taking into account the financial implications. On the basis of this evidence, Surrey ICBs have chosen to depart from NICE CG156 recommendations and will not fund fertility treatment for women aged 40-42. In the context of this policy the upper age limit is 39. National and local provider data show that young women aged 18-39 achieve a much higher live birth rate than women in the older category. **August 2017:** Following amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 The policy would have a potential negative impact on all overseas visitors who would be eligible for treatment pre-21st August 2017.
	Disability A person has a disability if s/he has a physical or mental impairment which has a substantial and long-term adverse effect on that person's	No	This policy is inclusive to individuals with a disability. Individuals must conform to the "welfare of the child which may be born" as per the Human Fertilisation and Embryology Act 1990 and must take into consideration the importance of a

	ability to carry out normal day-to-day activities.		stable and supportive environment for children as well as the pre-existing health status of the parents. There may be situations where people with a disability could have reduced access to fertility treatment if in the opinion of the fertility consultant such access would likely worsen their medical condition.
	Gender reassignment The process of transitioning from one gender to another.	No	This policy is inclusive to male, female and individuals with Gender Dysphoria therefore this should have a positive impact compared with the original policy. **August 2017:** Following amendments to the NHS (Charges to Overseas Visitors) Regulations 2015. The policy would have a potential negative impact on all overseas visitors not ordinarily resident in the UK pre-21st August 2017, undertaking gender reassignment in their country of origin
	Marriage and civil partnership In England and Wales marriage is no longer restricted to a union between a man and a woman but now includes a marriage between a same-sex individuals. Same-sex individuals can also have their relationships legally recognised as 'civil partnerships'. Civil partners must not be treated less favourably than married individuals (except where permitted by the Equality Act).	No	This policy is inclusive to married individuals, people in a same sex relationship and single women.
	Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby.	No	Changes to this policy will not impact women who are already pregnant. In respect of women trying to become pregnant.

	Maternity refers to the period after the birth and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.		This policy change will have a positive impact on some women/individuals who previously were denied access to IVF because they had no source of sperm and donation was their only option. Now NHS funded sperm will be supported in eligible individuals. This policy change will have a positive impact on quality and safety in respect of the change to the NICE recommended embryo transfer strategy which will reduce multiple births. The policy will have a positive impact on the following groups by bringing the eligibility criteria for IUI in line with the recommendations of NICE CG156: - People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm - People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) - People in same-sex relationships or where there is a female with no partner - People with social, cultural, or religious objections to IVF This policy change will have a positive impact on the success of IVF as the use of FSH measurement as a predictor of ovarian reserve has now been removed due to poor evidence base. As a result, fertility providers will be expected to undertake appropriate diagnostic investigations to determine suitability for IVF in line with contemporary good practice and

			should take all reasonable measures to prevent the occurrence of Ovarian Hyper-stimulation Syndrome (OHSS) This policy stipulates that to be eligible for fertility treatment neither partner in a relationship can have a living child from their relationship or any previous relationship. This also applies to adopted child(ren); A situation may therefore present where a woman diagnosed with fertility problems is denied access to fertility treatment because her partner already has a child(ren). This aspect of the policy has not changed.
	Race Refers to the protected characteristic of Race. It refers to a group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.	No	There is no evidence that this policy will lead to a differential impact as a result of Race. **August 2017:** Following amendments to the NHS (Charges to Overseas Visitors) Regulations 2015. The policy would have a potential negative impact on all overseas visitors not ordinarily resident in the UK pre-21st August 2017
	Religion and belief Religion has the meaning usually given to it but belief includes religious and philosophical beliefs including lack of belief (e.g. Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition	No	There is no evidence that this policy will lead to a differential impact as a result of Religion or Belief; Furthermore, there will be a positive impact for people with cultural or religious objections to IVF as the policy has brought its IUI eligibility criteria in line with NICE CG156. **August 2017:** Following amendments to the NHS (Charges to Overseas Visitors) Regulations 2015.

			The policy could have a potential negative impact on those overseas visitors who might have received free access to assisted conception services before 21st August 2017 because of Female Genital Mutilation (FGM) or human trafficking.
	Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex or to both sexes.	No	Recent changes in civil partnership laws mean that same sex individuals have the same rights as married relationship when it comes to assisted conception and therefore do not face discrimination based on their gender; This Policy offers the opportunity for same sex individuals to apply for IVF regardless of their sexual orientation; However, there are some limitations to the above regarding same sex individuals as this policy does not fund surrogacy. For women in a same sex relationship or not in a partnership, funding will now be made available for sperm donation for use in IUI or IVF but only where the sperm are donated altruistically free-of-charge or are available via an NHS sperm bank or equivalent; Egg donation will not be funded routinely.
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the document/guidance likely to be negative?	N/A	
5.	If so, can the impact be avoided?	N/A	

6.	What alternative is there to achieving the document/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

For advice in respect of answering the above questions, please contact the Corporate Office, Surrey Downs ICB. If you have identified a potential discriminatory impact of this procedural document, please contact as above.

Names and Organisation of Individuals who carried out the Assessment	**Date of the Assessment**
Cyril Haessig/ Majorie De Vries/Andrea Golding	23.02.2016
Clare Johns/ Pollymarch Mather (Assessment completed in light of amendments to the NHS (charges to overseas visitors) Regulations 2015.	17.08.2017

Contents

1. Introduction

This policy covers Intra-Uterine Insemination (IUI), In Vitro Fertilisation (IVF) and Intra-cytoplasmic sperm Injection (ICSI).

The Surrey Heartlands ICB 'Assisted Conception Policy' describes the commissioning policy and the eligibility criteria for access to Assisted Conception in Surrey. Assisted Conception here is taken to include in-vitro fertilisation (IVF) with or without intracytoplasmic sperm injection (ICSI), and intrauterine insemination (IUI).

Over time, there have been three important pieces of policy/legislation that have meant that the Assisted Conception policy has needed to be updated. The first of these is the publication of the new NICE guideline on Assisted Conception (CG156), published in February 2013, the second is the ban on age discrimination in service provision under the Equality Act 2010 (EA 2010), which came into force on 1st October 2012 and the third is that following amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 that were introduced into Parliament on 19 July 2017, as of 21 August 2017, Assisted Conception services will no longer be included in the scope of services available for free for those who pay the Immigration Health Surcharge (IHS).

Having considered the above the Governing Body has decided to include the following changes to its Assisted Conception Policy. These are:

Funding will be provided for:

- Women of reproductive age and their partners who have not conceived after 3 years of regular unprotected vaginal intercourse

Funding will be provided for:

- For up to 6 cycles of IUI but only in eligible individuals meeting the criteria set out in this Policy;
- Eligibility for IVF in respect of age will be determined at the point of referral to an Assisted Conception Unit (ACU). This allows eligible women who have been referred to have appropriate cycles of treatment before their 40th birthday. Up to 2 full cycles of IVF, with or without ICSI, will be funded in eligible women who are aged not more than 39 years and zero days at the time of referral to the ACU.

Regarding embryo transfer this Policy will adhere to the NICE recommendations set out in CG156.

NHS funding will only be made available for sperm donation for use in IUI or IVF where the sperm are donated altruistically free-of-charge or are available via an NHS sperm bank or equivalent. Egg donation will not be funded routinely.

Eligible individuals under the age of 40 will be funded:

- For up to two cycles of IVF, with or without ICSI, if no previous cycles have been funded by the NHS;
- For up to one cycle of IVF, with or without ICSI, if the individuals have already received one NHS funded cycle;
- Any privately funded cycles previously received will not be taken into account (unless they resulted in the individuals having a living child).

Providers will be expected to undertake appropriate diagnostic investigations to determine suitability for IVF in line with contemporary good practice and should take all reasonable measures to prevent the occurrence of Ovarian Hyper-stimulation Syndrome (OHSS).

Assisted conception will not be provided to individuals if their sub-fertility is the result of sterilisation in either partner; unless the patient(s) sterilisation is the direct result of treatment for gender dysphoria.

In the context of gender dysphoria, gamete storage will follow similar protocols as with those receiving radiotherapy and other gamete damaging procedures.

Cryopreservation of embryos, oocytes and sperm will be funded for patients including those undertaking gender reassignment procedures (Female to Male and Male to Female) who are about to undergo medical treatment, which is likely to affect their fertility, following the recommendations in 'The effects of cancer treatment on reproductive functions' (2007).

Cryopreservation of eggs and sperm will be funded for young patients (18 and under and who are post pubertal), who are about to or have received treatment likely to affect their fertility. Subsequent assisted conception procedures will be funded in accordance with all eligibility criteria set out in this policy.

Cryopreservation of good quality embryos from NHS funded IVF will be funded for up to 2 years.

Sperm washing will be funded where the man is HIV positive in accordance with the criteria set out in this Policy.

IVF with or without ICSI will only be funded for women who have had a BMI between 19-30 for a period of at least 6 months prior to assessment for treatment.

Funding for Armed Forces personnel diagnosed with fertility problems will be the responsibility of NHS England.

The changes introduced in this policy have carefully considered the entire available evidence base to ensure that NHS resources are targeted at the patient group most likely to achieve the live birth of a healthy baby.

2. Policy Objective

The management of fertility includes both primary and secondary care support and intervention where appropriate, including advice on lifestyle changes that are likely to improve the probability of conception.

3. Definition

Assisted conception, which is here defined to include in-vitro fertilisation (IVF), intrauterine insemination (IUI), and intracytoplasmic sperm injection (ICSI), will normally only be funded in the context of the NICE Pathway for fertility.[1]

4. Funding

Funding will be provided for:[2]

- Up to 6 cycles of IUI but only in the following eligible individuals:
  - People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm
  - People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
  - People in same-sex relationships
  - People with social, cultural, or religious objections to IVF
  - Females with no partner requiring donor sperm

Eligibility for IVF in respect of age will be determined at the point of referral to an Assisted Conception Unit (ACU). This allows eligible women who have been referred to have appropriate cycles of treatment before their 40th birthday. Up to 2 full cycles of IVF, with or without ICSI, will be funded in eligible women who are aged not more than 39 years and zero days at the time of referral to the ACU. If the woman reaches the age of 40 during treatment, then the current full cycle will be funded but no further full cycles will be funded.

5. Gender Dysphoria

Funding will be provided to people with gender dysphoria in the following cases:

- For individuals whose sub fertility is the result of sterilisation in either partner, where it is established that such sterilisation is the direct result of treatment for Gender Dysphoria
- Access to the cryopreservation of embryos, oocytes and sperm will be funded for patients including those undertaking gender reassignment procedures (Female to Male and Male to Female) who are about to undergo medical treatment which is likely to affect their fertility

[1] NICE pathway for fertility, available at http://pathways.nice.org.uk/pathways/fertility/fertility-overview accessed 16th April 2013

[2] Eligibility criteria are listed in full in Section 2: Criteria for access to assisted conception

Eligible patients will be required to demonstrate that they have been or are going through a defined gender reassignment clinical pathway agreed by NHS England.

6. Access

Access to funding for specialist assisted conception treatments will normally be on the recommendation of a local NHS consultant gynaecologist or on some occasions a local NHS consultant urologist.

7. Providers

The current providers for treatment in Surrey are:

- Care Fertility, Woking
- Croydon Health Services NHS Trust
- Queen Mary's Hospital, Roehampton, Kingston Hospital NHS Trust

8. Responsibilities

These specialist fertility units will be **solely responsible** for initial consultation, treatment planning, counselling and advising patients, consent, all drugs, egg collection, semen analysis, embryo transfer, pregnancy testing, all consumables, pathology tests, imaging, and Human Fertilisation and Embryo Authority (HFEA) fees if required. Accordingly, the cost of all IVF treatment and drugs is included in the cost of the package maintained by the lead consultant provided by the specialist unit and will not be funded as separate elements by clinicians in primary care.

9. Private/Self-funding

Private/self-funding patients who are undergoing treatment outside of an NHS pathway will **not** be funded or reimbursed for drugs or additional tests incurred as a result of self-funded/private treatment.

10. Commissioning Policy

This commissioning policy should be read in conjunction with the criteria listed below for access to Assisted Conception. Individuals must meet all the criteria in order to be eligible for NHS funding of treatment.

11. Pre-implantation Genetic Diagnosis (PGD)

PGD can avoid the transmission of serious genetic disease. However, funding of PGD is separate from infertility treatment and is covered by the London Genetics Panel and South East Coast Specialised Commissioning Group. Referral is made directly by the consultant to this panel.

12. Sperm Donation, Oocyte Donation, In-vitro Maturation (IVM) and Surrogacy

Sperm donation will be funded only where the sperm are altruistically donated without charge or can be accessed from an NHS sperm bank or equivalent.

Oocyte donation will not be funded routinely.

IVM will not be funded, due to limited evidence of effectiveness.

No elements of surrogacy procedures will be funded. Therefore, the ICB will:

- Not be involved in the recruitment of surrogate mothers
- Not fund any element of treatment which relates specifically to addressing fertility treatments directly associated with surrogacy arrangements
- Not fund any payments to a surrogate mother (to cover expenses, legal costs, treatments abroad or transport costs)

13. Blood-borne Viruses and Sperm Washing

Sperm washing will be funded if the man is HIV positive and either he is not compliant with HAART or his plasma viral load is 50 copies/ml or greater, as it reduces but does not eliminate the risk of HIV transmission.

Sperm washing will not be funded for men with Hepatitis B or Hepatitis C, as the current evidence does not support this.

14. Cryopreservation to preserve fertility in people diagnosed with Cancer

Cryopreservation of sperm, embryos, or oocytes for an initial period of 10 years will be funded in people before starting chemotherapy or radiotherapy that is likely to affect their fertility.

Further storage of sperm in men who remain at risk of significant infertility will be funded.

The eligibility criteria used for cryopreservation will not be the same as the eligibility criteria for conventional infertility treatment. However, the conventional criteria will apply when it comes to using stored material for assisted conception in an NHS setting.

Patients seeking oocyte donation are not covered by this policy.

15. Cryopreservation of eggs and sperm for young patients

Cryopreservation of eggs and sperm will be funded for young patients (18 and under and who are post pubertal), who are about to or have received treatment likely to affect their fertility. Subsequent assisted conception procedures will be funded in accordance with all eligibility criteria set out in this policy.

16. The Armed Forces

The Armed Forces community should enjoy the same standard of, and access to, healthcare as received by any other UK citizen in the area they live. Funding for Armed Forces personnel diagnosed with fertility problems will be the responsibility of NHS England. The assessment and treatment pathway for individuals with fertility problems (based on NICE CG 156) are set out in the NHS England Clinical Commissioning Policy on Assisted Conception.[3]

17. Detailed criteria for access to NHS-funded Assisted Conception

17.1 Definitions

Term	Definition
Assisted Conception	Defined as including intrauterine insemination (IUI), in-vitro fertilisation (IVF), and intracytoplasmic sperm injection (ICSI)
Infertility	Defined in practice as the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented
Full Cycle of IVF	Defined as a full IVF treatment, which should include 1 episode of ovarian stimulation and the transfer of 1 set of fresh and 1 set of frozen embryos, if available
Mild male factor infertility	defined for the purpose of the recent NICE guideline (2013) and this policy document as when 2 or more semen analyses have 1 or more variables below the 5th centile (as defined by the WHO, 2010)
Low ovarian reserve	Defined locally by providers. Providers will be expected to undertake appropriate diagnostic investigations to determine suitability for IVF in line with contemporary good practice and should take all reasonable measures to prevent the occurrence of Ovarian Hyper-stimulation Syndrome (OHSS)

18. Baseline eligibility for Assisted Conception

All individuals will be expected to have completed the primary and secondary care pathways[4] appropriate to them before eligibility for IUI, IVF, or ICSI is considered (including all appropriate investigations and treatments). This includes consultation/specialist referral as follows:[5]

- Initial consultations:

[3] NHS England Clinical Commissioning Policy : Assisted Conception, Reference N-SC/037, Gateway Number 02285
[4] NICE pathway for fertility, available at http://pathways.nice.org.uk/pathways/fertility/fertility-overview accessed 16th April 2013
[5] Following the recommendations in NICE guideline CG156, subsection 1.2.13

a. To discuss lifestyle and sexual history in people who are concerned about delays in conception.

b. To discuss lifestyle and sexual history in people who are concerned about delays in conception.

- Specialist referral for further assessment and investigation:
  a. For women of reproductive age and their partners who have not conceived after 3 years of regular unprotected vaginal intercourse, or 6 cycles of artificial insemination, in the absence of any known cause of infertility.
  b. Earlier referral if the woman is aged 36 or over or there is a known clinical cause of infertility or a history of predisposing factors for infertility.
  c. Early referral for individuals where treatment is planned that may result in infertility (such as treatment for cancer)
- Appropriate specialist referral for people with chronic viral infections such as Hepatitis B, Hepatitis C, or HIV, to centres that have appropriate expertise and facilities to provide safe risk-reduction investigation and treatment. All individuals undergoing IVF treatment should be offered testing for HIV, Hepatitis B and Hepatitis C and referred in this way if found to be positive.[6]
- All individuals must be registered with a general practitioner (GP) in Surrey.

19. Embryo Transfer Strategies in IVF as set out in NICE CG156

This policy advocates the recommendations from NICE when considering the number of fresh or frozen embryos to transfer in IVF treatment as follows:[7]

19.1 For women aged under 37 years:

- In the first full IVF cycle use single embryo transfer
  - In the second full IVF cycle use single embryo transfer if 1 or more top-quality embryos are available. Consider using 2 embryos if no top-quality embryos are available

19.2 For women aged 37-39 years:

In the first and second full IVF cycles, use single embryo transfer if there are 1 or more top-quality embryos. Consider double embryo transfer if there are no top-quality embryos.

Where a top-quality blastocyst is available, use single embryo transfer.

No more than 2 embryos should be transferred during any one cycle of IVF Treatment.

[6] Following the recommendations in NICE guideline CG156, subsection 1.3.9
[7] Following the recommendations in NICE guideline CG156, subsection 1.12.6

19.3 Full List of Eligibility Criteria

Ref	Title	Criterion
1	Eligibility for IUI	• Up to 6 cycles of IUI will be funded for individuals who have not conceived despite evidence of normal ovulation, tubal patency, and semenalysis, if they fall into the following groups:[8] 1. People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm 2. People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) 3. People in same-sex relationships or where there is a female with no partner 4. People with social, cultural, or religious objections to IVF 5. Females with no partner requiring donor sperm • People with unexplained fertility, mild endometriosis, or mild male factor infertility not falling into the above groups will not be funded for IUI, with or without ovarian stimulation, but will be considered for IVF after trying to conceive for 3 years
2	Duration of infertility and eligibility for IVF/ICSI	• IVF with or without ICSI will be funded for women who have not conceived after 3 years of regular unprotected intercourse (which can include no more than 1 year prior to fertility investigations),[9] or a maximum of 6 cycles of IUI unless clinical judgement dictates otherwise
3	Age of woman and eligibility for IVF/ICSI	• Eligibility for IVF in respect of age will be determined at the point of referral to an Assisted Conception Unit (ACU). This allows eligible women who have been referred to have appropriate cycles of treatment before their 40th birthday. Up to 2 full cycles of IVF, with or without ICSI, will be funded in eligible women who are aged not more than 39 years and zero days at the time of referral to the ACU. If the woman reaches the age of 40 during treatment, then the current full cycle will be funded but no further cycles will be funded even if only 1 has been completed[10]

[8] Current evidence shows that current evidence shows that IUI is no better than regular vaginal intercourse in achieving a live birth, and so should not routinely be offered other than in these specified groups. Instead, individuals should be advised to attempt to conceive through regular vaginal intercourse for 2 years before being considered for IVF with or without ICSI (NICE guideline CG156, subsection 1.9.1)

[9] If the woman is aged under 40 years and the individuals have regular (every 2-3 days) unprotected sexual intercourse, over 80% of individuals will conceive in the first year and over 90% will have conceived by the end of the second year (NICE guideline CG156, subsection 1.2.1.1)

[10] Following the recommendations in NICE guideline CG156, subsection 1.11.1.3

Ref	Title	Criterion
		• Where a top-quality blastocyst is available, use single embryo transfer
4	Age of male partner and eligibility for IVF/ICSI	There is no upper or lower age limit for the male partner (as per adoption laws)
5	Women in same sex individuals and women not in a partnership and eligibility for IVF/ICSI	• NHS funding will only be made available for sperm donation for use in IUI or IVF where the sperm are donated altruistically free-of-charge or are available via an NHS sperm bank or equivalent • Egg donation will not be funded routinely • Women in same sex individuals and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish
6	Surrogacy	The ICB will not commission any form of fertility treatment to those in surrogacy arrangements (i.e., the use of a third party to bear a child for another individuals)
7	Previous infertility treatment and eligibility for IVF/ICSI	Eligibility in respect of age will be determined at the point of referral to an Assisted Conception Unit (ACU). Eligible individuals under the age of 40 will be funded: 1. For up to six cycles of initial IUI, as clinically indicated and at the discretion of the referring gynaecologist 2. For up to two cycles of IVF, with or without ICSI, if no previous cycles have been funded by the NHS 3. For up to one cycle of IVF, with or without ICSI, if the individuals have already received one NHS funded cycle Any privately funded cycles previously received will not be taken into account (unless they resulted in the individuals having a living child). • Individuals must take up the offer of IUI/IVF/ICSI within six months of being referred to the IUI/IVF/ICSI service provider • If a cycle is abandoned for reasons of poor response or failure of fertilisation this will count as one full cycle • If a cycle results in a miscarriage, this will count as one full cycle • Women who have attempted IVF with or without ICSI will not be offered subsequent IUI

Ref	Title	Criterion
8	Childlessness and eligibility for IVF/ICSI	Individuals cannot have a living child from their relationship or any previous relationships in order to be eligible for IVF. A child adopted by the individuals or adopted in a previous relationship is considered to have the same status as a biological child
9	Low Ovarian Reserve	Providers will be expected to undertake appropriate diagnostic investigations to determine suitability for IVF in line with contemporary good practice and should take all reasonable measures to prevent the occurrence of Ovarian Hyper-stimulation Syndrome (OHSS)
10	Sterilisation and eligibility for IVF/ICSI	Assisted conception will not be provided to individuals if their sub-fertility is the result of sterilisation in either partner, unless the patient(s) sterilisation is the direct result of treatment for gender dysphoria
11	Eligibility for cryopreservation to preserve fertility in people diagnosed with cancer	Cryopreservation of sperm will be funded for post-pubertal males who are about to undergo medical treatment, which is likely to affect their fertility, following the recommendations in 'The effects of cancer treatment on reproductive functions' (2007).[11] Subsequent assisted conception procedures using the sperm will not be funded unless all the eligibility criteria listed here are met by the individuals. In the context of gender dysphoria, gamete storage will follow similar protocols as with those receiving radiotherapy and other gamete damaging procedures. Cryopreservation of embryos, oocytes and sperm will be funded for patients including those undertaking gender reassignment procedures (Female to Male and Male to Female) who are about to undergo medical treatment, which is likely to affect their fertility, following the recommendations in 'The effects of cancer treatment on reproductive functions' (2007). They also must satisfy the criteria:[12] 1. They are well enough to undergo ovarian stimulation and egg collection **AND** 2. This will not worsen their condition **AND** 3. Enough time is available before the start of their cancer treatment

[11] Royal College of Physicians, The Royal College of Radiologists, Royal College of Obstetricians and Gynaecologists. (2007) The effects of cancer treatment on reproductive functions: guidance on management. Report of a Working Party. London: RCP. NICE guideline CG156, subsection 1.16.1 recommends that for cancer related fertility preservation, the eligibility criteria for conventional fertility treatment should not be used.
[12] Following the recommendations in NICE guideline CG156, subsection 1.16.1.10

Ref	Title	Criterion
		Subsequent assisted conception procedures using the embryo/oocytes will not be funded unless all the eligibility criteria listed here are met by the individuals. When deciding to offer fertility preservation to people diagnosed with cancer, take into account the following factors: 1. Diagnosis 2. Treatment plan 3. Expected outcome of subsequent fertility treatment 4. Prognosis of the cancer treatment 5. Viability of stored/post-thawed material Funding will be provided for storage for an initial period of 10 years, and beyond 10 years for sperm in men who remain at risk of significant infertility.
12	Eligibility for cryopreservation of surplus embryos following a fresh cycle of NHS funded IVF/ICSI	Cryopreservation of good-quality embryos from NHS funded IVF will be funded for up to 2 years. All frozen cycles will usually be expected to be completed prior to the commencement of a second fresh cycle.
13	Eligibility for surgical sperm retrieval for IVF/ICSI	Surgical sperm retrieval will be funded in appropriately selected patients, provided that the azoospermia is not the result of a sterilisation procedure or the absence of sperm production, and providing the individuals meet all other criteria.
14	Eligibility for sperm washing	Sperm washing will be funded where the male is HIV positive, and any of the following criteria are met:[13] • The male is not compliant with highly active retroviral therapy (HAART) • The male has a plasma viral load of ≥50 copies/ml Sperm washing will not be funded for men with Hepatitis B or Hepatitis C virus.

[13] Sperm washing reduces but does not eliminate the risk of HIV transmission. If the man is HIV positive, compliant with HAART, has a plasma viral load of <50 copies/ml for 6 months, there are no other infections present, and unprotected sexual intercourse is limited to the time of ovulation, then sperm washing may not further reduce the risk of infection and may reduce the likelihood of pregnancy (NICE guideline CG156, subsection 1.3.10)

Ref	Title	Criterion
15	Body mass index and eligibility for IVF/ICSI	• IVF with or without ICSI will only be funded for women who have had a BMI between 19-30 for a period of at least 6 months prior to assessment for treatment[14] • Women who have a BMI of 30 or over should be informed that they are likely to take longer to conceive. If they are not ovulating, they should be informed that losing weight is likely to increase their chance of conception • Women must be informed of this criterion at the earliest possible opportunity as they progress through infertility investigations in primary and secondary care • GPs are encouraged to provide unambiguous and clear information about BMI criteria to infertile individuals
16	Smoking status and eligibility for IVF/ICSI	• IVF with or without ICSI will only be funded for individuals where both partners have been non-smokers for a period of at least 6 months prior to assessment for treatment[15] • Smoking individuals must be referred to NHS smoking cessation services and demonstrate that they are non-smokers for a period of at least 6 months prior to assessment for treatment • Individuals must be informed of this criterion at the earliest possible opportunity as they progress through infertility investigations in primary and secondary care. GPs are encouraged to provide unambiguous and clear information about smoking criteria to infertile individuals, including the negative effect of passive smoking • Alongside BMI and smoking, GPs should also advise infertile individuals that the effectiveness of assisted reproduction procedures, including IVF, is reduced by the consumption of more than 1 unit of alcohol per day and maternal caffeine consumption[16]
17	HFEA Code of Ethics and eligibility for any assisted reproduction procedures	Individuals not conforming to the HFEA 'Code of Ethics' will be excluded from having access to NHS funded assisted reproduction procedures. This includes consideration of the 'welfare of the child which may be born' which may take into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.

[14] Female BMI outside of the range 19-30 is likely to reduce the success of assisted reproduction procedures (NICE guideline CG156, subsection 1.10.4.1)
[15] Smoking is likely to reduce fertility in women, and there is an association between smoking in men and reduced semen quality, although the impact of this on male fertility is uncertain (NICE guideline CG156, subsections 1.2.4.1-1.2.4.4)
[16] As per recommendations in NICE guideline CG156, subsection 1.10.5

Ref	Title	Criterion
18	The Armed Forces Covenant	Funding for Armed Forces personnel diagnosed with fertility problems will be the responsibility of NHS England. The assessment and treatment pathway for individuals with fertility problems (based on NICE CG 156) are set out in the NHS England Clinical Commissioning Policy on Assisted Conception[17]

20. Operating Procedures for Managing Assisted Conception Applications

20.1 Introduction

This guidance sets out the process for managing Assisted Conception funding applications. Assisted Conception procedures are restricted to clinical criteria set by Surrey Heartlands Integrated Care Board (ICB). This Operating Process policy should be read in conjunction with the ICBs Assisted Conception policy (above).

20.2 Assisted Conception Application Process

20.2.1 Prior Approval Application Form

A Prior Approval application form is required for ALL procedures listed within the Assisted Conception Policy, unless the case has funding approval following a formal IFR application.

All Prior Approval application forms must be completed and submitted using the secure online Blueteq database and should only be submitted by the clinician administering the treatment at the Assisted Conception Unit.

The onus is on the requesting clinician to ensure that a Prior Approval application form is submitted prior to any treatment taking place. Treatment which takes place without Prior Approval from the ICB will not be paid for.

20.2.2 Who can submit a Prior Approval Application Form

Prior Approval application forms for Assisted Conception must only be submitted by the Assisted Conception Unit (ACU) responsible for administering the treatment ("the requesting clinician").

Prior Approval application forms should only be submitted when the patient fully meets the criteria for the procedure requested.

It is the responsibility of the requesting clinician completing the Prior Approval application form to confirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the form is submitted.

If the male patient requires either Sperm Retrieval or Sperm Freezing, then the ACU must submit a separate online Prior Approval application form for this treatment.

[17] NHS England Clinical Commissioning Policy: Assisted Conception, Reference N-SC/037, Gateway Number 02285

20.2.3 Accessing Blueteq to submit a Prior Approval Application Form

In order for a clinician to submit a Prior Approval application form using the secure online Blueteq database, they will need to be registered as a user.

A user name and password are required to log on and can be obtained this by emailing Blueteq directly at tnrf@blueteq.co.uk, providing them with a full name, job title, nhs.net or nhs.uk email address, and provider name and requesting access to the IFR portal. Once registered, clinicians can access Blueteq at https://blueteq-secure.co.uk/trust

Please note: if providers are registered for both the Individual Funding Requests (IFR) portal and the Hi-Cost Drugs portal, the clinician will need to select which "trust mode" they will be working on. This does not apply if the clinician is only registered for IFR's.

20.2.4 Submitting a Prior Approval Application Form

All Prior Approval application forms completed and submitted will be populated by the secure online Blueteq database and a unique identifier will be created.

A process map for Assisted Conception Prior Approvals is included within this policy (Appendix 1).

Once received, a response will be provided to the requesting clinician within 72 hours. If additional information is required to support the request, the Effective Commissioning Initiative (ECI) Team will contact the clinician via the Blueteq database. The clinician will have 5 working days in which to respond to the ECI Team. If no response is received, then the request will be withdrawn, and the procedure will not be authorised to take place.

20.2.5 Auditing

All procedures which take place following the submission and ICB agreement of a Prior Approval form will be subject to periodic auditing by the ECI Team.

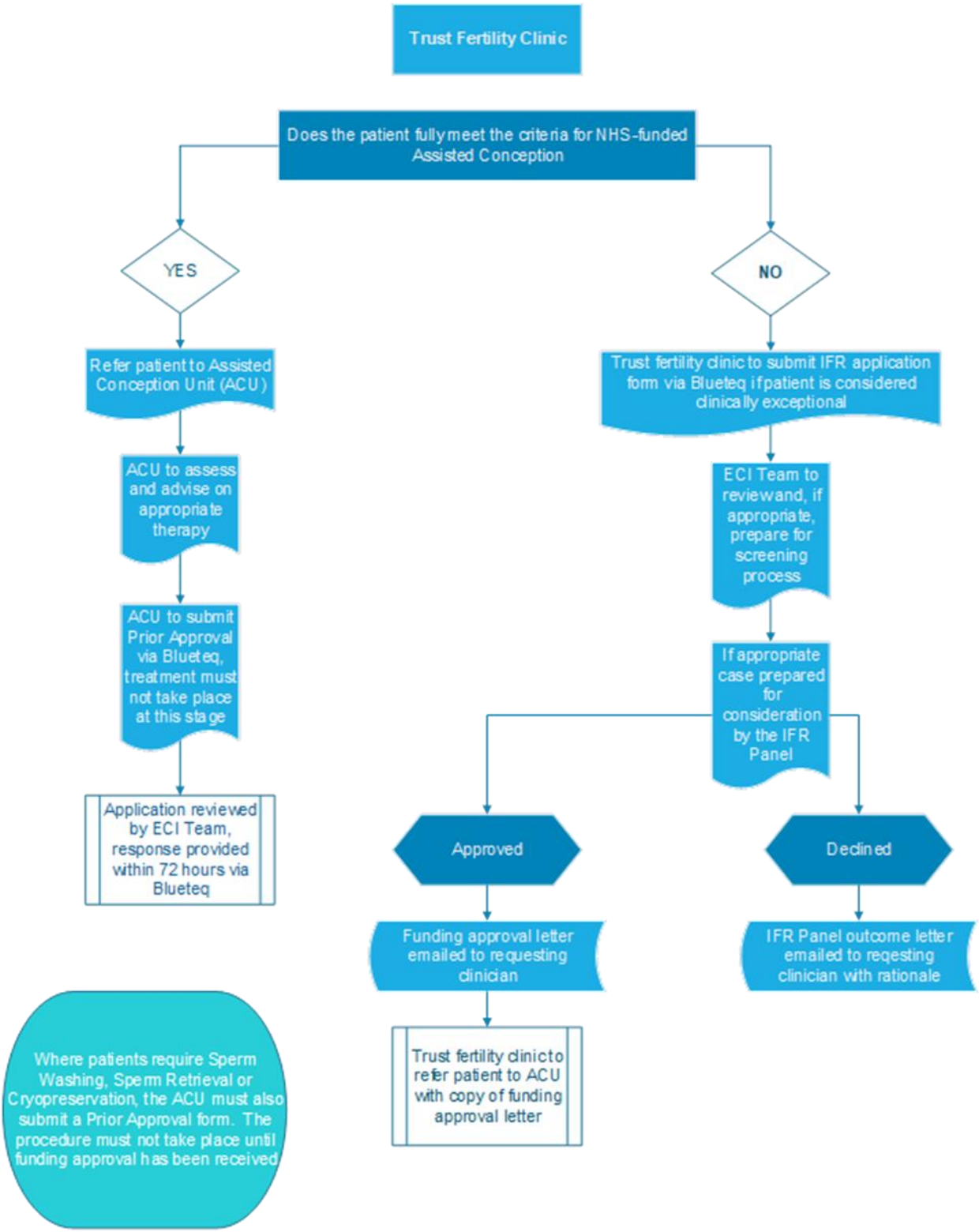
20.2.6 Funding Validity

Individuals must initiate treatment within six months funding approval.

20.2.7 Patients that do not meet the criteria for NHS-funded Assisted Conception Procedures

Where patients do not fully meet the criteria for a procedure listed within the Assisted Conception policy, the clinician has the option of submitting an IFR application if there is evidence that the patient presents with exceptional clinical circumstances. Further information relating to the submission of an IFR application can be found within CLIN01 Clinical Commissioning Policy: Individual Funding Requests.

21. Appendix A – Managing Assisted Conception Funding Applications



22. Appendix B – Procedural Document Checklist for Approval

Title of document being reviewed:		Yes/No/ Unsure	Comments/ Details
1.	**Sponsoring Director**		
	Is there a sponsoring director?	Yes	
	Have they approved **this version** of the policy?	Yes	
2.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
3.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
4.	**Development Process**		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	Within Public Health evidence reviews
5.	**New or review**		
	Is this a new document?	No	
	Is the ratification date stated on the front cover?	Yes	
	Is the ratification Committee stated on the front cover?	Yes	
	Is the review date stated on the front cover?	Yes	
	Is the version control detailing the version history of the document?	Yes	
	If this is a review document, has the version number been amended throughout?	Yes	
6.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target group clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
7.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	No	Policy developed with evidence reviews agreed

Title of document being reviewed:		Yes/No/ Unsure	Comments/ Details
			by SPC and HCPC
	Are key references cited?	Yes	
8.	**Quality and Equality Impact Assessment**		
	Has a QEIA been completed?		
	Is the QEIA attached?	Yes	This will be updated to new template at next review
9.	**Style and Format**		
	Is the style and format in line with the *Framework for the Production of Procedural Documents*?	Yes	
	Does the footer include the title, date of ratification and version number?	Yes	
	Are definitions provided for the key terms used in the document?	Yes	
	If applicable, are abbreviations written according to the guidance in *Framework for the Production of Procedural Documents*?	Yes	
10.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
11.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how the document will be disseminated and implemented amongst the target group? Please provide details.	Yes	Policies circulated by SH Contract Team
12.	**Process for Monitoring Compliance**		
	Have specific, measurable, achievable, realistic and time-specific standards been detailed to monitor compliance with the document? Complete Compliance & Audit Table.	Yes	
13.	**Review Date**		
	Is the review date identified?	Yes	
14.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for implementing and reviewing the documentation i.e., who is the document owner?	Yes	

23. Appendix C – Compliance and Audit Table

Criteria	Measurable	Frequency	Reporting to	Action Plan/ Monitoring
Review of clinical evidence of procedures	N/A	5-year cycle	HCPC	SPC work plan/NICE guidance/EBI thresholds