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<b>SUMMARY</b>	This clinical business rule has been developed to guide clinical practice at the Fertility & Research Centre (FRC), Royal Hospital for Women, for patients undergoing IVF treatment. It provides guidance on superovulation cycles for Assisted Reproductive Technology including treatment types, monitoring, and prevention & management of adverse outcomes
<b>Key Words</b>	In vitro fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI), Follicle Stimulating Hormone (FSH), Gonadotrophin Hormone-Releasing Hormone (GnRH) Luteal Phase Support (LPS)

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## In Vitro Fertilisation (IVF) -Management and Treatment of a Superovulation cycle

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*Within this document we will use the term woman, this is not to exclude those who give birth and do not identify as female. It is crucial to use the preferred language and terminology as described and guided by each individual person when providing care.*

### 1 BACKGROUND

This CBR refers to the management of superovulation cycles within the Fertility and Research Centre (FRC) at the Royal Hospital for Women (RHW). The aim of the CBR is to provide a basis for consistent In Vitro Fertilisation (IVF) treatment for patients and provide framework for management of superovulation cycles inclusive of prevention and management of adverse outcomes.

### 2 RESPONSIBILITIES

#### 2.1 Medical Director

Oversee all policy development and final approval of all clinical documentation in accordance with Reproductive Technology Accreditation Committee (RTAC) Guidelines

#### 2.2 Medical Staff

Development and management of individualised and comprehensive IVF treatment inclusive of monitoring of results and counselling

#### 2.3 Embryology staff

Appropriate handling of gametes and collaborative care within multidisciplinary team

#### 2.4 Registered nurses

Recognition, education and support to patients undertaking IVF treatment via superovulation inclusive of direct patient contact, triaging and escalation where appropriate

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### 3 3 DEFINITIONS

AFC	Antral Follicle Count
AMH	Anti-Mullerian Hormone
ANZARD	Artemis for the Australian and New Zealand assisted reproduction database
ART	Assisted Reproductive Technologies
FBC	Full Blood Count
GnRH Agonists	Gonadotropin Releasing Hormone
FSH	Follicle Stimulating Hormone
LFT	Liver Function Test
ICSI	Intracytoplasmic Sperm Injection
IVF	In Vitro Fertilisation
LH	Luteinising Hormone
LMP	Last Menstrual Period
LPS	Luteal Phase Support
PGD	Pre-implantation Genetic Diagnosis
PGT	Pre-implantation Genetic Testing
OPU	Oocyte Pick-up

### 4 PROCEDURE

#### 4.1 General Principles

The choice of superovulation protocol and the choice of medications prescribed such as gonadotrophin preparation including dosage, is the decision of the medical staff based on the individual circumstances of the patient.

- Review patient prior to commencing a superovulation cycle all patients must be reviewed by an attending medical officer.
- Perform an Antral Follicle Count (AFC) and Anti-Mullerian hormone (AMH) prior to commencing assisted reproductive treatment, this should be used to guide management. Additional serology should also be completed for both the female and partner, refer to *table 1*. Serology results are valid for 12 months, repeat serology where applicable.
- Complete a nurse orientation prior to commencing treatment.
- Consent woman and partner prior to commencement of treatment - inclusive of spouses, partners, or parents (in the case of minors or patients who are unable to provide informed consent) consents are valid for 12 months.
- Record woman's height and weight into Artemis for the Australian and New Zealand assisted reproduction database (ANZARD).
- The recommendation for admission form must be completed at the beginning of each IVF stimulation cycle.

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Table 1. Pathology tests to be ordered prior to commencing superovulation treatment

<p><b>Female Screening</b></p>	<p>AMH, Serology (hep B, hep C, HIV, syphilis), Blood Group and antibodies, TSH, Varicella IgG, Rubella IgG, Full blood Count, iron studies, HbEPG</p> <p>Karyotype – Mandatory for all Pre-implantation Genetic Diagnosis (PGD), optional for all other IVF patients</p> <p>Pelvic ultrasound with AFC</p> <p>Genetic Carrier screening – Discussion with patient mandatory (consent form to be signed), optional take-up of this testing</p>
<p><b>Male Screening</b></p>	<p>Serology (hep B, hep C, HIV, syphilis), FBC, iron studies, HbEPG</p> <p>Karyotype – Mandatory for all Pre-implantation Genetic Diagnosis (PGD), optional for all other IVF patients</p> <p>Semen Analysis</p> <p>Genetic Carrier screening – Discussion with patient mandatory (consent form to be signed), optional take-up of this testing</p>
<p><b><u>All Donors</u></b></p>	<p>Blood tests - all donors (male and female): Serology (hep B, hep C, HIV, syphilis), FBC, iron studies, HbEPG, karyotype</p> <p>Urine tests – all donors (male and female): MSU, Chlamydia PCR, Gonococcal PCR</p> <p>Additional tests for female donors: AMH, pelvic ultrasound with AFC</p> <p>Additional tests for male donors: Semen Analysis with DNA fragmentation</p> <p>Genetic Carrier screening – Discussion with patient mandatory (consent form to be signed), optional take-up of this testing (as agreed by recipient(s) and donor(s))</p>

**4.2 Antagonist Protocol**

Starting the cycle

with natural menstruation – Woman to:

- Complete a nurse orientation prior to cycle commencement.
- Contact the RHW fertility & research clinic nursing team to notify of day 1 of full flow menstrual period.
- Perform baseline blood tests prior to the commencement of Follicle Stimulating Hormone (FSH), on day 1, 2 or 3 of the cycle.
- If hormone levels baseline (range shown below), instruct the woman to commence FSH

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- Follicle stimulating hormone < 15IU/L
  - Oestradiol < 300pmol/L
  - Progesterone < 5nmol/L
- Medical officer to determine whether to start FSH, postpone IVF treatment to a different month, or to postpone the start of FSH for few days if levels fall outside of the above parameters
- Document Last Menstrual Period (LMP) date and FSH date.
- FSH is to be administered at the same time every day

### Inducing menstruation to start

- The induction of menstruation using the oral contraceptive pill can be utilised to time commencement of cycles that require set Oocyte Pick-up (OPU) dates e.g Preimplantation Genetic Testing (PGT) or surgical aspiration of sperm
- Instructions for the use of the OCP (active pill only) should be given as determined by the medical & nursing team and take into consideration the lab availabilities. Clear instructions are to be given for when the patient is to cease the active OCP and attend their first blood test prior to commencing FSH.
- Anovulatory women with baseline oestradiol and progesterone concentrations, FSH can normally be commenced without any need for a menstruation. Where there is an intention for a fresh embryo transfer a period may be induced prior to stimulation utilising ten days of Medroxyprogesterone (Provera®)10mg or the active oral contraceptive pill (OCP)

### Random start antagonist regime

- Commence an FSH on the date specified by the medical team (this may or may not coincide with the commencement of a period – if the start date does not coincide with the start of a period, all embryos created must be frozen, ie, a fresh embryo transfer will not be conducted); if E2>600 and LH >10 the commencement date may be delayed by 1-2 days to permit ovulation to occur prior to the start of FSH treatment
- This type of regime may be conducted in the following scenarios:
  - For oncology patients, to facilitate urgent fertility preservation prior to the commencement of cancer treatment
  - For women whose male partner requires a surgical sperm extraction which is scheduled for a particular date
- Medical team to specify the date of first monitoring and the commencement of ovulation suppression medications (GnRH antagonist or GnRH agonist)
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### Fixed start date of antagonist

- Commence GnRH antagonists on FSH stimulation day 5
- Perform blood tests & transvaginal/abdominal ultrasound on day 7-8 of treatment and continue 2-3 daily at the medical team's discretion
- Review blood tests and ultrasound results document any changes to medication regimes
- Continue FSH and antagonist injections at 24hour intervals until the directive of the administration of a GnRH (Decapeptyl, Synarel) or hCG (Ovidrel) trigger is given

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### Dosage and administration

- GnRH antagonists are available in two administrations Ganirelix (Orgalutran®) 250 microg or Cetorelix (Cetrotide®) 250 microg allowing for treatment flexibility.
- Self-administered GnRH antagonists by the woman or support person after the directive of clinical staff commencing on day 5 of treatment
- Administer antagonists after FSH and continue at the same time every day
- Administer both the FSH and antagonist medication into the subcutaneous layer in the lower abdominal area
- Injection site should vary daily.

### 4.3 Long down- regulation protocol

#### Starting the cycle

- Woman to inform FRC with day 1 of menstrual period to book in a day 21 midluteal phase blood test to confirm ovulation has occurred, prior to commencing the agonist medication.
- Progesterone level should be above 10nmol/L confirm of ovulation; b-hCG must be <5
- Instruct the woman to commence GnRH agonist, once ovulation is confirmed.
  - Ovulation has not occurred, options to repeat the blood test at an appropriate interval until ovulation occurs (waiting a further week).
- Arrange a blood test 12 days after commencement of the agonist medication OR advise the patient to contact the clinic with day 1 of their period to book in for a baseline blood test
- Instruct the woman where baseline hormone levels fall within normal ranges to commence FSH and continue GnRH agonist as previously administered
  - Oestradiol < 300 pmol/L, Luteinising hormone 5 IU/L, Progesterone <4 nmol/L
- Continue GnRH agonist if the Oestradiol and progesterone levels remain elevated, repeat blood test as determined by the managing doctor/fellow prior to commencing FSH
- Perform a blood test and ultrasound on day 7 of FSH stimulation and then every 2-3 days as per the direction of the managing doctor/fellow.
- Document changes to the medication regime where applicable
- Continue GnRH agonists and FSH until the day of hCG trigger administration (NB: hCG trigger is mandatory in a cycle in which downregulation is achieved through the use of a GnRH agonist; GnRH agonist triggers (Triptorelin (Decapeptyl®) or Nafarelin (Synarel®)) will be in effective triggers in an agonist downregulation cycle

### Dosage and administration

- GnRH agonists are available in two administrations
  - Triptorelin (Decapeptyl®) 100mcg is a daily injection administered into the subcutaneous layer of the lower segment of the abdomen



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- Nafarelin (Synarel®) is a nasal spray to be administered as one spray (200microg) twice daily, 12 hours apart. Patients using Nafarelin (Synarel®) should be advised to administer a further spray if they sneeze or blow their nose within 10 minutes of administration.

### 4.4 “Flare” GnRH agonist protocol

#### Starting the cycle

- Woman to contact the clinic on day 1 of their menstrual cycle to attend a blood test on day 2 or 3 of their cycle
- Instruct woman where baseline hormone levels fall within normal ranges to commence the GnRH agonist Nafarelin (Synarel®) or Triptorelin (Decapeptyl®) and commence FSH the following day
- Continue GnRH agonist and FSH daily until ovulatory trigger
- Monitor the cycle as per previous protocols

#### 4.4.1 Corifollitropin alfa (Elonva®) flare antagonist protocol

##### Starting a cycle

- Woman to contact the clinic on day 1 of their menstrual cycle to attend a blood test on day 2 of their cycle
- Instruct (where baseline hormone levels fall within normal ranges) woman to administer the Corifollitropin alfa (Elonva®) injection)
- Instruct the patient to commence the GnRH antagonist four days after the initial Corifollitropin alfa (Elonva®) injection
- Perform blood test and ultrasound on day 7 of the cycle
- Commence short-acting FSH (Gonal F, Puregon, Rekovelle, Bemfola, Menopur, Ovaleap) daily on day 7 of the cycle
- Administer daily FSH and GnRH antagonist, monitoring should continue as per the antagonist protocol until ovulatory trigger

##### Dosage and administration

- Corifollitropin alfa (Elonva®) is a long acting FSH injection and is prescribed in replacement of 7 days of short acting FSH injections
- Corifollitropin alfa (Elonva®) is dispensed in two concentrations 100 microg and 150 microg, the dosage prescribed is determined by the medical team based on clinical history and patient investigation results.
- Guideline for use, is a single dose of Corifollitropin alfa (Elonva®) is equivalent to 200/225IU of short acting FSH, if this concentration equivalent is deemed too high then an alternate FSH stimulation should be used.

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### 4.5 LH/hCG supplementation

- Utilised at the discretion of the managing doctor, and available in three forms to support LH. To continue until use of ovulatory trigger
- Menotropin (Menopur®) a combined urinary FSH preparation with mixture of uFSH and uHCG used as primary FSH stimulation
- Follitropin alfa/Lutropin alfa (Pergoveris®) a recombinant r-hFSH and r-hLH used as primary FSH stimulation
- Lutropin alfa (Luveris®) 75IU supplements FSH stimulation
- Alternate day Choriogonadotropin Alfa (Ovidrel®) 10microg (= one click). Both Lutropin alfa (Luveris®) and Choriogonadotropin Alfa (Ovidrel®) are integrated mid cycle

### 4.6 Timing of ovulatory trigger

- Consider timing of ovulatory trigger for egg collection based on hormone and ultrasound results as per the managing doctor/fellow instruction.
- Criteria for trigger includes 3 or more follicles measuring greater than 17mm
- If oestradiol level greater than 10 000pmol/L, or if 10 more follicles >15mm are present on ultrasound, senior medical staff must be consulted prior to the administration of an hCG (Ovidrel) trigger due to the risk of ovarian hyperstimulation syndrome
- Consider freeze all if Progesterone level >5 nmol/L
- Administer trigger (either hCG or GnRH agonist) at 36 hours prior to oocyte retrieval as per scheduled theatre time, unless otherwise specified by the medical team
- Administer final doses of FSH and GnRH agonist/antagonist at a maximum 2 hours prior to the trigger time

### Dosage and administration

- Choriogonadotropin Alfa (Ovidrel®) 250microg is the hCG trigger utilised when there is intention for a fresh embryo transfer OR where a GnRH agonist is used to suppress ovulation.
- Choriogonadotropin Alfa (Ovidrel®) 250microg is not to be administered if the E2 >10 000 without consultant approval due to the risk of ovarian hyperstimulation syndrome
- Choriogonadotropin Alfa (Ovidrel®) 250microg is not to be administered if more ten or more follicles >15mm are present on ultrasound without consultant approval due to the risk of ovarian hyperstimulation syndrome
- Triptorelin (Decapeptyl®) 200mcg or 400mcg agonist trigger is utilised during a freeze all stimulation cycle where there is no intention for embryo transfer or if there is a risk of ovarian hyperstimulation syndrome
- Before an GnRH agonist trigger (Decapeptyl, Syneral) is used the following steps are to be followed
  - Baseline LH concentration is reviewed and above 2 IU/L (if LH <2 IU/L, consultant approval is required)
  - An agonist trigger is being used in an antagonist cycle
  - Nil history of hypogonadal hypogonadism



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- Administer ovulatory triggers into the subcutaneous layer of the lower segment of the abdomen at a time specified by the managing doctor or nurse

### 4.7 Oocyte collection

- Liaise with embryology lab to confirm order of OPU cases
- Instructions for OPU are to be given 2 days prior to procedure
- Woman to be given clear instructions of final FSH antagonist/agonists dates and times and ovulatory trigger dates and times
- Advise that once the trigger is administered there is nil further stimulation medication to be administered
- Advise the woman of:
  - fasting times
  - to avoid wearing make-up and fragrances on day of OPU
- Admission to RHW admissions desk, Level 0 at the appropriate time of day with photo ID & Medicare card
- Inform if \$1000 Co-payment is required
- Advise male partner to ejaculate on the day of ovulatory trigger and abstain until day of OPU (if providing fresh sperm) nil instruction to be given where frozen or donor sperm is used or in case of oocyte freeze
- Male partner providing fresh sperm to arrive at same time as female having OPU
- Advise post OPU discharge from Day Surgery Unit
- Notify patient to expect call from embryology with fertilisation update day following OPU
- Instruct to commence luteal support post OPU where hCG trigger is used and plan for fresh embryo transfer
- Follow-up support call to the woman the day post OPU

### 3.1.8 Prevention and management of Ovarian hyperstimulation syndrome (OHSS)

#### Risk factors

- Polycystic Ovarian Syndrome (PCOS)
- Hypogonadotropic hypogonadism
- Age <30
- High oestradiol levels (>10 000pmol/L)
- High number of follicles present on ultrasound prior to trigger injection
- Use of an hCG (Ovidrel) trigger
- Large number of oocytes collected (>15)
- Low Body Mass Index (BMI)
- High AMH
- Increased AFC >20
- Pregnancy

A woman with mild – moderate OHSS can be managed in the outpatient environment.

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Inform women undergoing superovulation treatment on the risk of developing OHSS, including the afterhours contact number 9382 6111 (RHW-switch) to speak with the Gynaecologist on call.

Women should be advised to monitor for signs of OHSS including the following;

- Abdominal bloating
- Breathlessness, inability to lie flat or talk in full sentences
- Nausea & vomiting
- Reduced urine output
- Leg swelling
- Vulval swelling
- Abdominal discomfort/pain, need for analgesia

Table 2. Proposed classification of severity of mild to severe Ovarian Hyperstimulation Syndrome(OHSS) as per Royal College of Obstetricians and Gynaecologists (RCOG)

Category	Features
Mild OHSS	Abdominal Bloating Mild abdominal pain Ovarian size <8cm
Moderate OHSS	Moderate abdominal pain Nausea + vomiting Ultrasound evidence of ascites Ovarian size usually 8-12cm
Severe OHSS	Oliguria (<300mL/day or <30mL/hour) Clinical ascites Haematocrit >0.45 Hyperkalaemia (potassium > 5 mmol/L) Hypernatremia (sodium <135mmol/L) Hypo osmolality Ovarian size >12cm

Managing an over – response during a cycle

- Ensure the woman is counselled on OHSS risk
- Document advice of the risk of developing OHSS prior to oocyte collection
- Greater than 10 follicles above 15mm the woman – consultant approval must be sought prior to the use of an hCG trigger (Ovidrel)
- In a long down regulation or Flare agonist cycle where an agonist trigger cannot be used the consultant must be contacted to discuss dosage of hCG trigger

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### Ongoing management OHSS symptoms post oocyte collection

- Consideration should be made to a freeze oocyte with the following
  - peak oestriol level is equal to or greater than 10 000pmol/L
  - more than 15 eggs are collected
  - if patients become symptomatic on day of trigger leading into oocyte collection or prior to scheduled fresh embryo transfer
- Enoxaparin sodium (40mg/0.4mL) daily should be considered as thrombo-prophylaxis
- Consideration for Cabergoline (500microg per day) is effective in mild cases, early onset OHSS, but ineffective once pregnancy has occurred.
- Woman should avoid use of non -steroidal anti-inflammatory drugs (NSAIDS)
- Cessation of luteal phase support in cases where OHSS symptoms develop prior to a fresh embryo transfer and where a HCG trigger was used.
- Daily contact should be made with woman to monitor symptoms and be clearly documented.
- Suspected OHSS patients should be offered a face-to-face assessment with a clinician. Face to face clinical assessment allows examination and investigation to clarify and monitor the severity of OHSS.
  - Blood investigations to be taken FBC, EUC, LFT and Coagulation studies.
- Consider ovarian torsion if abdominal pain is unilateral, severe and accompanied by nausea & vomiting
- Suspicion of severe OHSS is to be managed in an inpatient environment & are to be reported to the RTAC governing body

**Refer to [Ovarian Hyperstimulation \(OHSS\)](#)**

### 3.1.8 Luteal support and management of early pregnancy

All patients intending to have a fresh embryo transfer following OPU are required to have luteal support

- Use of hCG is at discretion of medical team, and can increase risk of OHSS following superovulation cycle
- Woman should be advised to avoid attending pregnancy home urine test following use of hCG luteal support
- Commence vaginal progesterone the day following oocyte collection and continue until  $\beta$ HCG pregnancy test
- Book  $\beta$ HCG + P4 blood test 10 days post embryo transfer (15 days post OPU) and repeat at intervals advised by the medical team
- Consider ongoing use of luteal phase support for positive  $\beta$ HCG results
- Advise patients to cease luteal phase support when the  $\beta$ HCG is negative
- Consult medical team with all Negative  $\beta$ HCG results for next steps
- All positive  $\beta$ HCG results should monitored until dating scan and then referred for ongoing pregnancy care

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### Dosage and administration

- Vaginal Progesterone – Vaginal Progesterone Gel 8% (Crinone®) OR Progesterone pessaries 200mg (Utrogestan®, Oriprio®, Cyclogest®)
- hCG injections – Choriogonadotropin alfa (Ovidrel®) 80mcg (8 clicks of Ovidrel® 10microg pen day 3, 6, 9 post ovulation/OPU day)

### 4.8 Documentation

- Medical File
- eMR
- Artemis database
- IMS+
- RTAC reporting of adverse events

### 4.9 Educational Notes

#### Indications of IVF treatment

- Hydrosalpinx or blocked fallopian tubes
- Oncology treatment
- Poor semen count or motility
- Ovulation disorders
- Premature ovarian failure
- Endometriosis
- Uterine fibroids
- Previous tubal sterilisation
- Genetic disorders
- Failure of intrauterine insemination treatment
- Unexplained infertility

#### Patient Inclusion Criteria

- Woman to start treatment prior to turning 41 years of age
- Woman is eligible for two superovulation cycles OR three in the case of woman undergoing Pre-implantation Genetic Testing (PGT)
- Woman is a NSW resident
- BMI between 18 and 35. If outside these limits, see BMI policy

#### Hyperstimulation Syndrome

- OHSS occurs when the ovaries are overstimulated by gonadotrophins
- Severe OHSS is represented in 1:500 cases
- Use of GnRH antagonist with agonist trigger provides the lowest chances of ovarian hyperstimulation (OHSS) of any stimulation protocol.
- The changes in the vascular system at the onset of OHSS are primarily vascular dilation and increased permeability. These changes initiate a cascade of events

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- starting with a loss of fluid and proteins from intra-to extravascular (third) space so reducing intravascular volume.
- OHSS worsens under influence of hCG secreted by a pregnancy. Segmentation of the cycle, with agonist trigger and avoidance of fresh embryo transfer prevents secondary OHSS due to pregnancy secreted hCG.

### Ovarian Torsion or adnexal torsion

- Occurs when the ovary and in some cases the fallopian tube twist on the tissues that support them
- Serious condition which can result in the loss of ovarian function
- Incidence is 0.2% of patients undergoing superovulation treatment
- Requires surgical intervention unless self resolves

#### 4.10 CBR should include implementation, communication and education plan

The revised CBR will be distributed to all medical, nursing and midwifery staff via @health email. The CBR will be discussed at ward meetings, education and patient quality and safety meetings. Education will occur through in-services, open forum and local ward implementation strategies to address changes to practice. The staff are asked to respond to an email or sign an audit sheet in their clinical area to acknowledge they have read and understood the revised CBR. The CBR will be uploaded to the CBR tab on the intranet and staff are informed how to access

#### 4.11 Related Policies/procedures

- RHW Local Operating Procedures Ovarian Hyperstimulation Syndrome (OHSS) – [Ovarian Hyperstimulation \(OHSS\)](#)
- In Vitro Fertilisation (IVF) – Embryo Transfer

#### 4.12 References

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3. Royal College of Obstetricians and Gynaecologists (2016) The management of Ovarian Hyperstimulation Syndrome. Green top guideline no. 5 [Ovarian Hyperstimulation \(OHSS\)](#)
4. Reproductive technology Accreditation Committee (2021) Code of Practice for Assisted Reproductive Technology Units [Guidelines for RTAC \(fertilitysociety.com.au\)](https://www.fertilitysociety.com.au)
5. [eMIMS Elite MIMS Medicines Information](#)

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**5 ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION**

- Considerations for culturally safe and appropriate care provision have been made in the development of this Business Rule and will be accounted for in its implementation.
- When clinical risks are identified for an Aboriginal and/or Torres Strait Islander woman or family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal liaison officers, health workers or other culturally specific services

**6 CULTURAL SUPPORT**

- For a Culturally and Linguistically Diverse CALD woman, notify the nominated cross-cultural health worker during Monday to Friday business hours
- If the woman is from a non-English speaking background, call the interpreter service: [NSW Ministry of Health Policy Directive PD2017\\_044-Interpreters Standard Procedures for Working with Health Care Interpreters.](#)

**7 NATIONAL STANDARDS**

- Standard 1 - Governance
- Standard 5 – Comprehensive Care
- Standard 6 – Communicating for Safety

**8 REVISION AND APPROVAL HISTORY**

Date	Revision No.	Author and Approval
24.9.24	1	Ashlee Rea
21.10.24	1	RHW BRGC