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| <ul style="list-style-type: none"> Electronic copy is controlled under document control procedure. Hard copy is uncontrolled & under responsibility of beholder. It is allowed ONLY to access and keep this document with who issued, who is responsible and to whom it is applicable. Information security code: <input checked="" type="checkbox"/> Open <input type="checkbox"/> Shared -Confidential <input type="checkbox"/> Shared-Sensitive <input type="checkbox"/> Shared-Secret | <ul style="list-style-type: none"> النسخة الإلكترونية هي النسخة المضبوطة وفق إجراء ضبط الوثائق. النسخ الورقية غير مضبوطة وتقع على مسؤولية حاملها. يسمح بالوصول وباحتفاظ بهذه الوثيقة مع مصدرها أو مع المسؤول عن تطبيقها أو مع المطبق عليهم. تصنيف امن المعلومات: <input checked="" type="checkbox"/> بيانات مفتوحة <input type="checkbox"/> مشارك -خاص <input type="checkbox"/> مشارك -حساس <input type="checkbox"/> مشارك -سري |
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| Document Type: Policy | Code: DHA/HRS/HPSD/HP-28 | Version Number: 1 |
| Document Title: Collection and Cryopreservation of oocytes | Issue Date: 25/12/2023 | Effective Date: 25/02/2024 |

Ownership: Health Regulation Sector - Health Policies & Standards Department and Clinical Audit & Control Department.

Applicability: DHA licensed Fertility Centers, licensed specialized physicians working in IVF Centers.

1. Purpose:

- 1.1. The collection and cryopreservation of oocytes policy aims to fulfil the overarching Dubai Health Sector Strategy 2026:
 - 1.1.1. Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
 - 1.1.2. Make Dubai a lighthouse for healthcare governance, integration and regulation.
- 1.2. Fulfil people's needs and provide the righteous guidance of medical assistance for child bearing in accordance with applicable legislations.
- 1.3. To support In Vitro Fertilization centres (IVF) in assessing their oocyte retrieval procedures for the category specified in accordance with the policy and to update them to the highest standards of patient care and best practices in the field.

2. Scope:

- 2.1. To retrieve oocytes safely from the unmarried woman as defined under the policy, that will

subsequently be cryopreserved through Assisted Reproductive Technology (ART).

3. Definitions/Abbreviations:

Healthcare Professional: Is a natural person authorised and licensed by the DHA to practice any of the healthcare professions in the Emirate of Dubai.

IVF Centre: A Licensed health facility or unit offering the assisted reproductive technology services.

Oocyte (egg) retrieval: is a procedure in which eggs are taken from an unmarried woman's ovaries.

Unmarried woman: Divorced women, widows, excluding single woman.

ART : Assisted Reproductive Technology

DHA : Dubai Health Authority

HRS : Health Regulation Sector

IVF : In vitro fertilization

4. Policy Statement

4.1. DHA licensed IVF centres and healthcare professionals that provide the service of collection and cryopreservation of oocytes from unmarried women shall adhere to the provisions of Federal Law No. (7) of 2019 regarding Medically Assisted Reproduction and the decisions issued pursuant thereto, and to follow the recognized scientific and technical principles in order to provide the necessary care to the patient.

4.2. IVF centres shall commit to maximum of six (6) trials of oocyte retrieval for each patient per year, counting from the date of the first retrieval procedure/attempt.

4.3. IVF centres shall preserve the frozen oocytes for a period of five (5) years starting from the date

of the fist retrieval/procedure and subject for extension for another five (5) years upon a written request submitted by the concerned parties.

- 4.4. Oocyte retrieval and preservation are performed by physicians who are specialised, licensed and trained in the field of medical assisted reproductive services and embryologist, in accordance with the applicable federal and local legislations, approved health regulations and standards in this regard, and any circulars issued by the DHA in this regard; and in accordance with the highest recognized scientific and professional principles and controls determined by applicable legislation.
- 4.5. Oocyte retrieval is performed under sedation/general anesthesia, and all necessary checks should be completed prior to the procedure, in accordance with the health regulations approved by the DHA regarding pre-operative management.
- 4.6. Accurate patient's medical history shall be taken before oocyte retrieval to highlight the potential comorbidities and to prevent any possible associated complications.
- 4.7. Oocyte aspiration may be done transvaginally or through other possible medical alternatives.
- 4.8. For application of the procedure on unmarried women it is required that there is/are medical reasons that are evaluated by the specialised physician and documented in the patient's health records.
- 4.8.1. Refer to **(Appendix 1)** for the criteria for Collection and Cryopreservation of oocytes from unmarried women.
- 4.8.2. Consent form **(Appendix 2)** must be signed by unmarried woman before physician can proceed with the ovarian stimulation and retrieval.
- 4.9. The IVF centre and healthcare professionals shall maintain the privacy and confidentiality of

patients' information in accordance with applicable legislations, including Federal Decree Law No. (17) of 2023 and the Ministerial Resolution No. (14) of 2021 regarding the Patient Rights and Duties Charter.

4.10. The IVF centre and healthcare professionals shall document all medical reviews and consultations that are provided to unmarried women wishing to undergo oocytes collection and cryopreservation.

4.11. Physicians must document their counselling with unmarried women who request oocyte cryopreservation.

4.11.1. The counselling should include the number of procedures and oocytes advised to be cryopreserved in reference to the patient's age at the time of oocyte retrieval and all possible risks.

4.12. The IVF centre shall keep all related patient's information and patient's medical records for the period specified according to the legislations in force and Federal Law No. (2) of 2019 regarding the use of information and communication technology in the health fields and its executive regulations and the decisions issued according to it.

4.13. The IVF centre shall maintain clear and readable documentation for the oocyte retrieval description with images and results (i.e. number of oocytes obtained, difficulties during the procedure, and others).

4.13.1. Forms should be available for admission, discharge, consents and for details of the procedure.

4.13.2. The IVF centre shall maintain proper documentation for DHA periodic audit and inspection.

4.14. The IVF centre should ensure that the requirements for accreditation of assisted reproduction

laboratories are met in accordance with the Dubai Health Authority's medical laboratory accreditation policy through the following link:

<https://www.dha.gov.ae/uploads/112021/8dda21d6-35ac-4e1a-92bb-62b75f2b6043.pdf>

4.15. Quality assurance in oocyte retrieval performance should comply with the key clinical performance indicators set by DHA for IVF centres.

5. References

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- 5.17. The Facility Guidelines Institute (US) (2018). Guidelines for Design and Construction of Outpatient Facilities. Refer to website: www.fgiguideines.org.
- 5.18. UAE Federal decree law No. (17) of 2023 for the amendments on Federal Law No. (7) of 2019

regarding Medically Assisted Reproduction.

5.19. UAE Federal Law no. (7) of 2019 concerning Assisted Reproduction.

5.20. UAE Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law No. (7) of 2019 regarding medical assistance for Childbearing Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law No. (7) of 2019 regarding medical assistance for Childbearing.

6. Appendices:

Appendix 1:

CRITERIA for Collection and Cryopreservation of Oocytes from unmarried women

| معايير المرأة غير المتزوجة للاستفادة من خدمة تجميد البويضات Unmarried women can benefit from oocyte freezing | | |
|---|---|---|
| Cancer patients. | مرضى السرطان. | 1 |
| Women with genetic diseases that can lead to premature ovarian failure or have a decrease in ovarian reserve. | المرأة المصابة بأمراض وراثية والتي يمكن أن تؤدي إلى فشل المبيض المبكر أو لديها تناقص في احتياطي المبيض. | 2 |
| Women with endometriosis who need surgical treatment. | المرأة المصابة بالانتباز البطاني الرحمي وتحتاج إلى علاج جراحي. | 3 |
| Women with poor ovarian reserve and decreased number eggs. | ضعف مخزون المبيض وتناقص البويضات. | 4 |

Appendix 2:

**Informed Consent for Transvaginal Collection and Cryopreservation of Oocytes procedure for
Unmarried Women**

| |
|--------------------------|
| Patient's name: |
| File No.: |
| Emirates ID/Passport No: |

Procedure Description:

- Applying for an adult (unmarried) woman who wants to preserve her fertility by Cryopreservation of her oocyte that will be retrieved after ovarian stimulation, recurrent vaginal ultrasound examination, and vaginal oocyte retrieval or through other possible medical alternatives.
- The procedure for oocytes retrieval and cryopreservation may be repeated to have a reasonable number of cryopreserved oocytes that would give the patient a good chance of achieving pregnancy.
- Oocyte retrieval which will be performed under sedation/general anaesthesia with full blood count and any additional tests that may be required by the treating physician
- As the procedure is done under sedation/anaesthesia, the patient shall go home on the same day, (usually 2 hours after the completion of the procedure), it is required that the patient is escorted and driven home and taken care of during the first few days after surgery.
- The patient must be explained the possible medical alternatives and treatment according to the case and the discussion with the attending physician, including the expected results and the success rate of the procedure.

Expected benefits: Preserving the fertility of unmarried women and enhancing the chances of pregnancy in the future.

Possible risks oocyte retrieval:

- Infection: bacteria, normally present in the vagina, may inadvertently infect the wound.
- Bleeding, which usually settles down within few days.
- Pain and discomfort at the wound area.
- Pain during intercourse (after marriage).
- Fear of having intercourse (Vaginismus).

- Anesthesia can produce unintended complications such as allergic reaction, hypotension, nausea or vomiting.
- In the unlikely event of significant/severe discomfort during or after the procedure a team of physicians (both males and females) may be involved in treating your condition. If required you may be shifted to another DHA facility for further management.

Possible Medical Alternatives (might include transabdominal)

- Abdominal egg retrieval that does not require vaginal ultrasound examination nor vaginal oocyte collection.
- Abdominal oocyte collection is associated with more complications, and it may yield a lesser number of oocytes when compared with vaginal oocyte collection.

Validity of the consent form:

- This consent is valid only for one month from the date of signature.

Acknowledgment of the consent form:

- I understand that based on the enforced UAE Federal laws and regulations concerning medical assistance for child bearing allows only a maximum of six (6) oocyte retrieval procedures per year starting from the date of the first trial \ procedure.
- I am aware, as per UAE Federal Law, Oocyte Cryopreservation period is valid for 5 years and renewable for 5 years upon individual request/consent to proceed for renewal and clearance of outstanding dues.
- I also acknowledge that all applicable UAE laws and regulations are being followed concerning the transfer of the frozen eggs from one IVF center to another center inside or outside the country.
- I understand that my frozen oocytes will not be used except upon my request and after I am legally married and they are to be fertilized only with my future husband's sperm.
- I understand that my oocytes may not survive when thawed, hence cannot be used for fertilization to create embryos. In general, the older the woman (>37-years old), the lower the post-thawing survival rate.
- I understand that the use of frozen oocytes with Intra Cytoplasmic Sperm Injection (ICSI) may not be successful in producing a pregnancy. A pregnancy that does occur may not result in a healthy live birth.

I, the undersigned, acknowledge that I have read the above consent in its entirety and have had all my questions clearly and completely answered to my satisfaction and a translator was available (upon my request) and I have understood the benefits, results and possible risks of this procedure.

| Patient's details: | |
|-------------------------------|-------|
| Patient Name: | ----- |
| Emirates ID: | ----- |
| Mobile Number: | ----- |
| *Signature: | ----- |
| Physician Name and signature: | ----- |
| Date: | ----- |

In case of emergency, I authorize the IVF centre to contact -----
who is my ----- and his\her mobile phone number is -----

| | | |
|------------------------|-------|------------------|
| Patient Name: | ----- | Signature: ----- |
| Next of kin sequences: | ----- | Signature: ----- |
| Date: | / / | Date: |

*The consent and signature of the guardian shall be considered if the patient is less than 18 years old

الملحق (2)

الموافقة الكتابية على إجراء سحب وحفظ البويضات بالتجميد للمرأة غير المتزوجة

| | |
|-------|---------------------------------|
| ----- | أسم المريضة: |
| ----- | رقم الملف الطبي: |
| ----- | الهوية الاماراتية / جواز السفر: |

وصف الإجراء:

- تنطبق الخدمة المقدمة على المرأة البالغة غير المتزوجة والتي ترغب في الحفاظ على فرصة الحمل مستقبلاً عن طريق تجميد البويضات والتي سيتم سحبها من خلال تحفيز المبيض، الفحص المتكرر عبر الموجات فوق الصوتية، وإجراء سحب البويضات عن طريق المهبل أو البدائل الطبية الممكنة.
- قد يستلزم الامر تكرار إجراء عملية سحب البويضات وتجميدها للحصول على عدد كاف من البويضات المجمدة التي من شأنها إعطاء فرصة جيدة لتحقيق الحمل.
- يتم سحب البويضات تحت التنويم / التخدير العام بعد اجراء فحوصات الدم الكاملة وغيرها من الفحوصات الطبية الاخرى اللازمة.
- يتم إخراج المريضة في نفس اليوم (عادة بعد ساعتين من الإجراء)، ويلزم ذلك وجود مرافق مع المريضة لضمان سلامة العودة الى المنزل وللعناية بالحالة خلال الأيام الأولى التالية للجراحة.
- يتم شرح البدائل والعلاج الممكن حسب الحالة والمناقشة مع الطبيب المعالج ومن ضمنها النتائج المتوقعة لنسبة نجاح الاجراء.

المخاطر المحتملة لسحب البويضات:

- العدوى: البكتيريا الموجودة عادة في المهبل، والتي قد تصيب الجرح بشكل عرضي.
- نزف دموي، والذي يختلف عادة في غضون أيام قليلة.
- ألم وشعور بعدم الراحة في منطقة الجرح.
- ألم أثناء الجماع (بعد الزواج).
- الخوف من الجماع (التشنج المهبلي).
- يمكن أن ينتج عن التخدير مضاعفات عرضية مثل رد الفعل التحسسي، أو انخفاض ضغط الدم أو الغثيان أو القيء.
- في الحالات النادرة والتي قد يحدث فيها مضاعفات خطيرة / حادة، يقوم فريق من الأطباء (الأناث والذكور) بمعالجة الحالة، وقد يُضطر إلى إحالة المريضة الى مستشفى متخصص لمزيد من الرعاية والعلاج.
- **الفوائد المتوقعة:** الحفاظ على خصوبة المرأة غير المتزوجة وتعزيز فرص الحمل مستقبلاً.

البدائل الطبية الممكنة: (قد يتم إضافة السحب عبر البطن)

- سحب البويضات عن طريق البطن ولا يتطلب هذا الاجراء فحص المهبل عبر الموجات فوق الصوتية أو جمع البويضات مهبلية.
- قد يرتبط سحب البويضات عن طريق البطن باحتمالية الإصابة ببعض المضاعفات المحتملة والتي قد تشمل إصابة الأمعاء، المثانة أو إصابة الاوعية الدموية، والحصول على عدد أقل من البويضات مقارنة بجمع البويضات مهبلية.

مدة سريان صلاحية الموافقة الكتابية:

- صالحة لمدة شهر واحد فقط من تاريخ التوقيع.

الأقرار بما ورد في النموذج:

- أقر بإعلامي أنه وفقاً للقوانين والتشريعات السارية في الدولة بشأن المساعدة على الإنجاب فإنه يتم إجراء عمليات سحب البويضات بحد أقصى 6 مرات في السنة الواحدة إعتباراً من تاريخ اول محاولة / إجراء.
- وقد تم إعلامي أنه وفقاً للقانون الاتحادي لدولة الإمارات العربية المتحدة فإن مدة حفظ العينات المجمدة هي سارية لمدة 5 سنوات وقابلة للتجديد لمدة 5 سنوات أخرى بناءً على طلب كتابي يقدم من ذوي الشأن.
- كما أقر بإعلامي أنه يتم اتباع كافة القوانين والتشريعات السارية في الدولة بشأن الرغبة في نقل البويضات المجمدة الخاصة بي من مركز إخصاب إلى مركز إخصاب آخر داخل أو خارج الدولة.
- لن يتم استخدام البويضات المجمدة الخاصة بي إلا بناءً على طلبي وبعد الزواج وفقاً للتشريعات السارية بالدولة وأنه لن يتم تخصيبها إلا بالحيوانات المنوية الخاصة بزوجي في المستقبل.
- كما أتفهم أنه قد يلحق الضرر بسلامة البويضات الخاصة بي عند إذابتها من التجمد، مما قد يتسبب في عدم صلاحيتها للإخصاب ، كما تم الشرح انه ينخفض معدلات بقاء البويضات حية بعد إذابتها، كلما زاد عمر المرأة عن سن الـ 37 عاماً.
- أقر بإعلامي أن استخدام البويضات المجمدة للإخصاب في المختبر عن طريق إما التلقيح الاصطناعي أو حقن الحيوانات المنوية داخل البويضة قد لا تكون ناجحة في حدوث الحمل أو أن الحمل قد لا يؤدي إلى ولادة طفل سليم.

أقرنا ، الموقعة أدناه، بانني قد قمت بقراءة كافة البنود الموجودة في نموذج الموافقة الكتابية وأنه قد تمت الإجابة على الأسئلة بشكل واف وواضح وفي حضور المترجم (حسب طبي) . كما أتفهم الفوائد والنتائج، والمخاطر المحتملة من الاجراء بيانات المريضة

| بيانات المريضة: | |
|------------------------|-------|
| الاسم: | ----- |
| رقم الهوية: | ----- |
| رقم الهاتف: | ----- |
| التوقيع*: | ----- |
| اسم الطبيب وتوقيعه: | ----- |
| التاريخ: | ----- |

* في حالة الطوارئ، أفوض أنا الموقع أعلاه مركز الاخصاب بالإتصال بـ ----- وصفته: -----

على الهاتف رقم: -----

| | | |
|---------------|-------|----------------|
| أسم المريضة: | ----- | التوقيع: ----- |
| درجة القرابة: | ----- | التوقيع: ----- |
| التاريخ: | / / | |

• يجب أخذ موافقة ولي الأمر / الوصي في حالة كانت المريضة أقل من 18 سنة ميلادية