COUNCIL ON HUMAN REPRODUCTIVE TECHNOLOGY
人類生殖科技管理局

APPLICATION FOR TREATMENT LICENCE (FIRST-TIME APPLICATION)
治療牌照申請書(首次申請)

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese: ……
中心名稱 (中文)：

Council Reference Number 管理局參考編號：……
(For official use only) (只供管理局職員填寫)

The completed form should be returned together with supporting documentation and the application fee to:
填妥的申請書須連同證明文件及申請費用交回：

By Post 郵寄
Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen's Road East
Wanchai, Hong Kong
香港灣仔
皇后大道東 213 號
胡忠大廈 17 樓 58 室
人類生殖科技管理局

By email 電郵
hrtc@dh.gov.hk

Payment of application fee can be made by a crossed cheque or e-cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the crossed cheque. Please do not send cash by post. Please contact the Council if you wish to settle the payment of application fee by other means.
申請費用須以劃線支票或電子支票支付，收款人註明「香港特別行政區政府」，並請在劃線支票背面寫上中心名稱，請勿郵寄現金。如欲透過其他途徑繳交申請費用，請聯絡管理局。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form. Details of centre, including but not limited to names of staff, the address of the premises where relevant activities are intended to be carried out and the class of licence applied for will be published in the website of the Council on Human Reproductive Technology as and when required for public access.
* 本申請書末頁載有填寫須知，可供參考。當有需要時，人類生殖科技管理局會於網頁公佈牌照中心的資料，包括但不限於職員姓名，擬進行有關活動的處所地址及所申請的牌照類別，以供公眾查閱。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the reproductive technology procedures are intended to be carried out belong to the following class (please tick the appropriate box) :
擬進行生殖科技程序的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343)
根據《診療所條例》(第 343 章)註冊的診療所 ☐

(b) a private healthcare facility within the meaning of Private Healthcare Facilities Ordinance (Cap. 633) for which a licence under that Ordinance is in force
根據《私營醫療機構條例》(第 633 章) 所指的、根據該條例領有有效牌照的私營醫療機構 ☐

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113)
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院 ☐

(d) a private consulting room of a Small Practice Clinic as defined under section 2 of the Private Healthcare Facilities Ordinance (Cap. 633) that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明及《私營醫療機構條例》(第 633 章)第 2 條定義的小型執業診所的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號)

Hospital Authority facility 醫院管理局轄下設施 ☐ **Private** 私營機構 ☐ **Other institutions** 其他機構 ☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

3. Details of Applicant 申請人資料

Name
姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. :
香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name
姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. :
香港身分證/護照號碼： _____

5. Details of Accredited Specialist 認可專家資料

Name 姓名： _____

Position 職位： _____

6. Information about treatments to be offered 擬提供的治療的資料

6.1 Date centre opened 中心開業日期： _____

6.2 Date centre first offered treatment:
中心擬首次提供治療的日期： _____

6.3 Please tick the appropriate boxes below to indicate the treatment services for which the centre wishes to be licensed:
請在下列適當方格加上✓號，以說明中心擬領牌提供的治療服務：

Treatment services *治療服務*	*To be included in licence* *擬納入牌照的治療服務*
In vitro fertilization (IVF) 體外受精	☐
Artificial insemination by husband (AIH) 夫精人工授精	☐
Artificial insemination by donor (AID)/ Donor insemination (DI) 他精人工授精	☐
Removal of oocytes from ovaries 從卵巢取出卵母細胞	☐
Retrieval of sperm from testis 從睪丸取出精子	☐
Retrieval of sperm from epididymis 從附睪取出精子	☐
Frozen-thawed/ fresh embryo transfer (ET) 凍融/新鮮胚胎移植	☐
Microinjection intra-fallopian transfer (MIFT) 顯微注射輸卵管內移植	☐
Fallopian replacement of eggs with delayed insemination (FREDI) 輸卵管內置放卵子後進行授精	☐
Intra cytoplasmic sperm injection (ICSI) 細胞漿內精子注入法	☐
Pre-implantation genetic testing (PGT)[1] 植入前基因檢測 [1]	☐
Sperm sorting technique[2] 精子分類技術 [2]	☐
Sperm washing 精子洗滌	☐
In vitro maturation of oocytes 卵母細胞體外成熟	☐
Storage of semen/sperm (donor/patient*) 儲存精液/精子(捐贈人/病人*)	☐
Storage of oocyte (donor/ patient*) 儲存卵母細胞(捐贈人/病人*)	☐
Storage of embryo (donor/patient*) 儲存胚胎(捐贈人/病人*)	☐

[1] A treatment licence may grant general permission for RT centre to carry out PGT. RT centre licensed to carry out PGT and which intends to carry out tissue typing in conjunction with PGT is required to submit an application form (Annex 9 of the "Licensing Manual for Reproductive Technology Centres") together with a clinical report to the Council to seek prior approval on a case-by-case basis before commencement of each treatment involving tissue typing in conjunction with PGT. The principles of the "Ethical Guidelines on Pre-implantation Genetic Testing" in the Code should be followed.
[1] 治療牌照可就生殖科技中心進行植入前基因檢測給予一般許可。獲發牌照進行植入前基因檢測的生殖科技中心如擬把植入前基因檢測與組織分型結合使用，須向管理局提交申請書(《供生殖科技中心參考的發牌手冊》 附件 9)及臨牀報告，以就每宗涉及把植入前基因檢測與組織分型結合使用的治療逐一徵求事先批准，並須遵照《實務守則》附錄「植入前基因檢測倫理指引」中訂明的原則。
[2] Sperm sorting technique means a technique intended to separate sperm carrying a Y chromosome (which would create a male embryo) from sperm carrying X chromosome (which would create a female embryo).
[2] 精子分類技術指:「擬將帶有 Y 染色體(將會製造男性胚胎)的精子和帶有 X 染色體(將會製造女性胚胎)的精子分隔的技術。」

Treatment services *治療服務*	*To be included in licence* *擬納入牌照的治療服務*
Storage of testicular tissue[3] 儲存睪丸組織 [3]	☐
Storage of ovarian tissue[3] 儲存卵巢組織 [3]	☐
Embryo donation 胚胎捐贈	☐
Sperm donation 精子捐贈	☐
Oocyte donation 卵母細胞捐贈	☐
Assisted hatching 輔助孵化	☐
Embryo micromanipulation (other than assisted hatching) 顯微操控胚胎技術(輔助孵化除外)	☐
Sex selection 性別選擇	☐
Surrogacy arrangement 代母安排	☐
Other micromanipulation (please specify) 其他顯微操控技術(請註明)	☐
* Please delete as appropriate. 請刪去不適用者。	
Others (please specify) 其他(請註明)	☐

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

6.4 Will the facilities/ services of the centre be used by other centres, clinics or practitioners for carrying out treatment procedures or other supporting services? (Please tick the appropriate box)
中心的設施/服務會否供其他中心、診所或醫生使用以進行治療程序或提供其他支援服務？(請在適當方格加上✓號)

Yes 會 ☐ **No 不會** ☐

[3] Storage of testicular and ovarian tissue will require a licence only if gametes are present in the tissue. The Council works according to the following definition of gametes: "Gametes refer to reproductive cells, sperm and egg, which fuse to form a zygote. Each human gamete contains a basic set of 23 chromosomes – a haploid set; on fusion of egg and sperm a full (diploid) set of 46 chromosomes results. All other (somatic) cells in the body contain 46 chromosomes in their nuclei".
[3] 儲存含有配子的睪丸和卵巢組織必須領牌。管理局行事時所依據的配子定義為：「配子指生殖細胞，即男性的精子和女性的卵子；精子及卵子融合後便形成合子。每個人類配子包含內有 23 個染色體的基本組合(單倍體的組合)。卵子與精子融合時，便成為內有 46 個染色體的完整組合(雙倍體組合)。其他所有軀體細胞的細胞核，均含有 46 個染色體。」

If the answer is **yes**, please provide the details of the facilities/services and of the centres/ clinics/ practitioners who will be using them:
如**會**，請就該等設施/服務及將會使用該等設施/服務的相關中心/診所/醫生提供有關詳情：

Details of facilities/services to be used:
擬使用的設施/服務詳情：

Name of centre/ clinic/ practitioner using the facilities/ services:
使用該等設施/服務的中心/診所/醫生的名稱或姓名：

Address 地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable) :
電郵地址(如適用):

Website address (if applicable) :
網址(如適用)：

Contact person 聯絡人：

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7. Staff 職員

7.1 Please list the staff at the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed below.
請列明中心內擔任下列職位的職員，並就下表所列全部職員提交履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	Proposed Licensee 準持牌人	See CV 見履歷表
……	Proposed Person Responsible 準負責人	See CV 見履歷表
……	Accredited Specialist 認可專家	See CV 見履歷表
……	Embryologist in charge 主任胚胎學家	See CV 見履歷表
……	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
……	Counsellor in charge 主任輔導員	See CV 見履歷表

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.2 Please list below all staff members in the centre involved in the treatment of patients or who have access to patient records.
請列明中心內參與治療病人或會接觸病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/ 職位*	*Qualification/Experience* *資格/ 經驗*
……	……	……
……	……	……
……	……	……
……	……	……
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……	……	……

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.3 Please provide the details of the centre's complaint officer.
請提供中心內投訴主任的資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……

8. Supporting Documentation 證明文件

8.1 In order to process this application it is essential that the Council be provided with a full set of the appropriate supporting documentation. This should include all agreements signed with the related centres, clinics or practitioners listed in paragraph 6.4. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。文件應包括與第 6.4 段所列相關中心、診所或醫生所簽訂的全部協議書。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

8.2 CVs for each of the staff listed in paragraph 7.1 (marked collectively as Appendix A). They may include:
第 7.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括：

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Accredited Specialist(s) 認可專家
(d) Embryologist in charge 主任胚胎學家
(e) Nurse Co-ordinator 護士統籌主任
(f) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

8.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B).
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。

8.4 One complete set of all consent forms to be used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

8.5 One complete set of all treatment record forms to be used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部治療記錄表格的整套資料一份，包括問卷(一律標明為附錄 D)。

8.6 One complete set of all standard operating procedures and protocols to be used by the centre, including procedures and protocols appertaining to assessment of patients/donors, assessment of the welfare of the child, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與病人/捐贈人評估、兒童福利評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

8.7 One copy of all agreements signed with related centres, clinics or practitioners listed in paragraph 6.4 (marked collectively as Appendix F).
中心與第 6.4 段所列相關中心、診所或醫生所簽訂全部協議書的整套文件一份(一律標明為附錄 F)。

8.8 One copy of contingency plan to be adopted by the centre (marked as Appendix G).
中心所用應變計劃的複本一份(標明為附錄 G)。

9. Additional Information 其他資料

9.1 Is there any other information regarding your centre which you may wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed in this form? If so, please give details below.
是否還有其他與中心和本申請有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

_____

_____

_____

_____

_____

_____

9.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

_____

_____

_____

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

10. Declarations 聲明

10.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

10.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

10.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

10.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Accredited Specialist 認可專家

10.5 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the accredited specialist.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任認可專家。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Treatment Licence Application Form
治療牌照申請書填寫須知
(First-time Application)
(首次申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) other qualification in the medical, nursing, scientific or management field that is considered by the Council as acceptable for the purposes of supervising the relevant activity specified in the application.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 5
第 5 部分：
The accredited specialist is the medical practitioner who holds the overall clinical responsibility.
認可專家即承擔整體臨牀責任的醫生。

Section 6
第 6 部分：
This section contains a list of relevant activities governed by the Human Reproductive Technology Ordinance (Cap. 561). Centre must indicate the reproductive technology services for which it wishes to be licensed.
此部分載列《人類生殖科技條例》(第 561 章) 所規管的有關活動。中心必須列明擬領牌照的生殖科技服務。

Section 7
第 7 部分：
All staff who will be directly involved in the treatment of patients or who have access to patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與治療病人或會接觸病人記錄的全部職員及其職位。

Section 10
第10部 分：
When signing the declarations section, the following should be noted:

(a) If the proposed person responsible is also the accredited specialist, he or she should sign both sections;
(b) If the proposed person responsible is also the applicant, he or she should sign both sections.

在簽署聲明時，請注意下列各項：

(a) 準負責人如同時亦是認可專家，則應簽署聲明中兩個相關部分；
(b) 準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。