

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

APPLICATION FOR RESEARCH LICENCE (RENEWAL)
研究牌照申請書 (續期申請)

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

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

Licence Number:
牌照號碼 :

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

Title of Project 項目名稱 :
.....
.....
.....

The completed form should be returned together with supporting documentation and the application fee of HK\$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回 :

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 e-mail 電郵
hrtc@dh.gov.hk

Payment of application fee should 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.

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。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form.

* 本申請書末頁載有填寫須知，可供參考。

1. Details of the Centre Undertaking Research 進行研究的中心的資料

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 embryo research project is intended to be carried out belong to the following class (please tick the appropriate box):

擬進行有關胚胎研究項目的處所屬以下類別(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 hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院 ☐
- (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 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？(請在適當方格內加上✓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. Title of Research Project 研究項目的名稱

5.1 Please give the full title of the project.

請提供擬續牌的研究項目的全稱。

5.2 Has the title of the project changed since the previous licence was granted? (Please tick the appropriate box)

自上次獲發牌照後，項目名稱有沒有改動？(請在適當方格加上✓號。)

Yes 有 ☐ No 沒有 ☐

6. Expiry of Current Licence 現有牌照的屆滿日期

6.1 Please give the date your current licence expires.

請提供現有牌照的屆滿日期。

7. Duration of Project 研究項目的期限

- 7.1 Please indicate the period of time for which you wish the renewal licence to be granted (not more than 3 years).
請說明希望獲批的牌照有效期(不超過3年)。

8. Receipt and Usage of Material 所接獲及使用的物料

- 8.1 Please indicate in the boxes below the number of oocytes and embryos received and the number that were used during the period of the current licence, in the research project for which you are applying. This allows audit of embryos allocated to research, including those found to be unsuitable for research. Please give the name(s) of the centre(s) which supplied the material and give the data for each supplying centre separately.
請於下列方格填寫現有牌照的有效期內中心就擬續牌的研究項目所接獲及使用的卵母細胞及胚胎數量，以便審查該項目所獲分配的胚胎數目，包括其後發現不宜用於研究的胚胎數目。
請填寫供應有關物料的中心的名称，並就每一供應中心提供相關資料。

Dates From _____ To _____
日期：由：_____至：_____
Centre Name _____
供應中心名稱：_____

Total no. of embryos received 所接獲的胚胎總數	Total no. of embryos used 所使用的胚胎總數	Total no. of oocytes received 所接獲的卵母細胞總數	Total no. of oocytes used 所使用的卵母細胞總數
Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：
Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：
		Failed to Fertilize 不能受精：	Failed to Fertilize 不能受精：

Dates From _____ To _____
日期：由：_____至：_____
Centre Name _____
供應中心名稱：_____

Total no. of embryos received 所接獲的胚胎總數	Total no. of embryos used 所使用的胚胎總數	Total no. of oocytes received 所接獲的卵母細胞總數	Total no. of oocytes used 所使用的卵母細胞總數
Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：
Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：
		Failed to Fertilize 不能受精：	Failed to Fertilize 不能受精：

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

- 8.2 Have any of the above embryos been used in licensed research projects at other centres? If so, please list the research project numbers and the number of embryos concerned.
上述胚胎曾否用於其他中心領有牌照的研究項目？如有，請列出有關研究項目的編號及所涉胚胎的數量。

- 8.3 If the numbers recorded in 8.1 above differ substantially from those estimated in the original proposal, please give the reasons below.
如上文 8.1 段所述數量與原來建議書的預計數量差別甚大，請在下面說明原因。

9. Estimated Use of Material During Renewal Period

續期牌照有效期內預計使用物料的數量

- 9.1 Please indicate in the boxes below the estimated numbers of oocytes and embryos you expect to use during the renewal period applied. If more than one year has been requested please indicate the yearly usage in the appropriate boxes.
請於下列方格填寫預計會於續期牌照有效期內使用的卵母細胞及胚胎數量。如為牌照申請續期超過一年，請在適當方格填上每年的使用數量。

Material 物料	Year 1 第一年	Year 2 第二年	Year 3 第三年
Fresh Oocytes* 新鮮卵母細胞*			
Frozen Oocytes 冷藏卵母細胞			
Failed to fertilize Oocytes 不能受精的卵母細胞			
Fresh Embryos 新鮮胚胎			
Frozen Embryos 冷藏胚胎			

(*If immature oocytes will be used, please indicate.) (*如將使用未成熟的卵母細胞，請加以註明。)

10. Progress Report on Work Undertaken During Period of Previous Licence
上次牌照有效期內所進行的工作的進度報告

10.1 Please give a report below in scientific terms specifying clearly how the actual outcome of the research relates to its stated objectives, under the following headings:

請於下面以科學用語作出匯報，以清楚說明研究的實際結果與所訂目標有何關係，請按以下標題提供資料：

- (a) how the work undertaken relates to the objectives and purposes of your previous application;
所進行的工作與先前申請書所載的目標及目的有何關係；
- (b) research undertaken to date;
至今已進行的研究；
- (c) results;
結果；
- (d) if progress was slower than anticipated, the reasons for this;
進度如較預期慢，原因何在；
- (e) if work originally proposed was not carried out, again, the reasons for this.
如原擬進行的工作並無落實，原因何在。

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

11. Future Work 未來工作

11.1 Please summarize below the work that you propose to carry out during the period for which you are applying to be licensed and how it relates to the results of the work undertaken on the previous licence. Please use the following headings:

請於下面概述擬於續期牌照有效期內所進行的工作，以及該等工作與上一牌照所得研究結果有何關係。請按以下標題提供資料：

- (a) renewed objectives;
更新後的目標；
- (b) methods;
方法；
- (c) discussion (with particular reference to how the proposed studies relate to the objectives outlined in the licence application and to the findings to date as outlined in Section 10 above).
討論(重點說明建議研究與本續期申請書所述的目標有何關係，以及與上文第10部分所述至今所得研究結果有何關係)。

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

12. Publications 發表

12.1 Please list below any publications which have resulted from this work.

請在下面列出曾就有關研究工作所發表的資料。

13. Staff 職員

13.1 Please list any staff changes that have taken place.
請列出任何人事變動的資料。

Staff who have joined 新加入的職員

Name 姓名	Profession/Position 專業/職位	Qualification/Experience 資格/經驗
.....
.....
.....
.....

Staff who have left 已離職的職員

Name 姓名	Profession/Position 專業/職位	Qualification/Experience 資格/經驗
.....
.....
.....
.....

14. Institutional Research Ethics Committee 機構的科技研究倫理委員會

14.1 Please provide a current list of the membership of the research ethics committee.
請列出科技研究倫理委員會的現任主席及現有成員。

Name 姓名	Profession/Position 專業/職位	Qualification/Experience 資格/經驗
<u>Chairman 主席</u>		
.....
<u>Membership 成員</u>		
.....
.....
.....
.....
.....
.....
.....
.....

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

15. Funding 撥款

- 15.1 Please supply copies of the sections on the objectives and protocols in any funding application made, excluding financial details.

如曾就擬續牌項目申請撥款，請提供撥款申請書中有關目標及方案部分的副本(財務詳情除外)。

16. Supporting Documentation 證明文件

- 16.1 In order to process this application it is essential that the Council is provided with a full set of the appropriate supporting documentation. 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。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)。

Appendix A: CVs (see Annex 10 of the “Licensing Manual for Reproductive Technology Centres”) of any new staff engaged directly in the research project
Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.

Appendix B: Any new clinical or laboratory protocols that may be relevant

Appendix C: Any new consent forms

Appendix D: Contingency plan (if revised)

Appendix E: Any publications resulting from this project

附錄 A： 任何直接參與研究計劃的新職員的履歷表(《供生殖科技中心參考的發牌手冊》附件 10)
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。

附錄 B： 任何可能有關的新增臨牀或化驗室方案

附錄 C： 任何新增的同意書

附錄 D： 應變計劃(如曾修訂)

附錄 E： 曾就擬續牌研究項目所發表的資料

17. Declarations 聲明

- 17.1 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。

- 17.2 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

- 17.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I accept that should the application be approved for licensing, I will be required to jointly submit a report of the findings to the Council when the research is completed. I agree to act as the licensee.

盡本人所知、所得資料及所信，本申請書及其附錄提供的資料真確無誤。本人接受，牌照申請如獲批准，本人須於研究完成後聯同負責人向管理局提交一份研究結果報告。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

- 17.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I accept that should the application be approved for licensing, I will be required to jointly submit a report of the findings to the Council when the research is completed. I agree to act as the person responsible.

盡本人所知、所得資料及所信，本申請書及其附錄提供的資料真確無誤。本人接受，牌照申請如獲批准，本人須於研究完成後聯同持牌人向管理局提交一份研究結果報告。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完 -

Guidance Notes on Completing Research Licence Application Form
研究牌照申請書填寫須知
(Renewal Application)
(續期申請)

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 7

第 7 部分：

Give a realistic timescale for the duration of the study. Please note that under section 25(a)(i) of the Human Reproductive Technology Ordinance (Cap. 561), the maximum duration for a licence is 3 years.

此部分須就擬續牌項目提供切合實際的期限。請注意，根據《人類生殖科技條例》(第 561 章) 第 25(a)(i)條，牌照期以三年為限。

Section 13

第 13 部分：

Any changes on staff who is directly involved in the research project 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擬續牌項目的職員的任何變動，包括有關職員的姓名及職位。

Section 14**第 14 部分：**

Centres should provide a full list of all members of the research ethics committee which oversees their work, including any qualifications and experiences which are relevant to their membership of the committee.

此部分須列明負責監管中心工作的科技研究倫理委員會的全部成員，包括各成員所具備與其委員會工作相關的資格及經驗。

Section 17**第 17 部分：**

When signing the declarations section, it should be noted that 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。

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

COLLECTION OF PERSONAL DATA FOR LICENCE APPLICATION
收集個人資料以處理牌照申請

Statement of Purposes 目的聲明

1. Purposes of Collection 收集資料的目的

Personal data are provided by applicants to the Council on Human Reproductive Technology for a licence to carry on a relevant activity, as the term is defined under section 2(1) of the Human Reproductive Technology Ordinance (Cap. 561). The personal data provided will be used for the following purposes:

申請人向人類生殖科技管理局申請牌照以進行有關活動(按照《人類生殖科技條例》(第 561 章)第 2(1)條的定義)時會提供個人資料，此資料將作下述用途 -

- (a) to facilitate the Council on Human Reproductive Technology in carrying out activities relating to the processing of your application via this form;
為利便人類生殖科技管理局為處理你透過本申請書提出的申請所進行的活動；
- (b) to facilitate communication or follow up action in relation to the purposes stated in (a) above;
為上述(a)段所指的目的利便相互溝通和所需的跟進行動；
- (c) for statistical and other legitimate purposes;
統計及其他法定用途；
- (d) administration and enforcement of relevant legislation and regulations; and
有關法例及附屬法例的執行和執法；及
- (e) to handle complaints against licence applicant, licensee and person responsible under a licence.
處理對牌照申請人、持牌人或牌照負責人的申訴。

The provision of personal data asked for in the relevant application form is obligatory by virtue of section 22 of the Human Reproductive Technology Ordinance.

根據《人類生殖科技條例》第 22 條，申請人必須按照有關申請書的要求提供個人資料。

2. Classes of Transferees 獲轉授資料者的類別

The personal data which you have provided is mainly for use within the Council on Human Reproductive Technology but they may also be disclosed to government bureaux, departments and any other agencies or organizations for the purposes mentioned in paragraph 1 above. Apart from that, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance (Cap. 486).

申請人所提供的個人資料，主要供人類生殖科技管理局內部使用，但亦可能向政府政策局、部門及任何其他機構或組織披露以作上文第 1 段所提及的用途。此外，有關資料只會披露給申請人已同意向其披露的相關各方，或用作《個人資料(私隱)條例》(第 486 章)所核准的資料披露。

3. Access to Personal Data 查閱個人資料

You have a right to access and make correction with respect to the personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 to the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data provided by you during the occasions as mentioned in paragraph 1 above. A fee may be imposed for complying with a data access request.

根據《個人資料(私隱)條例》第 18 和 22 條及附表 1 的第 6 原則，申請人有權查閱和更正個人資料。申請人的查閱權力包括索取其在上文第 1 段所述情況下提供的個人資料的副本。查閱資料或須收費。

4. Enquiries 查詢

Enquiries concerning the personal data provided, including requests for access and the making of corrections, should be addressed to:

如對所提供的個人資料有任何查詢(包括要求查閱和更改資料)，請按下列聯絡方法提出-

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