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

APPLICATION FOR RESEARCH LICENCE (FIRST-TIME APPLICATION) 研究牌照申請書 (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.

申請費用可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 the Centre Undertaking Research 進行研究的中心的資料					
1.1	.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名科					
1.2	Addre	ss 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		address (if applicable): 址(如適用):				
1.6		te address (if applicable): □適用):				
1.7	follow	emises where the embryo research ing class (please tick the appropriat 有關胚胎研究項目的處所屬以下類別		g to the		
		clinic registered under the Medical 據《診療所條例》(第 343 章)註冊的				
	F ir 相	force	ne meaning of Private Healthcare hich a licence under that Ordinance is) 所指的、根據該條例領有有效牌照的			
	(c) a		ction 2(1) of the Hospital Authority			
	(d) a	private consulting room of a Small ection 2 of the Private Healthcare Fa				
	名 戶 (i	i) not located in premises used for	》(第 633 章)第 2 條定義的小型執業診			
	(e) a	medical or research laboratory that esidential purposes 法指价於作住字用涂的處所的醫務或	•			

2.	Corporate Information 機構資	料			
2.1	Is the centre a Hospital Author appropriate box)中心是否醫院管理局轄下設施及/	,		•	•
	Hospital Authority facility 醫院管理局轄下設施]	Private 私人機構		Other institutions 其他機構
2.2	If private, please provide the foll 如為私營機構,請在下面提供適質		ormation as	appropi	riate:
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 Name 姓名: HKID Card / Passport No.: 香港身分證/護照號碼: Correspondence address: 通訊地址:	資料 :			
	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):				

HKID Card / Passport No.: 香港身分證/護照號碼: 4. Details of Proposed Person Responsible 準負責人 Name 姓名: Position 職位: HKID Card / Passport No.: 香港身分證/護照號碼:	ish Chine
Title of Research Project 研究項目的名稱 Title of Research Project 研究項目的名稱 5. Title of Research Project 研究項目的名稱 5.1 Please give the full title of the project.	ish Chine
Name 姓名: 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.	ish Chine
姓名:	ish Chine中文
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.	
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.	
5.1 Please give the full title of the project.	
5.2 If you have previously held a research licence for project title(s) and research licence number(s). 如曾持有相關範疇的研究牌照,請提供該牌照所涉項目	

5.3	proje 請根	se indicate the purpose(s) of research (as defined in paragraph 11.5 of the object falls under. You may tick more than one box. 據《生殖科技及胚胎研究實務守則》第 11.5 段所界定的類別,說明有關項目的研超過一個方格加上✔ 號。	•
	(a)	to promote advances in the treatment of infertility 促進不育治療的發展	
	(b)	to increase knowledge about the causes or treatment of congenital disease 增進有關先天性疾病的成因或治療方面的知識	
	(c)	to increase knowledge about the causes or treatment of miscarriages 增進有關流產問題的成因或治療方面的知識	
	(d)	to develop more effective techniques of contraception 發展更有效的避孕方法	
	(e)	to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation 發展技術,在胚胎植入母體前,偵察胚胎內基因或染色體的異常情况	
	(f)	to increase knowledge about the development of embryos 增進有關胚胎發展的知識	
	(g)	to increase knowledge about serious diseases 增進有關嚴重疾病的知識	
	(h)	to enable such knowledge to be applied in the development of treatments to combat serious diseases 致使所得知識用於發展相關治療方法,以對抗嚴重疾病	
	(i)	others (please specify) 其他(請註明)	
6.	Dur	ation of Project 研究項目的期限	
6.1	Pleas	se give the proposed date of commencement for the project. 供研究項目的建議開始日期。	
6.2	than	se indicate the period of time for which you wish the licence to be granted 3 years). 明希望獲批的牌照有效期(不超過3年)。	(not more

7.	Estimated	Usage	of Material	擬使用的物料
<i>,</i> .	Louinatea	Couge	or muccinar	120C1X_/ 13 H 3 1/3/1/

7.1 Please indicate in the boxes below the estimated numbers of oocytes and embryos you expect to use during the period of the licence. 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牌照有效期內使用的卵母細胞及胚胎數目。如申請有效期超過一年的牌照,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			

8. Centre(s) Providing Gametes/Embryos 供應配子/胚胎的中心

8.1 Please give the names of the centres that will be supplying materials for this project, together with an indication of the number of embryos and/ or oocytes they each will be providing.

請提供將為擬領牌的研究項目供應物料的中心的名稱,並說明每一中心將會分別供應的胚胎 及/或卵母細胞數量。

Name of Centre	Semen Provided	No. of Embryos	No. of Oocytes
中心名稱	(Yes/ No)	Provided	Provided
	供應精液 (是/否)	所供應胚胎的數量	所供應卵母細胞的數量

9. Current Research Projects 現有研究項目

9.1	If you currently hold a research	licence,	please	give the	licence	number(s)	and tit	tle(s) of
	current research projects below.	If you	do not	currently	y hold	a research	licence	, please
	proceed to section 10.							

如現時持有研究牌照,請在下面提供該牌照的編號及現有研究項目的名稱。若現時並無持有任何研究牌照,請繼續填寫第 10 部分。

9.2 Please indicate in the boxes below the number of oocytes and embryos received and the number that were used in all your currently licensed research projects. This allows audit of embryos received but 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.

請於下列方格填寫中心就各項現已領有牌照的研究項目分別接獲及使用的卵母細胞及胚胎數量,以便審查已接獲但後來發現不宜用於研究的胚胎數量。請填寫供應有關物料的中心的名稱,並列出每一供應中心分別提供的物料的數量。

Dates From		То	
日期: 由:		至:	
Centre Name			
供應中心名稱:			
		1	1
Total no. of embryos	Total no. of embryos	Total no. of oocytes	Total no. of oocytes
received	used	received	used
所接獲胚胎的總數	所使用胚胎的總數	所接獲卵母細胞的總數	所使用卵母細胞的總數
Fresh	Fresh	Fresh	Fresh
新鮮:	新鮮:	新鮮:	新鮮:
Frozen	Frozen	Frozen	Frozen
冷藏:	冷藏:	冷藏:	冷藏:
		Failed to	Failed to
		Fertilize	Fertilize
		不能受精:	不能受精:
1	<u> </u>		
Dates From		То	
日期: 由:		至:	
Centre Name			
供應中心名稱:			

Total no. of embryos	Total no. of embryos	Total no. of oocytes	Total no. of oocytes
received	used	received	used
所接獲胚胎的總數	所使用胚胎的總數	所接獲卵母細胞的總數	所使用卵母細胞的總數
Fresh	Fresh	Fresh	Fresh
新鮮:	新鮮:	新鮮:	新鮮:
Frozen	Frozen	Frozen	Frozen
冷藏:	冷藏:	冷藏:	冷藏:
		Failed to	Failed to
		Fertilize	Fertilize
		不能受精:	不能受精:

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

1 No.
10. Abstract 摘要
10.1 Please give a summary of the work you propose to undertake (maximum of 200 words). 請概述擬進行的研究工作(以 200 字為限)。
Please continue on a separate sheet if required. 如有需要,請另頁續寫。
11. Objectives 目標
11. Objectives 目標 11.1 Please state the aims and objectives of the project. 請說明擬領牌的研究項目的目的及目標。
11.1 Please state the aims and objectives of the project.
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12.	Background 背景
12.1	Please state how the project fits into the current state of knowledge on this subject (maximum of 1,500 words). 請說明擬領牌的研究項目如何切合有關學科的現有知識範疇(以 1,500 字為限)。
Pleas	se continue on a separate sheet if required.如有需要,請另頁續寫。
13.	Methodology/Experimental Design/Analysis of Results 方法/實驗設計/結果分析
13.1	Please state how this work is to be carried out. 請說明如何進行研究工作。

14. Staff 職員

14.1 Please list all the staff who will be involved in the proposed research. 請列明將會參與擬領牌的研究項目的全部職員及其相關資料。

Name 姓名	Profession/Position 專業/職位	Qualification/Experience <i>資格</i> /經驗

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

15.1 Please state the role of the research ethics committee. 請說明科技研究倫理委員會的角色。

15.2	Please list the chairperson and membership of the research ethics committee.
	請列明科技研究倫理委員會的主席和成員及其相關資料。

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

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

15.3	Details of the approval of the research ethics committee on the research project under licence application. 科技研究倫理委員會審批擬領牌的研究項目的詳情。

16. Funding 撥款

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

如曾就擬領牌的研究項目申請撥款,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)。

17. Supporting Documentation 證明文件

17.1 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 all 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: Relevant clinical and laboratory protocols, and protocol for the research

Appendix C: Consent forms regarding use of oocytes/embryos for this project

Appendix D: Contingency plan to be adopted by the centre

Appendix E: Up to three most recent relevant publications (if any)

附錄 A: 所有直接參與研究項目的職員的履歷表(《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: 與擬領牌的研究項目相關的臨床、化驗室及研究方案 **附錄 C:** 關於擬領牌的研究項目使用卵母細胞/胚胎的同意書

附錄 D: 中心所用的應變計劃

附錄 E: 最近發表的資料(如有,請提供最多三份資料)

18. Declarations 聲明

18.1 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。

18.2 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	申請人	pplicant
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18.3 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 18.4 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。

- END 完-

Signature 簽署 Name 姓名 Date 日期

Guidance Notes on Completing Research Licence Application Form 研究牌照申請書填寫須知 (First-time Application) (首次申請)

General Information 一般資料

1. The Human Reproductive Technology Ordinance (Cap. 561) requires centres undertaking embryo research to first obtain a licence from the Council on Human Reproductive Technology. The Council puts strict limitations on the type of research permitted. Under normal circumstances, the Council will not grant a licence unless the project is considered necessary or desirable for the furtherance of one or more of the following purposes –

《人類生殖科技條例》(第 561 章) 訂明,進行胚胎研究必須先向人類生殖科技管理局申領牌照。管理局對獲准進行的研究種類嚴加限制。在一般情況下,管理局不會發出牌照,除非管理局認為該項目對促進以下一個或多個目的屬必需或合宜:

- a. to promote advances in the treatment of infertility; 促進不育治療的發展;
- b. to increase knowledge about the causes or treatment of congenital disease; 增進有關先天性疾病的成因或治療方面的知識;
- c. to increase knowledge about the causes or treatment of miscarriages; 增進有關流產問題的成因或治療方面的知識;
- d. to develop more effective techniques of contraception; 發展更有效的避孕方法;
- e. to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;

發展技術,在胚胎植入母體前,偵察胚胎內基因或染色體的異常情況;

- f. to increase knowledge about the development of embryos; 增進有關胚胎發展的知識;
- g. to increase knowledge about serious diseases; and 增進有關嚴重疾病的知識;及
- h. to enable such knowledge to be applied in the development of treatments to combat serious diseases. (*Paragraph 11.5 of the Code*) 致使所得知識用於發展相關治療方法,以對抗嚴重疾病。(《實務守則》第 11.5 段)
- 2. The proposed project must be considered to be scientifically valid by the Council. Otherwise, it will not be approved.

擬領牌的研究項目必須是管理局認為是具有充分科學根據的,否則不會獲得批准。

3. The following activities are prohibited by law:

香港法例禁止以下活動:

- a. keeping or using an embryo after the appearance of the primitive streak. For this purpose, the primitive streak shall be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored; 保留或使用已出現原痕的胚胎。就此而言,原痕須視為在自配子混合當日起計的14日期間屆滿時或之前已在胚胎內出現,而該胚胎儲存時的任何時間則不計算在內;
- b. bringing about the creation of an embryo for the purposes of embryo research; 為胚胎研究的目的,促成胚胎的製造;
- c. combining human and non-human gametes / embryo or any part thereof such as to give rise to a 2 cell zygote for the purposes of embryo research; 為胚胎研究的目的,將人類及非人類配子或胚胎或其任何部分結合,以形成雙細胞合子;
- d. placing any non-human gametes or embryo or any part thereof in any human; 將非人類配子或胚胎或其任何部分放置於人體內;

- e. placing any human gametes or embryo or any part thereof in any animal; 將人類配子或胚胎或其任何部分放置於動物體內;
- f. replacing the nucleus of a cell of an embryo with a nucleus taken from any other cell; 將胚胎的細胞核以取自其他細胞的細胞核取代;及
- g. cloning any embryo. 將胚胎進行無性繁殖。

(Section 15(1) of the Ordinance) (《條例》第15(1)條)

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 6

第6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.

此部分須為擬領牌的研究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 10

第 10 部分:

The Council has a responsibility to inform the public of the research work it has licensed. Please summarize in non-technical/lay language the aims and designs of your work (maximum of 200 words).

管理局有責任把獲發牌照的研究工作告知公眾。請以淺白易明的文字概述研究工作的目的及設計 (以 200 字為限)。

Section 11

第 11 部分:

State clearly and briefly the scientific objectives of the research and how any knowledge gained will help to achieve the purposes of research under the Code.

此部分須清楚扼要地說明擬領牌的研究項目的科學目標,以及所得知識如何有助達到《實務守則》所訂明的研究目的。

Section 12

第12部分:

Explain how the proposed research fits into the current state of knowledge on the subject and make clear what your own contribution to this has been. Indicate how work on model systems is irrelevant or has been exhausted and therefore the use of human embryos is justifiable (maximum of 1,500 words).

此部分須闡釋擬領牌的研究項目如何切合有關學科的現有知識範疇,並清楚說明中心在這方面所作出的貢獻。請說明為何利用模擬系統的方法並不相關或已經用盡,以致有充分理由支持要用人類胚胎進行研究(以 1,500 字為限)。

Section 13

第13部分:

Show how the work is to be carried out indicating -

- experimental design;
- techniques to be used;
- measurements to be made;
- statistical methods to be used for analysis of results.

此部分須就下列各項闡明研究工作如何進行:

- 實驗設計;
- 將會採用的技術;
- 將會進行的測量工作;
- 將會用作分析結果的統計方法。

Section 14

第 14 部分:

All staff who will be <u>directly</u> 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領牌的研究項目的全部職員及其所任職位。

Section 15

第 15 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 18

第18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。