



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

一、合作移植醫院申請辦法 Cooperation Transplant Center Application
：

1. 目的：為確保本中心供髓的移植醫院合法執行移植醫療，並確保合作移植醫院在移植技術及經驗上符合本中心的標準。

Purpose: To ensure that bone marrow donated via Tzu Chi stem cells center has legally performed the transplant operation and the medical institute that perform such operation has qualified techniques and experience.

2. 申請文件：Application for participation as a transplant center(合作移植醫院申請書)。

Document: Application for participation as a transplant center.

3. 申請所需條件 Qualification of the medical institute.：

- (1) 移植醫院必須經過當地衛生主管機關核可之醫療機構。

The transplant center must be a certified Medical Institute approved by local Health Authorities.

- (2) 過去兩年內，包含自體及異體移植案例資料（含疾病名及存活率）。

Bone marrow transplant case of autologous and allogenic donor marrow source within the past 2 years. (including disease names and survival rate)

- (3) 移植病房負責人之學歷及經歷、移植醫療團隊專業背景。

The qualification and experience of such transplant unit person in charge and the transplant medical profession team.

- (4) 政府機關核准進行骨髓幹細胞移植核可文件。

Approval documents of bone marrow transplant issued by government authority.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

4. 注意事項：本中心僅供髓給合作移植醫院。若尚未成為本中心合作移植醫院者，於本中心為病患配對到合適的捐贈者，可以要求捐贈者進行HLA配型複檢時，同步進行合作移植醫院的申請程序，以便為病患爭取移植時效。

Notice points: Tzu Chi stem cell center solely supply donor's bone marrow to the cooperative transplant center. In case of the institute has yet to establish the cooperation partnership, Tzu Chi stem cell center is willing to accept the application while patient has found a match and undergoing a HLA matching confirmation exam. This may be more efficient for patient's sake of receiving the transplant.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

二、移植醫院及骨髓資料庫為病患進行非親屬配對注意事項：

Important Notes for Transplant Center/ Registry to apply an unrelated search request for the patient

1. 初配階段 Preliminary Matching Stage

(1)非正式配對 Informal Matching：

①目的：協助初步了解病患與本中心捐贈者的潛在配型相合人數。

Aim: To assist the applicant gaining the initial understanding of the quantity of potential matching donors from our center with the patient.

②申請條件：任何人皆可提出非正式配對的申請。

Application Requirements: Anyone can file a preliminary matching request.

③申請文件：檢附病患之HLA檢驗報告，須有A、B、DR三個位點(Locus)，解析度(Resolution)不拘。

Application Documents: Examination report of the patients HLA examination, which must contain A, B and DR three locus, regardless of resolution.

④申請方式：請註明申請聯絡人姓名與聯繫方式並將上述之檢驗報告用電子郵件或傳真至本中心。

Application Methods: Please put down the applicants name and contact information, and sent the above-mentioned examination reports through e-mail or fax to Tzu Chi Stem Cells center.

(2)正式配對 Formal Matching：

①目的：提供主治醫師非親屬捐贈者的HLA配型及配對結果以便後續配對程序的進行。

Aim: To provide the patients doctor with unrelated donors HLA typing and its matching result for further matching process.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

- ②申請條件：病患與其主治醫師確認要進行非親屬間的造血幹細胞移植後，由骨髓資料庫或移植醫院醫師提出申請。

Application Requirements: Application either from the registry or the doctor of the transplant center once the patient and his doctor confirmed to proceed the unrelated stem cells transplantation.

- ③申請文件：病患配對申請表(Preliminary Search Request Form)、研究同意書及相關規定文件。

Application Documents: Patients Preliminary Search Request form, letter of authorization for research and related documents.

- ④申請方法：請將申請文件備齊後用電子郵件或者傳真傳送至本中心
- Application Methods: Please fax all above-mentioned documents to our center. (Please see Note)。

- ⑤注意事項：本中心提供造血幹細胞標準為：造血幹細胞捐贈者 HLA-A,-B,-DRB1 低解析度配型與病患達到 5/6 相合。臍帶血 HLA-A,-B,-DRB1 低解析度配型與病患達到 4/6 相合。

Points of Attention: The standards of the center on providing stem cells are as below: Stem cells donors HLA low resolution must reach 5/6 matched with the patients. HLA low resolution of umbilical cord blood matching must reach 4/6.

2. 啟動捐贈者配對程序 Initiating Donors Matching Process

- (1)目的：聯繫捐贈者並確認捐贈者捐贈意願及健康篩檢後抽取捐贈者血樣進行配型複檢(Confirmatory Test, 簡稱 CT)及感染性疾病檢測(Infectious Disease Markers, 簡稱 IDMs)。

Aim: Contact the donor and ensure donors willingness on donation. Extracting second blood sample has to be done after the health screening for the Confirmatory Test (CT) and test of Infectious Disease Markers (IDMs).

- (2)申請條件：由骨髓資料庫或合作移植醫院的主治醫師提出啟動配對程序。

Application Requirements: The registry or the doctor of the transplant center can initiate the matching process.

- (3)申請文件 Application Documents：



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

- ①可回傳配對報告表，註明捐贈者編號、需檢驗位點等相關文件。
Returning the preliminary results and indicating donor ID, typing to be tested as request.
- ②如需指定非本中心 HLA 實驗室者，請填 Sample Shipment Request Form，並註明捐贈者編號、需檢驗位點及指定 HLA 檢驗實驗室的相關文件。
When request blood samples shipping to transplant center's cooperative lab, please fill out Sample Shipment Request Form, which states the donors ID, locus of examination and designated HLA examination laboratory.
- (4)申請方式：請將申請文件備齊後用電子郵件或者傳真傳送至本中心。
Application Methods: Please e-mail or fax all the documents to our center.
- (5)注意事項 Points of Attention：
 - ①本中心所進行的捐贈者血樣複檢(CT)為高分辨(High Resolution)的 HLA-A,-B,-C,-DRB1 四位點的檢驗。並同時進行感染性疾病檢測 (IDMs)。
The CT of the donor processed by BTCSCC is a High Resolution examination of HLA-A, B, DRB1 three locus, plus the test of IDMs.
 - ②寄送捐贈者血樣至指定的 HLA 實驗室：需填寫 Sample Shipment Request Form，並回覆捐贈者檢驗配型結果。CT 血樣的總採集量上限為 30 ml。
A Sample Shipment Request Form must be filled out if the donors blood sample is to be sent to the designated HLA laboratory, and the testing result must be returned to BTCSCC by the transplant center. The total collection of CT blood samples is limited to 30 ml.
 - ③感染性疾病檢驗(IDMs)的有效期限為 30 天。
The validity of IDMs is 30 days.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

勾選捐贈者進行身體檢查前，捐贈者需完成 C 檢驗

台灣病患：經簽約移植醫院勾選的前五位捐贈者進行

CT(A、B、DRB1)或 DRB1 費用由本中心吸收，C 位點檢測，本中心則僅優免一位捐贈者進行。其餘 C 與 DQB1 或其它位點需由病患依據本中心收費標準付費。若勾選超過五位優免捐贈者時，每位捐贈者的檢驗費用須由病患依據本中心收費標準付費。

Starting from 2010/01/01, before the donor is selected for PE, C loci test must be finished testing.

Taiwan patient: The fee for the first 5 matching donors chosen by the contracted transplant centers to do CT (A, B, DR) or DR is covered by Tzu Chi Stem Cells center. Patient has to pay for the exams of Cw or DQB1 or other loci according to the centers fee schedule. If more than 5 matching donors are chosen, each extra donors examination expense will need to be paid by the patient according to our centers fee schedule.

3. 捐贈者身體檢查程序 Donors Health Check-Up Procedure

(1)目的：在回覆捐贈者配型複檢報告及感染性疾病檢測報告後，若主治醫師確定要採用該位捐贈者進行造血幹細胞捐贈時，為確保捐贈者的健康並評估適宜的捐贈方式，安排捐贈者身體檢查。

Aim: After receiving donors CT and infectious disease makers (IDMs) report, if the doctor decided to choose this donor for SC donation, then the donor must be arranged for a health check-up in order to ensure the donor is in a good condition.

(2)申請文件 Application Documents :

①身體檢查申請表(Work-up Request Form)
Work-up Request Form.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

(3)方式：請主治醫師備齊填寫完備的表單後，用電子郵件或者傳真傳送至本中心。

Application Methods: Patients doctor is asked to prepare and fill in all the forms and send to our center by e-mail or fax upon completion.

(4)注意事項 Points of Attention：

①捐贈者是否適合捐贈由本中心醫務主任做最後核定。

The Medical Director of BTCSCC will have the right of final approval on whether or not the donor is suitable for donation.

②不論捐贈者身體檢查結果顯示該捐贈者是否適合進行造血幹細胞捐贈，已產生的身體檢查費用皆須請病患支付。

Regardless to donors health check-up results on the suitability of SC donation, all the expenses generated from the health check-up must be paid by the patient.

③女性捐贈者進行身體檢查時，會加做血清驗孕。若發現捐贈者懷孕了，將即刻回覆移植醫院捐贈者最快能夠捐贈的日期。

When a female donor undergoes health check-up, a blood serum pregnancy test will also be done. The earliest possible date of donation will be drawn up and reply to TC immediately if the donor is pregnant.

④本中心捐贈者身體檢查報告有效期間為6個月。另外本中心將於身體報告有效期限提前一個月告知移植醫院並詢問是否繼續進行，若移植醫院於一個月內未回覆，本中心將此捐贈者結案，提供給其他需要之患者。

The health check-up report issued by Tzu Chi Stem Cells center is valid for 6 months. We will inform the TC one month before the validity expired, and inquire if TC want to continue this case. If TC did not reply in that month, we shall close the donor case in order to provide for other patients.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

4. 捐贈者造血幹細胞採集程序 Procedure of collecting donors stem cells

(1)目的：採集捐贈者造血幹細胞以植入病患體內。

Aim: Collecting donors stem cells for transplant to the patient.

(2)所需文件 Application Documents：

①Donor Final Clearance Donor Final Clearance Report

②Prescription for Mobilized Stem Cells Collection

Prescription form for bone marrow or mobilized stem cells product

(3)申請方式：在中心同仁回覆捐贈者體檢報告後，由骨髓資料庫或移植醫院對可進行造血幹細胞捐贈的捐贈者提出啟動捐贈程序。請骨髓資料庫或移植醫院主治醫師將填寫完整的上述兩種文件用電子郵件或者傳真傳送至本中心。

Application Methods: After receiving the health check-up report of the donor from BTCSCC, the registry or the transplant center can initiate the donation procedure for the qualified stem cells donors. The registry or the transplant centers doctor must complete the above-mentioned 2 documents, and sent to our center by e-mail or fax.

(4)本中心捐贈者幹細胞採集標準 Tzu Chi Stem Cells Centers

Collection Standards：

①骨髓：以受贈者或捐贈者體重較輕者為基準，若病患體重未達30kg，則以30kg計。依基準體重(kg)x 20 x 0.22 為總有核細胞數標準。

Bone Marrow: The body weight is based on the lighter of weight of the donor or the bone marrow recipient. If the patients body weight is less than 30 kg, 30kg will be used as criterion. Standard total Nucleated Cells counts is based on the body weight(kg) x 20 x 0.22.

②週邊血：受贈者體重(kg) x 5 x 10⁶ 為要求週邊血幹細胞 CD34+細胞數的標準。

PBSC: Recipients body weight (kg) x 5 x 10⁶ is the standard for requesting PBSC CD34 + cells count.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

- (5) 確認取髓移植日期後，請提供取髓人員的航班，以便安排取髓行程。
本中心配對小組同仁在與取髓人員交接時，會備妥通關用文件，以便取髓人員完成取髓工作。

Picking up marrow: Please provide the itinerary of the courier after picking up date and the transplanting date have been confirmed, so we can arrange the collecting schedule. Search Unit staff will prepare all clearance documents for the courier to pick up the marrow.

- (6) 注意事項 Points of Attention :

- ① 本中心所有 Pre-collection Sample 血量加總以 50 ml 為限。若移植醫院對捐贈者在進行造血幹細胞採集時，有特殊血品需要，例如：血漿(plasma)，請於 Prescription Form 特別註明。

The maximum pre-collection blood sample is limited to 100ml. Should the transplant center need special blood samples during the collection of HSC, such as plasma, please make a special note on the Prescription form.

- ② 幹細胞採集時血樣(Blood samples at time of collection)的血量加總上限為 20ml。

Total blood samples at time of collection are limited to a maximum of 20ml.

- ③ 凡造血幹細胞移植作業，皆應遵循國際幹細胞移植標準作業規範尊重捐贈者愛心，其捐贈之造血幹細胞只限用於治療受贈者致命之疾病並得於幹細胞採集後 48 小時之內輸入病患體內，不得擅自應用於研究或其他非治療性之用途。

All hematopoietic stem cell transplantation operations should follow the international stem cell transplantation standard operating procedures to respect the donor's love. The donated hematopoietic stem cells can only be used to treat the fatal diseases of the recipients and can be imported into the patients within 48 hours after stem cell collection. Do not apply to research or other non-therapeutic uses.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

5. 受贈者術後追蹤 Recipient post-operation follow-up

(1)目的：為了解受贈者在完成造血幹細胞移植後的恢復情形，也可以知道本中心供髓的品質是否兼顧國際標準及國內外移植醫院在幹細胞移植上的需要。

Aim: To understand the recovery status of the recipient after HSC transplantation, while checking if the quality of our Marrow meets the International Standard and the requirement of the HSC transplantation in both domestic and overseas TC.

(2)作業用表單：幹細胞移植術後追蹤(Stem Cell Transplantation Follow-Up)表。

Use the form “Stem Cell Transplantation Follow-up” as post-operation follow-up periodically after transplant.

(3)追蹤時程：受贈後一百天、一年、二年、三年、五年、七年

Follow-up period: 100 days, 1 year, 2 years, 3 years, 5 years, and 7 years.

(4)作業上注意事項 Points of attention in the process：

①本中心承辦同仁在追蹤時程發送術後追蹤表後，從表單收取日起算，請於一個月內完成。

Each follow-up report should be completed within 1 month starting from the day the form was received.

②請移植醫院醫師在完成填寫追蹤表後，再次確認資料完整性後，用傳真或是電子郵件傳送電子檔的方式回覆。

Ask the Physician of the TC to confirm the completeness after filling up the form, then fax or e-mail back to us.

6. 再次捐贈 Subsequent donation

(1)目的：經主治醫師評估受贈者病情後需要捐贈者再次進行捐贈，以提升受贈者移植成功率。

Purpose: to elevate the patient's transplant success rate when the attending physician assesses that the recipient requires a subsequent donation from the donor.

(2)啟動文件及啟動方式 Documents and method for initiating a subsequent donation：



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

①請主治醫師詳細填寫再次捐贈申請(PREVIOUS TRANSPLANT HISTORY and FORMAL REQUEST for SUBSEQUENT STEM CELL COLLECTION)表後，用電子郵件或者傳真傳送至本中心。
The attending physician shall complete the Subsequent Donation Request form in detail and send it to the Center by e-mail or fax.

②由本中心醫務主任判定捐贈者是否適宜再次捐贈，並同時請捐贈者中心(Donor Center)同仁詢問捐贈者意願，兩天內回覆移植醫院。
The Center's medical director will determine if the donor is suitable for the subsequent donation, then the staff from the Donor Center will inquire the donor for agreement to do the subsequent donation, and will reply the answer to the transplant center within two days.

(3)本中心再次捐贈標準，如下表所示

The Center's criteria for subsequent donations is as follows :

		第一次捐贈 First Donation	
		Marrow	PBSC
第二次捐贈 Second Donation	Marrow	12 星期 12 weeks	4 星期 4 weeks
	PBSC	4 星期 4 weeks	不被執行 not allowed
	淋巴球 TCT	4 星期 4 weeks	4 星期 4 weeks
	全血 WB	12 星期 12 weeks	4 星期 4 weeks



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

(4) 注意事項 Please note :

- ① 捐受贈者皆需符合本中心再次捐贈條件。

Both recipient and donor must meet the Center's criteria for subsequent donations.

- ② 捐贈者於再次捐贈時距離上次身體檢查超過 6 個月，將再次安排捐贈者進行身體檢查。此項身體檢查的費用將發送收費通知單以便患者匯款。

If the date for the subsequent donation is over 6 months from the date of the donor's last work-up, then the donor will undergo another work-up. A statement for the cost of this work-up will be sent to facilitate payment by electronic fund transfer.

(5) 捐贈者再次捐贈之政策 Policy for Donor Subsequent Donation :

- ① 維持一生只能捐贈三次(含骨髓、週邊血、淋巴球及全血)，其中週邊血捐贈僅能捐贈一次。

A donor may contribute to a maximum of three donations in a lifetime, regardless of the categories of the first donation and the second donation, but PBSC only once in a lifetime.

- ② 一生最多只能捐贈骨髓二次。

A donor may donate Bone Marrow (BM) only twice in a lifetime.

- ③ 若是第二次捐贈是捐贈給第二個患者須間隔一年以上，若是第三次捐贈時才捐贈給第二個患者，則必須間隔第二次捐贈三年以上。

If the second donation is for another recipient, then the donation must be at least 1 year apart. If the third donation is for another recipient, then the donation must be at least 3 years apart from the second donation.

(6) 再次捐贈必須是受贈者移植後有立即、急迫性之需要，方得由其主治醫師以書面向本中心資料庫暨行政組提出申請，若為研究或其他非治療性之用途則不予受理。

Subsequent donations must be an immediate and urgent need for the recipient to be transplanted, and the application must be submitted in writing to the Center's database and administrative group. If it is for research or other non-therapeutic purposes, it will not be accepted.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

- ①如因捐贈者為 Poor Mobilizer 導致幹細胞成品細胞數過低需進行再次捐贈時，須間隔兩星期以上，方可詢問捐贈者再次捐贈之意願。
If the donor is Poor Mobilizer and the number of cells after the stem cells are too low to be re-donated, it must be more than two weeks before asking the donor to donate again.

7. 臍帶血配對 Cord blood matching

- (1)目的：本中心除了提供非親屬骨髓捐贈者配對報告之外，也提供臍帶血配對報告以供移植醫院選擇。

Purpose – the Center not only provides matching results for unrelated bone marrow donors, but also matching results for cord blood for the transplant hospital's option.

- (2)申請方式：國內外的骨髓資料庫或合作移植醫院於配對申請表上註明提供臍帶血配對結果即可。臍帶血配對程序與造血幹細胞捐贈者配對類似，不同之處為不用安排身體檢查的過程，只要臍帶血的 HLA-A,-B,-DRB1 配型與病患達到至少 4/6 相合，待移植醫院回覆預計臍帶血出庫時間即可。

Application method: bone marrow registry or participating transplant centers need only to specify the need for cord blood matching report on the application form. The matching process for cord blood is similar to that for hematopoietic stem cells, where they differ is that no health check is needed for cord blood, because the cord blood's HLA typing needs only to achieve at least a 4/6 match with the patient, and the transplant center need only to reply to the Center with the expected time for the cord blood bank to provide the cord blood.

- (3)申請文件：Patient Status Report and Prescription for Cord Blood Unit 主治醫師可填寫此表單，以便啟動血樣複檢確認臍帶血的 HLA 配型。

Forms required for cord blood matching: Patient Status Report and Prescription for Cord Blood Unit: this may be completed by the attending physician so as to initiate the Confirmatory Test on Cord Blood Unit to ascertain the cord blood's HLA typing.



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

(4)注意事項 Important information :

- ①骨髓資料庫或海外合作移植醫院可要求寄送臍帶血樣本至各庫(院)指定之HLA實驗室進行HLA配型檢驗。

Bone marrow registry or participating transplant centers may request to have the cord blood sampling sent to a specified HLA laboratory to conduct HLA typing test.

- ②Cord Blood Summary Report：提供臍帶血寶寶及母親血樣的檢驗結果。可供主治醫師確認此袋臍帶血是否曾遭感染。在合作移植醫院或骨髓資料庫要求進行臍帶血的配型複檢時，本中心將提供Summary Report給合作移植醫院。

Cord Blood Summary Report: provides blood sampling test results on the infant and birth mother donating the cord blood. It can aid attending physicians in determining whether the bag of cord blood has been infected. When participating transplant centers or bone marrow registry submit a request for cord blood typing test, the Center will provide a Summary Report.

- ③骨髓資料庫或合作移植醫院確認將要採用臍帶血時，請回覆預計臍帶血移植日期及希望寄送臍帶血日期。

When the bone marrow registry or participating transplant center has ascertained its intention to use the said cord blood, it shall reply to the Center with the expected cord blood transplantation date and the date it wishes the cord blood to be sent.

- ④移植醫院可自行指定或是由本中心提供合作快遞公司的聯絡資料，以便協調臍帶血運送事宜。

The transplant center may specify a desired courier service, or the Center will provide the contact information of a courier service it uses to facilitate the arrangement for the cord blood's delivery.

8. 捐贈者保留原則 Donor Reservation Principle

- (1)目的：在配對程序的進行中，會因為病患病情及療程的情況導致配對程序無法順利的進行，本中心捐贈者保留原則為保障移植醫院保留捐贈者的權利。



佛教慈濟骨髓幹細胞中心

Buddhist Tzu Chi Stem Cells Center

病患申請作業程序

Purpose – the donor reservation principle is the Center’s way of protecting the transplant center’s right to reserve the donor during the matching process, in case the matching process cannot be implemented smoothly due to complications in the patient’s condition or treatment.

(2) 定義及原則：在移植醫院要求啟動捐贈者進行血樣複檢後，以下程序每一階段，僅能保留 6 個月為限。

Definition and principle of implementation: the reservation can be done after the transplant center requests to initiate the donor CT test, at the following stages of the process, but with a 6 months maximum limitation.

① 自回覆捐贈者確認配型檢驗報告，至移植醫院要求安排捐贈者進行身體檢查。

from the time the donor’s CT report is received, until the time transplant center requests a work-up for the donor.

② 自回覆捐贈者身體檢查結果，至移植醫院要求安排捐贈者進行造血幹細胞採集。

from the time the donor’s work-up results is received, until the time transplant center requests collection of the donor’s hematopoietic stem cells.

③ 臍帶血配對的保留最長期限與骨髓幹細胞捐贈者同樣為 6 個月。

The maximum reservation time for cord blood matching is also 6 months, the same as bone marrow.

9. 財務&收費 Fees & Payment

(1) 依本中心公告收費方式收費

Fees are collected according to the Center’s published schedule.

(2) 收費方式：骨髓庫採月結制、移植醫院採預付制

Fee collection method: collection is done on a monthly basis for marrow registries, and pre-pay for transplant centers.

(3) 匯款時，請註明病患編號及病患姓名

When paying via electronic fund transfers, please specify patient’s name and ID number.