Transplant Center Request for Cryopreservation

(Completed by SCU Staff)

Date Requested: _____ ☐ Unplanned Cryo

TC#: _____ ☐ Planned Cryo

Recipient ID: _____ Recipient Name: _____

Donor ID: _____ Donor Center#: _____

Diagnosis: _____ Disease Stage: _____

Product: ☐ BM ☐ PBSC ☐ DLI

Stem Cell Collection Date: _____ CC # / AC #: _____

Reasons: _____

_____

_____

Planned Date for Infusion: _____

TC coordinator: _____

NMDP SCU staff: _____

NMDP Medical Director / Designee Approval: ☐ Yes ☐ No

Comments: _____

_____

NMDP Approving Signature: _____ Date: _____

Reasons: ☐ Patient Condition ☐ Others _____

☐ Donor Schedule

☐ CC/AC Schedule Conflict

☐ Copy to Search Quality Assurance Nurse (in lieu of QIF)

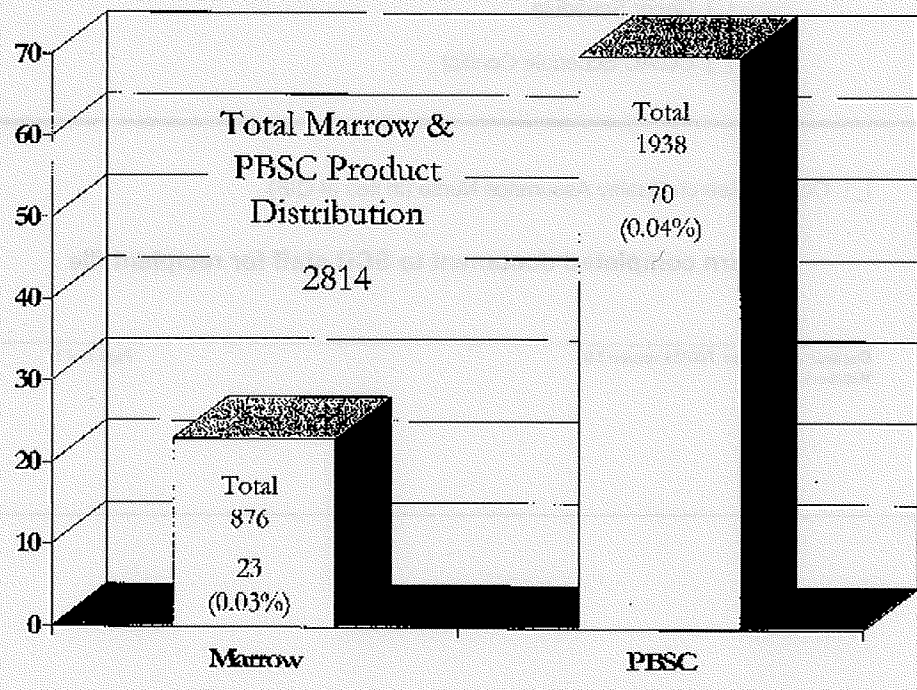
Return completed document to SCU staff for recipient file

【資料 4 】

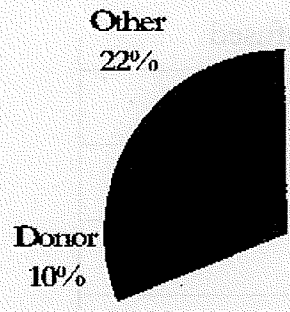
Cryopreservation Data

- Collect data manually
  - Every request recorded
  - Reason
  - Infusion
  - Outcome
- Review data from 2006

Cryopreservation Data



Cryopreservation Data - Reason



Other:

No backup product

Bed space

PBSC only

Clerical error

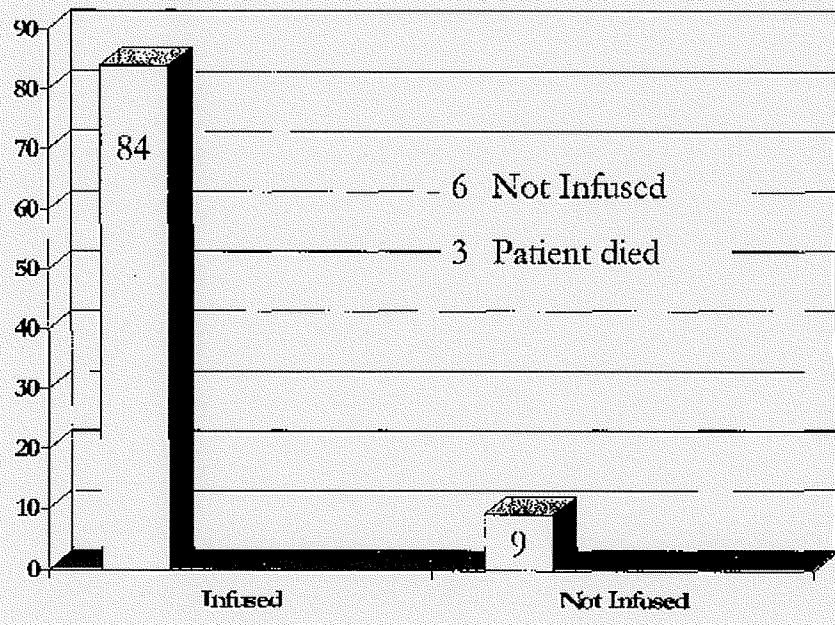
Staffing issues

Scheduling

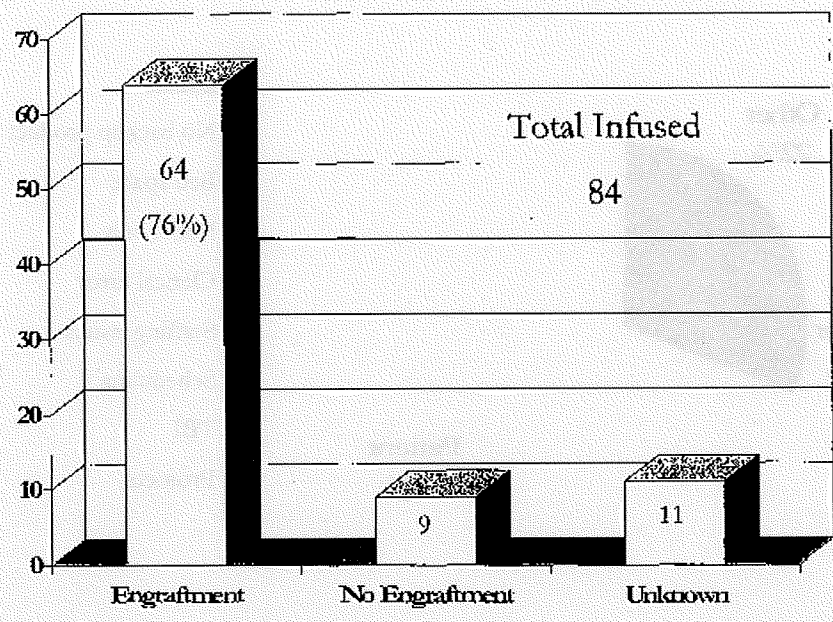
TBI

Protocol

Cryopreservation Data - Infusion



Cryopreservation Data - Engraftment



■G-CSF の投与について

1.G-CSF 投与は連日実施することが基本だが、何らかの事情でドナーが G-CSF 投与を受けられなかった事例はあるか。その場合、どう対応したか。

・これは非常に稀なケースであるが、NMDP のメディカルディレクターがドナーセンター・採取医と一緒にどのように進めるか検討することになる。

2.医療上の理由ではなく予定された G-CSF 投与を受けなかった場合、PBSC 採取を予定どおり行うか。

・これは G-CSF 投与何日目かによる。おそらく血液中の CD34 陽性細胞数を測定して PBSCT を行うか、同一ドナーからの骨髄採取を検討することになる。

3.その他
・G-CSF 投与期間中のドナーの健康状態チェックシートがあり、NMDP へ報告されるシステムになっている。G-CSF 投与の日程調整や予定通り行われているかの確認はドナーセンターの責任下で行う。
・G-CSF 投与 1 日目はアレルギー反応等をみるため、医療従事者が投与する。
・2 日目以降はホームドクターや派遣されたナース、アフェレーシスセンター等が行う。
・ドナーは提供の流れについて十分理解しているので、もしナースが現れないようなことがあった場合には、ドナーセンターへ連絡するなど自発的に行動している。
・ドナーセンターとドナーはコミュニケーションをとり合い、よい関係が出来ていると言える。

■患者の幹細胞ソースのリクエストについて

1. 患者側の幹細胞ソースのリクエストについて

①疾患別、年齢別でリクエストはどのような割合になっているか。
・統計データを見たことはないが、年齢と疾患によるリクエストの傾向は確かにある。
・例えば小児患者はBMを、高齢者のミニ移植ではPBSCを、代謝異常症はBMをリクエストする傾向がある。
・因みにNMDPで行っている採取のうち約70%がPBSCであり、最も多い疾患は急性骨髄性白血病である。

②患者側が当初のリクエストを変更することはどれくらいの頻度で起こるか。
・非常に稀である。PBSCに変更することは4%、BMに変更することは1%である。

③患者側がリクエストを変更するのはドナーの希望と合わない場合のみか。
・ドナーの希望により変更されることもあるが、一般的なのはドナーセンターの医師が、そのドナーはどちらか一方しか提供できないと判断した場合である。例えば、脊椎に整形外科的問題のあるドナーはPBSCのみ、鎌状赤血球傾向があるドナーはBMしか提供できないと判断されるなど。

④ドナーが患者のリクエストしている採取方法を断った場合、セカンドリクエストを出すタイミングはいつか。
・ワークアップ（最終同意）の際が、移植施設が希望を提示する最初のタイミングである。移植施設は、「どちらか一方しか許容できない」、または「第一希望・第二希望」というかたちでリクエストを提示する。
・移植側がどちらか一方しか許容できない場合にドナーがそれを拒否したら、移植施設へすぐに報告する。
・第2希望が記載されている場合は、原則連絡されない。その報告を受けて移植施設は、もう一方のプロダクトの提供を受けるか、別ドナーにあたるかを決める。
・しかしドナーがどちらか一方しか提供しないということは非常に稀であり、おそらく1%以下である。

2. PBが主流となっている理由
①ドナーの健康回復が早いこと
②そのためコストが安くなること
③医師がBM採取をする機会が減って時間が出来ること
その他の理由はあるか。
・③は、少なくとも非血縁者間移植では主な理由ではないと思われる。BM採取をする医師は、患者が入院している病院とは別の医師だからである。
・NMDPでは、PBSCvsBMについてドナーと患者550組のランダマイズ試験を終えたところで、あと2年で解析結果が出る。患者の移植成績に関してこの研究でどのような結果が出るかによってまた幹細胞の選択に変化が起こることが予想される。

・一方の採取法しか受け付けないドナーが少ないにも関わらず、PBSCT の件数が増えている理由は、移植施設からのリクエストが多いからかという問に対しては「約 90%のドナーは移植側のリクエストを受け入れる。PBSCT が増加しているのは PBSC をリクエストする移植側が多いからと言える。ドナーにとっても PBSC 提供の方が負担が少ないと思う（拘束時間が短い、覚醒した状態で提供できる等の理由から）。」とのことであった。

■ドナーコーディネートについて＞

1. PBSC・BM ドナーワークアッププロトコール
（資料　5　）参照

2. PBSC ドナーと BM ドナーのワークアッププロトコールに違いはあるか。
・1 番最初の PBSCT のプロトコールでは、ドナーは PBSC も BM も適格でなくてはならないと考えていた。しかし経験を積むにつれて、両方の基準をまったく同様にして常にすべてを満たす必要はないことがわかった。現時点では PBSC・BM いずれもが適格なドナーだけを適格としているわけではない。
・現在のプロトコールでは、ワークアップの行程（ドナー選定、インフォメーションセッション、同意書への署名、健康診断等）は BM も PBSC も同じだが、健康診断では PBSC ドナーには正中静脈アクセスが可能か、中心静脈アクセスが必要になる可能性があるかの評価が加わること等多少の違いがある。
・ただし、一方が不適格の場合は採取前にその情報を移植側へ伝えている。例えば、移植側が PBSC を希望していて、ドナーも同意し適格性も問題ないが、脊椎に整形外科的問題がある等の理由で BM は不適格であればその旨を伝えておく。その情報を知っていれば、もし Poor　mobilize r だった場合、BM 採取への移行ができないことを考慮して、前処置に入らず凍結して移植する計画を立てる等の余地を与えることができる。
・PBSCT は FDA の Investigative New Drug のカテゴリーに含まれているためプロトコールが必要だが、BM のプロトコールはない。

3. ドナーコーディネート運用マニュアル
（資料　6　）参照

○登録時
・ドナーが PBSC/ BM のどちらを選択するか確認はしない。
○最終同意時
・移植側の希望をドナーへ伝える（理由も含めて）。移植側がどちらか一方しか許容できない場合はコーディネーターが「なぜこの一方のみなのか」を説明する。ただし、患者の疾患や年齢等の一般的な情報であり、医学的な詳細説明まではしない。
・ドナーへ提供する患者情報は、年齢、疾患、性別である。移植側のリクエストに関して追加情報が欲しい場合は、ドナーセンターのコーディネーターがサーチコーディネーターへ問い合わせる。そのため、サーチコーディネーター教育（疾患や、2 つの提供方法の利点・リスク等）には時間をかけている。
・ドナーセンターのコーディネーターとサーチコーディネーターは、情報を提供して移植側のリクエストのサポートはするが、ドナーを説得して同意させることはしない。ドナーがあくまでも一方しか提供しないと言う場合にはそれを尊重し移植側へ報告する。
・それを受けて移植側は、ドナーが提供すると言う方を受諾するか、別ドナーにあたるかを決定する。多くのドナーは患者側の意向に同意するので、難しい問題はほとんどない。
・PBSC でも骨髄でも、移植側は 90%くらいの確率で、希望する幹細胞の提供を受けられる。ただし、ドナーの希望ではなく適格性の問題で一方しか提供できないことはある。

・また、例えば確認検査の時点でドナーが断固として PBSC しか提供しないと意思表示をしている場合には、最終同意の前にドナーセンターからサーチコーディネーターへ報告が入り、移植施設へ伝える。
・もし、ドナー候補者が一人しかいなければ、移植側は BM を希望していてもそのドナーを選定することもある。しかし、そのドナーの選択が健康上の理由ではなく希望によるものであれば意思が変わる可能性もあるので、ドナーが PBSC を希望しているとわかっていても、最終同意の際には移植側は BM を希望していることを伝える。
○その他
・NMDP では同一患者への 2 回目提供（セカンドドネーション）のみで PBSCT を導入し、1999 年に 1 回目提供からの PBSCT を開始した。
・当初は、移植側のリクエストを叶えたいが、患者側の希望を伝えることによってドナーにプレッシャーをかけるのではないかという、本邦で現在議論していることと同様の懸念があった。開始時にはドナーセンターのコーディネーターに PBSCT について十分教育を行った。また、移植施設側には第 1 希望の理由を 1 ～3 つ必ず提示させ、それがドナーへの説明に役立った。
・しかし NMDP は移植施設に対して、ドナーは両方の方法について考え、選択できる立場であることを明確に示した。また、ドナーが決断に迷っているときに情報や説明を提供してサポートはするが、説得するのはドナーセンターやレジストリースタッフの仕事ではないことも明確にした。
・開始当初はドナーに PBSC 提供という方法が受け入れられるかどうか不安があったが、時間がたつにつれてドナーにとって受け入れ難い方法ではないということがわかってきた。

【資料 5 】(抜粋)

Filgrastim-Mobilized Peripheral Blood Stem Cells for Allogeneic Transplantation with Unrelated Donors

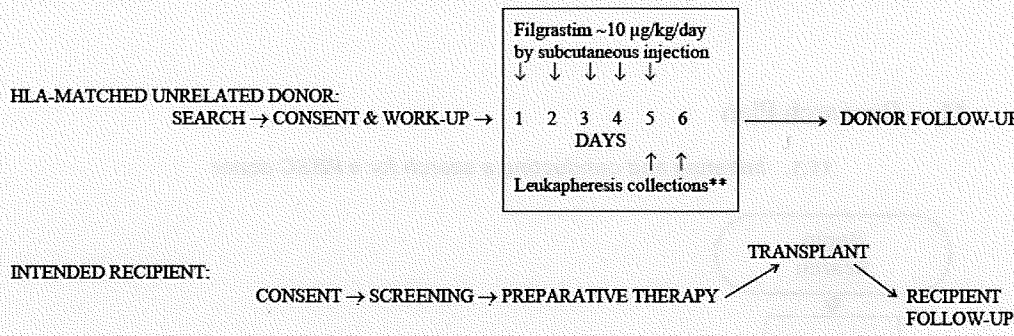
A protocol of

The National Marrow Donor Program®
3001 Broadway Street NE
Suite 500
Minneapolis, MN 55413
612-627-5800
800-526-7809

Principal Investigator:
John Miller, MD, PhD
Medical Director, NMDP

3. Study Schemata

Figure 1. Filgrastim-mobilized peripheral blood stem cells for allogeneic transplantation with unrelated donors.



* Mobilization: The donor receives filgrastim ~10 µg/kg/day subcutaneously for 5 consecutive days if one standard or two leukapheresis collections are scheduled.

** Collection: Leukapheresis is performed on day 5 alone or on days 5 and 6. The whole blood volume processed will be 12 to 24 liters per collection. See Section 11.4.1 and Table 3.

Table 1. Summary of evaluations, treatments and procedures.

Day	NMDP Forms Completed	Symptom Assessment	Vital Signs	Blood Work	Filgrastim Administration	Apheresis
Screening	700	X	X	X		
1	710	X	X	X	X	
2	710	X	X		X	
3	710	X	X		X	
4	710	X	X		X	
5	730	X	X	X*	X	X
6	730	X	X	X*		X†
2 days post	777	X				
1 week post ‡	777	X				
1 month post	760	X				
6 months post	760	X				
Annually	760	X				

* Blood testing is obtained both pre- and post-apheresis. See Section 11.4.4.

† Not all donors will have apheresis collection on day 6. See Section 11.4.1 and Table 3.

‡ Form 777 is completed weekly until full recovery is reported by the donor. See Section 11.6.1.

11. Research Plan

11.1. *Initiating and conducting a search for a PBSC donor*

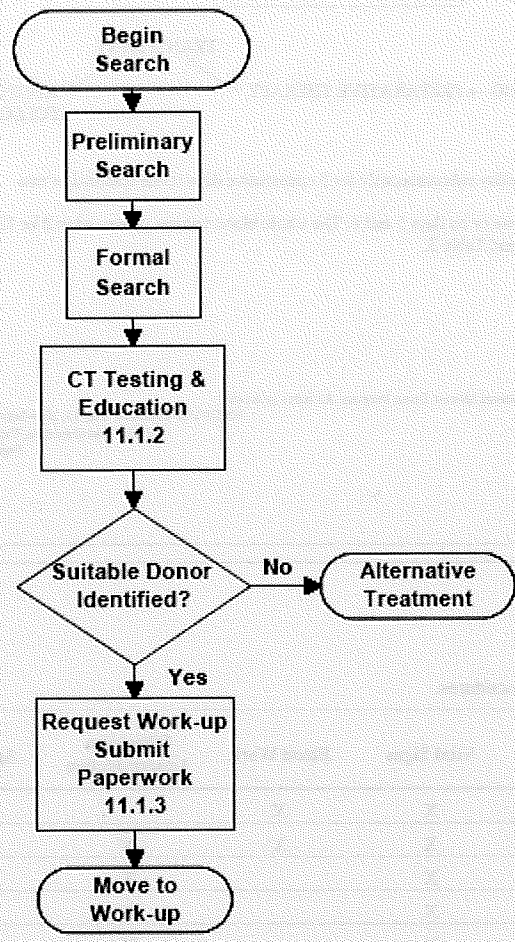
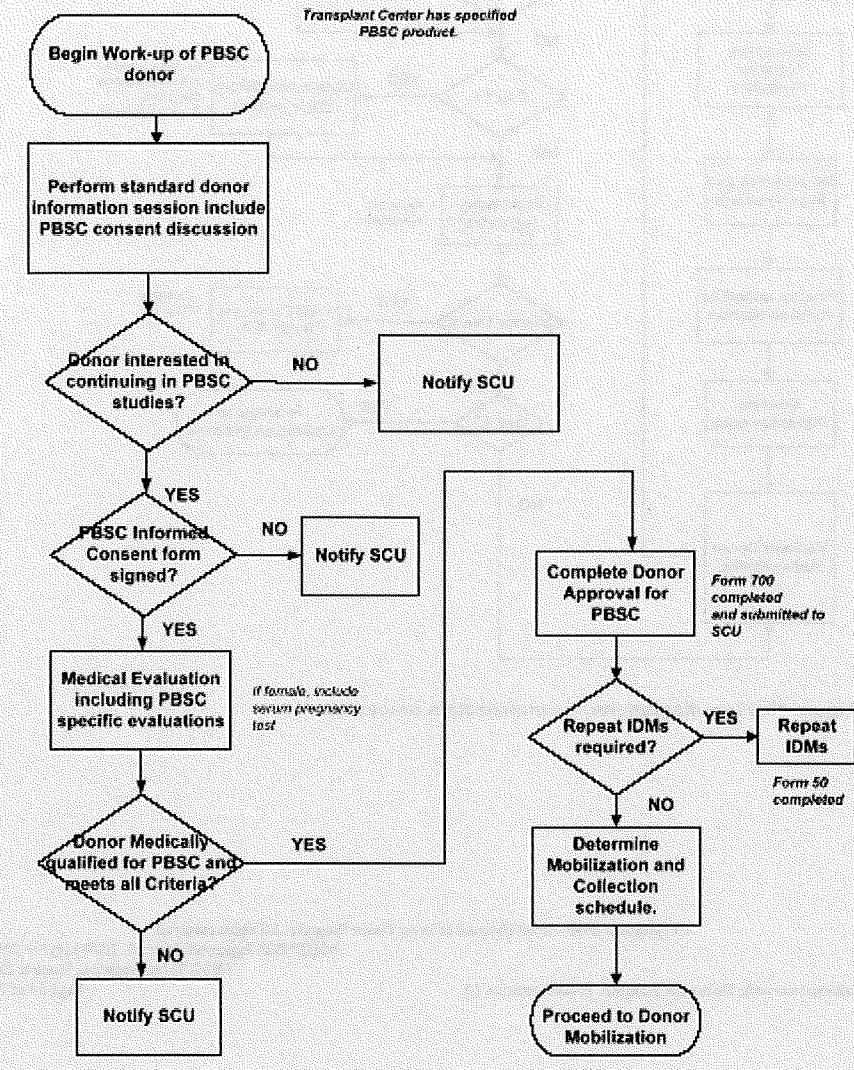


Figure 8. Flow diagram for the search process.

11.2. *Donor Work-Up Process*



11.3. *PBSC mobilization*

Donor Mobilization Process

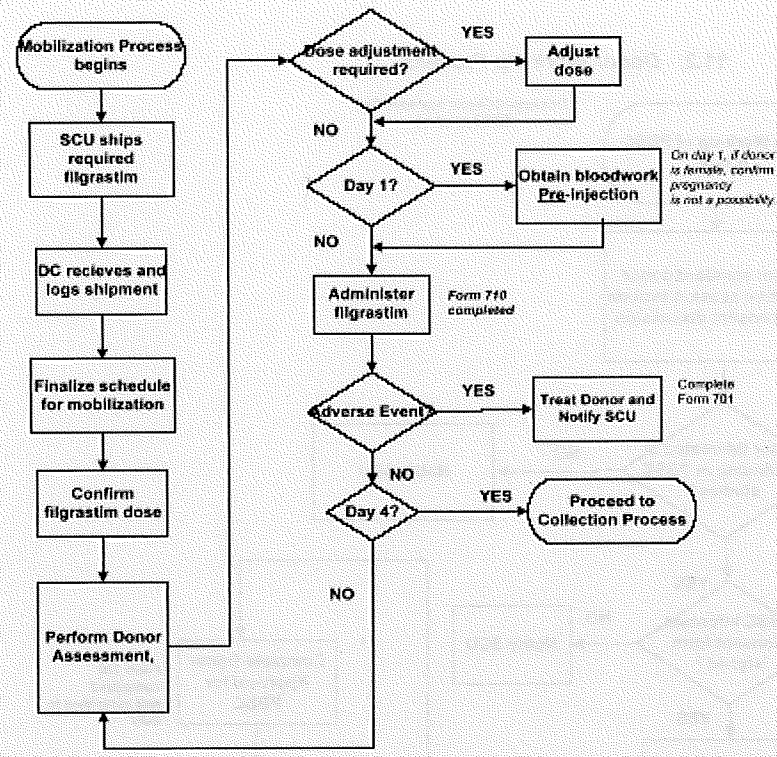


Figure 10. Flow diagram for the mobilization process.

11.4. *PBSC collection*

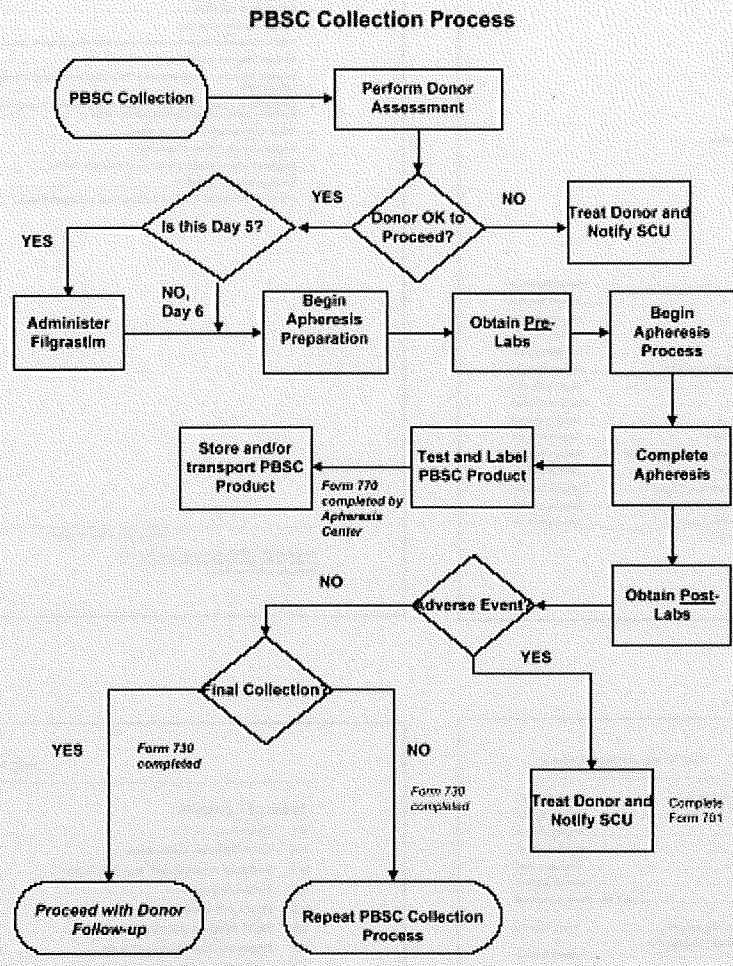


Figure 11. Flow diagram for the apheresis collection process.

【資料 6 】

9. PBSC Workup and Donation Process

Purpose
To provide information on donor activities to facilitate the PBSC workup process.

Tools and Resources

- Assessment Notebook at Search (Network Web site)
- Donor Forms Instruction Manual
- FedEx® Web Site
- Fee-For-Service Policies and Reimbursement Procedures
- FormsNet™ application
- FormsNet™ User's Guide
- NMDP Network Web Site
- National Marrow Donor Program Standards
- PBSC vs. Marrow Randomized Trial Donor Companion Manual
- STAR Link® application
- STAR Link® User's Guide
- Webmail
- Webmail User's Guide
- Webscripts
- Webscripts: Donor Center User Guide

Materials

- Administration of Filgrastim ..... NMDP generated
- Apheresis Center Reimbursement Chapter ..... Network Web site
- Approval of Extended Medical Fees ..... NMDP generated
- Assessment Tool at Workup ..... Network Web site
- Basics of Infectious Disease Testing for Stem Cell Donors ..... Network Web site
- Checklist for Contents of Donor Center/Apheresis Center Procedures (POI) ..... Network Web site
- Declaration of Urgent Medical Need ..... NMDP generated
- Donor and Patient Confidentiality Guidelines ..... Network Web site
- Donor Center Abnormal Findings Letter ..... NMDP generated
- Donor Center Manual of Operations: Adverse Events, Chapter 15 ..... Network Web site
- Donor Center Manual of Operations: Cellular Product Labeling and Transport, Chapter 12 ..... Network Web site
- Donor Center Manual of Operations: Donor Advocacy, Chapter 14 ..... Network Web site
- Donor Center Manual of Operations: Donor Center Support Services, Chapter 16 ..... Network Web site
- Donor Center Manual of Operations: Miscellaneous Donor Center Processes, Chapter 13 ..... Network Web site
- Donor Center Manual of Operations: Post Donation Follow-Up, Chapter 11 ..... Network Web site

- Donor Health History Screening Questionnaire for Use at HR/CT/Workup ..... Network Web site
- Donor Insurance Beneficiary Designation Form ..... Network Web site
- Donor Insurance Policy ..... Network Web site
- Donor Insurance Summary ..... Network Web site
- Donor Medical Services Coverage Card, catalog item P1044 ..... Materials Catalog
- Donor Physical Assessment ..... Network Web site
- Donor Workup Request Form or international equivalent ..... Network Web site/SCU generated
- FedEx® Pointers on Shipping: Clinical Samples, Diagnostic Specimens and Environmental Test Samples ..... FedEx Web site
- Filgrastim-Mobilized Peripheral Blood Stem Cells for Allogeneic Transplantation with Unrelated Donors Protocol ..... Network Web site
- Final Declaration of Donor Eligibility and Instructions ..... Network Web site
- Follow-up Questions for Reactive Chagas Screening Test Result ..... Network Web site
- Form 50, *Repeat Infectious Disease Markers* ..... Network Web site
- Form 700, *Determination of Stem Cell Donor Suitability* ..... Network Web site
- Form 701, *Stem Cell Donor Adverse Event Form* ..... Network Web site
- Form 702, *Determination of Stem Cell Donor Suitability, Greater Than 8—12 Weeks Post Medical Evaluation* ..... Network Web site
- Form 703, *Determination of Stem Cell Donor Suitability, Greater Than 12 Weeks—6 Months Post Medical Evaluation* ..... Network Web site
- Form 705, *Donor Pregnancy Testing and Evaluation* ..... Network Web site
- Form 710,*Filgrastim Mobilized PBSC Days One, Two, Three and Four Donor Assessment* ..... Network Web site
- Form 730, *Filgrastim Mobilized PBSC Days Five and Six Donor Assessment /Apheresis Procedure* ..... Network Web site
- Form 760, *Post-Donation - One Month, Six Months and Annual Donor Assessment* ..... Network Web site
- Form 770, *Peripheral Blood Stem Cell (PBSC) Product Analysis* ..... Network Web site
- Form 777, *Stem Cell Donor Follow-Up Evaluation* ..... Network Web site
- Guide for the Interpretation of Infectious Disease Marker (IDM) Testing Results ..... Network Web site
- IDM Eligibility and Labeling Guide ..... Network Web site
- Important Information For Your Safety and Your Recipient's Safety ..... Network Web site
- Instructions for Completion of F24 and F50 ..... Network Web site
- International IDM Testing Requisition ..... SCU generated
- NMDP Research Sample Excuse Code Forms ..... Network Web site
- NMDP Verify Condition of Drug Received ..... NMDP generated
- NMDP Verification of PBSC Request ..... Network Web site
- Non-Medical Factors Affecting Donor Suitability ..... Network Web site
- Notification of Donor Clearance for PBSC Donation ..... NMDP generated
- Now That You Are A Match Notebook and Video ..... Materials Catalog
- Now That You Have Donated Booklet ..... Materials Catalog

- Opportunity to Participate in the NMDP Research Sample Repository Brochure ..... Materials Catalog
- PBSC Donor/Subject Consent Form ..... Network Web site
- PBSC Information Session Outline ..... Network Web site
- PBSC Workup Checklist ..... Network Web site
- Policy for Disposition of Donor Products, Cord Blood Units and Specimens ..... Network Web site
- Policy for Subsequent Donations Following Initial Marrow or PBSC Donation by NMDP Donors ..... Network Web site
- Procedures of Interaction ..... Center generated
- Protocol Deviation Form 3000 ..... Network Web site
- Rationale and Action Guide for Health History Screening Questionnaire at HR/CT/WU ..... Network Web site
- Recipient Diagnosis Codes ..... Network Web site
- Research Database for Unrelated Donor Transplant Donor/Subject Research Consent Form ..... Network Web site
- Contribution of a Blood Sample to the National Marrow Donor Program's Research Sample Repository Donor/Subject Research Consent Form ..... Network Web site
- Research Repository Critical Facts Sheets ..... Network Web site
- Research Sample Excuse Code Forms ..... Network Web site
- Suggested Letter to Medical Providers and Collection Centers ..... Network Web site
- Summary of Donor Eligibility ..... Network Web site
- Willingness to Consider a Second Donation Letter and Questionnaire ..... STAR Link application

Table of Contents

9.1. Overview

NMDP donor centers and apheresis centers each play an important role in coordinating the PBSC workup and donation process. Donor centers are required to establish written procedures of interaction with each apheresis center that performs PBSC collections for their donors. The procedures of interaction define the tasks that are the center's responsibility.

The workup is a process to determine if the donor is medically suitable and willing to donate peripheral blood stem cells (PBSC). The activities described in this chapter are established by the protocol titled *Filgrastim-Mobilized Peripheral Blood Stem Cells for Allogeneic Transplantation with Unrelated Donors*. If the donor is suitable for donation (cleared to donate), the donor center is responsible for coordinating the donation process. The donor center is responsible for facilitating the day of donation activities and for monitoring the donor's recovery.

Throughout the entire process, the donor center is responsible for the workup activities described within this chapter, which may be tailored to local procedures using the procedures of interaction checklist for donor centers and apheresis centers. Each component of the workup process is highlighted as a separate function; however, some tasks may be performed in conjunction with other tasks for operational efficiency.

Prior to donation the donor center and apheresis center's roles during the PBSC workup process includes, but are not limited to:

DC Responsibility	AC Responsibility
▪ Assess donor's interest and perform a donor health history screening. ▪ Coordinate scheduling workup and collection dates ▪ Enter dates in the STAR Link application, webscripts, or send electronically ▪ Conduct the information session ▪ Provide donor with *Important Information For your Safety and Your Recipient's Safety* ▪ Obtain donor consent ▪ Coordinate a venous assessment. ▪ Coordinate the physical exam and approvals ▪ Provide appropriate documents to the NMDP Search Coordinating Unit (SCU) for donor clearance ▪ Confirm and continue coordinate scheduling the collection ▪ Determine donor's eligibility based on relevant communicable disease risk	▪ Schedule and conduct the physical exam or review physical exam results provided by a third party physician ▪ Sign appropriate NMDP forms indicating donor clearance (or the need for additional testing) ▪ Work with donor center personnel to coordinate the scheduling of the PBSC collection ▪ Work with donor center personnel to facilitate additional donor testing as required ▪ Coordinate donor filgrastim administration in conjunction with local donor center as needed ▪ Notify and counsel the donor regarding any abnormal test results or finding from the physical exam

DC Responsibility, continued	
▪ Facilitate donor activities including arranging for research and pre-collection samples, infectious disease marker and pregnancy testing, arranging for filgrastim injections, etc. ▪ Organize the labeling, transport and delivery of the product.	

After collection the donor center and apheresis center's roles during the PBSC workup process include, but are not limited to:

DC Responsibility	AC Responsibility
▪ Monitor donor recovery immediately after donation until completely recovered ▪ Perform a one-month, six-month, and annual follow up including assessment and if required, coordinate blood sample collection and report results	▪ Ensure the donor's health is appropriate for release ▪ Provide post-donation instructions to the donor ▪ Be available for emergency care

9.2. Confidentiality Guidelines

The need to adhere to strict confidentiality guidelines increases as the donor faces the decision of whether or not to donate stem cells. At this stage, the donor center and apheresis center learn the name and location of the recipient, as well as specific details regarding the recipient's clinical condition and disease. For specific guidance on how to manage confidentiality at the workup stage, see the *Donor and Patient Confidentiality Guidelines* on the NMDP Network Web site.

9.3. Software Applications and Processes

NMDP Network donor centers communicate with the NMDP using an approved process or application. In this chapter, the reader will find references to donor centers receiving or entering information in the STAR Link application. Donor centers that do not use the STAR Link application should receive and must enter the equivalent information using Webscripts or other NMDP-approved application. See the *STAR Link User's Guide* or *Webscripts: Donor Center User Guide* for additional information.

9.4. Forms Submission

In this chapter, when centers receive instruction to submit a form to the NMDP or SCU, the center is responsible for submitting the form in the appropriate manner. This may include submitting forms via the FormsNet™ application, fax or mail.

A data collection form (DCF) refers to the collection of required data for data entry and storage in the STAR® system. DCFs include the Form 700 series,

Form 24, Form 50 and Protocol Deviation Form 3000. Note: Forms 702, 703, 705, and 773 cannot be completed through the FormsNet application.

Infectious Disease Marker (IDM) information is used to determine eligibility of donors to donate their stem cells according to FDA regulatory requirements. Donor center staff must obtain IDM screening and confirmatory results from the CMS certified testing laboratory using FDA approved kits for donor screening and accurately report the results to the NMDP on the Forms 24 and 50. The reporting process must include at least a two-step review process to ensure accuracy.

Additionally, there are forms that donor centers complete or receive that are not entered into the STAR system, for example, the workup request form, product verifications, health history forms, etc. Apheresis centers are responsible for the Form 770/771, *PBSC Product Analysis*. Centers submit these forms as requested via fax, mail or other acceptable process.

The NMDP has a tracking system in place to assist centers in identifying when a form is due and if it has been received and entered at the NMDP. When a form becomes due, or is past due, it appears on a center specific forms due report. For additional information on forms submission, see the *FormsNet User's Guide* and *Donor Forms Instruction Manual*.

9.5. Held for Workup Request

A donor requested to be "held for workup" is reserved for the patient for up to 60 days. A transplant center may request that a donor be "held for workup" for two reasons:

- A donor may be requested for "held for workup" while another donor is asked to consider stem cell donation.
- A donor may be requested for "held for workup" when no other donor has been asked to donate.

The SCU will send donor center information about why a donor is being requested as "held for workup" and a tentative timeline for the request. The donor center should contact the donor, confirm the donor's willingness to continue, and ask if there have been any changes in the donor's health since the most recent health history screening was administered. If a recent health history screening is not available, it may be necessary to administer a new one. Confirm the donor's availability around the proposed collection date. Once completed, an "Inform Donor" date should be entered in the STAR Link application.
Inform the Search Coordinator of any time constraints or health problems regarding the donor's participation.

9.6. PBSC Workup Request

The transplant center selects a donor for workup by submitting a request to the SCU. The donor requested meets the transplant center's requirements for HLA

matching, CMV, age, sex, and other factors. The majority of workup requests result from a recent CT request; however, in some circumstances, a donor could progress from high resolution typing (HR) to workup. A donor may be requested for workup without a prior HR or CT request for the recipient. In these cases, the CT would be requested as part of the workup request

At the time of the workup request, the SCU reviews all previously reported infectious disease marker (IDMs) test results.

The donor center receives the workup request in three ways:

- An electronic message summarizing the workup request from the SCU.
- A new PBSC request in the "ABP Pending" section of the STAR Link® application, which may include information from the Donor Workup Request Form (if electronic workup).
- A fax request that includes either the *Donor Workup Request* form or the original *TC Donor Request Report* (if electronic workup).

NOTE: International transplant centers are allowed to submit workup request forms that vary slightly from NMDP forms. The World Marrow Donor Association (WMDA) creates standardized workup request forms that most countries agree to accept. Throughout this chapter these international forms are referred to as "international equivalents."

The donor center shall confirm receipt of the PBSC workup request in the STAR Link application within three calendar days. This happens automatically by accessing the donor center's workup screen or search folder in STAR Link. If there are multiple workup coordinators, inform the SCU of who will manage the workup activities. This may be accomplished while in the STAR Link application by assigning the workup request to a specific workup coordinator or by email notification. Update the SCU on the progress of the workup at least once a week by entering dates in the STAR Link application, through NMDP Web mail, or by phone.

9.7. Donor Workup Request Form

Donor centers may receive information from the *Donor Workup Request* form electronically through the STAR Link application ("electronic workup"). All donor centers will receive a faxed *Donor Workup Request* form or the original *TC Donor Request Report* as well. The *Donor Workup Request* form originated at the transplant center. When the request is from an international transplant center, the donor center may receive an international equivalent of this form. The form provides information about the PBSC workup request and includes the following:

- Recipient's current diagnosis
- Classification of workup

Urgent Request:

- Proposed time to collection less than four weeks
- Unstable or acute disease

Standard Request:

- Proposed time to collection is more than four weeks
- Stable disease

- Preferred type of stem cell donation
  - If a second choice (alternative) stem cell product is acceptable, the donor must be informed.
  - If a second choice stem cell product is not indicated and the donor declines the PBSC donation, the donor is released in the STAR Link application as "Not Interested in this product", identified by a code of NA.
- Desired PBSC and/or marrow cell doses
- Pre-collection sample requirements
- Proposed collection dates
- Day of collection sample requirements
- Product tag information
- Special Instructions (when applicable)
- International donor centers may receive an *Infectious Disease Marker (IDM) Testing Laboratory Requisition* from the SCU in addition to the *Workup Request Form*, instructing the donor center to collect and send a blood sample to the NMDP contract lab within 30 days prior to collection date. Blood tube and shipping requirements are provided within the form.

Donor center responsibilities include the following:

A. Review the forms and/or electronic information, if applicable, and utilize the information in preparation for contacting the donor.

B. Review readily available donor records for information affecting donor eligibility such as previous health history questionnaires, IDM test results, donor chart notes, previous eligibility status if donor previously donated, and additional documentation provided by the donor.

C. Construct a preliminary schedule of donor workup events.

D. Note the patient's weight and the suggested number of collections the transplant center indicates.

E. Provide a copy of the workup request forms to the apheresis center.

F. File the forms in the donor chart.

9.8. Locating and Contacting the Donor

After receiving the workup request, the donor center must establish direct contact with the donor. This may prove challenging if an extended period of time has elapsed since the donor was active on the search. Upon establishing contact, the donor center educates the donor about the request, acknowledges any limitation for participation, and supports the donor's decision to proceed or not.

The patient's name, age, sex and diagnosis are available in the STAR Link application. The donor center must not disclose the patient's name but may decide whether to share the patient's age, sex and/or diagnosis or not. For donor centers that do not use the STAR Link application, see the *Recipient Diagnosis Codes* for a definition of the patient's disease.

Donor centers have the discretion to schedule workup events as separate appointments or as a combination of appointments that occur on the same day. As an organizational tool, see the *PBSC Workup Checklist*.

The donor center is responsible for the following activities, which may be tailored to local procedures:

A. Create a donor chart and print a tracking sheet. It is recommended that pertinent information be documented in STAR Link.

B. Contact the donor.
   1. Introduce yourself and the NMDP.
   2. Confirm donor's identity and verify donor's legal name. Document how identity was verified.
   3. If appropriate, remind the donor of when he or she was previously requested for search activity or joined the NMDP.
   4. Explain that he or she is requested to consider PBSC donation.
   5. Enter "Initial Contact" date in the workup screen in the STAR Link application. This date is used for donor center tracking purposes and is not relayed to the SCU or transplant center.

C. If the donor is interested in proceeding:
   1. Discuss tentative schedule of workup events.
   2. Schedule an information session, physical exam, collection date(s) and other workup activities, as appropriate. Any collection dates discussed prior to clearance must be considered tentative.

3. Enter the appointment date(s) into the STAR Link application. These dates are relayed to the SCU and transplant center. Share any new information concerning a tentative workup plan with the SCU as it is known. If possible, present a complete tentative workup plan to the SCU within seven days of receiving the workup request.
4. Administer the health history questionnaire at a time that is convenient prior to the physical exam. A new workup health history screening questionnaire must be completed at the time of the workup request and prior to the PE, regardless of the amount of time that has elapsed since the health history questionnaire was administered at HR and/or CT.

D. Provide a written update to the search coordinator at three days to confirm status of donor contact and report any anticipated delays or constraints regarding donor's participation.

E. If the donor is not interested or unable to proceed, enter the appropriate resolution in the STAR Link application as identified in Table 9-1.

Table 9-1: Resolution Descriptions and Codes

Code	Resolution Description
TU	*Temporarily Unavailable* Donor is not available due to a temporary medical condition or personal conflict, but wants to participate at a later date. Use the code of "Temporarily Unavailable" only when direct contact has occurred. Do not use this code for less than one-month unavailability. If no Available date is entered, the default deferral is three months.
UC	*Unable to Contact* Donor cannot be located or does not respond to messages left and letters sent. The donor is deleted from the NMDP. Apply this code when it is felt that every effort has been made to try to locate this person. If donor subsequently contacts the donor center, it may be necessary to change the donor's status to available. See *Miscellaneous Donor Center Processes* chapter, of this manual.
DD	*Donor Deferred* Donor is deferred for medical reasons and deleted from the NMDP.
NI	*Not Interested* The donor has been located and contacted, but is not interested in participating and is deleted from the NMDP.
NA	*Not Interested in Product Request* Donor is interested in donating, but not the product requested.

9.9. Interaction between Donor Center and Transplant Center

To promote non-coercive decision-making, the donor center and transplant center must not communicate until donor clearance is achieved. The transplant center only receives information about a donor's workup from the SCU.

When the SCU sends the *Notification of Donor Clearance for PBSC Donation* to the donor and transplant centers, the donor is considered cleared for donation. It

is only then that the transplant and donor centers may begin direct communication, or they may choose to continue to communicate through the SCU.

9.10. Donor Transfer of Workup Request

In the event that the donor has relocated, or another donor center is geographically closer, the donor should be counseled about his or her option to work with the most geographically convenient donor center. Before transferring the donor, briefly describe the current request, assess the donor's continued interest, and complete the health history screening questionnaire. For additional information, refer to the NMDP donor transfer procedures located in the *Miscellaneous Donor Center Processes* chapter (chapter 13) of this manual.

9.11. Donor Health History Review

The purpose of the health history review is to assess the donor's current state of health and eligibility status in preparation for the physical exam. It is important to identify health concerns early in the management of the workup process.

The NMDP has developed several tools to assess a donor's health and eligibility. Donors with atypical responses to the screening questions must be evaluated on a case-by-case basis to determine donor eligibility and donor suitability. The individual performing or evaluating the health history should be knowledgeable by training or experience to accept or defer stem cell donors.

The donor center is responsible for the following:

A. Document the donor's current health and eligibility status using the *Donor Health History Screening Questionnaire for Use at HR/CT/Workup*, and any related addendums, when applicable. The health history questionnaire may be self administered or administered by a donor center representative.
   1. If the donor is reactive for Chagas, the addendum F00658, *Follow-up Questions for Reactive Chagas Screening Test Result*, must be administered and responses relayed to the SCU in a timely fashion, giving the transplant center more information for assessing potential risk to the patient.

B. If *Donor Health History Screening Questionnaire* (HHSQ) is self-administered:
   1. DC staff must VERBALLY interact with the donor to review and verify donor's responses to the *HHSQ*.
   2. This interaction must be documented utilizing Section 4B on the HHSQ.

3. This interaction must occur before donor clearance and again if an interval PE is required and the HHSQ is self-administered.
4. The same staff members do not need to complete both review sections.
5. Both review sections (Section 4A and 4B) do not need to be completed at the same time.

C. Compare the answers against the *Rationale and Action Guide for Health History Screening Questionnaire at HR/CT/Workup*, the *Assessment Tool at Workup, Non-Medical Factors Affecting Donor Suitability*, other applicable documents in the *Assessment Notebook at Search*, as well as readily available, previously completed HHSQ forms.
   1. Review questionable situations with donor center medical director, collection center medical director, or NMDP personnel.
   2. Inform the SCU of defined situations according to the above identified assessment tools.
   3. Positive responses to a question in Section Two (communicable disease assessment) must be relayed to the SCU prior to or at the time of donor clearance, if the response impacts the donor's eligibility status. (See table 9-2 in this chapter).
   4. Provide a copy of the completed Health History Screening Questionnaire to the physician performing the physical examination. (See Donor Physical Examination section in this chapter.)
   5. International donor centers and cooperative registries are required to ask all health history screening questions listed on the Ineligible Donor-International Health History Screening (A3). It is not required that questions be asked exactly as written, but the intended content of the question, once it is translated into the appropriate language, must be maintained.

D. Accept or defer the donor, as appropriate.
   1. Document the decision and inform donor, if necessary.
   2. If deferred, assign the resolution in the STAR Link application. See Table 9-1.

E. Provide the following document to the donor: *Important Information For Your Safety and Your Recipient's Safety*. Instruct the donor to inform the donor center if any changes occur between receipt of document and the collection date.

F. Obtain donor signature on the questionnaire prior to or at the time of the information session or physical exam.

G. Maintain the signed questionnaire in the donor chart at the donor center.

9.12. Information Session

The next step in the workup process is for the donor to participate in an information session, which assists the donor in making an informed decision. The donor center has the primary responsibility for scheduling and conducting donor information sessions.

During the information session the donor is educated about why the donation is needed, how the donation happens, the risks and benefits to the donor and the possibility of a subsequent product request for the same recipient. The information presented must reflect the content of the consent document.

It may be necessary for the information session to take place over the telephone. The presenter must develop skills to assess donor comprehension and emotional reaction to the information.

9.12.1. Preparing for the Information Session

The average length of an information session is one to two hours. Donors are encouraged to include a family member and/or friend. When scheduling the session, arrange for the donor center medical director to participate or at a minimum be available to answer questions. Educational materials are often provided to the donor prior to the information session.

The donor center coordinator is responsible for the following:

A. Schedule the information session appointment.

B. Notify the SCU of appointment date by entering it in the STAR Link application.

C. Make arrangements for the information session and gather appropriate materials including, but not limited to:
   1. *Now That You Are A Match: The PBSC Donation Process* video
   2. *Now That You Are A Match* notebook
   3. Educational articles
   4. Donor and apheresis center contact information
   5. Relevant local donor center information
   6. Consent form(s), donor insurance summary and beneficiary card
   7. *Important Information: For Your Safety and Your Recipient's Safety*, if not already provided

9.12.2. Conducting the Information Session

The NMDP encourages the use of the *PBSC Donor Information Session Outline* when counseling the donor. This outline may be tailored to reflect donor center processes.

The donor center is responsible for the following activities:

A. Ensure that the *Now That You Are A Match* video is viewed by the donor prior to or at the information session and discuss the content of the corresponding notebook.

B. Provide the donor with contact information for the NMDP Donor Advocate, and local donor advocate if available.

C. Review the information contained in the *PBSC Donor/Subject Consent Form.*

D. Ensure that the donor center medical director is available to answer any questions in person or by phone.

E. Answer any questions or concerns. If applicable, contact the donor center medical director for assistance.

9.12.3. Outcome of the Information Session

A donor may sign the consent form immediately or may choose to take additional time to consider his or her decision. The donor center shall obtain a decision from the donor within a reasonable timeframe. If the donor has not signed the consent within 72 hours, alert the SCU.

Outcomes of the information session may include:

- Donor expresses a commitment to proceed and signs the consent form. See *Donor Consent to Donate* section of this chapter.
- Donor is not interested in proceeding with any type of donation. Enter the donor's status as "Not Interested" in the STAR Link application.
- Donor is not interested in PBSC but willing to donate marrow as requested as an alternate source of stem cells. Enter the donor's status as "Donor not interested in prod" in the STAR Link application and/or contact the SCU.
- Donor is willing to donate marrow and/or PBSC, but an alternate source of stem cells is not indicated on the *Donor Workup Request Form.* Contact the SCU to discuss the proposal.
- Donor is willing to donate PBSC but marrow is contraindicated. Alert SCU that marrow is not an alternative option in this situation. (For example, donor diagnosed with sleep apnea or a back issue that would preclude the donor from donating marrow.)

- Donor wishes to continue with the program but is unable to participate at this time. Enter the donor's status as "Temporarily Unavailable" and record the date that the donor anticipates being available.

9.13. Medical Services Coverage Card

The purpose of the *Medical Services Coverage Card* is to improve the billing process between medical service providers and the NMDP. Donor centers should provide this card and letter to all workup donors. In turn, the donor presents this card to medical providers at each medical appointment scheduled by the donor center. The letter is available as a template in the STAR Link application for printing on stationery similar to the *Donor Welcome Letter*. The stationery is available through the *Materials Catalog*, item P0144.

9.14. Donor Advocate

The donor center is responsible for informing each donor about the availability of the NMDP Donor Advocacy Program. The donor advocate explains the donor's rights and responsibilities, and assists the donor in making an informed decision. See the *Donor Advocacy* chapter (chapter 14) of this manual for details regarding the function of the donor advocate. Donor centers may choose to also offer a local donor advocate, although this is not a requirement.

9.15. Donor Life, Disability and Medical Insurance

Donors must be provided with information and materials specific to the NMDP donor insurance coverage. See the *Donor Advocacy* chapter of this manual for complete details.

9.16. Consent to Donate

The donor may sign the *PBSC Donor/Subject Consent Form* at any time after the information session but it must be signed before the physical exam occurs.

If the donor decides to continue, the donor center's responsibilities are as follows:

A. Provide consent form to the donor.

1. Review the consent with the donor.
2. The donor shall read, sign, and date the consent form if proceeding.
3. The counseling health care professional shall sign and date the document.

B. Record the NMDP donor identification number (not the local ID) on each page of the consent form.

C. Provide the donor with a copy and file the original, signed consent at the donor center.

D. Enter the date in the "Consent" field in the STAR Link application. Record this date on the Form 700, *Determination of Stem Cell Suitability.*

9.17. Donor Physical Examination

The NMDP requires that the donor complete a physical examination (PE) to ensure that he or she meets the requirements necessary to serve as an unrelated stem cell donor. The PE must occur after the workup request is initiated and after the donor has signed the consent to donate form. The apheresis and donor center medical directors must both agree that the donor is suitable for donation.

9.17.1. Examining Physician

The examining physician is responsible for protecting the safety of the donor and for identifying conditions which may be transmissible by transfusion or transplantation. The physician performing the donor's examination shall not be the primary physician of the intended recipient. The physician (or appropriately licensed supervised mid-level practitioner) may be from the apheresis center or a third party. When using a third party physician, the donor center must communicate in advance that the NMDP has a fee schedule specifically related to the location of the apheresis center. Questions regarding rates paid to third party physicians can be directed to NMDP Accounts Payable, Medical.

Note: If information provided on the *NMDP Donor Health History Screening Questionnaire* (HHSQ) or other relevant medical records indicate a potential risk for a communicable disease, the donor may be deferred or the physical examination performed must include an assessment for specific signs/symptoms of a communicable disease. Refer to *Donor Physical Assessment,* A00220.

The examining physician must note any exclusion to donating marrow or PBSC regardless of the primary product requested. Any concern regarding a donor's safety in relation to anesthesia should be noted by the physician at the time of the initial physical evaluation.

9.17.2. Scheduling and Coordinating the Physical Examination

The apheresis and donor center medical directors must agree that the donor is suitable for donation. The donor center must schedule an appointment with the physician at the earliest convenient time for the

donor. Report the PE appointment date by entering it into the STAR Link application.

The donor center's responsibilities are listed as follows:

- Coordinate the scheduling of the donor PE with the apheresis center OR arrange for a third party physician, if necessary.
- Communicate the date and time of the PE along with logistical details such as parking and applicable admission procedure with the donor.
- Provide physician performing the PE with the document *Donor Physical Assessment* and IDM testing requirements
- Provide a copy of the completed HHSQ to the physician, or at a minimum the communicable disease assessment section (Section Two) of the HHSQ if donor responds "yes" to any question in that section, if the response makes the donor ineligible.
- Provide PE paperwork and requirements to the apheresis center and/or third party physician. See *Physical Examination Requirements* section of this chapter.
- Communicate to the PE provider that results and completed forms should be made available to the donor center within five business days of the examination.
- Arrange to receive history and physical results (PE results) for review by donor center medical director. See the *Donor Suitability and Clearance* section of this chapter for additional information.

9.17.3. Distant Donor Management

Donors who live a significant distance from the apheresis or collection center may require special management during the PE. Options include transferring the donor to a different donor center, arranging special transportation and/or lodging to allow the donor to be seen at the apheresis or collection center or third party physician. Contact the SCU or NMDP Donor Resources Liaison with questions regarding unique circumstances.

9.17.4. Physical Examination Requirements

The designated physician performs a medical history and physical examination according to standard medical practice. The donor shall meet the requirements as defined in the latest *National Marrow Donor Program Standards* and the protocol.

There are activities that must be performed and data that must be collected as part of the physical exam. The donor and apheresis or collection center must establish procedures of interaction defining who is responsible to perform the following activities: