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ORIGINAL PAPER

Validation of Musculoskeletal Tissue Capture from a Living Donor: Experience from a Multi-tissue Bank

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ABSTRACT

Introduction: The harvesting of musculoskeletal tissues is essential to ensure the supply of biological products of human origin with safety and clinical efficacy. The harvesting stage must undergo a validation process to guarantee the quality of the tissues. **Objectives:** This article describes the experience of a public human multi-tissue bank (HMTB) in validating the harvesting of musculoskeletal tissue (femoral head) from a living donor. **Methods:** This involves evaluating and adapting a harvesting protocol to promote excellence in the quality of tissues distributed for therapeutic and research purposes. To this end, a technical visit was carried out at another tissue bank, and meetings were held with the orthopedic service team to present and discuss the process flow. Donor screening was done by applying forms evaluating the selection and exclusion criteria. After acceptance, through the consent form, the donor's serological tests were requested and collected. The harvesting kit, control of the temperature thermal transport box, and collecting microbiological material from the piece at the time of removal were validated. The validated harvested tissue underwent macroscopic, radiological, and microbiological evaluations to consider the process valid. The forms and other documents in the medical record were audited by the institution's health quality and safety center. Process mapping was also carried out, targeting risks and opportunities for improvement. **Results:** The harvesting protocol was validated as foreseen in the action plan. The harvesting technique was performed sterilely in the operating room. Microbiological and serological analyses showed negative results, and the tissue was considered macroscopically viable. After the audit, the documentation was deemed adequate to comply with current legislation (Resolução da Diretoria Colegiada – RDC Nº 707, of July 1, 2022), and the mapping of processes guaranteed the security of harvesting and provided opportunities for improvement. **Conclusion:** A protocol for capturing musculoskeletal tissues in the reference service is presented, with the validation process being replicable through a fundamental tool to ensure harmlessness and safety in tissue harvesting.

Descriptors: Tissue donation; Tissue transplantation; Biological Quality Control; Harmless Products; Human Tissue Bank.

Validação da Captação de Tecido Musculoesquelético em Doador Vivo: Experiência de um Banco de Multitecidos

RESUMO

Introdução: A captação de tecidos musculoesqueléticos é fundamental para garantir o fornecimento de produtos biológicos de origem humana com segurança e eficácia clínica. Para assegurar a qualidade desses tecidos, é essencial que a etapa de captação passe por um processo de validação. **Objetivos:** Este artigo descreve a experiência de um banco de multitecidos humanos (BMTHs) público na validação da captação de tecido musculoesquelético (cabeça femoral) de doador vivo. **Métodos:** Trata-se da avaliação e adequação de um protocolo de captação visando promover a excelência na qualidade dos tecidos distribuídos para fins terapêuticos e de pesquisa. Para isso, foram realizadas uma visita técnica em outro banco de tecidos e reuniões com a equipe do serviço de ortopedia para apresentação e discussão sobre o fluxo do processo. A triagem do doador foi conduzida por meio da aplicação de formulários, avaliando os critérios de seleção e exclusão. Após a aceitação, mediante termo de consentimento, foram solicitados os exames sorológicos do doador e, por fim, a captação. Validaram-se o *kit* de captação, o controle de temperatura da caixa térmica de transporte e a coleta de material microbiológico da peça no momento da retirada. Para considerar válido o processo, o tecido captado passou por avaliações macroscópicas, radiológicas e microbiológicas. Os formulários e demais documentos do prontuário foram auditados pelo Núcleo de Qualidade e Segurança em Saúde

(NQSS) da instituição. Também foi realizado o mapeamento dos processos, visando os riscos e oportunidades de melhoria. **Resultados:** O protocolo de captação foi realizado e validado conforme previsto no plano de ação. A técnica de captação foi realizada de forma estéril no centro cirúrgico. As análises microbiológicas e sorológicas apresentaram resultados negativos e o tecido foi considerado macroscopicamente viável. Após auditoria, a documentação foi considerada adequada ao atender a legislação vigente (Resolução da Diretoria Colegiada – RDC Nº 707, de 1 de julho de 2022). Além disso, o mapeamento dos processos garantiu a segurança da captação e proporcionou oportunidades de melhoria. **Conclusão:** Apresenta-se um protocolo de captação de tecidos musculoesqueléticos no serviço de referência, sendo o processo de validação replicável, por meio de uma ferramenta fundamental para assegurar a inocuidade e segurança na captação de tecidos.

Descritores: Doação de Tecidos; Transplante de Tecidos; Controle de Qualidade Biológica; Produtos Inócuos; Banco de Tecidos Humanos.

INTRODUCTION

Human multi-tissue banks (HMTBs) are healthcare institutions that aim to ensure the safety of biological products provided during the tissue donation process[1]. Different types of tissues, such as cornea, sclera, skin, vessels, heart valves and musculoskeletal tissues, can be obtained from donors with brain death (BD) and/or donors with cardiorespiratory arrest (CPA). Furthermore, some of these tissues can be obtained from living donors after an interview and authorization by the donor or family member[2,3]. HMTBs are responsible for selecting potential donors, screening, collecting, processing, and distributing tissues for therapeutic and/or research/teaching purposes[4].

Tissue harvesting, although considered an invasive technique with a high risk of contamination, is a fundamental step to ensure the supply of biological products of human origin with safety and clinical efficacy[4]. In Brazil, the technical-sanitary requirements for tissue donation are regulated by Decree No. 9,175 of October 18, 2017, which deals with the disposal of organs, tissues and parts of the human body for transplantation and treatment in the Consolidation Ordinance No. 4 of September 28, 2017, which deals with the systems and subsystems of the Unified Health System (*Sistema Único de Saúde-SUS*), and the Resolution of the Collegiate Board (*Resolução da Diretoria Colegiada-RDC*) No. 707, of July 1, 2022, which provides for good practices in human tissues for therapeutic use[5-7].

Harvesting is the removal of tissues carried out in a sterile environment, with all aseptic precautions once the selected donor meets all established criteria. Living donors of musculoskeletal tissues can donate to the femoral head when undergoing hip arthroplasty surgery, in which prostheses replace their joint components (acetabulum and femoral head). The femoral head, commonly overlooked, is collected by a team of tissue banks to be processed and used as a bone graft later[8].

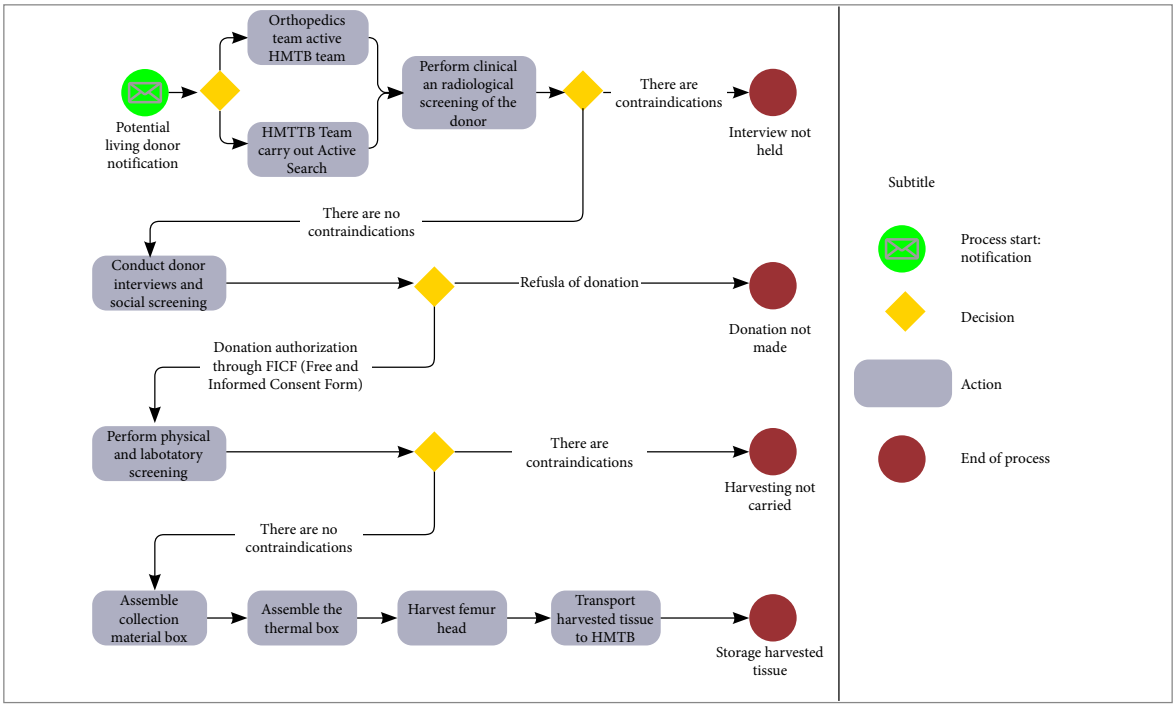
The search for operational excellence in harvesting based on regulatory instruments has led HMTBs to adopt rigorous process validation practices[9]. This validation integrates a set of programmed and ordered actions of the quality management system, which ensures that services, procedures and products comply with the evidence provided and current legislation[10]. Therefore, this article reports the experience of a public HMTB located in the interior of the state of São Paulo on the validation of the harvesting of musculoskeletal tissue (femoral head) from a living donor.

METHODS

This descriptive study of an experience report type addresses the actions developed in adapting and validating the harvesting of musculoskeletal tissue from a living donor at the HMTBs of the Hospital de Clínicas of the Universidade Estadual de Campinas. (HC-UNICAMP).

To develop a harvesting protocol that met the established regulatory requirements, detailed analyses of RDC 707/2022, which discusses good practices in human tissues for therapeutic use, were previously carried out. Furthermore, a technical visit was carried out to the Human Tissue Bank of the Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (HCFMRP)/ Universidade de São Paulo (USP) for technical/practical monitoring of the musculoskeletal tissue harvesting procedure from a living donor.

Additionally, the flowchart of the harvesting process (Fig. 1) was developed and presented to the orthopedics specialty team at HC-UNICAMP, responsible for performing hip arthroplasty surgeries for insertion of the tissue collection stage in surgery by the HMTBs team.



Source: Elaborated by the authors.

Figure 1. Flowchart of the process of harvesting musculoskeletal tissue from a living HMTBs donor.

In the days before the collection at HC-UNICAMP, the HMTBs team screened the potential donor to evaluate the selection and exclusion criteria for tissue collection, as established in RDC 707/2022. After the acceptance of the potential donor, an interview was conducted with the patient to authorize and sign the Free and Informed Consent Form (FICF). On the day of collection, laboratory tests were requested for serological screening and nucleic acid test (NAT), syphilis [venereal disease research laboratory (VDRL)], toxoplasmosis, cytomegalovirus (CMV), Chagas disease, hepatitis B (anti-HbsAg and anti-Hbc), hepatitis C (anti-HCV), human immunodeficiency virus (anti-HIV I and II) and human T-cell lymphotropic virus (anti-HTLV I and II)[7].

In addition, a collection kit was organized according to the checklist form of material necessary for collection from a living donor (Fig. 2), assembly of the thermal box with controlled temperature and validated by HMTBs and contact with the orthopedics team, as per previously developed operational procedures.

UNIVERSIDADE ESTADUAL DE CAMPINAS
HOSPITAL DE CLÍNICAS
FORM
Checklist for living donor harvesting material

Form	Elaboration	Page	Version
FO.HC.HMTB 002	07/07/2021	1/1	001

MAIN MATERIALS **Date:** / / **Harvester:**

MATERIALS	HMTB (suitcase)		QUANTITY (used)	MATERIALS	HMTB (suitcase)	QUANTITY (used)	
Extension 3 sockets				Sterile label Pack			
Skin marker				Sterile surgical grade package			
Physiological serum 250ml				Serum irrigator (protractor)			
Sterile spare scissors				Styrofoam test tube transporter			
Sterile 7.5 powder-free glove				Small sterile plastic packaging			
Sterile 8.0 powder-free glove				Single surgical field			
Sterile collector				Thioglycolate			
Sterile wipers pack				Sealers			
Serology tubes				NAT tubes			
Microbiological labels				Dress kit			

Source: Elaborated by the authors.

Figure 2. Checklist form for living donor harvesting material.

At the time of harvesting, three fragments of the femoral head were removed, and a sample of the saline solution used to wash the tissue was collected and sent for microbiological analysis to verify the absence or presence of growth of aerobic, anaerobic bacteria and fungi in the harvested tissue. After harvesting, the harvester conducted macroscopic tissue analysis, and the HC-UNICAMP radiology service performed radiological analysis. For this, the tissue was placed in a thermal box maintained at a controlled temperature (2-8 °C). During the analysis of the requested tests, the tissue was stored in an ultra freezer at a temperature of -80 °C, where it remained until the results were released.

The technical team and technical director, together with the Health Quality and Safety Center (Núcleo de Qualidade e Segurança em Saúde -NQSS), analyzed the results achieved through an internal audit to evaluate the integrity of the actions developed to validate the harvesting of musculoskeletal tissue.

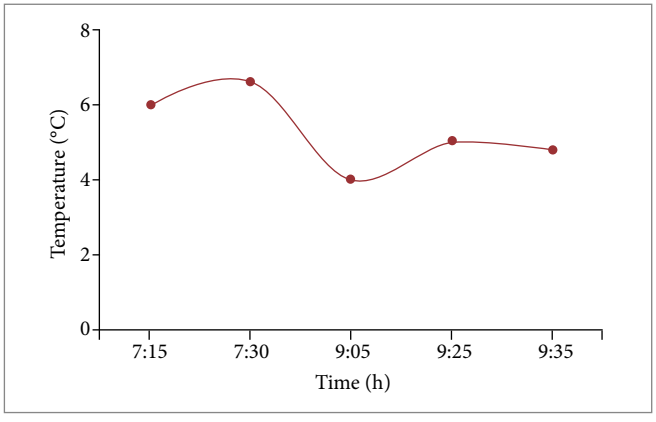
RESULTS

According to the action plan, three femoral heads were collected to validate the harvesting protocol. The harvesting technique was performed sterilely in a surgical center by the surgical team that performed the hip arthroplasty. After removing the femoral head, it was passed on to an HMTB employee, who was adequately dressed and present in the surgical field. Upon receiving the tissue, the professional removed three fragments of the femoral head with the help of a bone punch placed them in sterile vials, collected 5 mL of the saline solution used to wash the tissue and sent them for microbiological analysis. After macroscopic analysis of the pickup, the heads were considered suitable, placed in three triple-sealed packages, and identified using a sterile technique. All serological and microbiological analyses of the three tissues collected showed negative results.

During transport, the temperature was maintained between 2 and 8 °C (Fig. 3). The harvested tissue reception forms (Fig. 4a) and harvesting training forms (Fig. 4b) were filled out safely, with double check, following the requirements of the Quality Management System.

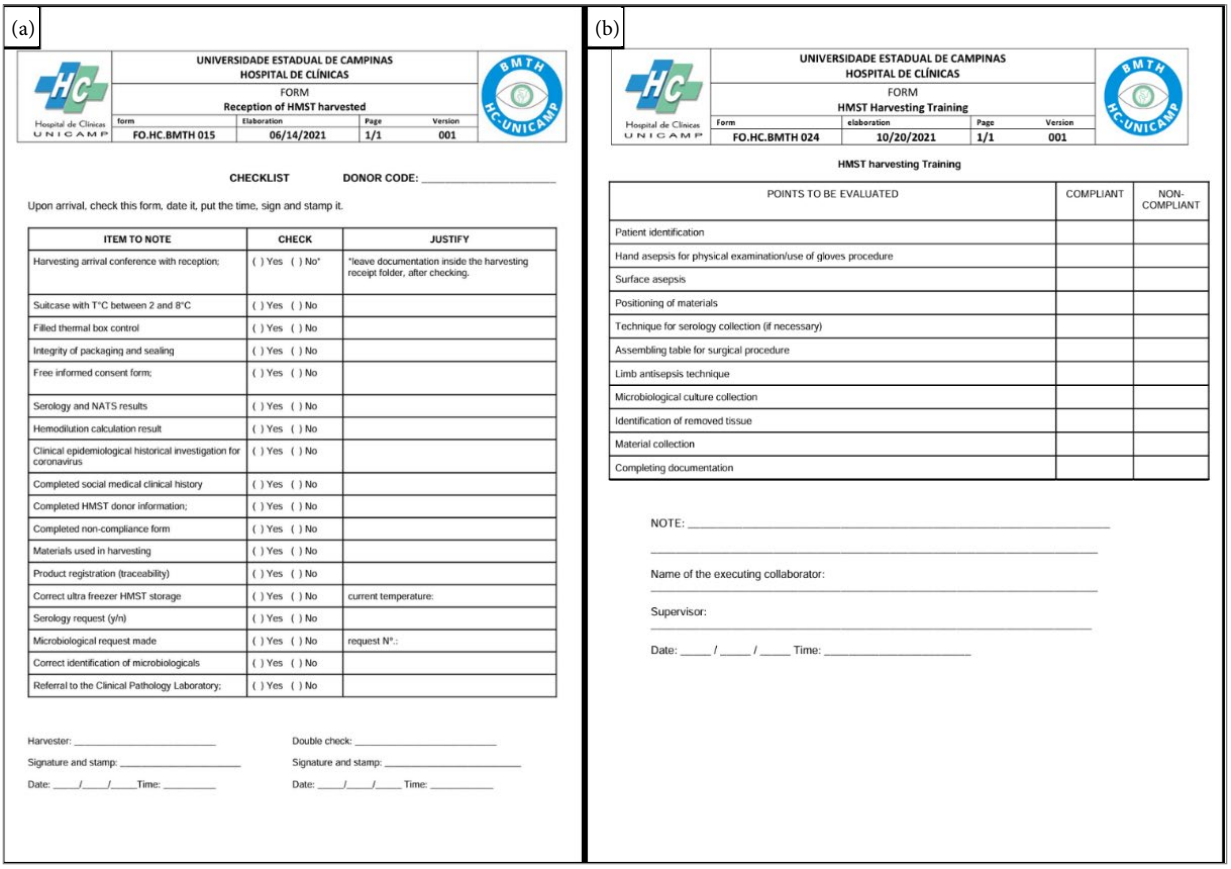
The NQSS team mapped the processes and possible risks related to harvesting using the failure mode and effect analysis (FMEA) tool (Fig. 5). This tool is used to identify risks and prevent failures in recognizing causes and effects, based on three factors: severity (S), occurrence (O) and detection (D). Each factor describes different aspects of failures and is crucial in calculating the failure risk priority number (RPN), allowing teams to prioritize the most critical ones to implement corrective and preventive actions[11].

Finally, to evaluate the protocol's compliance and the information inherent to the process, the NQSS audited, through a specific checklist, the forms and documents contained in the donor's medical records (Fig. 6a), the stability of the temperature of the thermal box of tissue transport and the results obtained from serological and microbiological tests. The internal audit validated the actions developed based on the standards described in RDC 707/2022, according to the Organizational Development Register (Registro de Desenvolvimento Organizacional- RDO) (Fig. 6b).



Source: Elaborated by the authors.

Figure 3. Temperature variation in the thermal box during the harvesting of musculoskeletal tissue from a living donor. 7:15 am = departure from HMTBs; 7:30 am = arrival at the collection site; 9:05 am = removal of the femoral head; 9:25 am = departure from the collection site; 9:35 am = arrival at HMTBs.



(a)

UNIVERSIDADE ESTADUAL DE CAMPINAS
HOSPITAL DE CLÍNICAS
FORM
Reception of HMST harvested

form	Elaboration	Page	Version
FO.HC.BMTH 015	06/14/2021	1/1	001

CHECKLIST DONOR CODE: _____

Upon arrival, check this form, date it, put the time, sign and stamp it.

ITEM TO NOTE	CHECK	JUSTIFY
Harvesting arrival conference with reception;	( ) Yes ( ) No*	*leave documentation inside the harvesting receipt folder, after checking.
Suitcase with T°C between 2 and 8°C	( ) Yes ( ) No	
Filled thermal box control	( ) Yes ( ) No	
Integrity of packaging and sealing	( ) Yes ( ) No	
Free informed consent form;	( ) Yes ( ) No	
Serology and NATS results	( ) Yes ( ) No	
Hemodilution calculation result	( ) Yes ( ) No	
Clinical epidemiological historical investigation for coronavirus	( ) Yes ( ) No	
Completed social medical clinical history	( ) Yes ( ) No	
Completed HMST donor information;	( ) Yes ( ) No	
Completed non-compliance form	( ) Yes ( ) No	
Materials used in harvesting	( ) Yes ( ) No	
Product registration (traceability)	( ) Yes ( ) No	
Correct ultra freezer HMST storage	( ) Yes ( ) No	current temperature:
Serology request (y/n)	( ) Yes ( ) No	
Microbiological request made	( ) Yes ( ) No	request N°.:
Correct identification of microbiologicals	( ) Yes ( ) No	
Referral to the Clinical Pathology Laboratory;	( ) Yes ( ) No	

Harvester: _____ Double check: _____
Signature and stamp: _____ Signature and stamp: _____
Date: ____/____/____Time: _____ Date: ____/____/____ Time: _____

(b)

UNIVERSIDADE ESTADUAL DE CAMPINAS
HOSPITAL DE CLÍNICAS
FORM
HMST Harvesting Training

Form	elaboration	Page	Version
FO.HC.BMTH 024	10/20/2021	1/1	001

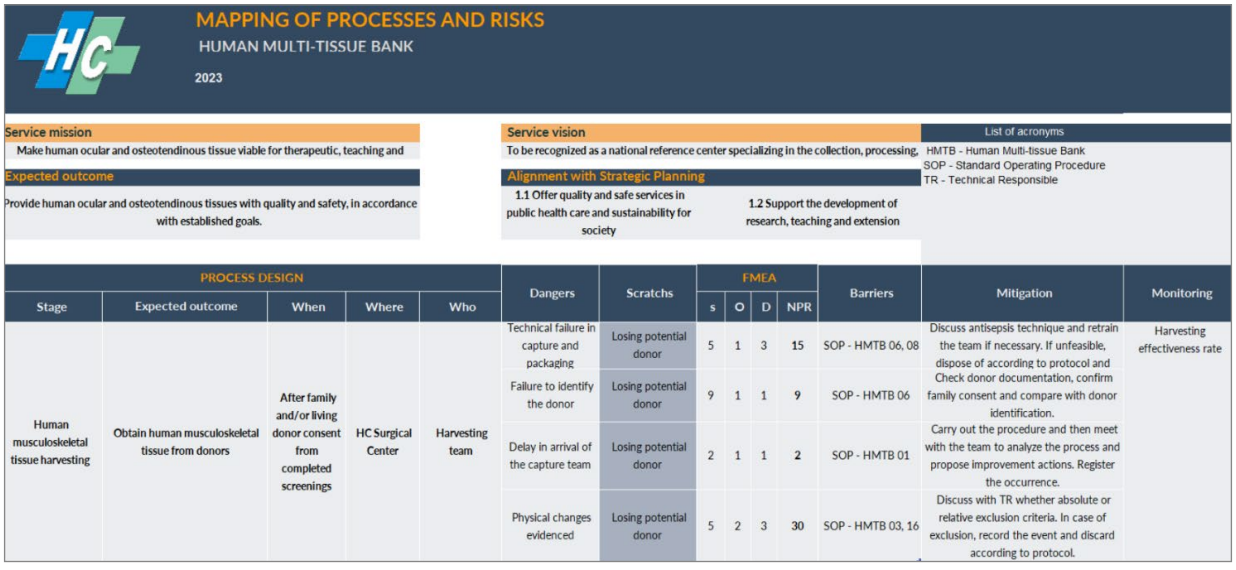
HMST harvesting Training

POINTS TO BE EVALUATED	COMPLIANT	NON-COMPLIANT
Patient identification		
Hand asepsis for physical examination/use of gloves procedure		
Surface asepsis		
Positioning of materials		
Technique for serology collection (if necessary)		
Assembling table for surgical procedure		
Limb antisepsis technique		
Microbiological culture collection		
Identification of removed tissue		
Material collection		
Completing documentation		

NOTE: _____
_____
Name of the executing collaborator: _____
Supervisor: _____
Date: ____ / ____ / ____ Time: _____

Source: Elaborated by the authors.

Figure 4. a) Reception form for harvested human musculoskeletal tissue (HMST); b) HMST harvesting training form.



MAPPING OF PROCESSES AND RISKS
HUMAN MULTI-TISSUE BANK
2023

Service mission
Make human ocular and osteotendinous tissue viable for therapeutic, teaching and

Service vision
To be recognized as a national reference center specializing in the collection, processing,

List of acronyms
HMTB - Human Multi-tissue Bank
SOP - Standard Operating Procedure
TR - Technical Responsible

Expected outcome
Provide human ocular and osteotendinous tissues with quality and safety, in accordance with established goals.

Alignment with Strategic Planning
1.1 Offer quality and safe services in public health care and sustainability for society
1.2 Support the development of research, teaching and extension

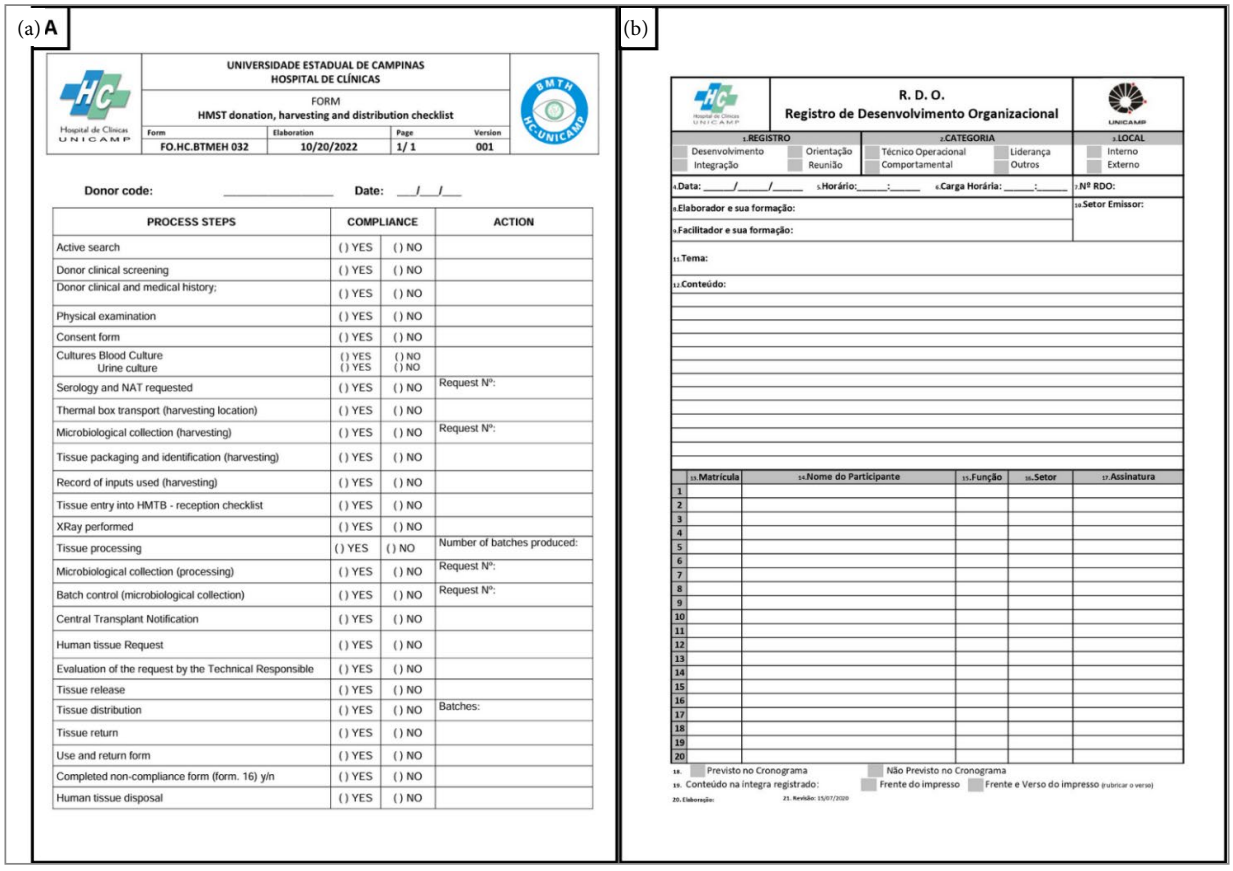
PROCESS DESIGN					Dangers	Scratchs	FMEA				Barriers	Mitigation	Monitoring
Stage	Expected outcome	When	Where	Who			s	O	D	NPR			
Human musculoskeletal tissue harvesting	Obtain human musculoskeletal tissue from donors	After family and/or living donor consent from completed screenings	HC Surgical Center	Harvesting team	Technical failure in capture and packaging	Losing potential donor	5	1	3	15	SOP - HMTB 06, 08	Discuss antisepsis technique and retrain the team if necessary. If unfeasible, dispose of according to protocol and	Harvesting effectiveness rate
					Failure to identify the donor	Losing potential donor	9	1	1	9	SOP - HMTB 06	Check donor documentation, confirm family consent and compare with donor identification.	
					Delay in arrival of the capture team	Losing potential donor	2	1	1	2	SOP - HMTB 01	Carry out the procedure and then meet with the team to analyze the process and propose improvement actions. Register the occurrence.	
					Physical changes evidenced	Losing potential donor	5	2	3	30	SOP - HMTB 03, 16	Discuss with TR whether absolute or relative exclusion criteria. In case of exclusion, record the event and discard according to protocol.	

Source: Elaborated by the authors.

Figure 5. Mapping of processes and risks related to fundraising using the FMEA tool.

DISCUSSION

This report describes a protocol for harvesting musculoskeletal tissues from living donors, the respective actions developed, and its validation to ensure the use of appropriate and reliable tools for harvesting human tissues. Furthermore, it was essential to promote the improvement of techniques relevant to the work and the improvement of the HMTBs team.



(a) A

UNIVERSIDADE ESTADUAL DE CAMPINAS
HOSPITAL DE CLÍNICAS

FORM
HMST donation, harvesting and distribution checklist

Form	Elaboration	Page	Version
FO.HC.BTMEH 032	10/20/2022	1/ 1	001

Donor code: _____ Date: ___/___/___

PROCESS STEPS	COMPLIANCE		ACTION
Active search	( ) YES	( ) NO	
Donor clinical screening	( ) YES	( ) NO	
Donor clinical and medical history:	( ) YES	( ) NO	
Physical examination	( ) YES	( ) NO	
Consent form	( ) YES	( ) NO	
Cultures Blood Culture Urine culture	( ) YES ( ) YES	( ) NO ( ) NO	
Serology and NAT requested	( ) YES	( ) NO	Request Nº:
Thermal box transport (harvesting location)	( ) YES	( ) NO	
Microbiological collection (harvesting)	( ) YES	( ) NO	Request Nº:
Tissue packaging and identification (harvesting)	( ) YES	( ) NO	
Record of inputs used (harvesting)	( ) YES	( ) NO	
Tissue entry into HMTB - reception checklist	( ) YES	( ) NO	
XRay performed	( ) YES	( ) NO	
Tissue processing	( ) YES	( ) NO	Number of batches produced:
Microbiological collection (processing)	( ) YES	( ) NO	Request Nº:
Batch control (microbiological collection)	( ) YES	( ) NO	Request Nº:
Central Transplant Notification	( ) YES	( ) NO	
Human tissue Request	( ) YES	( ) NO	
Evaluation of the request by the Technical Responsible	( ) YES	( ) NO	
Tissue release	( ) YES	( ) NO	
Tissue distribution	( ) YES	( ) NO	Batches:
Tissue return	( ) YES	( ) NO	
Use and return form	( ) YES	( ) NO	
Completed non-compliance form (form. 16) y/n	( ) YES	( ) NO	
Human tissue disposal	( ) YES	( ) NO	

(b)

R. D. O.
Registro de Desenvolvimento Organizacional

1.REGISTRO: Desenvolvimento, Integração, Orientação, Reunião
2.CATEGORIA: Técnico Operacional, Comportamental, Liderança, Outros
3.LOCAL: Interno, Externo
4.Data: ___/___/___ 5.Horário: ___:___ 6.Carga Horária: ___:___ 7.Nº RDO:
8.Elaborador e sua formação: 10.Setor Emissor:
9.Facilitador e sua formação:
11.Tema:
12.Conteúdo:

	13.Matrícula	14.Nome do Participante	15.Função	16.Setor	17.Assinatura
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

18. Previsto no Cronograma Não Previsto no Cronograma
19. Conteúdo na íntegra registrado: Frente do impresso Frente e Verso do impresso (rubricar o verso)
20. Elaboração: 21. Revisão: 15/07/2020

Source: Elaborated by the authors.

Figure 6. a) HMST donation, collection, and distribution checklist form; b) RDO (Organizational Development Register) used for internal auditing.

Similar experiences have already been described and published in Brazil by services located in São Paulo, such as the Hospital das Clínicas da Faculdade de Medicina da USP (HCFMUSP) and Santa Casa de São Paulo[12,13]. However, this report is the first to describe the validation and internal audit process carried out by the NQSS of HC-UNICAMP, which included mapping processes and risks to guarantee the harvesting protocol's quality and safety.

The mapping and management of processes and risks presented here are practical tools for preventing process failures like those described in this study[14].

Current legislation's increased complexity and requirements make this practice even more important. Despite this, little literature in Brazil addresses the subject, resulting in a heterogeneity of practices adopted by the most diverse services[12,13]. Teofili et al. (2022), in a study on the validation of bone marrow harvesting, developed a validation plan based on the FMEA methodology. Following this approach, the authors carefully reviewed the activities and procedures related to the collection, processing, and distribution of bone marrow at their institution, making it the first study to describe the use of this methodology in a bone marrow transplant program[15]. Shaping risk analysis based on local experience can be a reliable tool for identifying essential points, directing rigorous monitoring of critical steps, and/or even proposing improvements to related procedures. Thus, the authors describe that the FMEA approach allowed them to improve their processes, verifying their consistency over time[15].

Brazilian legislation establishes essential criteria, but no standardized protocol exists in the literature on harvesting musculoskeletal tissues. All steps involving harvesting must be carried out sterilely, and breaking this barrier from removal to tissue packaging can lead to important risks[9]. Possible risks during the process include errors in donor identification and screening, use of expired materials and supplies and inadequate technique, which favor microbiological contamination and tissue disposal[16].

Baseri et al. (2022) conducted a systematic review and meta-analysis of microbial contamination in human bone grafts from tissue banks from 2000 to 2021. In the studies analyzed, a global incidence of 7.5% bacterial contamination was observed in femoral heads harvested from living donors[17]. The study highlights the importance of implementing strategies such as process validation, which can identify possible risks inherent to the harvesting protocol.

The World Health Organization (WHO) proposed the development of a safe surgery checklist[18]. This initiative aimed to reduce the risk of complications, contribute to regulatory compliance and improve the traceability of information collected during surgical procedures[18]. Based on what was proposed by the WHO and by the normative instrument of good practices in human tissues for therapeutic use, the HMTB team created checklists to ensure that all necessary information is entered safely during tissue harvesting. The prior identification of process deviations through checklists allows corrective actions before they impact tissue quality and/or, consequently, patient safety[19].

Internal audit acts as a line of defense against irregularities[20]. By examining internal controls in HMTBs, the audit can prevent ethical deviations and inappropriate practices, ensure the safety and optimization of workflows, and ensure the quality of biological products of human origin provided[21].

Finally, process validation is an essential component in managing human tissue banks. This involves confirming that the procedures adopted can produce consistent and safe results[10]. Detailed recording of each validation process step is critical to documenting compliance and providing a complete audit roadmap. This meets regulatory requirements and serves as a valuable tool in identifying and correcting potential flaws in procedures[22].

CONCLUSION

The reported experience reinforces the importance of developing a rigorous protocol consistent with the methodology and validating the procedure for harvesting musculoskeletal tissue from a living donor. Validation proved to be an indispensable tool for identifying weaknesses, mitigating risks, and ensuring the use of appropriate and reliable instruments for tissue harvesting.

CONFLICT OF INTEREST

Nothing to declare.

AUTHOR'S CONTRIBUTION

Substantive scientific and intellectual contributions to the study: Freitas Filho LH, Neves CCS, Corsi CAC, Cardoso EM; **Conception and design:** Freitas Filho LH, Neves CCS, Corsi CAC, Cardoso EM; **Data analysis and interpretation:** Freitas Filho LH, Neves CCS, Corsi CAC, Cardoso EM; **Article writing:** Freitas Filho LH, Neves CCS, Corsi CAC, Cardoso EM; **Critical revision:** Silva NP, Campos GC; **Final approval:** Campos GC.

DATA AVAILABILITY STATEMENT

All dataset were generated or analyzed in the current study.

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Not applicable.

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