# Musculoskeletal tissues and human skin: ethical and kegal aspects of Brazil's scientific production

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**Abstract**

This study performed a critical analysis about the ethical and legal standards of papers published in national and international journals involving clinical cases and research regarding musculoskeletal and cutaneous organs or tissue grafts, also including dissertations and thesis of Brazilian Universities. Three databases from 2000 to 2010 were used, which are Scielo, MEDLINE and BIREME. It was concluded that in many cases Bioethics principles and legal criteria were not adopted regarding acquisition, utilization and disposal of musculoskeletal and cutaneous tissues used in scientific trials, thus demonstrating the need of highlighting ethical and legal standards for those professionals who use this type of material.
**Key words:** Bioethics. Laws. Homologous transplantation.

**Resumo**

**Tecidos musculoesqueléticos e pele de origem humana: aspectos éticos e legais da produção científica no Brasil**

Este trabalho realizou análise crítica acerca dos padrões éticos e jurídicos de trabalhos envolvendo casos clínicos e pesquisas que utilizaram enxertos de órgãos ou tecidos musculoesqueléticos e cutâneos publicados em revistas nacionais e internacionais, incluindo ainda dissertações e teses de universidades brasileiras. Foram utilizadas três bases de dados de 2000 até 2010: Scielo, Medline e Bireme. Concluiu-se que muitas vezes os princípios bioéticos e as normas jurídicas não foram adotados quanto à aquisição, a utilização e o descarte de tecidos musculoesqueléticos e cutâneos utilizados em estudos científicos, demonstrando a necessidade de se evidenciar normas éticas e legais para aqueles profissionais que utilizarão esse tipo de material.
**Palavras-chave:** Bioética. Leis. Transplante homólogo.

**Resumen**

**Tejidos musculoesqueléticos y piel de origen humano: aspectos éticos y legales de la producción científica en Brasil**

Este trabajo realizó el análisis crítico de los estándares éticos y jurídicos de trabajos que involucren casos clínicos e investigaciones que utilizaron injertos de órganos o tejidos musculoesqueléticos y cutáneos publicados en revistas nacionales e internacionales, incluyendo también disertaciones y tesis de universidades brasileñas. Se utilizaron tres bases de datos desde el año 2000 hasta el 2010: Scielo, Medline y Bireme. Se concluye que a menudo los principios de la bioética y las normas jurídicas no se han adoptado en la adquisición, uso y eliminación de los tejidos musculoesqueléticos y cutáneos utilizados en los estudios científicos, lo que demuestra la necesidad de evidenciar las normas éticas y legales para aquellos profesionales que utilizarán ese tipo de materiales.
**Palabras-clave:** Bioética. Leyes. Transplante homólogo.

Research article

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It is currently noted in the field of tissue engineering, the search for greater efficiency of materials and grafts by means of new technologies, driven towards contributing to individual health and the rise in expectation and quality of population life [1].

A great deal of the biomaterials utilized in Brazil are still imported and costly ones for the State or for the patients themselves and, therefore, held in restricted access to the smaller portion of society, whose increasing needs may be best met through technological development which will generalize the use of grafts – the dental ones, especially – and which will ease its overall usage, bearing respect for the presuppositions of principles-driven bioethics: beneficence, non-maleficence, justice and autonomy [2].

## Brief snapshot

In Brazil, there is a prevailing use of bio-materials originated from animals. Such fact is mainly due to the categorical prohibition, by Brazilian Constitution, of trading and utilization of materials from human origin. The law 9.434/97, which sets out on organs donations and procedures, vetoes any trading of organs or tissues of human origin in the country, prescribing penalties and administrative sanctions [4].

This law has been regulated by the Decree 2.268/07 [5], which regulates on the removal of organs, tissues and human bodily parts for the purposes of transplant and treatment. This decree created the National System of Transplants (SNT) of the Ministry of Health, entailing the rules of coordinating, prescribing and overseeing all the transplants performed in the country. Starting from 2002, SNT has accredited the authorized tissue banks to collect, process, store and distribute organs, tissues and human substances destined for transplants, research and treatments [1, 2].

The National Health Surveillance Agency (Anvisa) deemed it necessary to ensure the quality of the processes of sorting, removal, evaluations, processing, storage, transportation and availability, under the technical and quality standards which the underlying complexity of the procedure requires for musculoskeletal and cutaneous tissues of human origin and their derivatives, to be utilized in therapeutic procedures in humans. In order to do so, it has regulated the operations of musculoskeletal tissue banks and cutaneous banks of human origin, through a resolution by the Collegiate Board – RDC 220/06 [6].

This resolution determined the deadline of six months for adaptation of the existing cutaneous and musculoskeletal banks to the new regulation. In January, 2007, there were only six authorized bones/skeleton banks: one in Passo Fundo, in Rio Grande do Sul; two in "Paulista" capital (Capital of Sao Paulo); one in Marilia, inland in that state; one in the city of Rio de Janeiro and one in Curitiba. There still had not been any cutaneous banks authorized by the General Coordination of the National Transplant System (CGSNT) [4].

Musculoskeletal tissue banks (BTME) are understood as the services which, with physical installations, equipment and human resources and adequate techniques, have as attributions the realization of clinical, laboratorial and serologic sorting of tissue donators, as well as removal, identification, transportation to the bank, processing, storage and availability of skeletons/bones, soft tissues (cartilages, fasciae, serosas, muscle tissue, ligaments and sinews) and their derivatives of human origin, for therapeutic purposes, as well as for research and teaching [6].

A cutaneous bank (BP) is a service which, with physical installations, equipment and human resources and adequate techniques, has as attributions the performance of clinical, laboratorial and serological sorting s of tissue donators, as well as removal, identification, transportation to the bank, processing, storage and availability of cutaneous tissue and its derivatives of human origin for the purposes of therapies, research and teaching [6].

For the purposes of research and teaching, the BTME and the BP may make available tissues considered improper for therapeutic use, as well as those considered as proper ones, provided the demands for therapeutic usage are prioritized. The tissues and their derivatives may only be made available for undertakings of research previously approved by a research ethics committee [6].

At the moment, two conditions are acknowledged for donations of organs in Brazil: living donators, family members up to the 4th degree of kinship and the donation of organs or tissues of the deceased donator, so determined upon willingness on the part of the relatives up to the 2nd degree of kinship, under a donation authorization term [1].

Donation of organs such as kidneys, heart and corneas is much touted by the media, but only little is known about the equally wide demand for donations of musculoskeletal and cutaneous tissues. The discovery reaches out to medical professionals, who

ignore the methodology used for removal of such organs and tissues, or are not able to explain that the procedure does not change the body's appearance – a commonplace families' concern [2].

The utilization of materials of human origin for the performance of transplants and grafts is clearly recognized as a differential aspect in relation to auto-grafts, since the period of surgery and anesthesia is reduced, there is reduction of blood loss and possible focal complications, such as vascular and nervous damage, bruises and pain, and even though, it is also acknowledged that there is a chance of transmission of diseases, immunological reactions to the grafts and high rates of infection, and especially the discussion that involves such therapeutic maneuvers [4]. The search for technical standards and for quality standards which the method's underlying complexity requires is fundamental for the use of human tissues and organs in line with those bioethical principles of beneficence and non-maleficence [7].

Respect to human life demands ameliorated ethical reflection on professional acting, in face of scientific and technological advancements and new bio-medical findings. In situations wherein people, as vulnerable beings that they are, might end up being wounded amidst a series of new things, wind up referring to bioethics, which guides professionals to act in respect to citizenship and to human rights, both in recovery and promotion of health [2]. Seeking to comply with security and protection to patients, the discussion is raised about the use of bio-materials in the need to ensure the availability of musculoskeletal and cutaneous tissues of human origin and that their derivatives to be sorted, removed, analyzed, processed, stored, transported and made available under the premises of an adequate sanitary surveillance policy [7].

Thus, the goal of this work is to present the critical analysis of the ethical and juridical standards found in articles published in national and international magazines or post-graduation dissertations and theses in four Brazilian universities, on the clinical cases and research works conducted in the country, wherein cutaneous or musculoskeletal grafts were employed.

## Method

The research was based on critical review undertaken in three databases: Electronic Scientific Library in Line (Scielo), International Literature in Health Sciences (Medline) and Regional Library of Medicine (Bireme), encompassing the period from 2000 to 2010. The descriptors used in the search were: "human beings" (human) and *aloenxerto de músculo*" (muscle allograft); "human beings – *seres humanos*" (human) and "*enxerto homólogo de músculo*" (homologous muscle graft); "transplant of muscles" and "*seres humanos* – human beings"; human beings (human) and "*aloenxerto de pele*" (skin allograft); "*seres humanos*" (human) and "*enxerto homólogo de pele*" (homologous skin graft); "*seres humanos*" (human) and "*aloenxerto de ossos*" (bone allograft) and "*seres humanos*" (human) and "*enxerto homólogo de ossos*" (homologous bone graft).

The search also entailed digital libraries of theses and dissertations at the following universities: University of Sao Paulo (USP), State University of Campinas (Unicamp), State University of Sao Paulo (Unesp) and Federal University of Rio Grande do Sul (UFRS). The search was performed with the intent to lessen the trend of critical review, since not all the theses are published in periodicals. The same terms described for the articles were employed for this search.

The criteria for inclusion were: the deployment of research was in Brazil; deployment in the period encompassed by the study and utilization of cutaneous and/or musculoskeletal tissues of human origin, contained in clinical case reports and research works. The criteria for exclusion were the use of experimental models making use of animals; research works undertaken overseas and grafts employing commercialized biomaterials.

At the initial selection of the studies, these titles were assessed (n=249) and the summaries (n=95), identified in an independent and blind fashion, strictly following the inclusion and exclusion criteria in the protocol of this research. When the title and the summary were not clarified, a full work was attempted (n=40), so as to prevent the exclusion of studies relevant to a critical review.

After outlining the selection of studies to be assessed, the criteria for evaluation were set out for the assessment of the ethical and legal aspects concerning the research, which made use of homologous skin, muscle and bone grafts. The ethical aspects evaluated entailed the principles of beneficence, non-maleficence and autonomy, besides the approval of the research by an ethics committee. The legal aspects evaluated were alluded to stock keeping by the researcher or clinician, alluded to the distribution of the material, to the requirements for material acquisition and disposal of those. These assessments were based on decree set forth by the

Ministry of Health [8], resolutions by Anvisa [6], by the National Health Council [9], whose *caput* is presented at the end of this paper.

## Outcomes

The totality resulting from the search, according to the key words used was 249 studies, wherein 217 were articles found in the databases and 32 theses and dissertations. Among the articles published in national and international magazines on studies undertaken in Brazil, 101 were found in Scielo, 100 in Medline and 17 in Bireme. The most used term for tissue transplants searched for in the study among individuals of the same kind was homologous to Portuguese and *allograft* for English.

Among the 217 articles analyzed, 21 met the inclusion and exclusion criteria. Out of the 32 theses and dissertations analyzed, four met the selection criteria for inclusion in the sample and had not been published in periodicals. Relating the selected studies to the bioethical principles initially proposed, it was found that 92% did bear respect for beneficence, 80% for non-maleficence, 08% for autonomy and 27.,27% reported having been approved by an ethics committee. The ethics committee was analyzed under two aspects: one pertaining to the ethical aspect of the research and the other, pertaining to the fulfillment of the legal norms for acquisition of human materials.

In an analogy with the legal criteria, it has been noted that 56% did not report appropriate care with stock keeping of the used tissues, 32% described this care respecting the standardized norms and 12% did not respect such norms. The analysis of stocks was directed through decree 1.686/GM [8], taking heed of the time between the material's acquisition and its utilization.

The analysis about the acquisition of cutaneous and musculoskeletal tissues demonstrated that 48% did not specify where they had acquired the human tissue used in their research works or clinical case reports, 32% had acquired the tissues from authorized cutaneous and musculoskeletal banks and 20% had conducted the acquisition of these tissues from other places, such as, for instance, from the Death Verification Service, remaining surgical materials of hospitals, among others. Out of these acquired tissues, 80% disrespected resolution 196/96 by the National Council of Health [9], as they did not report a free and clarified consent term of use. The disposal or the re-utilization of the musculoskeletal and cutaneous tissues was not reported in 88% of the studies evaluated and 16% reported to have utilized all of the tissues.

One of the research works made use of skin allograft as a dermal substitute and evaluated, through histological verification, the clinical evolution of the case, hence, disrespecting RDC/Anvisa 220/06 [6].

## Discussion

There are legal norms and protocols for the use of transplants, targeted at each type of organ to be donated, accepted universally; anyhow, many jurists discuss the laws and postulate relevant considerations. Among those, some values are highlighted, which must be preserved: life, wherein the donator must be thoroughly safeguarded; and the cadaver's dignity, for this one is not an object and, although it is subject to decomposition, it must be surrounded by respect, for it continues to represent the human quality of people [10].

The confirmation of the consent term by the patient will depend on his acknowledgement of what is to be carried out in the research – as in the case of donations in life. The person must not be exposed to a situation of pressure, wherein he must be a volunteer in a free and clarified manner. In the cases of patients who still have not reached full legal age or who are not properly able to understand the situation, the signature does not contain legal validation. In these cases, there is the need for a legal representative's authorization [11].

The laws are aimed at preserving human life, while they resort to the use of transplants as a therapeutic conduct when there is not any other applicable treatment, wherein it is clear, in the case of donations in life, that it must not and may not cause any evident damage to the donor [10]. Rocha [12] and França [13] questioned organ donations from live patients, stressing the importance of a greater interest on the part of society in relation to cadaver organ transplants. In Brazil, one may not use his/her body as their own object; and the law reprobates trading of organs. Donations must take place in a spontaneous fashion, provided they are not utilized as a source of profits [10].

The skin banks, with their innovations, allowed for advancement in the use of biological materials as compared to past times; the search for treatments with lower costs made the creation of new

installations possible in Brazil, not holding it contingent only on imported biological materials [1]. The skin banks are governed by norms which must be respected by people who make use of specific tissues and the ones adequate for grafts, wherein it is necessary to clarify in works and research works, about the place where such materials were obtained – however, many articles evaluated in this paper had not respected this criterion [6].

Among the most evoked bioethical principles, the following ones emerge: autonomy, beneficence, non-maleficence and justice, all advocated by several authors and are material under the ethical standpoint, so that certain research works may be considered adequate and the rights of the research-subjects may be safeguarded [14,15]. There are principles and laws which imply in favoring rights and care for the individuals involved in research works, sparing them from the risks which might take place, since any act must be reversed for the benefit of patients [16].

The researchers must treat the individual as a human being and not as a subject, not just favoring his own interests, but collaborating for the well-being of those who are open for a treatment. According to Monte [17], one must not draw back from benefitting another on the grounds of the risk of injuring, but indeed, avoid taking on as absolute the prevalence of harming over benefitting. In face of certain circumstances, one must take measures so that people who will receive biological material transplants from cutaneous and musculoskeletal banks do not undergo any maleficence.

Due to the critical analysis that encompassed the ethical and legal standard of the clinical cases and theses or scientific articles published in magazines over the last 10 years, it is feasible to list out the factors involved in violation of the bioethical and legal principles, on the part of the researchers. It must reported that in the majority of the works evaluated, the principles of benefaction and non-maleficence, holding high regard to care and protection of the patient in relation to the risks which are entailed in the use of homologous cutaneous and musculoskeletal tissues, as well as the concern for obtaining these tissues from authorized and normalized places, were all identified in a satisfactory manner.

At some point, few research works and clinical cases evaluated mentioned the employment of the term of free and clarified consent (TCLE) ensuring patients' autonomy; those involved in the studies. On the other hand, about one fourth of the studies reported that the works had not been approved by an ethics committee. Nonetheless, the works and research involving human beings must meet the ethical and scientific fundamental needs, among which is the employment of TCLE on the part of the target individuals and the protection of vulnerable groups and the ones not legally self-sufficient (autonomy). In this sense, the research involving human beings must always treat them with dignity, respect them in their autonomy and defend them in their vulnerability.

Other aspects, such as inspection by hospitals and legal medical institutes where the organs and musculoskeletal/cutaneous tissues had been acquired and employed in the studies, as well as the disposal of the material which would not be used, were also heeded, since many authors omitted that information. Many times the juridical norms had not been followed by the researchers who utilized these tissues in their practical works, acquiring them, utilizing them and disposing of them in an illegal way. Thus, professionals, researchers and institutions must pull together in a reciprocal fashion for the availability, handling and disposal of musculoskeletal and cutaneous tissues of human origin, likewise with their derivatives. Such process seeks to guarantee that these tissues be sorted, removed, assessed, processed, stored, transported and made available within the technical and quality standards which the underlying complexity of the procedure requires, fulfilling the lawful precepts characteristic to this activity.

Therefore, signaling the positive and negative points of the works which employed materials originally from human bodies may add up to a greater demand by magazines and theses' advisors, also as a greater demand so that all the clinical cases and research works attain approvals from the ethics committee, so that they abide by the legal aspects of acquisition, storage and disposal of tissues and organs of human origin and keep on fulfilling the bioethical principles, allowing for operations under a more ethical form by professionals and under the legal norms.

## Final considerations

After an analysis of the articles included in this critical review, it is possible to draw the conclusion that often bioethical professionals themselves and the legal norms are not suitable as for the acquisition, utilization and disposal of musculoskeletal and

cutaneous tissues used in scientific studies, demonstrating the need for emphasizing ethical and legal norms for the professionals who will make use of this type of material.

Similarly, it has been verified that the expressive development of biomaterials for use in dentistry clinics over the last decade has represented a powerful therapeutic instrument in surgical activities, which, nevertheless, although there are proven benefits, demands sensible ethical care in the analysis of the risk-benefit relation that each biomaterial may present. For such, presently, principles-driven bioethics offers study and ethical-moral tools, directed towards the respect to morale and justice. From such verification, it is clearly fathomed, therefore, that the stimulus to teaching, studies and to bioethical reflection reveal themselves as indispensable at the clinic job for all who practice the profession – which implies in the care to people in especially vulnerable circumstances, both in access and search for health.

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**Authors' participation of in the article**
Silvia Sales Peres and Arsenio Sales Peres advised in all the stages of the work, analysis of the data and in the final writing of the article; Fernanda Pigatti and Maria Carolina and Mussi were the authors of the theoretical conception, collection, preliminary analysis of the data and initial writing of the text; Adriana Caetano collaborated on the collection, data analysis and updating of the literature review, as well as on the discussion of the data and critical review of the text.


Research article

## Attachment

*Decree No. 1.686/GM, in September, 20th, 2002*

*"Stock-keeping of processed and released tissues. The sinews and fasciae must be ultra-frozen at 80°C negative for the period of 2 years at most. The meniscuses may be kept in stocks at 80°C negative with usability of 4 weeks at most, lyophilized with proper use time of 5 years or at 4°C( +/- 2°) with a medium of cultivation for the period of 5 days. The processed and frozen osteo-chondral tissues must be kept in stocks in a refrigerator at four+/- 2° Celsius for the period of thirty days, at the most (in a medium which allows keeping certain viability of chondrocytes). The bone tissues must be kept in stocks at a temperature equal to or below 80°C negative for the period of 5 years at most. In case the stock-keeping temperature is between 20 ° and 40° C negative, the time for storage must be 6 months at the most. Transitional temperature drops for the period below 12 hours do not turn the bone tissues unusable. The lyophilized bone tissues may be stored at room temperature for the period of 5 years."*

***Resolution of the Collegiate Management – RDC No. 220, in December, 27th, 2006:*** *"5th Article - For effectiveness of this RDC, the identification, processing, storage and availability for the distribution of the tissues and their derivatives for allogeneic usage are attributions which must be undertaken exclusively by the BTME/BP".*

***Resolution No. 196 in October, 10th, 1996 by the National Council of Health:*** *"II.11 – Free and clarified consent – the subject's formalized assent on the research and/or his legal representative/guardian exempt from vices (simulations, fraud or error), dependence, subordination or intimidation, after thorough and detailed explanation on the nature of the research, its objectives, methods, anticipated benefits, potential risks and the drawbacks which it may incur, written down in a term of consent, authorizing his voluntary participation in the research."*

***Resolution by the Collegiate Administration – RDC No. 220, in December, 27th, 2006:*** *"23.2 The tissues will only be made available for research under the condition of documented request by the researcher who will make use of it, who must present the documentation which certifies the approval of the research project by an ethics committee in research, and who has his information (full name, ID, address, telephone number, academic or professional relationship), place where the project will take place, features and quantity of the requested tissue, anticipated date for usage of the tissues and a declaration by the researcher acknowledging the impossibility of using those tissues for clinical research in humans".*

***Resolution by the Collegiate Administration – RDC No. 220, in December, 27th, 2006: "****24.4. The tissues distributed may not be re-stored or destined for therapeutic use in/on another receiver, neither for usage in research projects or teaching projects, being liable to be disposed."*