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STEM CELL BANKING AND INDIAN LAWS
RELATING IT

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ABSTRACT

This research paper talks of collection, storage, and processing of stem cells. It inculcates all the legal regulations that are to be complied with while indulging in collection, storage, and processing of stem cells. It mainly chalks out and explains in detail the important sections, taken from varied statutes of Indian Law that relate to the concept of stem cell banking.

KEY WORDS:
Stem Cells; Collection; Storage; Processing; Drugs and cosmetics act, 1945; The drugs and magic remedies act, 1954; Indian patent act, 1970; Indian Medical Council Regulations 2002 (MCI Code); Drugs Price Control Order, 1995; Uniform Code for Pharmaceutical Marketing Practices; Information Technology Rules, 2011; National List of Essential Medicines.
INTRODUCTION

STEM CELL BANKING

Stem cells are special cells that have the potential to develop into many different cell types in the body. Blood collected from the umbilical cord of the new born is a rich source of blood. This blood is preserved in a cord blood bank in liquid nitrogen. There is no expiry date for stem cells. However, evidence exists that they can be stored for about 20-24 years.

Stem cells are firstly concentrated and then injected into the patient. Once they are transfused into the patient’s blood, they produce new cells of each kind.

Stem cells taken from the umbilical cord blood are like those taken from bone-marrow. They are capable of producing all types of blood cells such as red cells, platelets, and immune system cells. These stem cells can then be used to treat around 80 blood related illnesses like leukemia, lymphomas, several genetic conditions, and immune related disorders.
COLLECTION OF STEM CELLS

PROCESS OF COLLECTING STEM CELLS FROM UMBILICAL CORD

Cord blood is the blood that is left in the placenta and umbilical cord after a baby is born. Collecting cord blood is a painless process for both- the mother as well as the baby. After the umbilical cord is clamped and cut, the placenta and umbilical cord are cleaned. This cord blood is then put into a sterile container, mixed with a preservative, and frozen until needed. This is how stem cells are collected.

NATIONAL GUIDELINES GIVEN BY MEDICAL COUNCIL OF INDIA AND DEPARTMENT OF BIOTECHNOLOGY

INFORMED CONSENT:

It is mandatory to obtain informed consent from the voluntary donor before the isolation or processing of such stem cells. This shall include video consent as per the CDSCO guidelines for audio-visual recording dated 9th January 2014 (schedule Y). When certain tissues are extracted and thus donated, it raises a question of ethical and moral conduct. Hence, in order to protect such interests and confidentiality of information of the donor, some special laws have been made.

1. The donor must be informed about the need for screening of transmittable diseases and of any other risk which may be transmitted due to blood donation.
2. Further, procedural risks involved during collection of organ/tissue/ cells, under local or general anesthesia must be explained appropriately. The information sheet must contain all such details. The donor shall be informed about the same in his/ her preferred language.

1 National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017
2 Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trial issued by Central Drugs Standard Control Organization Directorate General of Health Services Ministry of Health & Family Welfare, Govt. of India
3 Article 4.1.1.1 of National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017
4 Article 4.1.1.2 of National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017
3. The donor shall also be instructed\textsuperscript{5} that the cell lines/products may be banked and shared with other scientific groups under exceptional circumstances.

4. The cell lines/products may undergo genetic manipulation\textsuperscript{6} and have the potential for commercialization. The donor may not be provided with the intellectual property rights under commercialization of such cell lines. However, if it brings any financial benefits, then, efforts shall be made to pass on the same to the donor/community.

5. The donors shall be well-informed\textsuperscript{7} about the fact that they may be contacted in future for any specific requirements.

6. There are specific criteria for selection of a donor accompanied by several laboratory investigations\textsuperscript{8}.

\section*{COLLECTION OF PROCESSED UMBILICAL CORD BLOOD COMPONENT}

1. Criteria for Collection of Cord Blood:

(a) Umbilical Cord blood of an individual shall be collected only after having signed an agreement with the parents of that individual. Private and Public Umbilical Cord blood banking to have different agreements under this process;

(b) Umbilical Cord blood shall be collected from hospitals, nursing homes, birthing centers and from any other place where a consenting mother delivers. It should be done only under the supervision of a qualified, Registered Medical Practitioner who shall be responsible for the delivery;

(c) The cord blood shall be collected aseptically, (i.e., free from contamination or germs) in a disposable PVC bag. It shall contain an adequate quantity of sterile, pyrogen free anti-coagulant and sealed effectively. Such PVC Bags shall be purchased from a licensed manufacturer to avoid any kind of discrepancy;

\textsuperscript{5} Article 4.1.1.3 of National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017

\textsuperscript{6} Article 4.1.1.4 of National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017

\textsuperscript{7} Article 4.1.1.5 of National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017

\textsuperscript{8} Article 4.1.1.6 of National Guidelines for Stem Cell Research by Indian Council of Medical Research & Department of Biotechnology 2017
(d) The Umbilical Cord blood shall be collected from hygienic operating premises to allow proper operation and maintenance.
PROCESSING OF STEM CELLS

After the collection of cord blood, the stage of processing begins, whereby as per the Legal regulations, testing of the blood is the primary step. In order to ensure that the blood does not contain any infectious disease, mother’s blood and baby’s cord blood is tested to guarantee quality and verify sterility.

Then, the cord blood is processed by initially mixing it with the processing agent. After which it is divided in its constituent parts by suspending and centrifuging it. Ultimately, completing the stage of processing by collecting it and separating it and finally store it as per the next step by the process of cryo-preservation.

It is to be noted that the stage of cell processing and manufacturing should be in compliance with requirements as per the Schedule M of Drugs and Cosmetics Act, 1940 and Rules, to ensure the quality control and quality assurance for the product development.

As per the Schedule L1 and M of Drugs and Cosmetics Act, 1940 and Rules, SCPD shall only be handled in a CDSCO-certified GLP and GMP facility.

Requirements for Processing, Testing and Storage Areas for Umbilical cord blood stem cells:

There shall be separate areas for designated work purposes namely:-

(1) Cord blood processing area: To provide a Class 10,000 environment the room shall be cleansed properly and should have an air handling system. only air lock entry shall be granted in this area. The room will constitute Class 100 biological safety cabinets for Umbilical cord blood processing. The temperature of the clean room shall be maintained 20 °C to 25°C and with a positive differential pressure of 10-15 pascals and Relative.

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9 Cryo-Cell International; https://www.cryo-cell.com/
10 PART XII, (A)-General Requirements, Rule 5 of The Drugs and Cosmetics Rules, 1948
11 PART XII, (A)-General Requirements, Rule 5(b)(ii) of The Drugs and Cosmetics Rules, 1948
STORAGE OF STEM CELLS

The method that is used to store the cord blood of the stem cells is called cryopreservation. Under this method, stem cells are stored at a temperature below -150°C by immersing it in nitrogen vapor. They are frozen using a protective compound called cryoprotectant so that the cells survive for a longer time.

REQUIREMENTS\textsuperscript{12} FOR PROCESSING, TESTING AND STORAGE AREAS FOR UMBILICAL CORD BLOOD STEM CELLS:

Separate areas for work shall be designated namely:-

1. Cord blood Reception\textsuperscript{13}: It is the area with space for temporary storage of units and physical examination should have adequate facilities for registration, date entry and generation of bar-coded labels. There should be at least 10.00 Sq. meters of air conditioning area to be provided;

2. Records and Storerooms\textsuperscript{14}: A designated record room(s) and store room(s) of at least 10.00 Sq. meters each should be provided. Only authorized persons shall be permitted access to the record room. The room should have adequate preservative facilities as the documents and records are to be conserved for long years.

3. Cryogenic Storage room\textsuperscript{15}: Licensee should provide at least 20.00 sq. meters of space. The cryogenic storage room should have facilities for temperature monitoring of storage vessels, liquid nitrogen level in storage vessels and oxygen meter. There should be a minimum 1.00 sq. Meters of service space between each liquid nitrogen storage vessel, supply cylinders and connecting hose. Separate storage space for other accessories required shall be provided. The room shall be air conditioned.

4. General Storage area\textsuperscript{16}: General storage area shall be provided to store all the consumables, under conditions deemed optimum for storage by manufacturers.

\textsuperscript{12}\textsuperscript{13}\textsuperscript{14}\textsuperscript{15}\textsuperscript{16} PART XII, (A)- General Requirements; Rule 5 of The Drugs and Cosmetics Rules,1948.

PART XII, (A)- General Requirements; Rule 5(b) (i) of The Drugs and Cosmetics Rules,1948.

PART XII, (A)- General Requirements; Rule 5(b)(viii) of The Drugs and Cosmetics Rules,1948.

PART XII, (A)- General Requirements; Rule 5(b)(ix) of The Drugs and Cosmetics Rules,1948.

PART XII, (A)- General Requirements; Rule 5(b)(x) of The Drugs and Cosmetics Rules,1948.
STORAGE OF PROCESSED UMBILICAL CORD BLOOD COMPONENT

CRITERIA FOR STORAGE\(^{17}\) OF CORD BLOOD

1. The Umbilical cord blood shall be cryopreserved. The frozen storage shall range between minus 150ºC and minus 196ºC.
2. This product will not expire.

MISLEADING ADVERTISEMENTS

Stem cells and their derivatives fall under definition of ‘drug’\(^{18}\) as per the Drugs and Cosmetics Act 1940\(^{19}\). They are even classified as ‘investigational new drug (IND)’ or ‘investigational new entity (INE)’ when they are used for any clinical application.

As per the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954\(^{20}\)

Schedule-J of Drugs and Cosmetics Act, 1940 mentions those diseases which are incurable. Advertising treatment of such diseases with the help of stem cells under the concept of magic remedies is not at all permissible. Central Drugs Standard Control Organization (CDSCO) and other relevant state authorities are mandated to take strict action in case of violation of this act.

SECTION 4 - PROHIBITION OF MISLEADING ADVERTISEMENTS RELATING TO DRUGS\(^{21}\)

No person shall publicize any advertisement regarding a drug if the advertisement contains any matter which:

a) Directly or indirectly gives a false impression of the nature of the drug.
b) Makes any false claim.
c) Is false or misleading in any other form.

\(^{17}\) PART XII; (B)-Collection and Storage of Processed Umbilical Cord Blood Component; Rule 3 of Drugs and Cosmetics Rule, 1948.

\(^{18}\) Section 3(b) of Drugs and Cosmetics Act, 1940

\(^{19}\) (Act No. 23 of 1940)

\(^{20}\) Act No. 21 of 1954

\(^{21}\) Section 4 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
SECTION 5 - PROHIBITION OF ADVERTISEMENTS OF MAGIC REMEDIES FOR CERTAIN DISEASES AND DISORDERS\textsuperscript{22}

No person carrying on the profession of administering magic remedies shall directly or indirectly publish any advertisement that claims to be efficacious.

SECTION 7 - PENALTY\textsuperscript{23}

Whoever violates the provisions of this Act, shall on conviction, be punishable-

a) with imprisonment which may extend to six months, or with fine, or with both (in the case of first conviction).

b) with imprisonment which may extend to one year, or with fine, or with both (in the case of subsequent conviction).

\textsuperscript{22} Section 5 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

\textsuperscript{23} Section 7 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
STEM CELL TECHNOLOGY- PATENTABLE

A patent is an exclusive right granted for an invention, which excludes others from making and selling that particular invention.

Stem cells are auto-generative cells which have the capability of indefinite division and can be easily kept in laboratories in the form of cell lines. Since they can divide and differentiate to form different cells of the body, they have vast scope in the medical realm with respect to repair and replacement of human tissues along with a potential to cure copious diseases that are conventional or non-conventional in nature.

Patentability of a stem cell technology raises the question - whether or not it is an invention, and can it be patented?

As per S.3(b) of The Patents Act, 1970\(^{24}\) - “an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment is not an invention.”

Embryonic stem cells are pluripotent (i.e., they have the ability to develop into different cell types of the human body), thereby extraction of cord blood from embryonic stem cells becomes quite difficult and unethical. Extraction of these cells from the embryo itself raises the question of immorality and contradiction of public order.

As per S.3(j) of The Patents Act, 1970\(^{25}\) - “plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals is not an invention.”

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\(^{24}\) Act No. 39 of 1970
\(^{25}\) Ibid, 24
Patentability of stem cell technology which primarily deals with the making and selling of stem cell products questions the possibility of destruction of human embryos\textsuperscript{26}. In other words, it questions whether or not a microorganism or a part of an animal/plant (referring to an embryo) be patented and sold for commercial purposes?

India, like other countries, believes to accept patentability of stem cell technology as long as ethical ways\textsuperscript{27} are used to derive embryonic stem cells. These ethical ways include deriving stem cells from umbilical cord blood, which is deemed to be more acceptable ethically, and therefore, this process has become very popular in exercising benefits out of stem cell technology.

**DRUGS PRICE CONTROL ORDER AND NATIONAL LIST OF ESSENTIAL MEDICINES**

It has been witnessed that pharmaceutical companies or hospitals charge exorbitant prices from their patients thereby exploiting them in the name of providing essential medicines. Thus, to protect such interests of the consumers, that is, patients in the above case regarding donation of stem cells, various laws and rules have been jotted down and discussed in detail.

**NATIONAL LIST OF ESSENTIAL MEDICINES**\textsuperscript{28}

It is published by the Ministry of Health and Family Welfare in 2011 as updated or revised from time to time and incorporated in the first schedule of this order by the Government through a message in the Official Gazette;

**NEW DRUG**\textsuperscript{29}

It implies formulation of a drug as specified and listed in the National List of Essential Medicines by an existing manufacturer. The formulation shall be done by combining the drug with another drug either listed or not listed in the National List of Essential Medicines.

\textsuperscript{26} https://www.legaleraonline.com/articles/patenting-stem-cell-inventions-in-india-what-to-expect
\textsuperscript{27} Patentability of Stem Cell Banking By www.Mondaq.com
\textsuperscript{28} Section 2(t) of Drugs Price Control Order, 1995 (DPCO)
\textsuperscript{29} Section 2(u) of Drugs Price Control Order, 1995 (DPCO)
Price of formulations (branded or generic version) listed in the National List of Essential Medicines, launched by a manufacturer. – 30

1) A manufacturer shall be free to fix the price of the scheduled formulation equal to the Price list; to or below the ceiling price set for that schedule formulation by the Government.

Fixation of retail price of a new drug for existing manufacturers of scheduled formulations 31.–

1) on the principles of “Pharmacoeconomics”, the Government shall form a Standing Committee of Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs.

2) As specified in the National List of Essential Medicines an existing manufacturer of a drug with dosages and strengths launches a new drug, such existing manufacturers shall apply for prior price approval of such a new drug from the Government in Form-I as specified under Schedule-II of this Order.

3) The Government shall fix the retail price of the new drug accordingly in case the new drug is available in the domestic market. However, in case the new drug is not available in the domestic market, the Government shall forward the same to the Standing Committee of Experts. The committee should then examine the application and thereby make recommendations of its retail price to the Government. It should be done within 30 days of the receipt of application.

4) The Government shall, on receipt of recommendation, within thirty days, fix the retail price of such new drug and it shall be applicable to the applicant of such new drug.

5) If the existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug, then he shall be liable to deposit the overcharged amount, if any, along with interest thereon from the date of launch of the new drug.

6) No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price fixed by the Government. In case such a manufacturer is found to do so, he shall be liable to deposit the overcharged amount along with interest from the date of overcharge.

30 Section 12 of Drugs Price Control Order, 1995 (DPCO)
31 Section 15 of Drugs Price Control Order, 1995 (DPCO)
Revision of ceiling price on the basis of moving annual turnover (MAT)\textsuperscript{32} –

It shall be carried out -

(i) within 5 years from the date of fixing the ceiling price under this Order or when the Ministry of Health and Family Welfare revises the National List of Essential Medicines, (whichever is earlier);

(ii) when the number of manufacturers of a scheduled formulation, having a price more than or equal to 75\% of the ceiling price fixed and notified by the Government, has decreased by 25\% or more than the number of manufacturers as existing on the reference date;

(iii) when the number of manufacturers of a scheduled formulation, having prices of their scheduled formulation equal to or lower than 25\% of the ceiling price fixed by the Government, has increased by 25\% or more than the number of manufacturers as existing on the reference date.

UNIFORM CODE FOR PHARMACEUTICAL MARKETING PRACTICES

As we know, Stem cells are a type of magic remedy, hence there is a chance whereby pharmaceutical companies may promote such unethical marketing practices to lure the patients and thus extract exorbitant amounts from them. Thus, in order to protect such interests, this code\textsuperscript{33} envisages various features that controls unethical practices in the marketing of drugs:-

GENERAL POINTS\textsuperscript{34}

a) Receipt of the marketing approval of that drug must be obtained before its sale or supply.
b) The promotion of a drug must be consistent with the terms of the marketing approval
c) Information about the drugs must be verifiable.
d) Information should not be misleading in any way.

CLAIMS AND COMPARISONS\textsuperscript{35}

\textsuperscript{32} Section 18 of Drugs Price Control Order, 1995 (DPCO)
\textsuperscript{33} Uniform Code for Pharmaceutical Medical Practices (UCPMP) By Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals; F. No. 5/3/2009-PI-I/PI-II (Vol. III)
\textsuperscript{34} Rule 1 of Uniform Code for Pharmaceutical Marketing Practices
a) A drug must be evaluated appropriately with the necessary evidence in order to claim its usefulness.
b) Comparisons of a drug must be factual and should not be misleading.

**TEXTUAL AND AUDIO-VISUAL PROMOTIONAL MATERIAL**

a) All promotional material must be in accordance with this code.

**MEDICAL REPRESENTATIVES**

a) Medical representatives must maintain a high standard of ethical conduct in discharge of their duties. They must comply with all relevant requirements of the code.

**SAMPLES**

a) Free samples of drugs should not be supplied to any person who is not qualified to prescribe such a product.

**GIFTS**

a) No gifts shall be supplied to persons qualified to prescribe such drugs.
b) Gifts for personal benefit of healthcare professionals or their family members are also not to be offered.

**INFORMATION TECHNOLOGY RULES, 2011**

Stem cell research requires storage of data which needs to be protected at all times to protect leakage and misuse of such data.

**SENSITIVE PERSONAL DATA OR INFORMATION**

Information of a person that is personal in nature including medical records and history, passwords, financial information, etc. is sensitive personal data.

35 Rule 2 of Uniform Code for Pharmaceutical Marketing Practices
36 Rule 3 of Uniform Code for Pharmaceutical Marketing Practices
37 Rule 4 of Uniform Code for Pharmaceutical Marketing Practices
38 Rule 5 of Uniform Code for Pharmaceutical Marketing Practices
39 Rule 6 of Uniform Code for Pharmaceutical Marketing Practices
40 Rule 3 of Information Technology Rules, 2011(Data Protection Rules)
PROVIDED - It does not include that data or information which is available or accessible to
the public openly.

BODY CORPORATE TO PROVIDE POLICY FOR PRIVACY AND DISCLOSURE
OF INFORMATION41 -

Body Corporates who collects, receives, possesses, stores, deals or handles information of
providers of information, are duty bound to provide a privacy policy for dealing in personal
information. Such policy shall be published on the website of body corporate or any person
on its behalf.

COLLECTION OF INFORMATION42 -

Rule 5 provides the guidelines that need to be followed by a Body Corporate while collecting
information and imposes the following duties on the Body Corporate:

1. Requirement of consent from the person(s) providing information in writing or by
email before collecting such delicate personal data. According to the press note dated
August 24, 2011 issued by the Ministry of Communication and Information
Technology it was stated that consent covers consent given by any mode of electronic
communication;

2. Information shall only be collected for lawful purpose and is considered necessary for
the same. The information collected shall be used only for the purpose for which it is
collected and shall not be held on for a period longer than which is required;

3. Ensure that the person(s) who is providing information are aware about the fact that
the information is being gathered and accumulated, its purposes & beneficiary, name
and addresses of the agencies keeping and collecting the information;

4. The information shall be retained for the required purposes and shall be used lawfully

5. Offer the person(s) providing information a chance to examine the information
provided and make alterations, if required;

6. Before collection of the information, facilitate an option to the person(s) rendering
information to not provide the information furthermore;

41 Rule 4 of Information Technology Rules, 2011 (Data protection Rules)
42 Rule 5 of Information Technology Rules, 2011 (Data protection Rules)
7. Maintain the safety of the information; and
8. Designate a Grievance Officer should be hired, whose name and contact details are to be incorporated on the website and he/she shall be responsible to address grievances of information providers. A maximum period of one month has been provided for a decision of such grievances.

DISCLOSURE OF INFORMATION

Body Corporate must seek prior permission of the information provider before disclosing any sensitive information to a third party. However, if government agencies request for such information, then no prior permission is required as they are mandated under law.

REASONABLE SECURITY PRACTICES AND PROCEDURES

(1) A body corporate shall be considered to have complied with reasonable security practices and procedures, if they have implemented such security practices and standards. They must have documented information of security programmes.

In the event of an information security breach, the body corporate shall be required to denote that they have enforced security control measures as per their recorded information security programme.

(2) The international Standard IS/ISO/IEC 27001 on "Information Technology - Security Techniques - Information Security Management System - Requirements" is one such standard.

(3) Any industry association, whose members are self-regulating and follows other than IS/ISO/IEC codes of best practices for data protection, shall get it duly approved and notified by the Central Government for effective implementation.

(4) The body corporate who have implemented either IS/ISO/IEC 27001 standard or the codes of best practices for data protection shall be deemed to have complied with reasonable security practices and procedures.

PROVIDED

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43 Rule 6 of Information Technology Rules, 2011 (Data protection Rules)
44 Rule 8 of Information Technology Rules, 2011 (Data protection Rules)
such codes of best practices must be certified or audited on a regular basis by entities through independent auditors, duly approved by the Central Government. The audit shall be carried out at least once a year.
CONCLUSION

To put it briefly, Stem cells are special cells which aid to cure various blood related illnesses. The process of collection, processing and storage of stem cells has been discussed in detail above whereby it gives an insight to the reader about the legal regulations that are required to be performed under the Indian Law. It mainly directs its fingers to the national guidelines issued by the Medical Council of India and Department of Biotechnology.

Stem Cell Technology is a concept which has not been fully explored by India yet. Only guidelines have been issued, there are currently no codified laws in India with respect to Stem Cell Banking. The concept of stem cell banking is perceived to be of utmost importance in todays times since it proves to be the key to unlock the door of curing those illnesses which were earlier incurable. After the analysis of these facts, I believe, India should invest its energy and funds in improving the healthcare sector of its country and codify laws relating to stem cell banking. This will ultimately provide the patients with effective remedies of treating those incurable diseases which they have to get it cured from other countries.

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11) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6801994/