



CODE OF ETHICS

BIOCELL CENTER's CODE OF ETHICS is intended to make clear the ethical principles that characterize the company, its business and its development, and to define how they are fully accomplished through the pursuit of its social purpose.

The Code therefore intervenes to clarify the objectives and activities of the company, its structure, its ethical inspiring principles. Then, it proceeds to identify who are the people who have to share the principles expressed, as these principles can be inferred in the major projects underway or in the various sectors of activity.

Finally it examines the specific issues that have been identified as particularly relevant for the purposes of completeness of the Code of Ethics.

The people that dealt with the drafting of the Code are:

- Professor Michele Aramini - Professor of Theology at Università Cattolica of Milan and Bioethics at the Università Carlo Cattaneo (Castellanza), a priest, author of numerous books on the topics of bioethics, translated into several languages.

- Professor Giuseppe Simoni - former professor of Medical Genetics at the University of Milan, Scientific Director of Biocell Center, author of numerous publications in international scientific and important scientific innovations, among which we note that of the prenatal diagnostic method on the chorionic villi.

- Reguzzoni Marco - Biocell Center CEO, entrepreneur, always engaged in social and political matters, author of publications and innovations in the field of ethics, codes of behavior.

The Code of Ethics, which was approved by the Board of Directors of Biocell Center SpA, is an official and binding document for the whole company.

Changes, modifications, or additions may be made only upon unanimous agreement of the drafters.

OBJECTIVES AND ACTIVITIES

Biocell Center aims to be a center of excellence in birth-related practices (before, during and after conception), particularly with regard to the new field of stem cells.

As the literal translation of the name clearly indicates, our company is a center of "life cells", and the human life as a fundamental value is the basis of existence of Biocell Center, also defined a "center of support for procreation and life".



To achieve this goal, Biocell Center has developed - within its structure of Viale Stelvio 125 in Busto Arsizio - a center of excellence in the field of stem cell storage, according to law.

In addition, Biocell Center has developed a method of isolation, subsequent storage and re-use of stem cells that are present in the amniotic fluid extracted during prenatal examination (*i.e.* amniocentesis).

To adequately support the research and clinical analysis, while still providing a high quality health service, Biocell Center also built a private clinic, including a center for level I assisted reproduction (*i.e.* artificial insemination), with the purpose to gather – based on the excellence developed in the stem cell field - the best medical professionals (*e.g.* geneticists, gynecologists, urologists, psychologists, sonographers) in order to form a unique structure in the field of birth-related practices, thus addressing those that occur before conception, during pregnancy and in the period immediately following it.

Medical and diagnostic activities will be extended to both members of the couple, in case of fertility problems, and to both the mother and the child after birth.

Biocell Center does not perform abortion or carry out activities in support of it, since these practices are in contrast with the main ethical objective of Biocell Center.

THE STRUCTURE

The BIOCELL CENTER S.p.A. is a joint-stock company established in June 2006, whose corporate research objective in the field of biology and genetics is in accordance to high quality standards, high ethical standards and strict compliance with the regulations.

The Scientific Director of the CENTER BIOCELL is Professor Giuseppe Simoni - long-time professor and considerable expert in the field of biomedical research, particularly in molecular genetics - which is entrusted with the task of coordinating the research group, among whom there ITOMA Laboratory Advanced Biomedical Assays of Busto Arsizio.

In addition, to achieve its investment objective, BIOCELL CENTER SpA relies also on the contributions of other members of the corporate structure, external structures, medical professionals and biologists established, among which there are several hospital Chiefs of Department and university Professors.



INSPIRATIONAL ETHICAL PRINCIPLES

Biocell Center wants to act in accordance with ethical and moral principles laid down by its members, at the same time being open to the discoveries of science and to the contribution of newcomers, and being firm in requesting all the respect for their beliefs.

In fact Biocell Center is a center of "love of life" and as such wants to be seen and experienced.

The motto of the company is:
"The love of life, from conception to the first steps"

Therefore, although in the absolute respect for the convictions of each individual, Biocell Center considers imperative to put the respect for and protection of life at the base of their work, meaning in this sense both the Human Life, and the life of the single cells that form an individual, specifically embryonic cells.

In absolute secularism that characterizes the shareholder structure, management and personnel, Biocell Center has chosen anyway - in the drafting of this Code and in absolute autonomy - to be guided by the moral principles of their doctrine of the Catholic Church.

In this regard, the Love for Life is addressed both through a religious and a secular attitude is full agreement - for example, in the words of Pope John Paul II "the task of accepting and serving life involves everyone and should manifest itself mainly to the living in conditions of greater weakness".

So it is at the embryo – the man who has yet to be born and the most fragile and defenseless human life form – that goes our most care and attention.

Studying their weaknesses and preparing the ground for a difficult birth can find achievement, by using methods and techniques to provide the best possible performance for all medical practices.

With great attention to the child, but also affection and love for the mother's life, and in a gesture of love and absolute selflessness, accepting motherhood proves that a mother can come into play with all of herself.

All of our care, attention and concerns go to mothers and to those who want to become mothers.

Our respect goes first and foremost to mothers, as it is demonstrated by the fact that in our operative protocols there's always an "informed consent" form.

Of course the parents usually are a couple, so, also to future fathers, Biocell devotes much attention, but life is brought up for nine months in the womb, so it is at the mother and the unborn child that we give our first thoughts and the recognition of a great gesture of love.

For couples who have difficulties in conceiving, the effort is on both the gynecology and the andrology sides.



Combining the experiences on both sides with aspects of genetic and psychological assistance could improve our support to the couple and - consequently – help us apply the right techniques to achieve the desired result: the birth of a new life.

The birth of a new life is a goal that must be guaranteed to parents, if science and ethics allows the opportunity that might occur: their desire to be supported with therapeutic purposes must not be for mere scientific objectives or - worse - to satisfy morbid curiosity or whims.

But this "care to the person" – the attention to the activities outpatient clinics and health – adds an important action to scientific research.

The field of stem cells and genetic analysis, which is the field that promises more technological progress and scientific research, is still very large: the Socratic "know thyself" has not yet been fully implemented, despite thousands of years of history in medicine.

In this sense Biocell Center shares the spirit repeatedly recited and demonstrated by Don Luigi Verzè, founder of the Hospital San Raffaele, which states: "The San Raffaele – the temple of medicine – cannot fully be itself – a big hospital of excellence – if it is not a temple of excellent research and clinical-molecular body of thought at the same time, thus enriching and causing endless discussions among men".

With the proper proportions, Biocell also feels the need to combine research, application and discussion, and to debate clinical and health-related certainties. And of course, moral principles and ethical rigor.

Moreover, Biocell takes into high consideration the cultural effect of each employee or contractor of the company, each of whom is a professional, who started working in a different field of activity, and which came together to achieve the objective of serving a higher purpose and high ideals.

Ideals that have not only an absolute value, but - no use denying it - even a relative value: they are the principles and objectives that apply itself in a utilitarian perspective, as Biocell - like San Raffaele - believes that the long-term reliability, the scientific rigor and the moral adherence to solid ethical principles repay in the field of economics and entrepreneurship.

BIOCELL STAFF AND ITS CUSTOMERS

Biocell Center requires from its directors, employees, directors, contributors and professionals, to share the ethical principles guiding its activities. In fact, the acceptance of the basic principles and the sharing of common objectives is considered essential in order to follow a path of long-term within the same corporate structure.

Are therefore "interested parties" to the scope of the Code of Ethics, all those who have been previously mentioned.



To these must be added, however, the recipients of the corporate structure, that is, users and patients: customers and users of all types, Biocell Center announces their beliefs, offering insight to the reasons of others, but at the same time demanding respect absolute for their own.

Thus, for example, the staff of Biocell Center not only will not practice abortion, but - highlighting the ethical reasons for this choice – will not suggest an abortion procured as a clinical practice.

MAIN ON-GOING PROJECTS

By 2008, we want to start the first phase of conservation of stem cells derived from amniotic fluid, finishing a research project started in 2006 and called "BIO CELL SAVING.

Indeed, the goal is to develop a service that allows to recover the stem cells that are present in the amniotic fluid extracted for prenatal screening (*i.e.* amniocentesis). This heritage of stem cells today is simply ignored and - as a consequence - destroyed.

Biocell Center has therefore set a world-leading service that allows the extraction, the culture and the subsequent storage of human cells to various purposes, according to law, both in the field of health care, both in the medical research and pharmacology.

The company also takes care of the "qualitative" aspects of their work, with the aim of creating a powerful example of excellence in all areas.

In this respect, has been working to achieve quality certification, compliance with EU directives, environmental certificates issued by accredited bodies, meaning higher costs and charges due to these choices which contribute ethically correct to the quality of services offered .

OPERATIVE FIELDS

The company operates in various fields through the provision of various services; the purpose of this code is, however possible, to group activities into three distinct areas:

- Private Clinic
- Cryobank
- Center for Artificial Insemination
- Analysis/Research Lab



The provisions of the Code of Ethics shall cover all activities of the company, being all operators - even medical professionals or external independent researchers - required (as part of the activities developed in collaboration with Biocell Center or in the premises or the same) to comply with the ethical principles inspiring and objectives as represented in this Code.

EXAMINED ETHICAL ISSUES

Regarding some specific issues that may be, due to their nature, situations that are controversial and not easily solvable, the Code of Ethics shall adopt the guidelines and operational decisions below.

In particular, although they can not anticipate every ethical issue that can be recognize below, some aspects of Genetic Diagnosis, Artificial Insemination, Cryobank and finally - having regard to the absolute novelty of the service - the conservation Stem Cells from Amniotic Fluid have been taken into consideration.

For each aspect that is not considered, what was previously said about the "guiding principles" must be considered as valid, without prejudice to the commitment of Biocell to bring together the drafters of this Code for the purpose of producing updates on the issues that presented with continued activity and the novelty of science.

Genetic Diagnosis

Each genetic diagnosis performed by Biocell Center must comply with the basic principle by which the diagnostic report must contain only scientifically proven facts, then possibly adding the chances left open by the case.

In the latter case, the doctor can mention - for guidance only - the statistics in his possession, noting, however, the diagnosis is not definitive.

If the genetic disorder diagnosed demands the patient or the couple to use a therapy and/or surgical interventions that can be performed by Biocell Center, the doctor is required to emphasize the potential conflict of interest that it might generate, therefore informing the patient and/or the couple, then free to choose whether to take the action suggested at Biocell Center's Clinic or elsewhere.

Issues related to Artificial Insemination

Among the various techniques of Artificial Insemination, Biocell intends to practice only the Artificial Homologous Insemination. It is assumed that the Ethics Committee considers the therapeutic purpose as the only reason that justifies the use of techniques of Artificial



Insemination. Reasons that might harm the rights of the unborn are not considered valid. Below are some answers to the most important ethical issues or frequency, referring to the other with the above principles.

- **Donation of eggs, sperm, preimplantation genetic diagnosis:**
Biocell Center will not make practices Artificial Insemination that might include any of the above-mentioned options.
- **Access to Artificial Insemination by seropositive for HIV:**
It is permissible, if the person affected is the man, as the risk of transmitting the virus to the unborn child is - applying modern techniques on sperm - practically none. It is not eligible if the mother or both parents are HIV-positive, in which case Biocell Center, still respecting the wishes of the couple, will not perform Artificial Insemination techniques.
- **Access to Artificial Insemination by couples affected by major diseases and genetic risk of disease transmission to the unborn child:**
Eligible - subject to adequate highlighting of the risks for the couple and for the unborn child.
- **Access to Artificial Insemination by persons suffering from infective diseases which can be definitely treated with specific therapy:**
Ineligible. It requires the use of already-undergone therapies for such disease.
- **Freezing of ovarian tissue or semen in patients who have to support therapeutic treatments (eg chemotherapy cycles), which can cause irreparable damage to the reproductive functions:**
Permitted and encouraged, with indication of the possibility of restoration of ovarian function or conception of the future, still making clear what it is not certain.

Issues related to the management of the Cryobank

Below are some answers to the most important ethical issues or frequency, referring to the other the principles outlined above.

- **Cryopreservation of human embryos:**
Biocell Center will not produce and will not retain human embryos from external sources.
- **Preservation of human material for autologous use:**
Permissible, provided they have clear mind about the ownership of the material, the time for which you require storage (which can be reduced or extended) and the ultimate fate of the material.



- **Retention of human organs, tissues, human material or autologous autologous use:**
Permissible if justified by a written demand by the Health Care system, that underlies specific medical protocol. The acceptance will be subject to verification of ownership of the material, of the time for which you require storage (which can be reduced or extended), and of the ultimate fate of the material. Even in the absence of the above requirements, any pre-acceptances may be made only in cases of urgency or where required by Court.
- **Research activities on their own – Research as a support to other centers:**
All the research activities carried out by Biocell, whether in their own or in support of projects of other institutions, universities or institutions, will be carried out in accordance with the above-mentioned principles. In addition, the selection of partners will be tight and made on the basis of sharing the same goals, focusing on national or international facilities with adequate experience, size and reliability.

Storage of Stem Cells extracted from the Amniotic Fluid

The service of extraction and subsequent storage of stem cells from amniotic fluid is completely in accordance with ethical principles, since the extracted cells are not embryos, they would otherwise be destined for destruction and, instead, they may be useful to the future of the individual or others.

Moreover, as it is also exposed in the contract and in the illustrative brochure, there are additional elements important for the expression of a positive ethical judgment, among which:

- There is no added risk to the mother or the fetus, since the extracted liquid be destroyed otherwise.
- The mother is committed to use it according to solidarity if necessary.
- Amniocentesis is done not just to collect the above mentioned cells, but only for reasons beyond that.
- The retail price of the service is not speculative and, when compared with other similar services or equivalent, appears to be inexpensive.

Also, to avoid any possible conflict of interest, Biocell not practice amniocentesis on patients who wish to preserve the stem cells of the amniotic fluid.



Finally Biocell is committed:

- To receive, process and store the amniotic fluid of mothers with serious economic difficulties and a demonstrable clinical history that it deems appropriate, in the opinion of doctors and geneticists, without requiring any fee.
- To allocated any operative profit coming from such services to research on the use of stem cells.

APPLICATIONS OF THE CODE OF ETHICS

This Code is respected and enforced by administrators, managers, employees and collaborators of Biocell Center.

All the actors (and users) are required to report to the Administrative Body and/or the Oversight Committee (if established) any breach thereof.

The Governing Body or the Supervisory Board (if established) are required to apply administrative sanctions and disciplinary function in compliance with the Code of Ethics, working - even in full compliance with corporate, commercial and employment law and labor contracts - as follows:

A) Reporting to Superiors possible infringements.

B) Depending on the severity, Superiors can issue:

- letter of reprimand;
- application of administrative measures;
- temporary suspension from service.

C) In cases of absolute gravity and/or the lack of recurrence despite more measures referred to in point B, superiors have to inform the Board of Directors. The Board, assess its severity and its recurrence, shall:

- register a note of malice, of which the corporate offices - while in full compliance with employment law - must adequately consider the subject of contract renewals, promotions, assignments, ...;
- dismissal and/or breach of contract of collaboration and/or delivery of services.



In all cases, if it is technically possible, superiors will activate the necessary resources and/or measures to alleviate and/or remedy the failing without any delay.

The Chief Executive Officer shall ensure that the Code of Ethics is made available on paper or computer to anyone who requests it.