

## Section I

# Basic Tenets of Cell Based Medicine

The ICMS supports legitimate medical innovation outside of the context of a formal clinical trial.

The ICMS defines legitimate medical innovation as the clinical application of innovative therapy that is based upon good patient care, is intended to improve or ameliorate an individual patient's condition and evidences a reasonable chance of success for the patient being treated.

In order to advance the field of adult stem cell medicine, the ICMS establishes these basic tenets that:

1. The use of autologous, adult stem cells is the practice of medicine and, as such, is subject to the laws and regulations that cover the practice of medicine.
2. An informed patient has the right to access innovative therapies and that ethical physicians must be trusted to use their professional judgment and experience in determining a treatment regimen for his or her patient.
3. Cell based medicine is a new and innovative field and, as such, requires specific, unique and global mechanisms for scientific transparency, medical oversight and patient protections.
4. The procurement of cells from patients must be conducted using sterile techniques and universal precautions to minimize the risks of contamination and infection.
5. The level of oversight should be proportional to the degree of risk associated with the treatment.
6. Every patient should be monitored for long-term health effects.
7. Every treatment protocol needs to include a clear, timely and effective plan for adverse event reporting.
8. All treatments utilizing stem cells must be subject to on-going review and evaluation by an independent oversight body.
9. Any medical or scientific claim must be based on accepted and acknowledged scientific evidence and medical experience.

10. Governments should develop, in association with the ICMS or other oversight organizations, a set of standards and guidelines to evaluate the practice of stem cell medicine at the national, regional or local level.

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