Charter for Regenerative Medicine

All human rights and freedoms derive from, and are founded on, the recognition of the **inherent dignity of the human person**.

International **human rights** are indivisible such that one cannot stand without the other. These rights provide entitlements to individuals while imposing correlative obligations on States. States are required to progressively realize human rights in a way that is consistent with the promotion of the general welfare in a democratic society.

Without prejudice to other rights, three international human rights undergird, promote, and give meaning to this ***Charter for Regenerative Medicine***: the right to science, the right to health, and the right to non-discrimination.

The **right to science** includes freedom and rigour of scientific inquiry, the duty to provide an enabling environment for responsible science, and the right of everyone to benefit from scientific advancement.

The **right to health** mandates that healthcare services, goods and facilities be available, accessible, and of good quality. The highest attainable standard of health is progressively realized through advances in research and clinical practice.

The **right to non-discrimination** entitles all humans to equitable access to preventative and therapeutic health services.

Regenerative medicine is a multidisciplinary field that combines knowledge and technologies from fields such as biology, chemistry, engineering, medicine, and pharmaceutical and material sciences to develop therapies for the repair or replacement of damaged tissues and organs. These technologies raise legal and ethical issues both in biomedical research and in their potential and actual clinical applications in way that draws upon existing legal and ethical approaches within each discipline while posing novel concerns when combined. In response to the challenges of regenerative medicine and in particular, gene editing, the World Health Organization has emphasized the need for "a set of clearly defined ethical values and principles", while the International Commission on Heritable Human Genome Editing prioritized both safety and efficacy, an incremental approach to clinical applications and international scientific collaboration. In that same vein, the International Society for Stem Cell Research's *Guidelines for Stem Cell Research and Clinical Translation* reiterated the need for a "compelling scientific rationale, a plausible mechanism of action, and an acceptable chance of success" prior to advancing to clinical trials in gene editing. These positions are emblematic of the ongoing need to establish principles and actionable norms not only for gene editing, but for regenerative medicine as a whole. Researchers, clinicians, patients, funders and governments have obligations to responsibly steward this discipline for the benefit of current and future generations.

CGP Centre of Genomics and Policy
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This *Charter for Regenerative Medicine* endorses a vision for the future of regenerative medicine. It is a vision that acknowledges the potential life-changing benefits of regenerative medicine while recognizing the need for national and international oversight based on shared ethical norms to frame its future and maintain public trust. The **Charter** further recognizes the impact of regenerative medicine on the design and conduct of basic and translational research as well as its implications for the future.

Founded on **human rights** and recent **international** guidance, the ensuing obligations can be largely regrouped into three categories of **principles and procedures** whose promotion and adoption create the need to **commit to**:

1. Quality/Safety

· Implementing safety and oversight mechanisms, including in relation to unproven therapies

· Ensuring ongoing and robust risk-benefit assessment processes sensitive to the risks and benefits that regenerative medicine poses for individuals, communities and future generations.

· Taking seriously the distinction between the technical safety of a therapeutic product or procedure and its broader implications for human welfare.

2. Integrity/Responsibility

· Exemplifying the letter and spirit of international scientific and regulatory norms based on the highest standards of scientific training and researcher integrity

· Respecting individual choices with respect to the generation and use of their cells, organs and tissues.

· Providing proof of scientific and ethical provenance for any cell lines, organs or tissues created and used in both the public and private sectors.

3. Transparency/Accountability

· Participating, actively and respectfully, in public debates about the regulation of regenerative medicine and its associated disciplines.

· Avoiding overstating the potential benefits of regenerative medicine, to both future patients and the general public.

· Facilitating public access to information concerning the outcomes of ongoing clinical trials via international registries.

· Fostering public and patient engagement and participation in local, national and international dialogue.

· Promoting ongoing national and international ethics review, effective oversight, and equitable access.

· Engaging in open science practices, including sharing

The Charter is the result of international collaboration (see List of Collaborators). Hopefully, it will be an important tool in both anticipating and setting a direction for "ethics in practice" norms for regenerative medicine in research and in the clinic. The creation of the Charter also speaks to the need to continuously evaluate the norms set by the scientific community. We hope that by updating the past Stem Cell Charter we have set a precedent to continue to re-evaluate international guidance, as well as what information the public needs to properly address and evaluate future technologies.

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