Alliance for Regenerative Medicine

Code of Conduct

I. Commitment to Regulatory Oversight to Protect Patient Safety

The Alliance for Regenerative Medicine is committed to promoting the development of safe and effective forms of regenerative medicine and advanced therapies, which include, but are not limited to, cell therapy, gene-modified cell therapy, gene therapy, gene editing, tissue engineering and other therapies to induce stem or progenitor cell differentiation and cellular immunotherapies. In fulfilling this commitment, we promise to adhere to the following principles:

- Experimental regenerative medicine and advanced therapies undertaken by Alliance members should be subject to regulatory guidelines established by appropriately authorized and duly empowered agencies, including the FDA, EMA, Japanese PMDA and others to best ensure patient safety and product efficacy;
- Research, development and commercialization of regenerative medicine and advanced therapies products by Alliance members or their affiliates should occur in a manner that is consistent with the rules and regulations established by such agencies;
- Ensuring the safety and well-being of clinical trial participants is paramount. Informed consent regarding potential risks and benefits of potential therapies based on rigorous scientific and clinical standards is essential and should never be compromised;
- The safety of marketed products is our priority. Commercialization of potential therapies without appropriate demonstration of safety and efficacy, informed consent or compliance with defined regulatory standards permitting such commercialization, constitutes unethical and inappropriate behavior and should never be tolerated;
- Commercialization of potential therapies in a country, region or geographic jurisdiction that does not have well defined regulatory standards or an appropriately authorized regulatory framework or oversight to ensure the quality, safety and effectiveness of such therapies should never be exploited as a way to enable or justify circumvention of standards designed to ensure the safety and well-being of patients.

II. Support ARM Mission

ARM members shall act in a manner consistent with ARM's mission statement. That statement says the following:

"The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and to modernize healthcare systems so that patients benefit from durable, potentially curative treatments.

As the global voice of the sector, we represent more than 400 members across 25 countries, including emerging and established biotechnology companies, academic and medical research institutions, and patient organizations."

III. Conduct Policy Pledge:

We hereby pledge our adherence to this set of principles and understand that clear evidence of a violation of one or more of these principles as determined by a two-thirds vote of the ARM Board of Directors is grounds for revocation of membership.

Name:

Title:

Company:

_____ _____

Signature Date