

Section IV Standards for the Use of Patient Claims

Clinics that seek to position cell based medical treatments as a “Miracle product” and / or claim to cure serious conditions are not credible, pose a significant risk to public health and safety and are not acceptable practices.

All claims made by clinics and or physicians, with regard to cell based medical treatments, must be based on accepted and acknowledged scientific evidence and medical experience. Data must be provided to substantiate any claim. Claims based upon subjective patient testimonials, and not objective medical follow up, are not a reasonable substitute or alternative. All claims should provide a reasonable balance between positive and non-positive results in patients.

Data used to substantiate any claim should be based upon the long term follow up of patients. Claims of safety should be, at the least, based upon the collection of data through an established and accepted grading scale, such as the Adverse Event Reporting system used by the Department of Health and Human Services Office of Human Research Protections (OHRP)- <http://www.hhs.gov/ohrp/>. Claims of outcome should be based exclusively upon the collection of data through an established and accepted grading scale based upon the indication treated. All data should be validated by an independent, third party organization prior to publication of any claim of safety or outcome. Whenever possible, patient data should be independently collected and managed in Treatment Registry.