The ICMS aligns its founding with the history of the in-vitro fertilization procedures developed in the 1970’s. Developed by pioneering OB/GYN’s, this medical procedure rapidly expanded to be practiced by tens of thousands of physicians throughout the world. IVF has long been classified as a medical procedure, and thus not regulated by the Food and Drug Administration (FDA). Like IVF, autologous, adult stem cell therapies (A-ASC) rely on a minimal culture expansion of human cells with direct physician oversight. Unlike IVF, the FDA has attempted to classify and thus regulate A-ASC therapies as biologic drugs. To serve physicians who want to provide these safe and effective therapies, the ICMS has established procedures and lab guidelines. Innovations in this area of cell therapy have occurred at a rapid pace because the clinicians on the ground have been able to safely innovate without the need for federal biologic drug approval.

The History of Stem Cell Research

The history of stem cell research began in the mid 1800’s with the discovery that some cells could generate other cells. Now stem cell research is embroiled in a controversy over the use of human embryonic stem cells for research. In the early 1900’s the first real stem cells were discovered when it was found that some cells generate blood cells.

The history of stem cell research includes work with both animal and human stem cells. Stem cells can be classified into three broad categories, based on their ability to differentiate. Totipotent stem cells are found only in early embryos. Each cell can form a complete organism (e.g., identical twins). Pluripotent stem cells exist in the undifferentiated inner cell mass of the blastocyst and can form any of the over 200 different cell types found in the body. Multipotent stem cells are derived from fetal tissue, cord blood, and adult stem cells. Although their ability to differentiate is more limited than pluripotent stem cells, they already have a track record of success in cell-based therapies.

A prominent application of stem cell research has been bone marrow transplants using adult stem cells. In the early 1900’s physicians administered bone marrow by mouth to patients with anemia and leukemia. Although such therapy was unsuccessful, laboratory experiments eventually demonstrated that mice with defective marrow could be restored to health with infusions into the blood stream of marrow taken from other mice. This caused physicians to speculate whether it was feasible to transplant bone marrow from one human to another (allogeneic transplant). Among early attempts to do this were several transplants carried out in
France following a radiation accident in the late 1950’s. Performing marrow transplants in humans was not attempted on a larger scale until a French medical researcher made a critical medical discovery about the human immune system. In 1958 Jean Dausset identified the first of many human histocompatibility antigens. These proteins, found on the surface of most cells in the body, are called human leukocyte antigens, or HLA antigens. These HLA antigens give the body’s immune system the ability to determine what belongs in the body and what does not belong. Whenever the body does not recognize the series of antigens on the cell walls, it creates antibodies and other substances to destroy the cell.

A bone marrow transplant between identical twins guarantees complete HLA compatibility between donor and recipient. These were the first kinds of transplants in humans. It was not until the 1960’s that physicians knew enough about HLA compatibility to perform transplants between siblings who were not identical twins. In 1973 a team of physicians performed the first unrelated bone marrow transplant. It required 7 transplants to be successful. In 1984 Congress passed the National Organ Transplant Act, which among other things, included language to evaluate unrelated marrow transplantation and the feasibility of establishing a national donor registry. This led ultimately to National Marrow Donor Program (NDWP) a separate non-profit organization that took over the administration of the database needed for donors in 1990. The 1990’s saw rapid expansion and success of the bone marrow program with more than 16,000 transplants to date for the treatment of immunodeficiencies and leukemia. Adult stem cells also have shown great promise in other areas. These cells have shown the potential to form many different kinds of cell types and tissues, including functional hepatocyte-like (liver) cells. Such cells might be useful in repairing organs ravaged by diseases.

In the 1970’s, the technique of in-vitro fertilization was developed by pioneering OB/GYN’s. This medical procedure rapidly expanded to be practiced by tens of thousands of physicians throughout the world. Culture expansion of human cells remains a procedure with direct physician oversight. IVF organizations have established procedure and lab guidelines and have partnered with other lab based organizations like the American College of Pathologists. These medical specialist run labs usually adhere to CLIA guidelines and are state inspected. Innovations in this area of cell therapy have occurred at a rapid pace because the clinicians on the ground have been able to safely innovate without the need for federal biologic drug approval.