

AnoviumTM Solution

University of Utah Cell Therapy & Regenerative Medicine Program

- Established early 1990's
- Provide Cells to Huntsman Cancer Institute and Primary Children's Hospital
- Profits returned to fund research

- Goal of Program is Research and Development
 - o Requires stringent regulatory approval / classification for drug development
 - o Phase I Lou Gehrig's Disease
 - o Phase I Kidney Disease
 - o Liver Disease, Degenerative Disc Disease

 - o Requires more than FDA registration under 21 CFR Part 1271 & AATB Accreditation

- Must Follow Stringent Standards to enable accreditation and clinical trial
 - o FACT Accreditation (Foundation for Accreditation of Cellular Therapy)
 - o University of Utah Institutional Review Board (IRB) approved Tissue Bank
 - o AATB Accreditation (American Association of Tissue Banks)
 - o FDA Registration 21 CFR Part 1271
 - o Board Certified Hematologist to determine patient eligibility
 - Medical records, History, Infectious Disease

- Gather during C-section with aseptic recovery and processing
 - o Secondary sterilization with proprietary filtration process
 - o Process cells within 48 hours of collection
 - o Stringent Quality Control Procedures approved by FDA, Accreditation Bodies and University IRB
 - o Vendors, Reagents and all material required to demonstration quality testing criteria
 - o Follow FDA IQOQPQ Standards (Installation Qualification, Operation Qualification and Performance Qualification for equipment)
 - o REESE 24 Hour Temperature Monitoring and Validation (-80 degree)
 - o Environmental Monitoring and Quarterly Testing

- Pure Product with proprietary filtration process
 - o 27 gauge needle
 - no hair, epithelial cells, vernix, vesicles
 - Body can perceive as foreign substances, elicit mild immune response / inflammation

 - Cytokines & Growth Factors
 - Anti-inflammatory
 - Anti-bacterial / anti-microbial
 - Anti-Fibrotic
 - Immuno-privileged
 - Response not from stem cells
 - o 600ml fluid = 10,000 – 20,000 stem cells
 - Requires millions of cells to achieve therapeutic function
 - o Testing other company products
 - No or minimal live mesenchymal stem cells
 - Apoptosis, Freezing kill cells

 - o Office storage at -20 degrees Celsius