INTERNATIONAL
CELLULAR MEDICINE
SOCIETY

Clinic Accreditation Application

Defining the future of cell based medicine.

ACCREDITATION OVERVIEW

The ICMS Clinic Accreditation Process is a 10-step program that provides on-going transparency, oversight and patient outcome tracking to cell based medical clinics worldwide. This rigorous process combines patient outcome tracking with medical review of treatment and clinical protocols and laboratory practices to provide the only comprehensive accreditation of cell based medical clinics in the world.

Step 1: Initial evaluation of treatments and protocols provided through a standard

Step 2: IRB Review and Evaluation of treatment protocols, informed consent, patient candidacy and outcome measures.

Step 3: Participation in the ICMS Treatment Registry to track outcomes and complications for all patients treated at the clinic

Step 4: Random Process and Data Audit by the ICMS to assure that patients are being follow up on and that complaints are being adjudicated.

Step 5: Initial Site Audit to evaluate compliance with ICMS Best Practice Standards

Step 6: 2nd IRB Review to evaluate patient outcomes and complication rates.

Step 7: Clinic Self Assessment to evaluate on-going compliance with ICMS Best Practice Standards

Step 8: 3rd Party Laboratory Audit by independent firm to show compliance with ICMS Lab Practice

Step 9: 2nd Site Audit to assure to evaluate compliance with ICMS Best Practice Standards

Step 10: Final Review and Evaluation by the ICMS Medical Board

Upon Accreditation, Clinics are required to submit to on-going Audit and Evaluation of compliance to all ICMS Standards and Guidelines.

CLINIC INFORMATION

Clinic Name:

Primary Contact:

Physician Name(s):

Is each physician licensed to practice medicine in the jurisdiction where treated are given?
☐ Yes ☐ No

Clinic Address:

URL:

Procedure Cost:

Number of Patients Treated Monthly:

Total Number of Patients Treated by Clinic:

Is the clinic licensed by appropriate local authorities to provide the treatment(s)?

☐ Yes ☐ No

CONDITIONS TREATED

Please list the diseases/conditions currently treated by your clinic:

Is the same cell line used to treat all conditions? ☐ Yes ☐ No

Is there support in peer reviewed journals for the use of adult stem cells in the treatment of these conditions? ☐ Yes ☐ No

If yes, please list:

OVERVIEW OF TREATMENT

Briefly describe the treatment provided to patients at your clinic:

Has an Institutional Review Board (or local equivalent) provided review and approved this treatment?

☐ Yes ☐ No

If yes, please provide proof of approval.
If no, please refer to the ICMS IRB for application.

Is each patient provided with an Informed Consent prior to treatment?

☐ Yes ☐ No

Please provide a copy of Informed Consent

Is each patient graded for candidacy (Good, Fair, Poor) prior to treatment?

☐ Yes ☐ No

Please provide a copy of the patient candidacy protocol.

CELL LINE INFORMATION

1. Source of cells: ☐ Autologous ☐ Allogeneic

   If Allogeneic:

   a. What is the exact source of the cells?

   b. How are donors screened? (i.e. bacterial, fungal or viral contamination)

   c. Details of the tissue source (i.e. local hospital provided cord blood):

2. How are the stem cells isolated? (i.e. centrifuge spins, buffy coat isolation, etc.)

3. Are stem cells culture expanded? ☐ Yes ☐ No

   If yes:

   a. How are cells culture expanded?

   b. What is the period of incubation?

   c. What is the cell culture type (i.e. monolayer, roller, etc)?

   d. What are the basic steps in the incubation process?

4. To what animal components are the cells exposed (if any)?

5. What media, serum, growth hormones, etc. are used?

   a. National Drug Code numbers:
   http://www.fda.gov/drugs/informationondrugs/ucm142438.htm

6. What are the cell quality control assurance protocols?
   ☐ Flow cytometry (Please list markers tested and frequency of testing)

   ☐ Karyotype with metaphase spread (Please detail protocol used)

   ☐ Fluorescent In-situ Hybridization (FISH) (Please detail genetic abnormalities FISHed)

   ☐ Bacterial, Fungal, and/or Viral testing (Please detail frequency)

7. Is a separate quality assurance sample of this cell line cyro-preserved?
   ☐ Yes ☐ No

8. Are any aliquots of the cell lines cryo-preserved for use in subsequent treatments?
   ☐ Yes ☐ No

   If yes, please describe the freezing agent:

IMPLANTATION INFORMATION

1. Are the cells mixed with other elements at the time of injection? ☐ Yes ☐ No

   If yes, please list:

2. What is the delivery method for these cells?

3. Is delivery of cells image guided? ☐ Yes ☐ No

   If yes:

   What imaging is used?

ICMS TREATMENT REGISTRY ACKNOWLEDGEMENT

Participation by the clinic requires that patients receiving stem cell treatments are entered into the ICMS Treatment Registry and that the negotiated, onetime, per patient procedure fee, is paid to the ICMS.

The clinic shall provide to the patient the ICMS Patient Registry Form and an ICMS IRB-Approved Informed Consent Form prior to the time of treatment, and that both documents are signed and delivered back to the clinic at the time of the treatment. The clinic shall keep these signed documents in the patient file.

Participation in the ICMS Treatment Registry authorizes the ICMS to publish non proprietary information about the clinic's collection, processing, implantation and procedural processes in the Society's annual Stem Cell Clinic Report. Prior to inclusion, the clinic shall have the right to review and edit any and all information included in this report.

The clinic agrees to input all required patient data into the secure and clinic specific web interface found at www.cellregistry.org

Participating clinics can only claim in its promotional materials that it participates in the ICMS Comprehensive Treatment Registry and as such, has an independent 3rd party collect complications and outcome data on patients and that it follows the ICMS registry guidelines as to how this information is adjudicated.

(initial) _____

I attest the information provided in this application is true.

_____
Clinic Name

_____
Name (Primary Contact)

_____
Title

_____
Date