Treatment Registry Application Complications

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Complications Treatment Registry Overview

The ICMS Complications Treatment Registry is a patient reported data collection and reporting tool managed by the International Cellular Medicine Society (ICMS) for the purpose of tracking complications and adverse effects from cell based therapies and to provide patient follow up and reporting based upon the ICMS Re-Implantation Registry Guidelines. Participation in the Complications Treatment Registry requires that a $50 per patient fee be paid to the ICMS. The purpose of the ICMS Complications Treatment Registry is to provide clinics and patients an independent, third party, non-profit collect patient complications data. All follow up provided by the ICMS in the Complications Treatment Registry is conducted via secure email communication with patients.

Clinic applying for participation in this Registry must fill out this form. Once received and evaluated by the ICMS, the clinic will be provided with a standard patient data collection form that is to be signed by each patient to be treated. This form directly matches the clinic's secure patient collection form. After receiving the signed form from a patient, the participating clinics enter the required pre-procedural information for all patients being treated with stem cells into the secure and customized page found at cellregistry.org. The Registry will then assign a unique patient identification number from which all follow up will be coordinated.

On a regularly scheduled basis, patients will receive an email asking them to take a standard complications survey. Using their unique patient ID, patients will access a form customized to the condition treated. No personal information about the patient is made available through this page. All personal information about the patient is stored in a separate, secure database that can only be accessed by the clinic and the ICMS.

Any reported complication will cause an alert to be sent to the ICMS and a complaint file to be opened on the patient's record. Upon receipt of any alert, the ICMS will initiate a Complaint Adjudication Process that will alert both patient and physician of the complication. Clinics are required to adjudicate all complaints in a timely manner and provide proof of adjudication to the ICMS. Any non adjudicated complaint will be reported. Clinics with an unreasonably high level of non adjudicated complaints will face possible response from the ICMS, including, but not limited to, public censure or expulsion from the Registry.

Participation in the Complications Treatment Registry provides clinics with access to complications reporting from the ICMS. This report allows for an individual patient's complication history to be view by the clinic and compared against both the clinic mean and the mean of all registry participants. Additional customized reports are made available to clinics on a monthly, quarterly or annual subscription basis.

Clinic Information

Clinic Name: _____

Primary Contact: _____

Physician Name(s): _____

Clinic Address: _____

URL: _____

Procedure Cost: _____

Number of Patients Treated Monthly: _____

Total number of Patient Treated by Clinic: _____

Conditions Treated

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

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

Cell Line Information

1. Source of cells: ☐ Autologous ☐ Allogeneic

   If Allogeneic:

   a. What is the exact sourcing 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 provide cord blood)

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

   _____

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 incubation process: _____

4. To what animal components are these cells exposed (if any): _____
5. What media, serum, growth factors, 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?
   a. If Flow cytometry, include markers tested/frequency of testing.

      _____
   b. If Karyotype with metaphase spread, include protocol.

      _____
   c. If Fluorescent In-situ Hybridization (FISH), include genetic abnormalities FISH'd.

      _____
   d. If Bacterial, Fungal and/or Viral testing, include frequency.

      _____
7. Is a separate quality assurance sample of this cell line cyro-perserved: ☐ 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 _____
9. Other information about the cell utilized (Clinics may attach separate forms):

Implantation Information

1. Are the cells mixed with other elements at the time of injection? ☐ Yes ☐ No
2. What is the delivery method for these cells?

3. Is delivery of cells image guided? ☐ Yes ☐ No
   a. If yes, then what imaging is used?

Complications Treatment Registry Acknowledgment

Participation by the clinic requires that patients receiving stem cell treatments are entered into the Treatment Registry and that the negotiated, onetime, per patient procedure fee of $50 is paid to the ICMS. The ICMS will provide an invoice to the clinic for all registry participation fees on the 15th and 30th of each month. Fees may be paid to the ICMS via check, credit card or wire transfer.

The clinic shall provide to the patient the ICMS Patient Registry Form and an Informed Consent authorized by the ICMS prior to the time of treatment, and that both documents are signed and delivered back to the clinic at the time of the treatment.

Participation in the Complications 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 Complications 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. Clinics cannot claim accreditation by the ICMS, or assert or imply that the clinic, its lab or its procedures are certified by the ICMS.

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