Indication for CRID Assignment (Form 2814)

- Currently under revision
- Tentative release – Summer
- Deleting Questions 7 & 8
Indication for CRID Assignment (Form 2814)

Complete Form 2814

- Initiating a new CRID
- Existing patient– new indication
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What is the indication for CIBMTR Research ID (CRID) assignment?</td>
</tr>
<tr>
<td></td>
<td>- HCT</td>
</tr>
<tr>
<td></td>
<td>- Cellular therapy (non-HCT)</td>
</tr>
<tr>
<td></td>
<td>- Marrow toxic injury</td>
</tr>
<tr>
<td></td>
<td>- Non-cellular therapy (e.g. chemotherapy, immunotherapy, etc.)</td>
</tr>
</tbody>
</table>

**Hematopoetic Cellular Transplant (HCT)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Specify the planned cell source(s) for this HCT:</td>
</tr>
<tr>
<td></td>
<td>- Autologous</td>
</tr>
<tr>
<td></td>
<td>- Allogeneic, unrelated</td>
</tr>
<tr>
<td></td>
<td>- Allogeneic, related</td>
</tr>
<tr>
<td></td>
<td>- Planned HCT date: <em><strong>-</strong></em>-___</td>
</tr>
</tbody>
</table>

**Cellular Therapy**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Planned infusion date: <em><strong>-</strong></em>-___</td>
</tr>
</tbody>
</table>

**Marrow Toxic Injury**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Event date: <em><strong>-</strong></em>-___</td>
</tr>
</tbody>
</table>

**Non-Cellular Therapy**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Specify the disease for which non-cellular therapy was given</td>
</tr>
<tr>
<td></td>
<td>- MDS</td>
</tr>
<tr>
<td></td>
<td>- Other disease</td>
</tr>
<tr>
<td>9</td>
<td>Specify other disease: ____________________________</td>
</tr>
<tr>
<td>10</td>
<td>Enrollment date: <em><strong>-</strong></em>-___ (date of consent)</td>
</tr>
</tbody>
</table>

CIBMTR

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH
Hematopoietic Cellular Transplant

- Infusion of bone marrow, peripheral blood stem cells, umbilical cord blood, or other cellular product
- Intent is for hematopoietic replacement or recovery
- Product contains CD34+ cells
  - CD34+ cells are hematopoietic progenitor cells
Marrow Toxic Injury

Reported by Radiation Injury Treatment Network (RITN) centers

Event of mass casualty incident resulting in marrow toxic injury

Mass casualty scenarios resulting in marrow toxic injury
- military nuclear weapon detonation
- radiological dispersal device detonation
- nuclear power plant accident
- industrial/workplace accident

Do not report marrow toxic injury for individuals receiving pre-transplant radiation therapy or for accidental, isolated exposures to radiation
<table>
<thead>
<tr>
<th>Indication</th>
<th>Questions: 1 - 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 What is the indication for CIBMTR Research ID (CRID) assignment?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCT</td>
</tr>
<tr>
<td></td>
<td>Cellular therapy (non-HCT)</td>
</tr>
<tr>
<td></td>
<td>Marrow toxic injury</td>
</tr>
<tr>
<td></td>
<td>Non-cellular therapy (e.g. chemotherapy, immunotherapy, etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hematopoietic Cellular Transplant (HCT)</th>
<th>Questions: 2 - 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specify the planned cell source(s) for this HCT:</td>
<td></td>
</tr>
<tr>
<td>2 Autologous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>3 Allogeneic, unrelated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>4 Allogeneic, related</td>
<td></td>
</tr>
<tr>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>5 Planned HCT date: __________ - ______</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cellular Therapy</th>
<th>Questions: 6 - 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Planned infusion date: __________ - ______</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marrow Toxic Injury</th>
<th>Questions: 7 - 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 Event date: ______ - ______</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Cellular Therapy</th>
<th>Questions: 8 - 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 Specify the disease for which non-cellular therapy was given</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MDS</td>
</tr>
<tr>
<td>9 Specify other disease: ________________________________</td>
<td></td>
</tr>
<tr>
<td>10 Enrollment date: __ __ __ - __ __</td>
<td></td>
</tr>
<tr>
<td>(date of consent)</td>
<td></td>
</tr>
</tbody>
</table>
Cellular Therapies Data Collection

- HCT Indications
- Non-HCT Indications

Car T-cell
Cellular Therapy Registry

• Development led by Marcelo C Pasquini, MD, MS
• Formed a task force
• Objectives of CIBMTR Cellular Therapy Initiative
  – Initial objective was to create a registry
  – Determine what data to collect
  – Implement new data collection forms
Objectives of CIBMTR Cellular Therapy Registry

1. To study uses of cellular products for indications *other than* hematopoietic replacement or recovery

2. To provide an infrastructure to allow long-term follow-up of patients treated with cellular therapy products
Cellular Therapy Essential Data

Applies to all cellular therapies

Pre-CTED
- Demographic data, indication, disease status prior to CT (if applicable) and therapy prior to CT

Post-CTED
- Follow up infusions, patient survival and disease status, cause of death, development of malignancies, persistence of the product, development of CRS

Infusion form
- Description of the product, information on manufacturing, product analysis and infusion details
CRF level data for Cellular Therapies

- Data collected:
  - Disease information and follow up
  - Infection information and follow up
  - HLA typing and matching (if applicable)

- Case selection based on:
  - indication
  - cell product
Cellular Therapy Scenarios

- Cellular therapy only
  - Regenerative medicine
  - CAR T-cells
  - CTL for infection

- Co-infusions
  - HCT plus cellular therapy

- Cellular therapy to cellular therapy
  - New indication

- Cellular therapy followed by HCT
  - Bridge to HCT

- HCT followed by cellular therapy
  - DCI
HCT Cellular Therapy Indications

- **Promote stem cell engraftment**
  - e.g. Co-infusion with HCT

- **Suboptimal donor chimerism**
  - Post-HCT

- **Immune reconstitution**
  - Post-HCT

- **GVHD prophylaxis**
  - With HCT

- **GVHD Treatment**
  - Post-HCT

- **Prevent disease relapse**
  - Post-HCT

- **Relapsed, persistent or progressive disease**
  - Post-HCT
Non-HCT Cellular Therapy Indications

**Autoimmune disease**
- Crohn’s disease
- Systemic lupus erythematosus
- Rheumatoid arthritis
- Diabetes mellitus type I
- Ulcerative colitis
- Systemic sclerosis
- Other autoimmune disease
- Other autoimmune bowel disorder

**Cardiovascular disease**
- Acute myocardial infarction
- Chronic coronary artery disease (ischemic, cardiomyopathy)
- Heart failure (non-ischemic etiology)
- Limb ischemia
- Thromboangitis obliterans
- Other peripheral vascular disease
- Other cardiovascular disease

**Musculoskeletal disease**
- Avascular necrosis of femoral head
- Osteoarthritis
- Traumatic joint injury
- Osteogenesis imperfecta
- Other musculoskeletal disease

**Neurologic disease**
- Acute cerebral vascular ischemia
- Amyotrophic lateral sclerosis
- Parkinson’s disease
- Spinal cord injury
- Cerebral palsy
- Congenital hydrocephalus
- Myasthenia gravis
- Multiple sclerosis
- Other neurologic disease

**Neurologic disease**
Non-HCT Cellular Therapy

Indications

Ocular disease

- Specify ocular disease

Pulmonary disease

- Specify pulmonary disease

Neurologic disease

- Acute cerebral vascular ischemia
- Amyotrophic lateral sclerosis
- Parkinson’s disease
- Spinal cord injury
- Cerebral palsy
- Congenital hydrocephalus
- Myasthenia
- Multiple sclerosis
Non-HCT Cellular Therapy
Indications

Solid tumor
- Ovarian
- Same list as on Pre-TED

Malignant hematologic disorder
- Acute lymphoblastic leukemia (ALL)
- Acute myelogenous leukemia (AML)
- Chronic lymphocytic leukemia
- Same list as on Pre-TED

Non-malignant hematologic disorder
- Same list as on Pre-TED
Non-HCT Cellular Therapy
Indications

- **Infection**
  - Viral or fungal

- **B cell lymphoproliferative disorder**
  - PTLD, EBV lymphoma

- **Vaccine trials**

- **Immunomodulatory trials**
Questions