Cumda	WMDA Criteria and Process for Transplant Center Evaluation			
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WMDA Criteria and Process for Transplant Center Evaluation

INTRODUCTION and INTENT

The WMDA Registries Operation & Regulation Committee has set forth criteria and a process for evaluation of Transplant Centers (TC) that want to directly access the WMDA Search & Match Service. The criteria and evaluation process are intended to identify TCs with appropriate experience and infrastructure to pursue hematopoietic stem cell transplantation (HSCT) of an unrelated donor hematopoietic stem cell (HSC) product or cord blood unit. In addition, per WMDA Standard 1.07, the evaluation process also serves to ensure that transplant center processes comply with the relevant requirements from the WMDA Standards.

CONDITIONS for EVALUATION

A Transplant Center does <u>not</u> need to be evaluated for WMDA Search & Match Service access if the following apply:

- TC is currently affiliated/has a written agreement with a registry qualified or accredited by WMDA
- > TC is currently accredited by FACT-JACIE

The WMDA criteria may also be used by a registry to evaluate a TC under one or more of the following situations:

- > TC is located in a country without a registry
- TC is located in a country with a registry that does not have its own criteria for evaluating transplant centers
- > TC is not affiliated with a registry qualified or accredited by WMDA
- > TC is not evaluated according to WMDA Standard 1.07.1

INITIATION of EVALUATION PROCESS

Evaluation of a TC may be initiated by a TC's request to a donor registry, or by the WMDA office. The purpose and general process for each is outlined below.

1. WMDA office

<u>Purpose</u>: to evaluate and approve TCs for new or continuing access to WMDA Search & Match Service

Process:

- TC contacts WMDA to request access to WMDA Search & Match Service
- WMDA requests TC to complete and submit evaluation form;
- WMDA convenes review panel and determines decision of approval or denial within five business days;
- WMDA notifies TC of decision
 - If approved, WMDA posts name of TC and completed form on WMDA member-only website
 - \circ $\:$ If approved, WMDA provides TC access to WMDA Search & Match Service $\:$
 - If denied, WMDA issues TC a standard response which includes review checklist that indicates areas that do not meet criteria. TC can reapply at a later point in time.

- If denied, WMDA will post denial on WMDA member-only website.
- 2. DONOR REGISTRY

<u>Purpose</u>: to evaluate and approve TCs that wish to search their registry (in same country as TC or other country)

Process:

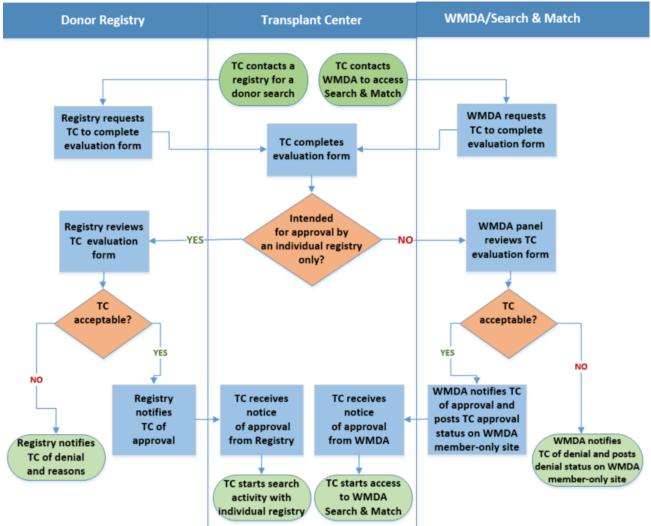
- TC contacts registry to run an unrelated cord blood unit or donor search
- Registry requests TC to complete and submit evaluation form back to registry;
- Registry reviews and determines approval;
 - \circ $\;$ If approved, registry notifies TC in writing and proceeds with search activity.
 - If denied, the TC will be provided with reasons and be given the chance to reapply at a later point in time.

WMDA CRITERIA for EVALUATION

- 1. TC must use patient treatment areas (both inpatient and outpatient/clinic areas) that minimize the risk of infection.
- 2. TC must be appropriately registered, licensed, or accredited by its national government (if applicable) and/or other agency relevant to HSCT.
- TC's overall survival rate for patients (both adult and pediatric as applicable) should be
 <u>></u> 50% at
 one year after allogeneic transplantation;
- 4. TC Medical Director must have at least two years of allogeneic HSCT experience, including at least one year of experience with unrelated donor transplantation, in his/her career. TC must provide a curriculum vitae of the Medical Director(s) that will be stored only for the duration of the review process.
- 5. TC must have at least one additional physician that has a minimum of one year of allogeneic HSCT experience.
- 6. TC must provide physician coverage 24 hours per day, seven days per week.
- 7. TC must have a transplant team that includes nurses with training and experience in the care of transplant patients.
- 8. TC must have a coordinator or other key personnel proficient in English and available to provide daily and emergency communication.
- 9. TC must have support from an HLA laboratory that is accredited by an established accrediting agency.
- 10. TC must have support from an IDM laboratory that is accredited by an established national agency.
- 11. TC must have support from a stem cell processing laboratory that is accredited by an established national agency and has the capability to perform product testing functions.
- 12. TC should identify a specific outcome registry to which they report patient outcomes.
- 13. TC must adhere to applicable WMDA Standards.
- 14. TC must have a policy regarding research studies and information to the registry.
- 15. TC must have a policy outlining diagnostic indications acceptable for unrelated HSCT.
- 16. TC must have a policy for an acceptable level of HLA matching between patient and donor for purpose of unrelated HSCT.
- 17. TC must have a policy for reporting serious adverse events.
- 18. TC must have a policy for protecting donor and patient confidentiality.
- 19. TC should have proof of insurance for professional and general liability.
- 20. TC must provide an empty copy of the patient informed consent used for unrelated donor searches.

On a case-by-case basis, the WMDA or Registry may, in its' discretion, approve deviations from these criteria upon demonstration by the TC of extenuating circumstances.

Figure 1. EVALUATION PROCESS FLOWCHART



WMDA Transplant Center Evaluation Process

MATERIALS FOR WMDA CRITERIA and EVALUATION OF TRANSPLANT CENTERS

- > WMDA Criteria and Process for Transplant Center Evaluation (this document)
- WMDA Transplant Center Evaluation Form
- WMDA Transplant Center Reviewer Checklist
- WMDA Standards

QUESTIONS?

Please contact the WMDA Office: mail@wmda.info