



AGNIS Certification for Forms

Version 1.1

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Document Revision History

| Date | Description | Version |
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| 2014-08-20 | Draft | 0.1 |
| 2014-09-29 | Initial release | 1.0 |
| 2014-09-29 | Added Criteria for 2804r5 and 2814r1 | 1.1 |
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1. Overview

AGNIS® users who wish to submit forms through AGNIS to the FormsNet database must demonstrate successful submission in a test environment prior to being certified for production submission of the form. Each form has its own particular criteria for what constitutes successful test submission, but for all forms successful submission means submitting a form to completion without any errors remaining.

2. Successful Form Submission Criteria

2.1 Form 2804 – Unique ID

| Certification Tasks | Reviewed by: | Date: |
|--|--------------|-------|
| Demonstrate successful creation of a CRID with no matches. | | |
| Demonstrate successful creation of a CRID with a fuzzy match. | | |
| Demonstrate successful processing of Registry ID module with multiple instances. | | |
| Demonstrate successful update submission with delete flag and new value. | | |

2.2 Form 2814 – Indication for CRID Assignment

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful initial submission for at least 2 different indications. | | |
| Demonstrate successful update submission with delete flag and new value. | | |

2.3 Form 2400 – Pre-Transplant Essential Data

| Certification Tasks | Reviewed by: | Date: |
|--|--|-------|
| Demonstrate successful processing of at least all of the following six primary diseases: AML or ANL, ALL, CML, MDS/MPN, Hodgkin Lymphoma and Non-Hodgkin Lymphoma. | | |
| Demonstrate successful processing of a preparative regimen. | | |
| Demonstrate successful processing of a comorbid condition. | | |
| Demonstrate successful processing of at least one of the modules where answers can appear multiple times (e.g. 2400R4: Race, Clinical Trials, or Donor Information). | General requirements for all form submission | |
| Demonstrate successful processing of a non-normalized module. | General criteria | |
| Demonstrate successful processing of a normalized module. | General criteria | |
| Demonstrate successful processing to TED track. | | |
| Demonstrate successful processing to CRF track. | | |

| | | |
|--|------------------|--|
| Demonstrate successful processing of an updated submission with delete flag and new value. | General criteria | |
|--|------------------|--|

2.4 Form 2000 – Recipient Baseline Data

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing of a fungal infection. | | |
| Demonstrate successful processing of a preparative regimen. | | |

2.5 Form 2004 – Infectious Disease Markers

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing for both scheduled and unscheduled forms. | | |
| Demonstrate successful processing for at least 2 testing targets. (Q1) | | |

2.6 Form 2005 – Confirmation of HLA Typing

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing for both scheduled and unscheduled forms. | | |
| Demonstrate successful processing for at least 2 typing targets. | | |

2.7 Form 2006 – HCT Infusion

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing of NMDP Donor, Non-NMDP Donor and Auto. (Q1 Specify donor). | | |
| Demonstrate successful processing of a form where the donor received a pre-collection therapy (Q: "Did the donor receive therapy, prior to any stem cell harvest, to enhance the product collection for this HCT?"). This will require that you pick the donor types non-NMDP product and auto. | | |

2.8 Form 2018 – Hodgkin and Non-Hodgkin Lymphoma Pre-HCT Data

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful process of a form where a transformation occurred. | | |
| Demonstrate successful processing for at least 2 different transplants. | | |

2.9 Form 2100 – 100 Days Post-HSCT Follow-Up

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing for at least 2 different transplants. | | |
| Demonstrate successful processing of form where Q6 (Specify the recipient's survival status at the data of actual contact:) is answered Dead. | | |

2.10\Form 2118 – Hodgkin and Non-Hodgkin Lymphoma Post-HCT Data

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing for at least 2 visits and at least 2 transplants. | | |

2.11 Form 2200 – Six Months to Two Years Post-HSCT Data

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing for at least 2 visits and 2 transplants. | | |
| Demonstrate successful processing of form where Q3 (Specify the recipient's survival status at the date of actual contact:) is answered Dead. | | |

2.12 Form 2300 – Yearly Follow-Up for Greater Than 2 Years Post-HSCT Data

| Certification Tasks | Reviewed by: | Date: |
|--|--------------|-------|
| Demonstrate successful processing for at least 2 visits and 2 transplants. | | |
| Demonstrate successful processing of form where Q4 (Specify the recipient's survival status at the date of actual contact) is answered Dead. | | |

2.13 Form 2450 – Post-Transplant Essential Data

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing of form for at least the three visits: 100 day, 6 months, 1 st annual. | | |
| Demonstrate successful processing of a form where Q19 (Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear that is different from the disease for which the HSCT was performed?) is answered yes. | | |
| Based off the primary diseases selected on 2400, demonstrate successful processing of non-malignant disease section and malignant disease section. | | |

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| Demonstrate successful processing of form where Q62 (Survival status at latest follow-up:) is answered deceased. | | |
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2.14 Form 2451 – Chimerism Studies

| Certification Tasks | Reviewed by: | Date: |
|--|--------------|-------|
| Demonstrate successful processing for at least 2 visits and 2 transplants. | | |
| Demonstrate successful processing of multiple cord product. | | |

2.15 Form 2455 – Selective Post-Transplant Essential Data

| Certification Tasks | Reviewed by: | Date: |
|--|--------------|-------|
| Demonstrate successful processing for at least 2 visits and 2 transplants. | | |

2.16 Form 2900 – Recipient Death Data

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful processing for at least 2 different transplants. | | |
| Demonstrate successful processing for both scheduled and unscheduled forms. | | |

3. Successful Form Retrieval Criteria

| Certification Tasks | Reviewed by: | Date: |
|---|--------------|-------|
| Demonstrate successful retrieval for all completed forms. | | |
| Demonstrate successful acknowledgement of retrievals. | | |
| Demonstrate successful retrieval for at least 2 different sequence numbers. | | |