



AGNIS Certification for Forms

Version 1.4

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Document Revision History

Date	Description	Version
2014-08-20	Draft	0.1
2014-09-29	Initial release	1.0
2017-07-13	Update and removal of Form certification tasks	1.3
2017-10-03	Updated All Pre/Post HCT Data Disease Inserts sections	1.4
2019-07-08	Update to include Cellular Therapy forms	1.5

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 General submission guidelines for all forms:

Certification Tasks	Reviewed by:	Date:
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).		
Demonstrate successful processing of a non-normalized module.		
Demonstrate successful processing of a normalized module.		
Demonstrate successful processing of an updated submission with delete flag and new value.		
*Demonstrate successful processing of at least one question that is "check all that apply" (e.g. 2402R2: AML cytogenetics).		
Demonstration of successful processing of at least 2 different transplants.		

*Only select forms contain this functionality.

2.2 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 a CRID request with a perfect match.		

2.3 Form 2814 – Indication for CRID assignment

Certification Tasks	Reviewed by:	Date:
Demonstrate successful updating of event date.		
Demonstrate successful processing of HCT indication and one other indication.		

2.4 Form 2400 – Pre-Transplant Essential Data

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing of a preparative regimen.		
Demonstrate successful processing of a comorbid condition.		

2.5 Form 2402 – Disease Classification

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing of at least one malignant and one non-malignant disease.		

2.6 Form 2000 – Recipient Baseline Data

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

2.7 Form 2004 – Infectious Disease Markers

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

2.8 Form 2005 – Confirmation of HLA Typing

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

2.9 Form 2006 – HCT Infusion

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing of NMDP Donor, Non-NMDP Donor and Auto (Q1 Specify donor).		

2.10 Form 2010, 2011, 2014, 2016 & 2018 – All Pre-HCT Data Disease Inserts

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing.		

2.11 Form 2110, 2111, 2114, 2116 & 2118 – All Post-HCT Data Disease Inserts

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing for at least 2 visits IDs.		

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

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing of 100 day		
Demonstrate successful processing of at least the 6-month, 1 year or 2 year visit ID.		
Demonstrate successful processing of the 3 year or greater visit ID.		
Demonstrate successful processing of form where Q2 (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-month, 1 st annual.		
Demonstrate successful processing of a form where Q48 (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 2402, demonstrate successful processing of non-malignant disease section and malignant disease section.		
Demonstrate successful processing of form where Q2 (Survival status at latest follow-up:) is answered Dead.		
Demonstrate successful processing of chimerism section for multiple cord products.		

2.14 Form 2900 – Recipient Death Data

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing for both scheduled and unscheduled submissions.		

2.15 Form 4000 – Pre-Cellular Therapy Essential Data

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing when triggered by both completion of 2814 indicating CT, and indicating CT on the 2450r4 or 2100r4.		
Demonstrate successful submission of more than 1 product reported so the appropriate 4003 forms come due.		

2.16 Form 4003 – Cellular Therapy Product

Certification Tasks	Reviewed by:	Date:
Demonstrate successful submission of more than 1 infusion reported so the 4006 forms come due.		
Demonstrate successful submission of 4003 with 1 product.		
Demonstrate successful submission of 4003 with 2 or more products.		

2.17 Form 4006 – Cellular Therapy Infusion

Certification Tasks	Reviewed by:	Date:
Demonstrate successful submission of single infusion of a single product.		
Demonstrate successful submission of single infusion with 2 products.		
Demonstrate successful submission of multiple (2+) infusions of a single product.		

2.18 Form 4100 – Cellular Therapy Essential Data Follow-Up Form

Certification Tasks	Reviewed by:	Date:
Demonstrate successful processing of 100 day		
Demonstrate successful processing of at least the 6-month, 1 year or 2 year visit ID.		
Demonstrate successful processing of the 3 year or greater visit ID.		
Demonstrate successful processing of form where Q3 (Specify the recipient's survival status at the date of actual contact:) is answered Dead.		

3. Successful Form Retrieval Criteria

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