# 2118: LYM Post-HCT

This form must be completed for all recipients whose primary disease, reported on the Pre-TED Disease Classification Form (Form 2402) is Hodgkin Lymphoma (HL). This form should also be completed for all recipients whose primary disease, reported on Form 2400, question 357, is non-Hodgkin Lymphoma (NHL), with the exception of Waldenstrom macroglobulinemia (MAC). The Hodgkin and Non-Hodgkin Lymphoma Post-HCT Data (Form 2118) must be completed in conjunction with each Post-HCT follow-up form completed (Forms 2100, 2200, and 2300). This form is designed to capture specific data occurring within the timeframe of each reporting period (i.e., between day 0 and day 100; between day 100 and the sixmonth date of contact; between six-month follow-up and the date of contact for the one-year follow-up, etc.).

Q1-9: Disease Assessment at the Time of Best Response Q10-24: Post-HCT Therapy Q25-54: Disease Relapse or Progression Post-HCT Q55-65: Disease Status at the Time of Evaluation for this Reporting Period

#### Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

Date	Manual Section	Add/ Remove/ Modify	Description
2/ 24/ 17	Comprehensive Disease- Specific Manuals	Modify	Updated explanations of triggers for disease inserts to refer to the primary disease reported on the Pre-TED Disease Classification Form (Form 2402) instead of the Pre-TED Form (Form 2400)
3/ 31/ 16	2118: LYM Post-HCT	Add	Added informational box for <u>questions 35-36</u> : Questions 35 and 36 are meant to refer to the PET or PET/CT scan at relapse.
6/ 12/ 15	2118: LYM Post-HCT	Add	Added instruction for <b>METHOD</b> and <b>DATE</b> reporting in the <u>Q55-65</u> : <u>Disease</u> <u>Status at the Time of Evaluation for this Reporting Period</u> section. <i>See text</i> <i>for full detail.</i>

# Q1-9: Disease Assessment at the Time of Best Response

Best response is based on response to the HCT, but does not include response to any therapy given for disease relapse or progression post-HCT. When determining the best response to HCT, compare the post-HCT disease status to the status immediately prior to the preparative regimen, regardless of the amount of time since the HCT. This comparison is meant to capture the BEST disease status in response to HCT that occurred in the reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous reporting interval, confirm the best response and indicate that the date was previously reported (Question 3).

# Question 1: Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report?

The intent of this question is to determine the best overall response to HCT. This is assessed in each reporting period. When evaluating the best response, determine the disease status within the reporting period and compare it to all previous post-HCT reporting periods. If the response in the current reporting period is the best response to date, report the disease status established within this reporting period. If a better response was established in a previous reporting period, report the date of the previously established disease status. Use question 2 to indicate that this disease status was previously reported.

See Lymphoma Response Criteria for disease status definitions.

# A Only report the best response to HCT from all reporting periods. See examples below.

**Example 1.** If a recipient with lymphoma goes to transplant having established a PR prior to transplant, achieved a CR during the first 100 days, and then relapses during the six-month reporting period, the best response to transplant should be reported as "CR" on all subsequent forms. See below:

<b>Reporting Period</b>	Disease Status	Q1. Best Response to HCT	Q2-3. Date Best Response Began
Pre-transplant	PR	_	_
100-days Post-HCT	CR	CR	[date of scan]
6-Months Post-HCT	Relapsed	CR	Previously Reported
1-Year Post-HCT	PR	CR	Previously Reported

**Example 2.** A recipient with lymphoma goes to transplant having established a CR prior to transplant and maintains the response after transplant, then relapses within the six-month reporting period. The best response to transplant would be reported as "CCR" for all subsequent reporting periods. See below:

Reporting Period	Disease Status	Q1. Best Response to HCT	Q2-3. Date Best Response Began
Pre-transplant	CR	-	-
100-days Post-HCT	CR	CCR	[date of scan that first confirmed continued CR]
6-Months Post-HCT	Relapsed	CCR	Previously Reported
1-Year Post-HCT	PR	CCR	Previously Reported

**Example 3.** A recipient with lymphoma goes to transplant having established a PR prior to transplant and maintains the response throughout the 100-day reporting period. During the six-month reporting period, the recipient progresses and begins unplanned therapy to treat the worsening disease. During the 1-year reporting period, the recipient achieves another CR. The best response to transplant occurred during the 100-day reporting period because response to unplanned therapy is not captured using this set of questions. See below:

Reporting Period	Disease Status	Q1. Best Response to HCT	Q2-3. Date Best Response Began
Pre-transplant	PR	-	-
100-days Post-HCT	PR	PR	[date of scan that first confirmed continued PR]
6-Months Post-HCT	Relapsed	PR	Previously Reported
1-Year Post-HCT	CR	PR	Previously Reported

Include response to any post-HCT treatment planned as of Day 0. If post-transplant therapy is given as prophylaxis or maintenance for recipients in CR or as preemptive therapy for recipients with minimal residual disease, consider this "planned therapy," even if it was not documented prior to the transplant.

# Do not include any treatment administered as a result of relapse or progression.

#### Question 2: Was the date of best response previously reported?

Indicate if the best response was reported on a previous post-HCT lymphoma form (Form 2118). If "yes," continue with question 10. If "no," continue with question 3.

If the best response is the same as the pre-transplant disease status, select "no" and report the date of the first assessment that confirmed the ongoing disease status post-HCT in question 3.

#### **Question 3: Date the best response first began:**

Enter the date the best response began. Report the date the CT, MRI, PET, or PET/CT scan was obtained.

If the best response is the same as the pre-transplant disease status, report the date of the first radiological assessment that confirmed the ongoing disease status or "previously reported" if the date was already reported on a previous form. See examples 2 and 3 above.

#### Question 4: Was the disease status assessed by molecular testing (e.g., PCR)?

Molecular assessment involves testing blood or bone marrow for the presence of known molecular markers associated with the recipient's disease. Molecular assessment is the most sensitive method of detection, and can indicate known genetic abnormalities (e.g., immunoglobulin (Ig) or T-cell receptor gene rearrangements, or other specific lymphoma gene rearrangements). PCR testing is an example of a molecular test method.

If molecular testing was performed at the time of the best response to HCT, indicate "yes" and continue with question 5.

If molecular testing was not performed, indicate "no" and continue with question 8.

#### **Question 5: Date assessed:**

If molecular evaluations were performed at the time of best response, report the date the sample was collected for molecular testing.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions, Guidelines for Completing Forms</u>.

#### Question 6: Was disease detected?

If a molecular marker associated with the recipient's disease was detected at the time of best response, indicate "yes" and continue with question 7. See Table 3 for common molecular markers associated with different lymphomas.

If no molecular marker associated with the recipient's disease was identified, indicate "no" and continue with question 8.

Oncogene	Protein	Translocation	Disease
BCL-1	Cyclin D <sub>1</sub>	t(11;14)	MCL
BCL-2	BCL-2 (anti apoptosis)	t(14;18)	FL, some DLBCL
BCL-3	NF-kB inhibitor	t(11;19)	CLL
MYC	Transcription factor	t(8;14)	Burkitt's Lymphoma
BCL-6	Zinc-finger transcription factor	t(3;14)	DLBCL (some follicular NHL)

## Table 1. Examples of Molecular Markers<sup>1</sup>

<sup>1</sup> National Comprehensive Cancer Network. *Practice Guidelines in Oncology*. v1. 2006

## Question 7: Was the status considered a relapse?

If there was evidence of disease, indicate if the status was considered a molecular relapse. Molecular relapse is the recurrence of an abnormal molecular marker or evidence of a new molecular marker that (in the physician's judgment) is compatible with the recipient's disease. Molecular relapse does not mean that the recipient also had a hematologic relapse (see Lymphoma Response Criteria for clinical/hematologic progressive disease criteria).

# Question 8: Was a PET (or PET/CT) scan performed?

Positron Emission Tomography (PET) is a type of nuclear medicine imaging in which a patient receives a small amount of radioactively labeled sugar. Because cancer cells absorb sugar more avidly than other cells of the body, the radioactively labeled sugar accumulates in these areas and reveals tumors as bright spots. A PET/CT combines the results of the PET scan along with the results of a CT (computed tomography) scan.

If a PET or PET/CT scan was performed at the time of best response to HCT, indicate "yes" and continue with question 9.

If a PET or PET/CT scan was not performed, indicate "no" and continue with question 10.

## Question 9: Was the PET (or PET/CT) scan positive for lymphoma involvement at any disease site?

Indicate "yes" if the PET (or PET/CT) scan showed areas of avid uptake consistent with tumor (i.e., lymphoma). Indicate "no" if the PET or (PET/CT) scan did not show areas of avid uptake consistent with tumor.

# Q10-24: Post-HCT Therapy

# Question 10: Was therapy given since the date of the last report for reasons other than relapse or progressive disease?

Indicate if the recipient received planned treatment post-HCT since the date of last report. If "yes," continue with question 11. If "no," continue with question 25.

Recipients are generally transplanted under a specific protocol that defines the radiation and/or systemic therapy the recipient is intended to receive as a preparative regimen prior to the HCT; infection and GVHD prophylaxis to be administered pre and/or post HCT; and any systemic therapy, radiation, and/or other treatments to be administered post HCT as planned (or maintenance) therapy. Planned (maintenance or consolidation) therapy is given to assist in prolonging a remission. This protocol may be either a research protocol or standard-of-care protocol and should be referred to when completing this section.

Additionally, if post-transplant therapy is given as prophylaxis or maintenance for recipients in CR or as preemptive therapy for recipients with minimal residual disease, consider this "planned therapy," even if this was not documented prior to the transplant. Do not include any treatment administered as a result of relapse or progression.

#### **Question 11: Systemic therapy**

Indicate if chemotherapy was given as planned treatment post-HCT since the date of the last report. If chemotherapy was not given as planned therapy, then indicate "no" and continue with question 18.

Post-transplant therapy given as prophylaxis or maintenance for recipients in CR or as preemptive therapy for recipients with minimal residual disease should be reported here, even if this was not documented prior to transplant. For example, if a physician decides to put the recipient on bortezomib and vorinostat maintenance therapy post-HCT, even if it the intent was not documented prior to transplant, report it here.

Do **not** report chemotherapy given for relapse or progressive disease.

#### **Questions 12-17: Specify therapy given:**

Treatments vary based on protocol and in most cases are administered in the outpatient setting. A treatment may consist of a single drug or a combination of drugs. Additionally, the drugs may be administered on one day, over consecutive days, or continuously. For the line of therapy being reported, indicate "yes" or "no" for each chemotherapy treatment drug administered. Do not leave any responses blank. If the recipient

received a treatment that is not listed, check "yes" for "other systemic therapy" and specify the treatment in question 17. Report the generic name of the agent, not the brand name.

## **Question 18: Radiation therapy:**

Radiation therapy uses high-energy radiation to kill cancer cells. For lymphoma, external-beam radiation is the type used most frequently. In this method, a beam of radiation is delivered to a specific part of the body such as the mediastinum. Radiation may be planned if bulky disease (having a large lymph node mass) was present just prior to transplant.

Indicate if the recipient received radiation as planned therapy post transplant since the date of the last report. If "yes," continue with question 19. If "no," continue with question 22.

#### **Questions 19-21: Specify radiation site(s):**

Indicate if the mediastinum or other site received radiation treatment. If "other site," specify area on question 21.

#### **Question 22: Surgery:**

Surgery may be planned post transplant to remove bulky disease. Indicate if surgery was done post-HCT as planned therapy. Indicate "yes" or "no" and continue with question 23.

#### Questions 23-24: Other therapy:

Indicate if a treatment not already listed was given as post-transplant planned therapy. If "yes," indicate the other therapy in question 24. If "no," continue with question 25.

# Q25-54: Disease Relapse or Progression Post-HCT

#### Question 25: Was a disease relapse or progression detected by molecular testing (e.g., PCR)?

Molecular assessment involves testing blood or bone marrow for the presence of known molecular markers associated with the recipient's disease. Molecular assessment is the most sensitive method of detection, and can indicate known genetic abnormalities (e.g., immunoglobulin (Ig) or T-cell receptor gene rearrangements, or other specific lymphoma gene rearrangements). PCR testing is an example of a molecular test method.

If molecular testing found evidence of molecular relapse or progression, indicate "yes" and continue with question 26.

If a molecular assessment was performed and found no evidence of molecular relapse or progression, or if molecular assessments were not performed, indicate "no" and continue with question 27.

#### **Question 26: Date assessed:**

Enter the date that the sample was collected for molecular assessment. If multiple molecular assessments were performed during the reporting period, report the first molecular assessment that detected relapse or progression.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions, Guidelines for Completing Forms</u>.

# Question 27: Was a disease relapse or progression detected by cytogenetic testing (conventional or FISH)?

Cytogenetic assessment involves testing blood or bone marrow for the presence of known chromosomal abnormalities that reflect the recipient's disease. FISH is categorized with cytogenetics. Although often used for finding specific features in DNA, FISH is not as sensitive as molecular methods, even though the markers identified may be the same. For more information about cytogenetic testing and terminology, see <u>Appendix C</u>.

FISH testing for sex chromosomes after sex-mismatched allogeneic HCT should not be considered disease assessment, because the purpose is to determine donor chimerism.

If cytogenetic testing found evidence of cytogenetic relapse or progression, indicate "yes" and continue with question 28.

If cytogenetic testing was performed and found no evidence of cytogenetic relapse or progression, or if cytogenetic testing was not performed, indicate "no" and continue with question 32.

#### Question 28: Was a disease relapse or progression detected via FISH?

FISH uses special probes that recognize and bind to fragments of DNA that may be found in lymphomas. These probes are mixed with cells from the recipient's blood. A fluorescent "tag" is then used to visualize the binding of the probe to the disease cells. FISH is capable of detecting disease in 1 in 1,000 cells. Examples include t(11;14) or t(14;18).

Indicate if the relapse or progression was detected via FISH. If "yes," continue with question 29.

If FISH testing was performed and found no evidence of FISH relapse or progression, or if FISH testing was not performed, indicate "no" and continue with question 29.

## **Question 29: Date assessed:**

Enter the date that the sample was collected for FISH assessment. If multiple assessments were performed during the reporting period, report the first assessment that detected relapse or progression.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions</u>, <u>Guidelines for Completing Forms</u>.

#### Question 30: Was a disease relapse or progression detected via conventional cytogenetics?

Conventional cytogenetics are performed by culturing cells (growing cells under controlled conditions) until they reach the dividing phase. Techniques are then performed to visualize the chromosomes during cell division so that various bands and reconfigurations can be seen. This is called karyotyping. Banding pattern differentiation and chromosomal reconfiguration demonstrate evidence of disease.

Indicate if the relapse or progression was detected via conventional cytogenetics. If "yes," continue with question 31.

If conventional cytogenetic testing was performed and found no evidence of cytogenetic relapse or progression, or if cytogenetic testing was not performed, indicate "no" and continue with question 32.

#### **Question 31: Date assessed:**

Enter the date that the sample was collected for conventional cytogenetic assessment. If multiple assessments were performed during the reporting period, report the first assessment that detected relapse or progression.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions, Guidelines for Completing Forms</u>.

#### Question 32: Was a disease relapse or progression detected by clinical/hematologic assessment?

Clinical/hematologic methods used to evaluate disease relapse or progression for HL/NHL include radiological assessments (e.g., CT, MRI, PET, or PET/CT scans) or a physician's clinical evaluation (i.e., physical exam at an office visit).

Indicate if the relapse or progression was detected via clinical/hematologic assessment. If "yes," continue with question 33.

If a clinical/hematologic assessment found no evidence of relapse or progression, indicate "no" and continue with question 55.

#### **Question 33: Date detected:**

Enter the date of the clinical/hematologic disease assessment that documented disease relapse or progression. Report the date disease was detected by radiographic examination (e.g., CT, MRI, PET, or PET/CT scans). If a radiographic assessment was not performed, report the date of the office visit at which the physician clinically documented the disease relapse or progression.

For more information regarding reporting partial or unknown dates, see <u>General Instructions</u>, <u>Guidelines for</u> <u>Completing Forms</u>.

#### Question 34: Was a PET (or PET/CT) scan performed?

Positron Emission Tomography (PET) is a type of nuclear medicine imaging in which a patient receives a small amount of radioactively labeled sugar. Because cancer cells absorb sugar more avidly than other cells of the body, the radioactive labeled sugar accumulates in these areas revealing tumors as bright spots. If a PET or (PET/CT) scan was performed at the time of relapse, indicate "yes" and continue with question 35. If a PET scan was not performed, indicate "no" and continue with question 38.

### Question 35: Date of most recent PET (or PET/CT) scan:

Questions 35 and 36 are meant to refer to the PET or PET/CT scan at relapse.

Enter the date of the PET or PET/CT scan.

For more information regarding reporting partial or unknown dates, see <u>General Instructions</u>, <u>Guidelines for</u> <u>Completing Forms</u>.

#### Question 36: Results of most recent PET (or PET/CT) scan:

Indicate "positive" if the PET (or PET/CT) scan showed areas of avid uptake consistent with tumor (i.e., lymphoma). Indicate "negative" if the PET or (PET/CT) scan did not show areas of avid uptake consistent with tumor. Indicate "indeterminate" if, after review by a physician, the results of the test could not be interpreted as absence of disease.

#### Question 37: Was the positive result considered a disease recurrence or progression?

A relapse is defined as the recurrence of disease following CR. A progression is defined as any new lesion or increase of > 50% of previously involved sites from nadir. For patients with liver or spleen involvement, criteria for progression also include > 50% increase from nadir of any previous lesions.

Indicate "yes" if the positive results were considered a disease recurrence or progression (rather than stable disease). Indicate "no" if the positive results did not meet the criteria for relapse or progression.

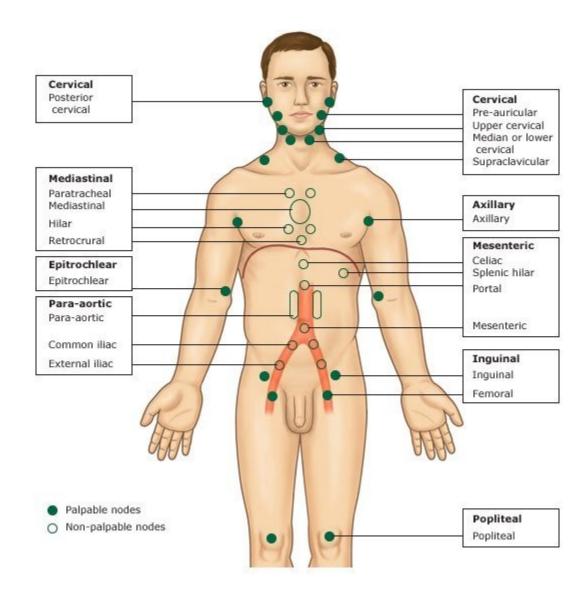
#### Question 38: Did the recipient have known nodal involvement?

Refer to <u>Graphic 1</u> below for identification of nodal areas. Nodal involvement may be assessed by a physician palpating lymph nodes, pathology from a lymph node biopsy, or radiological assessment (e.g., PET or CT imaging).

If evidence of nodal involvement was indicated at relapse or progression, select "yes," and continue with Question 39.

If there was no evidence of nodal involvement upon assessment, select "no," and continue with Question 40.

#### Graphic 1. Nodal Areas<sup>1</sup>



<sup>1</sup> "Lymphadenopathy." Web log post. *Horses and Zebras*. Morning Report at Toronto General Hospital, 20 July 2010. Accessed on 9/22/2013 at <u>http://morningreporttgh.blogspot.com/2010/07/lymphadenopathy.html</u>

#### Question 39: Specify the total number of nodal regions involved:

Lymph node regions or groups occur above and below the diaphragm. Nodal regions include cervical (neck), axillary (underarm), mediastinal (thoracic), mesenteric (abdominal), para-aortic (pelvic), inguinal (groin), epitrochlear (inside of arm just above elbow), and popliteal (back of knee). Refer to Graphic 1 for specific nodes within each nodal region. Indicate the total number of nodal regions with evidence of lymphoma involvement. Report "one nodal region," "two or more nodal regions," or "unknown."

#### Question 40: Was there any known extranodal or splenic involvement?

Extranodal refers to the presentation of lymphoma outside of the lymph nodes. Common areas of extranodal involvement may include bone, gastrointestinal tract, and skin. Splenic involvement in lymphoma is also common. It is usually evidenced by enlargement of the spleen (splenomegaly). Splenic or other extranodal involvement is most often detected by imaging techniques or pathological findings.

If extranodal or splenic involvement was identified at relapse or progression, indicate "yes" and continue with question 41.

If there was no evidence of extranodal or splenic involvement at relapse or progression, indicate "no" and continue with question 55. If extranodal or splenic involvement was unknown at that time of transformation, indicate "unknown" and continue with question 55.

#### **Questions 41-54: Specify site(s) of involvement:**

Answer each question with "yes" or "no." Do not leave any question unanswered. If "other site(s)" is selected, use question 54 to specify the site.

# Q55-65: Disease Status at the Time of Evaluation for this Reporting Period

Disease Status at Time of Evaluation for this Reporting Period Review the instruction below regarding method and date reporting for this section.

#### METHOD

This section should reflect the recipient's most recent disease assessment. Not all recipients have molecular, cytogenetic, and/or FISH abnormalities identified to monitor disease status. If no disease assessments exist for the applicable method, check "no."

Molecular and cytogenetic assessments may be performed for many reasons post-transplant, including monitoring for secondary malignancy. If the recipient did not have any identified molecular, cytogenetic, or FISH abnormalities at diagnosis or during their pre-transplant course, and post-HCT follow-up assessments continue to show that no abnormalities are detected, report "no" for these assessment data fields. However, if routine post-HCT molecular, cytogenetic, and/or FISH assessments identify a new abnormality associated with the recipient's disease process, begin reporting those assessments; report the assessment identifying the new abnormality, as well as all subsequent assessments for the abnormality by that method.

If the recipient had molecular, cytogenetic, and/or FISH abnormalities prior to transplant, ensure that post-HCT assessments of the applicable method are reported.

**Example:** The recipient has MYC abnormalities identified by PCR (molecular method) testing prior to transplant; however, they had normal FISH studies and karyotyping on all pre-transplant assessments. Post-transplant, MYC molecular studies should be reported; cytogenetic studies would not be reported (answer question 58 as "no") unless the recipient develops abnormalities associated with their disease detectable by FISH or conventional cytogenetics; the study identifying the new abnormalities and all subsequent cytogenetic studies would be reported.

#### DATE

If more than one test in the same assessment category is done on different days, report the date of the most definitive diagnostic assessment within a reasonable time frame of the date of contact (approximately 30 days). If there was only a single assessment performed within the reporting period, it should be reported, even if it was more than 30 days prior to the date of contact.

**Example:** The recipient has a PET study performed, which shows evidence of residual disease. Two weeks later, on the date of contact, they are evaluated by a physician. Report the date of the PET study, since it is the most definitive and diagnostic assessment within approximately 30 days of the date of contact.

## Question 55: Was the disease status assessed by molecular testing (e.g., PCR)?

Molecular assessment involves testing blood or bone marrow for the presence of known molecular markers associated with the recipient's disease. Molecular assessment is the most sensitive method of detection, and can indicate known genetic abnormalities (e.g., immunoglobulin (Ig) or T-cell receptor gene rearrangements, or other specific lymphoma gene rearrangements). PCR testing is an example of a molecular test method.

If molecular testing was performed at the time of evaluation for this reporting period, indicate "yes" and continue with question 56.

If molecular testing was not performed at the time of evaluation for this reporting period, indicate "no" and continue with question 58.

## **Question 56: Date assessed:**

If molecular evaluations were performed at the time of evaluation for this reporting period, report the date the sample was collected for molecular testing.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions</u>, <u>Guidelines for Completing Forms</u>.

#### Question 57: Was disease detected?

If a molecular marker associated with the recipient's disease was detected at the time of evaluation for this reporting period, indicate "yes." See <u>Table 1</u> for common molecular markers associated with different lymphomas.

If no molecular marker associated with the recipient's disease was identified at the time of evaluation for this reporting period, indicate "no" and continue with question 58.

# Question 58: Was the disease status assessed by conventional cytogenetics/FISH?

Cytogenetic assessment involves testing blood or bone marrow for the presence of known cytogenetic abnormalities that reflect the recipient's disease. FISH is categorized with cytogenetics. Although often used

for finding specific features in DNA, FISH is not as sensitive as molecular methods, even though the markers identified may be the same.

FISH testing for sex chromosomes after sex-mismatched allogeneic HST should not be considered disease assessment because the purpose is to determine donor chimerism.

If cytogenetic testing was performed at the time of evaluation for this reporting period, indicate "yes" and continue with question 59.

If cytogenetic testing was not performed at the time of evaluation for this reporting period, indicate "no" and continue with question 61.

#### **Question 59: Date assessed:**

If cytogenetic evaluations were performed at the time of evaluation for this reporting period, report the date the sample was collected for cytogenetic testing.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions, Guidelines for Completing Forms</u>.

## Question 60: Was disease detected?

If cytogenetic abnormalities associated with the recipient's disease were detected at the time of evaluation for this reporting period, indicate "yes."

If no cytogenetic abnormalities associated with the recipient's disease were identified at the time of evaluation for this reporting period indicate "no" and continue with question 61.

# Question 61: Was the disease status assessed by clinical/hematologic assessment?

Clinical/hematologic methods used to evaluate disease relapse or progression for HL/NHL include radiological assessments (e.g., CT, MRI, PET, or PET/CT scans) or a physician's clinical evaluation (i.e., physical exam at an office visit).

If clinical/hematologic testing was performed at the time of evaluation for this reporting period, indicate "yes" and continue with question 62.

If clinical/hematologic testing was not performed at the time of evaluation for this reporting period, indicate "no" and continue with question 64. This option should rarely be used because most recipients will have an office visit with a physical exam.

#### **Question 62: Date assessed:**

Enter the date of the clinical/hematologic disease assessment for this reporting period. Report the date disease was detected by radiographic examination (e.g., CT, MRI, PET, or PET/CT scans). If a radiographic assessment was not performed, report the date of the office visit in which the physician clinically documented the disease relapse or progression.

#### **Question 63: Was disease detected?**

If evidence of disease was detected by clinical/hematologic methods at the time of evaluation for this reporting period, indicate "yes."

If no evidence of disease was detected by clinical/hematologic methods at the time of evaluation for this reporting period, indicate "no."

#### Question 64: What is the current disease status?

Indicate the recipient's current disease status. **See <u>Lymphoma Response Criteria</u> for disease status definitions.** Molecular or cytogenetic evidence of disease should not be considered when answering this question.

#### **Question 65: Date assessed:**

Enter the date of the most recent assessment of disease status for this reporting period. Report the date imaging (CT, MRI, PET, or PET/CT) took place. If no radiographic assessment was performed, report the date of the most recent office visit in which the physician assessed the recipient's disease status.

If the exact date is not known, use the process for reporting partial or unknown dates as described in <u>General Instructions, Guidelines for Completing Forms</u>.