Instructions for Post-Infusion Follow-Up (2100)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Post- Infusion Follow-Up.

Post-Infusion Follow Up

A transplant center designated as a Comprehensive Report Form center will submit data on the Pre-TED and Pre-TED Disease Classification Forms, followed by either the Post-TED Form or the Comprehensive Report Forms. The type of follow-up forms required for a specific recipient is determined by the CIBMTR's form selection algorithm. The Post-Infusion Form (2100) must be completed at the following time points: 100 days, 6 months, annually for 6 years post-HCT, and biennially thereafter. This form should be completed as closely to these time points as possible. The following recipient data should be collected from an actual examination (or other recipient contact) by the transplant center physician or the local physician who is following the recipient post-HCT: vital status, hematopoietic reconstitution post-HCT, neutrophil recovery, platelet recovery, current hematologic findings, immune reconstitution, chimerism studies, engraftment syndrome, acute Graft-versus-Host Disease (GVHD), chronic GVHD, infections, organ function, new malignancy, functional status, and subsequent HCT.

Subsequent Infusion

If the recipient received a subsequent transplant (excluding an autologous rescue), the answers to all questions should reflect the clinical status of the recipient the day prior to the start of the preparative regimen or, if no preparative regimen was given, the answers to all questions should reflect the clinical status of the recipient the day **prior to HCT infusion**

Subsequent HCT

If a recipient receives a subsequent HCT between time points (100 day, 6 months, annually), the CRF form sequence will start over again with another Pre-TED.
However, if the recipient receives an autologous HCT as a result of a poor graft or graft failure, the CRF form sequence will not start over again. Generally, this type of infusion (autologous rescue) is used to treat the recipient's poor graft response, rather than to treat the recipient's disease, and is, therefore, not considered a subsequent HCT for reporting purposes.
Contact CIBMTR Center Support if the subsequent Pre-TED does not come due automatically.

Links to Sections of Form:

Manual Updates:

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

To review the historical Manual Change History for this manual, reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description

Q1 – 3: Vital Status

The date of actual contact with the recipient to determine medical status for this follow-up report is based on a medical evaluation conducted by a clinician with responsibility for the recipient's care. Report the date of the medical evaluation performed closest to the designated time period of the form (e.g., Day+100, 6 months, or annual follow-up visit). Time windows are provided to guide selection of dates for reporting purposes. Recipients are not always seen within the time windows used for reporting follow-up dates, and some discretion is therefore required when determining which date to report. If the recipient is not seen within the time windows, report the date closest to the date of contact within reason.

If the Post-HCT Follow-Up Form reports a subsequent infusion (transplant or cellular therapy), report the date of latest follow-up as the day prior to the start of the preparative regimen / systemic therapy. If no preparative regimen or conditioning / systemic therapy was given, report the day prior to infusion as the date of contact.

No Documentation of Contact Date
The contact date data field cannot be left blank and is required to be reported. In cases where the recipient passed away and there is no documentation to report the date of death, the guidelines for reporting estimated dates must be used

Reporting Latest Follow-Up
When reporting the date of latest follow-up prior to an infusion (HCT or cellular therapy), report the date specified above regardless of whether there is actual patient contact on the date. This is an exception to standard date of follow-up reporting to ensure all dates are captured within the sequence of forms.

Reporting the 1-Yeat Date of Contact
If this form is being completed for the 1-year reporting period, ensure the reported contact date is >Day 365. Review the 1 Year Date of Contact instructions below for additional information.

Combined Follow Up and Contact Date
When both HCT and cell therapy forms are being completed, the date of contact on the Post-Infusion Follow-Up (2100) Form should match the corresponding the Post-CTED (4100) Form.

Question 1: Date of actual contact with the recipient to determine the medical status for this follow-up report

Enter the date of actual contact with recipient to determine medical status for this follow-up report. Acceptable evaluations include those from the transplant center, referring physician, or other physician currently assuming responsibility for the recipient's care. Please capture a physician evaluation that falls within the appropriate range, if possible, rather than other types of patient contact that may be closer to the actual time point. If an evaluation was not performed at Day+100, at 6 months, or on the HCT anniversary, choose the date of the visit closest to the actual time point.

If the recipient has not been seen by a clinician during the reporting period but the survival status is known, complete the Survival Tool referenced in the CIBMTR Data Management Guide.

In general, the date of contact should be reported as close to the 100-day, 6 month, or annual anniversary to transplant as possible. Report the date of actual contact with the recipient to evaluate medical status for the reporting period. In the absence of contact with a clinician, other types of contact may include a documented phone call with the recipient, a laboratory evaluation, or any other documented recipient interaction on the

date reported. If there was no contact on the exact time point, choose the date of contact closest to the actual time point. Below, the guidelines show an ideal approximate range for reporting each post-transplant time point:

Time Point	Approximate Range
100 days	+/- 15 days (Day 85-115)
6 months	+/- 30 days (Day 150-210)
1 year	+ 60 days (Day 366 – 425)
Annual reporting 2+ years	+/- 30 days (Months 23-25, 35-37, etc.)

Recipients are not always seen within the approximate ranges and some discretion is required when determining the date of contact to report. In that case, report the date closest to the date of contact within reason. The examples below assume that efforts were undertaken to retrieve outside medical records from the primary care provider, but source documentation was available.

Date of Contact & Death

In the case of recipient death, the date of death should be reported as the date of contact regardless of the time until the ideal date of contact. The date of death should be reported no matter where the death took place (inpatient at the transplant facility, at an outside hospital, in a hospice setting, or within the recipient's home).

If the death occurred at an outside location and records of death are not available, the dictated date of death within a physician note may be reported. If the progress notes detailing the circumstances of death are available, request these records. These records are useful for completing required follow-up data fields and the cause of death data fields on this form. If the exact date of death is not known, use the processed described for reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Date of Contact & Subsequent Infusion

If the recipient has a subsequent infusion (HCT or cellular therapy), report the date of contact as the day before the preparative regimen / systemic therapy begins for the subsequent infusion. If no preparative regimen / systemic therapy is given, report the date of contact as the day before the subsequent infusion. In these cases, actual contact on that day is **not** required, and the day prior to the initiation of the preparative regimen (or infusion, if no preparative regimen / systemic therapy) should be reported. This allows every day to be covered by a reporting period but prevents overlap between transplant events.

Review the Contact Dates Reporting Instruction Overview for additional information on reporting contact dates for recipient death, subsequent infusions, and various contact date reporting examples.

Specify Survival Status

If the survival status is reported as **Dead**, the Recipient Death Data (2900) form will come due. It is encouraged to complete Recipient Death Data (2900) form along with the Post-Infusion Follow-Up (2100) form, when applicable.

Combined Follow Up and Survival Status
When both HCT and cell therapy forms are being completed, the survival status on the Post-Infusion Follow-Up (2100) Form should match the corresponding the Post-CTED (4100 Form.

Questions 2: Specify the recipient's survival status at the date of last contact.

Indicate the survival status of the recipient on the date of actual contact for follow-up evaluation. If the recipient has died, answers to subsequent questions should reflect the recipient's clinical status between the date of last report and their death. The center must also complete a Recipient Death Data (2900) Form.

Combined Follow Up and Subsequent Infusion
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, subsequent infusions are reported on the Post-Infusion Follow-Up (2100) Form and the question is disabled on the Cellular Therapy Essential Data Follow- Up (4100) Form.

Questions 3: Did the recipient receive a subsequent infusion?

Indicate if the recipient received a subsequent infusion during the reporting period. Subsequent infusions include transplant, cellular therapy, gene therapy, DLI, and 'boost' (autologous or allogeneic).

If **Yes**, complete the Indication for CIBMTR Data Reporting (2814).

For more information on infusion types, review Appendix D: How to Distinguish Infusion Types.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q4 – 10: Granulopoiesis/ Neutrophil Recovery

Granulopoiesis / Neutrophil Recovery
This section can only be completed on the 100-day, 6 month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Combined Follow-Up
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions do not apply and are disabled.

ANC / Platelet Recovery Reporting Overview
Refer to the ANC / Platelet Recovery reporting overview for information on reporting ANC recovery.

Not Applicable and Previously Reported
When **Not applicable** is reported for Day 100 reporting period, select **Previously reported** for all future reporting periods.

Question 4: Was there evidence of initial hematopoietic recovery?

Indicate if there was evidence of *initial* ANC recovery following this HCT.

- **Yes**: ANC ≥ 500/mm^3 (or ≥ 0.5 × 10^9/L) was achieved and sustained for three laboratory values.
- **No**: ANC ≥ 500/mm^3 (or ≥ 0.5 × 10^9/L) was not achieved.
- **Not applicable**: The ANC never dropped below 500/mm^3 (or ≥ 0.5 × 10^9/L) at any time post-infusion. This option is only applicable for the Day 100 reporting period.
- **Previously reported**: This is the six-month or annual follow-up, and the initial hematopoietic recovery was recorded on a previous report.

Question 5: Date ANC ≥ 500/mm^3 *(first of 3 lab values)*

Enter the first date of the three consecutive laboratory values obtained on different days where the ANC was ≥ 500/mm^3 (or ≥ 0.5 × 10^9/L). For an example of tracking ANC recovery, see the Tracking ANC Recovery in the ANC / Platelet Recovery reporting instruction overview.

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

Question 6: Following the initial hematopoietic recovery, was there subsequent decline in ANC to < 500/mm^3 for ≥ 3 days?

Indicate if there was subsequent decline in ANC < 500/mm^3 (or < 0.5 × 10^9/L) (three consecutive laboratory values obtained on different days where the ANC declined to < 500/mm^3.

Multiple Recoveries and Declines
The form does not allow for multiple recoveries and declines in the same reporting period. If the recipient's ANC initially recovers and then declines, followed by another recovery and another decline, report the date of the first (initial) recovery, the first decline, and the last recovery.

Question 7: Date of decline in ANC < 500/mm³ for ≥ 3 days *(first of 3 days that the ANC declined)*

Enter the first date of the three consecutive laboratory values obtained on different days where the ANC declined to < 500/mm³ (or < 0.5 × 10^9/L).

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

Question 8: Did recipient recover and maintain ANC ≥ 500/mm³ following the decline?

Indicate if there was evidence of ANC recovery following the decline (three consecutive laboratory values obtained on different days where the ANC was ≥ 500/mm³ (or ≥ 0.5 × 10^9/L).

Question 9 – 10: Date of ANC recovery

Report if the date of ANC recovery following the decline is **Known**. If the date of recovery is **Known**, enter the first date of the three consecutive laboratory values obtained on different days where the ANC recovered to ≥ 500/mm³ (or ≥ 0.5 × 10^9/L) following the decline. For an example of tracking ANC recovery, see the Tracking ANC Recovery in the ANC / Platelet Recovery reporting instruction overview.

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

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q11 – 14: Megakaryopoiesis / Platelet Recovery

Megakaryopoiesis / Platelet Recovery
The megakaryopoiesis / platelet recovery section can only be completed on the 100 day, 6 month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Combined Follow-Up
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions do not apply and are disabled.

ANC / Platelet Recovery Reporting Overview
Refer to the ANC / Platelet Recovery reporting overview for information on reporting ANC recovery.

Not Applicable and Previously Reported
When **Not applicable** is reported for Day 100 reporting period, select **Previously reported** for all future reporting periods.

Question 11: Was an initial platelet count ≥ 20 × 10^9/L achieved?

Indicate if there was evidence of *initial* platelet recovery following this HCT.

- **Yes**: Platelet count ≥ 20 × 10^9 / L was achieved and sustained for three consecutive laboratory values, obtained on different days without platelet transfusions administered in the previous seven days
- **No**: Platelet count was not ≥ 20 × 10^9 / L or if platelet transfusions were administered in the previous seven days.
- **Not applicable**: The platelets never dropped below 20 × 10^9/L at any time post-infusion *and* a platelet transfusion was never required.
    - If the recipient's platelet count drops below 20 × 10^9/L and/or the recipient received a platelet transfusion even once, do not use this option. This option is only applicable in the Day 100 reporting period.
- **Previously reported**: This is the six-month or annual follow-up, and the initial platelet recovery has already been reported on a previous form.

Reporting Estimated Dates
If a recipient is not seen within a month after their last platelet transfusion, an estimated date may be reported. In this case, the date seven days after the last platelet transfusion may be reported (see example below). However, if the recipient is seen within a month of the last platelet transfusion, an estimated date should not be reported.

Question 12: Date platelets ≥ 20 × 10^9/L

Enter the first date of three consecutive laboratory values obtained on different days where the platelet count was ≥ 20 × 10^9/L. Ensure that no platelet transfusions were administered for seven days immediately preceding this date. Include day seven, as

shown in the Reporting Platelet Recovery example in the ANC / Platelet Recovery reporting overview, when determining the recovery date.

If three laboratory values were not obtained on consecutive days, but a sequential rise of ≥ 20 × 10^9/L is demonstrated, follow the examples below when determining an estimated date.

Reporting Scenarios:

- Example 1: The recipient is being seen in the outpatient clinic and receives a platelet transfusion on January 1. The platelet count is 22 × 10^9/L on January 2, 24 × 109/L on January 3, and 28 × 10^9/L on January 4. The recipient does not come into the clinic for evaluation until one month later. The recipient has not received any more platelet transfusions and the platelet count is well above 20 × 10^9/L. Report January 8 (day seven post-platelet transfusion) for the date of platelet recovery.
- Example 2: The recipient is being seen in the outpatient clinic and receives a platelet transfusion on January 1. The platelet count is ≥ 20 × 10^9/L on January 2, January 3, and January 4. The recipient is then discharged back to their primary care physician. The transplant center receives a follow-up note from the primary care physician that states "recipient recovered their platelets in January of 2023." Report an estimated date of recovery using the guidelines available in General Instructions, General Guidelines for Completing Forms

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

Question 13: Was an initial platelet count ≥ 50 × 10^9/L achieved?

Indicate whether a platelet count of ≥ 50 × 10^9/L was achieved following this HCT.

- **Yes**: Platelet count ≥ 50 × 10^9 / L was achieved and sustained for three consecutive laboratory values, obtained on different days without platelet transfusions administered in the previous seven days
- **No**: Platelet count was not ≥ 50 × 10^9 / L or if platelet transfusions were administered in the previous seven days.
- **Not applicable**: The platelets never dropped below 50 × 10^9/L at any time post-infusion and a platelet transfusion was never required.
    - If the recipient's platelet count drops below 50 × 10^9/L and / or the recipient received a platelet transfusion even once, do not use this option. This option is only applicable in the Day 100 reporting period.
- **Previously reported**: This is the six-month or annual follow-up, and a platelet count of ≥ 50 × 10^9/L was achieved and reported previously.

Question 14: Date platelets ≥ 50 × 10^9/L

Enter the **first** date of three consecutive laboratory values obtained on different days where the platelet count was ≥ 50 × 10^9/L. Ensure that no platelet transfusions were administered for seven days immediately preceding this date. Include day seven, as shown in the Reporting Platelet Recovery example in the ANC / Platelet Recovery reporting overview, when determining the recovery date.

If three laboratory values were not obtained on consecutive days, but a sequential rise of ≥ 50 × 10^9/L is demonstrated, follow the examples included in the instructions above.

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

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q15 – 23: Growth Factor and Cytokine Therapy

Growth Factor and Cytokine Therapy
The Growth Factor and Cytokine Therapy section can only be completed on the 100-day follow-up form. These questions will not be answered for all subsequent reporting periods.

Combined Follow Up and Growth Factor and Cytokine Therapy
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions still apply and should be answered.

Reporting Multiple Growth Factor and Cytokine Therapy
Complete *Specify hematopoietic, lymphoid growth factor or cytokine received* through *Specify other agent* for each hematopoietic, lymphoid growth factor, and / or cytokine administered in this reporting period by adding additional instance(s) in FormsNet3SM.

Questions 15 – 23: Specify hematopoietic, lymphoid growth factor or cytokine received

A growth factor is a substance that stimulates cell growth, differentiation, and proliferation. Cytokines can act as growth factors or have an inhibitory effect on cell growth.

Select all agents given during the reporting period. For each agent administered during the reporting period, report the start date and the reason it was given.

- **G-CSF (granulocyte-colony stimulating factor):** Alternate names: filgrastim, pegfilgrastim, Neupogen, Neulasta, Lenograstim.
- **GM-CSF (granulocyte / macrophage-colony stimulating factor):** Alternate names: sargramostim, Leukine.
- **Erythropoietin (EPO):** Alternate names: Epogen, Procrit, darbepoietin alfa (Aranesp). EPO stimulates red blood cell production. If EPO is given, specify the drug given.
- **Thrombopoietin:** Alternate names: megakaryocyte growth and development factor. A glycoprotein hormone which regulates the production of hormones.
- **KGF (keratinocyte growth factor):** Alternate names: palifermin, Kepivance. KGF acts to stimulate the growth of cells that line the surface of the mouth and intestinal tract. KGF may also be given to treat oral mucositis or as GVHD prophylaxis. Report if administered to stimulate cell growth or to treat oral mucositis. If KGF is administered as GVHD prophylaxis, report in the Acute Graft vs. Host Disease section of this form.
- **Blinded growth factor or cytokine trial:** If the recipient is on a blinded randomized trial, specify the trial agent administered. Additionally, update this form (2100) once the trial is over to specify whether the recipient received the trial drug or placebo.
- **Other agent:** Specify any other hematopoietic growth factor, lymphoid growth factor, or cytokine administered.

If hematopoietic, lymphoid growth factor or cytokine was not administered in the reporting period, select **None received**.

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

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q24 – 33: Current Hematologic Findings

Current Hematologic Findings

Current Hematologic Findings sections can only be completed on the 100 day, 6 month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Combined Follow-Up
In scenarios where a cellular therapy is given after a HCT and this form is being completed based on the subsequent cellular therapy, these questions do not apply and are disabled if there is a corresponding Post-Cellular Therapy Follow-Up (4101) Form.

Questions 24 – 33: Provide the most recent laboratory values recorded

These questions are intended to determine the hematological status of the recipient after the infusion. Testing may be performed multiple times within the reporting period; however, report only the most recent (closest to the contact date) laboratory values. Report the date of the most recent complete blood count and select all hematologic results available. Report the associated laboratory value and unit (if applicable).

For hematocrit, check the box if red blood cells were transfused within 30 days prior to the testing.

For platelets, check the box if platelets were transfused within seven days prior to the testing.

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

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q34 – 49: Immune Reconstitution

Immune Reconstitution
The Immune Reconstitution section can only be completed on the 100-day, 6-month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Combined Follow Up and Immune Reconstitution
In scenarios where a cellular therapy was given after an HCT and this form is now being

completed based on the subsequent cellular therapy date, these questions still apply and should be answered.

These questions are intended to determine whether the recipient recovered their immune function post-HCT. Along with hematopoietic recovery, the infused allogeneic hematopoietic progenitor cells (HPCs) also generate a new immune system. This process may be slowed by immunosuppressants given to prevent GVHD.

Question 34: Select all known immunoglobulin (Ig) values *(check all that apply)*

Antibodies are produced by the immune system in response to foreign substances such as bacteria, viruses, or fungi. There are several types of immunoglobulins; the CIBMTR requests information on IgG, IgM, and IgA.

- **IgG** antibodies are present in all body fluids. They play a key role in fighting bacterial and viral infections.
- **IgA** antibodies are present in the nose, airway, digestive tract, ears, eyes, saliva, tears, and blood. They protect surfaces of the body that are exposed to outside foreign substances.
- **IgM** antibodies are present in blood and lymph fluid. They are the first type of antibody produced by the immune system in response to an infection.

If immunoglobulin testing was performed, select all immunoglobulins (antibodies) tested during the reporting period and answer the subsequent questions as follows. If immunoglobulin testing was not completed during the reporting period, select **No immunoglobulin testing performed**.

Questions 35 – 39: Specify the immunoglobulin values

Report the sample collection date for the immunoglobulin testing and indicate if the sample collection date was used for all immunoglobulin testing.

If immunoglobulin values were assessed on different dates, report the date of the most recent *IgG* test. If the exact collection date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms and select **Date estimated**.

In addition, for each immunoglobulin tested, report the value and specify the units of measurement.

IVIG Given without Immunoglobulin Testing
In some cases, IVIG may be given for low immune function without immunoglobulin testing. The transplant center should verify that IgG levels were not tested at another facility, as it is unusual for IVIG to be given without knowing what the IgG level is. In these cases, **No immunoglobulin testing performed** should be selected for_ Select

all known immunoglobulin values and Were supplemental intravenous immunoglobulins (IVIG) received_ should be answered **Yes**, even though testing was not done

Questions 40 – 41: Were supplemental intravenous immunoglobulins (IVIG) received?

Intravenous immunoglobulin (IVIG) is a substance made from antibodies derived from the blood of a donor. It is administered intravenously to treat autoimmune disorders, infections, or other conditions and can be given to prevent infections in recipients who have received a HCT or organ transplant.

Indicate if the recipient received IVIG within the current reporting period (regardless of if immunoglobulin testing was performed in the reporting period). If **Yes**, report the most recent date when IVIG was received. If the exact administration date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

If the recipient did not receive IVIG in the reporting period or it is unknown if administered, select **No**.

CD19 and CD20 (B lymphocyte cells)
If both CD19 and CD20 lymphocyte values are tested, it is not necessary to report both values. Only one of the two B lymphocyte cell values is required for reporting.

Question 42: Select all known lymphocyte values from the most recent testing *(check all that apply)*

Lymphocyte analyses are often performed post-infusion to evaluate the reconstitution of the immune system. Certain lymphocyte groups repopulate earlier than others post-HCT. From the list below, select all known lymphocyte values from the date of the most recent assessment, as reported in *Date lymphocyte analyses performed*.

- **CD3 (T cells)**
- **CD4 (T helper cells)**
- **CD8 (cytotoxic T cells)**
- **CD19 (B lymphocyte cells)**
- **CD20 (B lymphocyte cells)**
- **CD56 (natural killer (NK) cells)**

If lymphocyte testing was not completed during the reporting period, select **No lymphocyte analyses performed**.

Lymphocyte Analyses Units of Measurement
The following units of measurement are equivalent to each other:
10^9/L = 10^3/mm^3
10^6/L = 1/mm^3 = 1/µL cells / µL

Questions 43 – 49: Specify the lymphocyte analyses

Report the sample collection date for the lymphocyte analysis. If multiple lymphocyte analyses were complete in the reporting period, report the date of the most recent analysis.

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

For each lymphocyte tested, report the value, and specify the units of measurement.

If only the percentages of lymphocyte subsets are available, it is necessary to calculate the absolute value of each lymphocyte subset for reporting purposes. This can be done by multiplying the percentage of each subset by the absolute lymphocyte count. See the example below:

Example 1: Calculating lymphocyte counts
Absolute Lymphocyte Count: 4.8 × 10^9/L

Phenotype	Lab Report Percentage	Calculation (Percentage x ALC)	Absolute Value
CD3	74%	(0.74) × 4.8	**CD3:** 3.55× 10^9/L
CD3CD4	40%	(0.40) × 4.8	**CD4:** 1.92 × 10^9/L
CD3CD8	34%	(0.34) × 4.8	**CD8:** 1.63 × 10^9/L
CD19	NT	—	**CD19:** Unknown
CD20	NT	—	**CD20:** Unknown
CD56	NT	—	**CD56:** Unknown

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q50: Gene Therapy Persistence Testing

For gene therapy products, testing for the gene therapy may be completed post infusion. Testing for the persistence of gene therapy includes the following:

- Allelic editing frequency
- Clonal expansion

- Gene therapy globin expression
- Homology directed DNA repair (HAD) frequency
- Indel mutations frequency
- Transgene expression
- Vector copy number (VCN)

Question 50: Were tests performed to detect persistence of gene therapy product infusion?

Indicate if testing for the persistence of the gene therapy product was completed during the reporting period. If **Yes**, complete the Gene Therapy Persistence (2103) Form.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q51: Chimerism Studies

Autologous Transplants
If this was an autologous HCT, continue with the Engraftment Syndrome section. Chimerism testing and graft-versus-host disease sections should only be completed for allogeneic HCTs.

Syngeneic Transplants
If this was a syngeneic HCT, continue with the Engraftment Syndrome section. Chimerism testing is not collected for syngeneic HCTs.

Chimerism Studies
For non-malignant diseases and CBUs , the Chimerism Studies section can only be completed on the 100 day, 6 month, and 1 year follow-up forms. For malignant disease, the Chimerism Studies section can only be completed on the 100 day and 1 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Chimerism studies are performed to determine the percent of blood or marrow cells post-transplant that are produced from donor hematopoietic stem cells and the percent that are produced from host (recipient) hematopoietic stem cells. Different types of blood cells and a variety of laboratory tests can be used to determine if a chimera (presence of both donor- and host-derived cells) exists. If cytogenetic testing was performed to look for disease markers, and the donor and recipient are different sexes, the test may also be used to determine if a chimera exists. If the donor and recipient are

of the same sex, cytogenetic testing using the common staining technique, known as giemsa banding (G-banding), cannot be used to determine if there is a chimera. However, quinicrine banding (Q-banding) can be used to identify if the cells are of donor origin or not in a same-sex transplant, as this staining technique highlights inherited chromosome polymorphisms on certain human chromosomes including 3, 4, 13, 15, 21, 22, and Y. This is not a commonly used staining technique and is only helpful when the polymorphism is documented pre-HCT.

Failed Chimerism Studies
If chimerism studies were attempted, but no evaluable results were obtained, report **No**, chimerism studies were not performed.

Questions 51: Were chimerism studies performed post-HCT? *(Allogeneic infusions only)*

Indicate whether chimerism studies were performed within the reporting period. If **Yes**, the Chimerism Essential Data (2451) Form will come due to report the chimerism study results.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q52 – 62: Engraftment Syndrome

Engraftment Syndrome
The Engraftment Syndrome section can only be completed on the 100-day follow-up form. These questions will be skipped for all subsequent reporting periods.

Combined Follow-Up
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions do not apply and are disabled.

Questions 52 – 53: Did engraftment syndrome occur?

Engraftment syndrome typically occurs during neutrophil recovery post-HCT and is characterized by capillary leak syndrome, non-infectious fever, erythrodermatous skin

rash, and non-cardiogenic pulmonary edema. Engraftment syndrome is usually seen following autologous transplants but can occur after allogeneic transplants. It is associated with increased transplant mortality, generally from pulmonary and associated multi-organ failure. Corticosteroid therapy is often an effective treatment for engraftment syndrome, mainly for the treatment of pulmonary symptoms.

Indicate whether the recipient developed engraftment syndrome. If **Yes**, report the date of diagnosis.

If the recipient did not develop engraft syndrome or is unknown, report **No**.

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

Questions 54 – 55: Specify the symptoms of engraftment syndrome *(check all that apply)*

Specify the engraftment syndrome symptoms the recipient developed in the reporting period. Check all that apply. If **Other symptom** is selected, specify the symptom present.

Questions 56 – 59: Was a biopsy performed?

Indicate if a biopsy was performed to evaluate engraftment syndrome. If **Yes**, specify the site(s) and indicate whether documentation (pathology report) was submitted to the CIBTMR. If **Other site** is selected, specify the biopsy site.

For further instructions on how to attach documents in FormsNet3^{SM}, refer to the FormsNet3 Training Guide.

Questions 60 – 61: Specify therapy given for engraftment syndrome *(check all that apply)*

Specify any therapy given for engraftment syndrome. If **Other therapy** is selected, specify the treatment(s) administered. If therapy was not given in the reporting period, select **None**.

Question 62: Did engraftment syndrome resolve?

Indicate whether engraftment syndrome resolved during the reporting period. If engraftment syndrome was still present on the date of contact, report **No**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q63 – 111: Acute Graft vs. Host Disease (GVHD)

Autologous Transplants
If this was an autologous infusion, continue with the Infection Prophylaxis section. The graft-versus-host disease sections should only be completed if an allogeneic donor was used.

Acute GVHD Prophylaxis
Acute GVHD prophylaxis questions can only be completed on the 100-day follow-up form. These questions will be skipped for all subsequent reporting periods.

Combined Follow Up and Acute GVHD
In scenarios where an HCT was given after a cellular therapy and this form is now being completed based on the subsequent HCT date, acute GVHD will always be reported on the Post-Infusion Follow-Up (2100) Form and is disabled on the Cellular Therapy Essential Data Follow-Up (4100) Form.

Ex Vivo Manipulation for GVHD Prophylaxis
Ex vivo manipulation performed for GVHD prophylaxis should not be reported in the GVHD prophylaxis section of this form.

Questions 63 – 71: Select specific therapy used after the start of the preparative regimen to prevent acute GVHD *(Check all that apply) (Note: do not include growth factors reported in questions 15 – 23, or ex vivo T-cell depletion reported on the Product Insert. Do not include drugs given as part of the preparative regimen)*

Following an allogeneic HCT, specific immunosuppressive therapy may be administered to prevent GVHD or to immunosuppress the host marrow. Most transplant centers have specific GVHD prophylaxis protocols and graft rejection protocols. Any agent a recipient receives as a result of these protocols should be included in this section. The type of acute GVHD prophylaxis is included in almost every analysis of allogeneic transplantation.

The prophylactic drug options listed on the form are intended to be **systemic** (IV or oral administration).

The Post-Infusion Follow-Up (2100) Form lists the generic immune suppression drug names. The following website provides the trade names under which generic drugs are manufactured: http://www.rxlist.com/drugs/alpha_a.htm.

If GVHD prophylaxis is used for a syngeneic (monozygotic or identical twin) or autologous HCT, upload documentation in FormsNet3^{SM} using the attachment feature. Contact CIBMTR Center Support with questions.

Specify the therapy given after the start of the preparative regimen to prevent acute GVHD or graft rejection. Check all that apply. If acute GVHD prophylaxis was not given, report **None**.

- **Abatacept (Orencia):** Immunomodulator that works to block the activity of T-cells.
- **Alemtuzumab (Campath):** Monoclonal antibody that targets common antigens found on B-cells and T-cells (part of the body's immune system). If this drug was given as acute GVHD prophylaxis and report the total ordered dose administered in milligrams.
- **ALG (Anti-Lymphocyte Globulin), ALS (Anti-Lymphocyte Serum), ATG (Anti-Thymocyte Globulin) ATS (Anti-Thymocyte Serum):** Serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from horse or rabbits immunized against human lymphocytes. Also report the animal source. If **Other** is selected, specify the source.
- **Blinded randomized trial:** If the recipient is on a blinded randomized trial, specify agent being studied in the trial. Additionally, update the Post-Infusion Follow-Up (2100) once the trial is over to specify whether the recipient received the trial drug or placebo.
- **Corticosteroids (systemic) (e.g., prednisone, dexamethasone):** Usually combined with cyclosporine when used for prophylaxis. Only report systemic steroids in this section.
- **Cyclophosphamide (Cytoxan):** Given in high doses near the date of infusion as prophylaxis. Report the total administered dose in milligrams.
- **Cyclosporine (CSA, Neoral, Sandimmune, Gengraf):** Calcineurin inhibitor which decreases cytokine production by T-cells. Usually given for ≥ 3 months.
- **In vivo immunotoxin:** Antibody preparations linked to a toxin that is infused in the recipient following HCT. Specify the in vivo immunotoxin.
- **Methotrexate (MTX) (Amethopterin):** Inhibits the metabolism of folic acid. It is most often used with calcineurin inhibitors and is usually for a short duration of time.
- **Mycophenolate mofetil (MMF) (CellCept, Myfortic):** Inhibits the de novo pathway used for lymphocyte proliferation and activation.
- **Sirolimus (Rapamycin, Rapamune):** Inhibits the response to interleukin-2, blocking the activation of T-cells.
- **Tacrolimus (Prograf):** Inhibits the production of interleukin-2 by T-cells.

- **Other in vivo monoclonal antibody:** Antibody preparations that are infused for GVHD prophylaxis. Specify if an in vivo monoclonal antibody other than Alemtuzumab (Campath) or an in vivo immunotoxin was used.
- **Other agent:** If the drug is not listed on the form, select this option and specify the other agent being given as GVHD prophylaxis.

Do not report the following:

- Ex vivo T-cell depletion
  - Report ex vivo T-cell depletion on the HCT Infusion Form (Form 2006).
- Agents used to prevent infection
  - Report infection prophylaxis agents in the Infection section
- Topical corticosteroids or ursodeoxycholic acid (ursodiol, actigal).

GVHD Reporting Instruction Overview
Review the GVHD Reporting Instruction Overview for detailed GVHD reporting instructions and various GVHD reporting scenarios.

Acute / Chronic GVHD
If acute GVHD is diagnosed prior to chronic GVHD, report the diagnosis information, maximum severity of any symptoms, and treatment administered up to the date of diagnosis of chronic GVHD in the acute GVHD section of the form. Do not include any signs, symptoms, or treatment occurring on or after the onset of chronic GVHD when completing the acute GVHD section.
Report any **new or persistent** acute GVHD symptoms occurring on or after the onset of chronic GVHD only in the chronic GVHD section. If chronic GVHD was diagnosed in a prior reporting period, report **No** when asked if acute GVHD developed or persisted in each subsequent reporting period. See the reporting scenarios included in the GVHD Reporting Instruction Overview.

Question 72: Did acute GVHD develop?

Indicate whether acute GVHD developed in the reporting period.

The **Unknown** option should only be used when there is no information about the recipient's GVHD status for the entire reporting period. This option should be used sparingly and only when no judgement can be made about the presence or absence of GVHD in the reporting period.

For detailed instructions regarding whether a new development of acute GVHD should be captured, review the GVHD Reporting Instruction Overview.

Question 73: Date of acute GVHD diagnosis

Report the date of clinical diagnosis of acute GVHD. The clinical diagnosis date may not necessarily be the date the symptoms began (example: the recipient developed a rash

one week prior to the physician clinically diagnosing acute skin GVHD). If the clinical diagnosis is documented, but the diagnosis date is unclear, obtain documentation from the primary physician confirming the clinical diagnosis date.

If the recipient developed more than one episode of acute GVHD in the same reporting period, report the date of onset of the first episode of acute GVHD.

If the exact clinical diagnosis date is unknown, but the treatment start date is known, report the date treatment started as the date of acute GVHD diagnosis.

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

Persistent GVHD and Day 100 Reporting Period
Previously, reporting **Yes** for *Did acute GVHD persist since the date of last report* was not an applicable option for the Day 100 reporting period. However, if there was a prior infusion, the recipient developed acute GVHD in the last reporting period of the previous infusion *and* acute GVHD persisted into the Day 100 reporting period of the current infusion, report **Yes**, acute GVHD persisted since the date of last report.

Question 74: Did acute GVHD persist?

Indicate if acute GVHD was clinically diagnosed in the previous reporting period and persisted, with active symptoms, into the current reporting period. For detailed instructions on how to report a flare of acute GVHD, review the GVHD Reporting Instruction Overview.

The **Unknown** option should only be used when there is no information about the recipient's GVHD status for the entire reporting period. This option should be used sparingly and only when no judgement can be made about the presence or absence of GVHD in the reporting period.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 75: Was acute GVHD evaluated by biopsy (histology)? *(at diagnosis)*

Histological tests may be performed to confirm the clinical diagnosis of GVHD; however, the staging and grading of GVHD should be based on clinical evidence, not histological results.

Indicate if a biopsy was used to diagnose acute GVHD. If biopsy was not performed or unknown if performed at diagnosis, report **No**.

Questions 76 – 82: Specify result(s)

For each organ listed, indicate the test result documented on the pathology report as either **Positive**, **Suggestive**, **Negative**, **Inconclusive / equivocal**, or **Not done**.

Suggestive or Inconclusive / equivocal should be reported if in the final diagnosis or comments section of the pathology report, those words are used.

Biopsy report may use the term "consistent with GVHD" which could be interpreted as either **Positive** or **Suggestive**, depending on the comments listed in the report.

If the biopsy was performed on an "other site," specify the site biopsied.

Additionally, indicate whether documentation was submitted to the CIBMTR (e.g., pathology report). For further instructions on how to attach documents in FormsNet3, refer to the FormsNet3 Training Guide.

Questions 83 – 89: Overall grade of acute GVHD at diagnosis

These questions are intended to capture each organ stage and the overall grade at the time of acute GVHD diagnosis. For reporting purposes, "at diagnosis" is defined as the period between onset of signs / symptoms and the initiation of therapy to treat GVHD (topical or systemic). The acute GVHD grading scale is based on **clinical evidence** (physician observation), not histology. Pathology reports sometimes list a histologic grade of GVHD. Do not report the histologic grade. Biopsy of affected organs allows for more precise diagnosis as to the presence or absence of GVHD, not its severity. However, **overall grading remains clinical** and is based on the criteria published by Przepiorka et al., *Bone Marrow Transplant* 1995; 15(6):825-8, see the GVHD Grading and Staging table below.

Report the overall grade and organ staging at the diagnosis of acute GVHD. Review the GVHD Reporting Instruction Overview for additional information and on the criteria for each organ staging and grading.

Questions 90 – 91: Maximum overall grade of acute GVHD

These questions are intended to capture the *maximum* overall grade of acute GVHD *within the reporting period*.

Report the maximum acute GVHD grade in the reporting period and the first date of the maximum acute GVHD grade based on clinical judgement. If the recipient had multiple instances in which the GVHD reached the same maximum grade, report the earliest date, regardless of any variation in the organ staging.

If chronic GVHD was diagnosed during the reporting period, report the maximum overall grade of acute GVHD prior to the onset of chronic GVHD.

For detailed reporting instructions about reporting the maximum grade and organ staging of acute GVHD, review the GVHD Reporting Instruction Overview.

Maximum Organ Staging
Due to further clarification provided, the instructions for reporting the maximum organ staging were updated with the Fall 2023 Quarterly Release. The intent of the maximum organ staging questions is to capture the maximum stage of each organ involved with acute GVHD in the reporting period; not at the time of the maximum overall grade, despite what the question text states. The question text will be revised with the next revision of the Post-Infusion Follow-Up (2100) Form.

Questions 92 – 97: Specify organ involvement at time of maximum grade

These questions are intended to capture the maximum organ staging within the reporting period.

Report the *maximum acute GVHD stage of each organ involved, consistent with the reported maximum overall grade, in the reporting period.* The maximum staging does not need to be at the time when the maximum overall grade occurred.

If chronic GVHD was diagnosed during the reporting period, report the maximum organ staging of acute GVHD prior to the onset of chronic GVHD.

For detailed reporting instructions about reporting the maximum grade and organ staging of acute GVHD, review the GVHD Reporting Instruction Overview.

Question 98: Corticosteroids *(topical GI) (check all that apply)*

Select all topical corticosteroids (beclomethasone and / or budesonide) used to treat *GI GVHD*. If topical corticosteroids to treat GI GVHD were not given, select **None**.

Topical therapies used for skin or lung GVHD are not captured in this question. Also, do not report systemic corticosteroids such as prednisone or dexamethasone. Systemic therapies are captured below

Corticosteroids
Corticosteroids are captured differently depending on whether they are used topically or systemically. Use the following guidelines when determining how to report corticosteroids used to treat acute GVHD:
Topical Creams for Skin: Do not report topical ointments or creams used to treat skin GVHD including corticosteroid creams such as Triamcinolone or Hydrocortisone.
Other Topical Treatments: Certain corticosteroid treatments are not absorbed and are therefore considered topical. Examples include beclomethasone and budesonide. If these treatments are given for acute GI GVHD during the reporting period, report **Yes** for *Corticosteroids*. If these treatments were given for other organ involvement of GVHD, contact the CIBMTR Customer Service Center to determine the

best option for reporting this therapy.
Systemic Treatments: Systemic administration of corticosteroids, including use of prednisone and dexamethasone, should be reported in *Select systemic treatment used to treat acute GVHD*).

Reporting Multiple Systemic Therapies
Complete the GVHD specific therapy questions for each reported systemic therapy by adding an additional instance in the FormsNet3^{SM} application.

Questions 99 – 111: Was specific therapy given for acute GVHD?

Specify the systemic therapy used to treat acute GVHD during the reporting period. Report any prophylactic drugs as therapy for acute GVHD if they were continued after the date of diagnosis.

If systemic therapy was given to treat acute GVHD during the reporting period, specify the drugs given and indicate if the treatment was continued from prophylaxis. If the drug was continued from prophylaxis, select **Yes** and continue with *Specify if the treatment was continued from prophylaxis*. If the drug was started in a prior reporting period and continued into the current reporting period, select **Previously reported**.

The **Previously reported** option is not applicable for the Day 100 reporting period.

If the drug was not continued from prophylaxis and was not started in the prior reporting period and continued into the current reporting period, select **No** and report the therapy start date. When reporting the date started, report the first day the drug was given on or after the GVHD diagnosis date (reported in *Date of acute GVHD diagnosis*).

If **Alemtuzumab (Campath)** is selected, report the total administered dose in milligrams during the reporting period. Do not report the prescribed or daily doses.

If **ALG, ALS, ATG, ATS** is selected, report the total administered dose in milligrams during the reporting period. Do not report the prescribed or daily doses. In addition, specify the animal (horse or rabbit) source. If **Other** is selected, specify the source.

If **Anti CD25 (Zenapax, Daclizumab, AntiTAC), Blinded randomized trial, In vivo immunotoxin, Other in vivo monoclonal antibody,** or **Other JAK2** inhibitor is selected, specify the agent.

If the therapy is not listed on the form, select **Other agent** and specify the therapy.

If no therapy was given, indicate **None**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q112 – 181: Chronic Graft vs. Host Disease (GVHD)

Autologous Transplants
If this was an autologous HCT, continue with the Infection Prophylaxis section of the form starting. Chimerism testing and graft-versus-host disease sections should only be completed for allogeneic HCTs.

Combined Follow Up and Chronic GVHD
In scenarios where an HCT was given after a cellular therapy and this form is now being completed based on the subsequent HCT date, chronic GVHD will always be reported on the Post-Infusion Follow-Up (2100) Form and is disabled on the Cellular Therapy Essential Data Follow- Up (4100) Form.

GVHD Reporting Instruction Overview
Review the GVHD Reporting Instruction Overview for detailed GVHD reporting instructions and various GVHD reporting scenarios.

Question 112: Did chronic GVHD develop?

Indicate whether a new clinical diagnosis of chronic GVHD was documented during the reporting period.

The **Unknown** option should only be used when there is no information about the recipient's GVHD status for the entire reporting period. This option should be used sparingly and only when no judgement can be made about the presence or absence of GVHD in the reporting period.

For detailed instructions on whether a new development of chronic GVHD should be captured, review the GVHD Reporting Instruction Overview.

Question 113: Date of chronic GVHD diagnosis

Report the date of clinical diagnosis of chronic GVHD. The clinical diagnosis date may not necessarily be the date the symptoms began (example: the recipient developed shortness of breath one month prior to the clinical diagnosis of pulmonary chronic GVHD). If the clinical diagnosis is documented, but the diagnosis date is unclear, obtain documentation from the primary physician confirming the clinical diagnosis date.

If the recipient developed more than one episode of chronic GVHD in the same reporting period, report the date of onset of the first episode of chronic GVHD.

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

Persistent GVHD and Day 100 Reporting Period
Previously, reporting **Yes** for *Did chronic GVHD persist since the date of last report* was not an applicable option for the Day 100 reporting period. However, if there was a prior infusion, the recipient developed chronic GVHD in the last reporting period of the previous infusion *and* chronic GVHD persisted into the Day 100 reporting period of the current infusion, report **Yes**, chronic GVHD persisted since the date of last report.

Question 114: Did chronic GVHD persist?

Indicate whether chronic GVHD was clinically diagnosed during a previous reporting period and persisted, with active symptoms, into the present reporting period. Do not report quiescent or inactive chronic GVHD, or a prior history of GVHD. For detailed instructions on how to report a flare of chronic GVHD, review the GVHD Reporting Instruction Overview.

Indicate **Unknown** if there is no information about the recipient's GVHD status for the entire reporting period. This option should be used sparingly and only when no judgment can be made about the presence or absence of GVHD in the reporting period.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 115: Onset of chronic GVHD was

Indicate whether the onset of chronic GVHD was:

- **Progressive**: Acute GVHD present within two weeks prior to onset of chronic GVHD
- **Interrupted**: Prior acute GVHD resolved for greater than two weeks, then chronic GVHD developed
- **De novo**: Acute GVHD never developed

Question 116: Were signs of acute GVHD present at the time of chronic GVHD diagnosis (overlap syndrome)?

Chronic GVHD can be separated into two different categories; classical chronic GVHD and overlap syndrome. Overlap syndrome is a condition where there are features of both acute and chronic GVHD at the time of diagnosis. Indicate whether signs of acute GVHD were present at the time of diagnosis of chronic GVHD (overlap syndrome).

Refer to GVHD Reporting Instruction Overview for instructions on how to complete the acute and chronic GVHD sections for recipients with overlap syndrome.

Question 117 – 119: What was the scale used to determine the recipient's functional status? *(at time of chronic GVHD diagnosis)*

The Karnofsky Scale is designed for recipients aged 16 years and older and is not appropriate for children under the age of 16. The Lansky Scale is designed for recipients one year old to less than 16 years old. If the recipient is less than one year old, leave these questions blank.

Indicate the score (10-100) that best represents the recipient's activity status at diagnosis of chronic GVHD. The only valid scores are 10-100, zero is not a valid response for this scale, nor are values not ending in zero, such as "85." The Karnofsky/Lansky scale can be found in Appendix L: Karnofsky/Lansky Performance Status.

For further information on reporting Karnofsky / Lansky Scores refer to the instructions for reporting performance scores in the Functional Status section below.

Question 120: Platelets *(at diagnosis of chronic GVHD)*

Report the lowest platelet count recorded within 14 days (+ / -) of the diagnosis of chronic GVHD, whether or not the recipient has received a platelet transfusion. Indicate the units of measurement.

Question 121: Total serum bilirubin *(at diagnosis of chronic GVHD)*

Report the highest total serum bilirubin value (and units) within 14 days (+ / -) of the diagnosis of chronic GVHD. Indicate the units of measurement.

Question 122: Was chronic GVHD evaluated by biopsy (histology)? *(at diagnosis)*

Histological tests may be performed to confirm the clinical diagnosis of GVHD; however, the scoring of GVHD should be based on clinical evidence, not histological results.

Indicate if a biopsy was used to diagnose chronic GVHD. If a biopsy was not performed or it is unknown if performed at diagnosis, report **No**.

Questions 123 – 129: Specify result(s)

For each organ listed, indicate the test result documented on the pathology report as either **Positive**, **Suggestive**, **Negative**, **Inconclusive / equivocal**, or **Not done**.

Suggestive or **Inconclusive / equivocal** should be reported if in the final diagnosis or comments section of the pathology report, those words are used. Biopsy reports may

use the term "consistent with GVHD" which could be either **Positive** or **Suggestive**, depending on the other comments in the report.

If the biopsy was performed on an "other site," specify the site biopsied.

Questions 130 – 162: Specify organs involved and NIH scoring at diagnosis of chronic GVHD *(check all that apply)*

Report the organ involvement and NIH score of chronic GVHD for each organ / system listed at the time of diagnosis. For each involved organ, specify any features present at time of diagnosis. Refer to the Organ Scoring of Chronic GVHD Table in the GVHD Reporting Instruction Overview for organ scoring of chronic GVHD.

Signs or symptoms occurring at the time of diagnosis may be partially or entirely attributed to GVHD. Alternatively, reportable features may be observed at diagnosis but attributed entirely to non-GVHD causes. In any case, select the organ if any reportable signs / symptoms are documented during the reporting period regardless of whether those features are attributed to GVHD.

Features **entirely** explained by non-GVHD causes will be excluded when determining the overall severity of chronic GVHD but are still collected on the form. Spaces have been provided to document non-GVHD causes.

Specify all features observed at the time of diagnosis and report the score for each organ using the criteria from the Organ Scoring of Chronic GHVD Table. If any reported features are attributed **entirely** to non-GVHD causes, specify the non-GVHD cause(s) in the appropriate field. If a sign or symptom is caused by a combination of chronic GVHD and other causes, then the section on "non-GVHD causes" does not need to be completed. Further instructions are provided in the GVHD Reporting Instruction Overview for each organ.

If a recipient has signs / symptoms of both acute and chronic GVHD during the reporting period, refer to the GVHD Reporting Instruction Overview for additional instructions.

Question 163: Maximum grade of chronic GVHD *(according to best clinical judgment)*

Report the maximum chronic GVHD involvement, based on the opinion of the clinician (i.e., clinical grade), since the date of the last report. The intent of this question is to capture the maximum grade based on the best clinical judgment. If both the global severity score and the score based on the clinician's opinion are documented, report the clinician score. If the maximum clinical grade is not documented, request documentation from the recipient's primary care provider.

Additional guidelines on reporting the maximum grade of chronic GVHD are outlined in the GVHD Reporting Instruction Overview.

Question 164: Date of maximum grade of chronic GVHD

Report the date of maximum chronic GVHD involvement during the current reporting period, based on clinical grade. If the recipient had multiple instances in which their GVHD reached the same maximum grade, report the earliest date.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

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

Question 165: Specify if chronic GVHD was limited or extensive

Another grading system for chronic GVHD is divided into two categories: limited and extensive. Definitions are based on Sullivan KM, *Blood* 1981; 57:267.

Report the extent of chronic GVHD since the date of last report. Report **Limited** if chronic GVHD includes only localized skin involvement and/or liver dysfunction. Report **Extensive** if **any** of the following symptoms are attributed to chronic GVHD:

- Generalized skin involvement and / or liver dysfunction
- Liver histology showing chronic aggressive hepatitis, bridging necrosis, or cirrhosis
- Involvement of the eye: Schirmer's test with < 5 mm wetting, or
- Involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy (labial biopsy not required), or
- Involvement of any other target organ

The intent of this question is to capture if chronic GVHD was limited or extensive throughout the entire reporting period and is not dependent on the maximum grade and date of chronic GVHD. If the criteria to report extensive was met at any time in the reporting period, report **Extensive**.

Questions 166 – 167: Select other indicators, clinical features, or complications related to chronic GVHD *(check all that apply)*

Select other indicators, clinical features, or complications related to chronic GVHD (check all that apply)

- **Ascites (serositis):** Accumulation of fluid in the peritoneal cavity
- **Pericardial effusion:** Accumulation of fluid in the pericardial cavity
- **Pleural effusion(s):** Buildup of fluid between the chest and the tissues which line the lungs
- **Nephrotic Syndrome:** Kidney disorder that causes the body to excrete too much protein in the urine

- **Myasthenia gravis:** Weakness of muscles caused by antibodies to acetylcholine receptors
- **Peripheral neuropathy:** Nerve damage, usually in the hands and feet
- **Polymyositis:** Inflammation causing muscle weakness on both sides of the body
- **Weight loss >5% without GI symptoms**
- **Eosinophilia:** Elevation in eosinophils in the peripheral blood (> 500 cells / µL)
- **Platelets:** Decrease in platelets in the blood (< 100,000 / µL)
- **Other indicator:** If selected, specify the other indicator

If there were not any other indicators, clinical features, or complications related to chronic GVHD occurring in the current reporting period, select **None**.

Question 168: Corticosteroids *(topical GI) (check all that apply)*

Select all topical corticosteroids (beclomethasone and / or budesonide) used to treat GI GVHD. If topical corticosteroids to treat GI GVHD were not given, select **None**.

Topical therapies used for skin or lung GVHD are not captured in this question. Also, do not report systemic corticosteroids such as prednisone or dexamethasone. Systemic therapies are captured below.

Reporting Multiple Systemic Therapies
Complete *Select systemic treatment used to treat chronic GVHD* through *Specify other agent* for each reported systemic therapy by adding an additional instance in the FormsNet3^{SM} application.

Questions 169 – 181: Select systemic treatment used to treat chronic GVHD

Select all systemic agents used to treat chronic GVHD during the reporting period, including any prophylactic medications continued after the diagnosis of chronic GVHD. If systemic therapy was not given for treatment of chronic GVHD, select **None**. Review the Chronic GVHD treatment reporting scenarios below for examples.

If systemic therapy was given to treat chronic GVHD during the reporting period, specify the drugs given and indicate if the treatment was continued from prophylaxis. If the drug was continued from prophylaxis or acute GVHD treatment, select **Yes**. If the drug was started in a prior reporting period and continued into the current reporting period, select **Previously reported**. The **Previously reported** option is not applicable for the Day 100 reporting period.

If the drug was not continued from prophylaxis / acute GVHD treatment and was not started in the prior reporting period and continued into the current reporting period, select **No** and report the therapy start date. When reporting the date started, report the first day the drug was given on or after the GVHD diagnosis date (reported *Date of chronic GVHD diagnosis*). If treatment is started and subsequently escalated during the same reporting period, report the earliest date treatment was actually given during the

reporting period. Additionally, report the earliest start date if a drug is started multiple times during the same reporting period.

Report the total dose administered during the reporting period if a dose is required.

Refer to the acute GVHD treatment questions above for a description of most agents listed. Agents not described under acute GVHD are described below under Additional Agents. "Systemic" refers to drugs given by mouth, intramuscularly (IM), or intravenously (IV). "Topical" refers to drugs applied to the surface of skin or mouth, eye drops, or inhalation therapy. An exception to this would be the drug budesonide; it is a drug given by mouth for treatment of lower gut GVHD, but it is considered a "topical" drug since it is not absorbed.

Chronic GVHD Treatment Reporting Scenarios:

A. During the one-year reporting period, a recipient on cyclosporine for GVHD prophylaxis was diagnosed with chronic skin GVHD (5/1/2016). This was initially treated with topical steroids in addition to continuing their cyclosporine at the current dose. The chronic skin GVHD worsened shortly thereafter. On 5/15/2016, prednisone was started, and the dose of cyclosporine was increased. Symptoms persisted into the two-year reporting period but improved shortly thereafter. Upon resolution of symptoms, prednisone and cyclosporine doses were tapered.

One Year Post-HCT Data Form

Corticosteroids: Report **No** to indicate no topical GI corticosteroids were given. Topical steroids applied to the skin should not be reported here.
Select systemic treatment used to treat chronic GVHD: Select **Cyclosporine** to indicate systemic therapy was escalated to treat chronic GVHD.
Specify if the treatment was continued from prophylaxis / acute GVHD treatment: Report **Yes** to indicate cyclosporine was continued from prophylaxis / aGVHD treatment

Complete a second instance of the chronic GVHD treatment questions to capture the **Corticosteroids**, report **No** for *Specify if the treatment was continued from prophylaxis / acute GVHD treatment* and the start date as 5/15/2016.

Two Year Post-HCT Data Form

Corticosteroids: Report **No** to indicate no topical GI corticosteroids were given. Topical steroids applied to the skin should not be reported here.
Select systemic treatment used to treat chronic GVHD: Report two instances for **Cyclosporine** and **Corticosteroids** as treatment was continued into the two year reporting period and report **Previously reported** for *Specify if the treatment was continued from prophylaxis / acute GVHD treatment*.

B. During the one-year reporting period, a recipient on sirolimus for GVHD prophylaxis was diagnosed with chronic mouth and gut GVHD (7/1/2016). This was initially treated with topical steroids (oral dexamethasone and budesonide) in addition to continuing sirolimus at the current dose. Prednisone was started 7/30/2016 due to minimal improvement. The chronic mouth and gut GVHD resolved and dexamethasone, budesonide, as well as prednisone were discontinued. Sirolimus was continued. Later in the one-year reporting period, a severe flare of chronic gut GVHD occurred (10/15/2016). This was first treated by restarting prednisone on the date of diagnosis; however, no response was observed. Ruxolitinib was started on 10/20/2016 and symptoms resolved.

One Year Post-HCT Data Form

Corticosteroids: Report **Yes** to indicate topical GI corticosteroids were given. Budesonide should be reported here.
Select systemic treatment used to treat chronic GVHD: Report **Sirolimus** to indicate systemic therapy was given to treat chronic GVHD.
Specify if the treatment was continued from prophylaxis / acute GHVD treatment: Report **Yes** to indicate sirolimus was continued from prophylaxis / aGVHD treatment. Note, topical steroids, including dexamethasone and budesonide, should not be considered when completing the systemic chronic GVHD therapy questions.

Complete a second instance of chronic GVHD treatment questions to capture **Ruxolitinib**, report **No** for *Specify if the treatment was continued from prophylaxis / acute GVHD treatment*, and the start date as 10/20/2016.

Complete a third instance of chronic GVHD treatment questions to capture **Corticosteroids**, report **No** for *Specify if the treatment was continued from prophylaxis / acute GVHD treatment*, with a start date of 7/30/2016. Report the earliest start date if a medication is started multiple times during the reporting period.

C. During the six-month reporting period, a recipient off all immunosuppression was diagnosed with chronic mouth GVHD (9/15/2016). This was initially treated with topical steroids (oral dexamethasone). Cyclosporine was started on 9/20/2016 due to minimal response. Symptoms resolved by the one-year date of contact (10/1/2016) at which time dexamethasone was discontinued. The recipient remained on cyclosporine. During the one-year reporting period, a flare of chronic mouth GVHD occurred on 11/15/2016 while attempting to taper cyclosporine. This was treated by increasing the dose of cyclosporine on the date of diagnosis of the flare.

Six Month Post-HCT Data Form

Corticosteroids: Report **No** to indicate the recipient was initially treated with topical steroids.
Select systemic treatment used to treat chronic GVHD: Report **Cyclosporine** to indicate systemic therapy was given to treat chronic GVHD.

Specify if the treatment was continued from prophylaxis / acute GHVD treatment: Report **No** and specify 9/20/2016 as the treatment start date. This is the date cyclosporine was started as treatment for chronic GVHD. Note, topical steroids, including dexamethasone, budesonide, etc. should not be considered when completing systemic chronic GVHD treatment questions.

One Year Post-HCT Data Form

Corticosteroids: Report **No** to indicate the recipient was initially treated with topical steroids.
Select systemic treatment used to treat chronic GVHD: Report **Cyclosporine** to indicate systemic therapy was given to treat chronic GVHD.
Specify if the treatment was continued from prophylaxis / acute GHVD treatment: Report **No** and specify 11/15/2016 as the treatment start date.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q182- 188: Current GVHD Status

Combined Follow Up and Current GVHD Status
In scenarios where an HCT was given after a cellular therapy and this form is now being completed based on the subsequent HCT date, these questions still apply and should be answered.

Question 182: Are symptoms of GVHD still present on the date of actual contact (or present at the time of death)?

This question refers to any symptoms of GVHD (acute and / or chronic) observed during the reporting period. This section of the form must be completed if the center reported **Yes**, acute, or chronic GVHD developed or persisted.

Indicate whether the recipient has active clinical signs / symptoms of acute and/or chronic GVHD on the date of contact. If the recipient has died, indicate whether GVHD symptoms were present at the time of death.

Corticosteroids
Corticosteroids are captured differently depending on whether they are used topically or

systemically. Use the following guidelines when determining how to report corticosteroids used to treat acute GVHD:
Topical Creams for Skin: Do not report topical ointments or creams used to treat skin GVHD including corticosteroid creams such as Triamcinolone or Hydrocortisone.
Other Topical Treatments: Certain corticosteroid treatments are inhaled or ingested, but are not absorbed and are therefore considered topical. Examples include beclomethasone and budesonide. Do not consider these medications when answering *Is the recipient still taking systemic steroids*.
Systemic Treatments: Systemic administration of corticosteroids, including use of prednisone and dexamethasone, should be reported in *Is the recipient still taking systemic steroids*.

Question 183: Is the recipient still taking systemic steroids? *(Do not report steroids for adrenal insufficiency, ≤ 10 mg/day for adults, < 0.1 mg/kg/day for children)*

This question is intended to capture if the recipient was still receiving systemic steroids (steroid dose > 10 mg / day for adults, ≥ 0.1 mg / kg / day for children, excluding steroids for adrenal insufficiency) for GVHD on the contact date.

Indicate if the recipient was still taking systemic steroids (steroid dose > 10 mg / day for adults, > 0.1 mg / kg / day for children, excluding steroids for adrenal insufficiency) on the contact date. Review the GVHD Reporting Instruction Overview for reporting instructions to these questions.

Questions 184 – 185: Date final treatment of systemic steroids administered

Indicate whether the date systemic steroids was discontinued is **Known**. If the final treatment date is **Known**, report the date when the final dose of systemic steroids was administered.

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

Immunosuppressive Agents
As of December 9, 2023, questions regarding if the recipient is still taking immunosuppressive agents are required to be answered for all allogeneic infusions, regardless of if GVHD developed.

Question 186: Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?

These questions are intended to capture if the recipient was still receiving non-steroid immunosuppressive agents for GVHD on the contact date.

Indicate if the recipient was still taking non-steroid immunosuppressive agents on the contact date. Review the GVHD Reporting Instruction Overview for reporting instructions to these questions.

Question 187 – 188: Date final treatment administered

Indicate whether the final administration date of non-steroidal immunosuppressive agents (including PUVA) is **Known**. If the final treatment date is **Known**, report the date when the final treatment or prophylaxis dose of non-steroidal immunosuppressive agents was administered.

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

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q189 – 204: Infection Prophylaxis

Infection Prophylaxis
This section can only be completed on the 100-day follow-up form. These questions will be skipped for all subsequent reporting periods.

Infection Prophylaxis and the Medication Administration Record
It is important to look at the Medication Administration Record (MAR) throughout the entire reporting period to ensure medications are not missed. Also, the use of some infection prophylactic drugs may not start immediately post-HCT (example: Pentamidine).
Do not report agents used as treatment for documented or suspected infections.
Report prophylactic immunoglobulins in the Immune Reconstitution section.

Combined Follow Up and Infection Prophylaxis
In scenarios where an HCT was given after a cellular therapy and this form is now being completed based on the subsequent HCT date, these questions still apply and should be answered.

Antimicrobial therapy is generally given to HCT recipients to help prevent infections. The following questions are intended to obtain information on the first infection prophylaxis regimen received by the recipient (see example below). In general, most

centers have a standard cocktail of drugs used which include an antibacterial agent (or agents), antiviral agent, antifungal agent, and an anti-pneumocystis agent. This information is often available in a transplant center SOP for infection prevention. Sometimes, recipients are on one of these medications prior to starting the preparative regimen and therefore it could be treating an infection or is being used as "secondary prophylaxis." Information regarding primary and secondary prophylaxis can provide insight into the development of resistant infections.

Example 1: A recipient is admitted for transplant on day -6, 1/2/2022, with the transplant occurring on 1/8/2022. The recipient receives the following medications based on the medication administration record:

- Ciprofloxacin started on 1/07/22
  - Ciprofloxacin is discontinued on 1/14/22, and the recipient begins treatment for a neutropenic fever with Cefepime and Vancomycin on the same day.
- Valacyclovir started on 1/7/2022.
- Fluconazole started on 1/7/2022.
  - Fluconazole is discontinued on 1/16/22, and the recipient begins Micafungin due to a toxicity on the same day.
- Bactrim given from 1/2/22 to 1/6/22 and again at discharge.

In this scenario, the infection prophylaxes would be reported as the following:

- Antibacterial prophylaxis: Ciprofloxacin
  - Cefepime and vancomycin were empiric treatments (not prophylaxis) for a neutropenic fever and thus would not be reported as the antibacterial prophylactic drugs.
- Antiviral prophylaxis: Valacyclovir
- Antifungal prophylaxis: Fluconazole
  - Micafungin was the second antifungal administered and likely still served as prophylaxis. However, the switch from Fluconazole to Micafungin was due to the recipient's increase in liver function tests (AST, ALT, etc.), and thus is not reported as an antifungal prophylaxis since only the first prophylactic drug administered during the reporting period is reported.
- Anti-PJP prophylaxis: Bactrim

Reporting Infection Prophylaxis
When reporting infection prophylaxis, select the drug in each group the recipient received *first* and *closest* to the start of the preparative regimen, even if the drug was started prior the preparative regimen. Include any prophylactic medications started prior to day +45 post-infusion; however, only report the first drug received during the reporting period.

Reporting Infection Prophylaxis Start Dates
When reporting the start date for all prophylaxis medications (antibacterial, antiviral,

antifungal, and anti-PJP), refer to the medical administration record to confirm the date. In the case where the start date is prior to the start of the preparative regimen and the date is unknown, report the date as seven days prior to the start of the preparative regimen.

Questions 189 – 191: Specify the first antibacterial drug given *(select one)*

Report the *first* antibacterial drug administered for prophylaxis and closest to the start of the preparative regimen / infusion and started no later than day +45. This may include antibacterial drugs started prior to the start of the preparative regimen as long as they were continued at the start of the preparative regimen.

Only one antibacterial drug may be reported. If multiple antibacterial drugs were started on the same day, report whichever drug is considered the standard prophylaxis agent at the transplant center. Centers should have an SOP defining infection prophylaxis. Seek physician clarification, as needed.

If **Other antibacterial drug** is selected, specify the drug. Do not include vancomycin IV or Trimethoprim/Sulfamethoxazole (Bactrim, Septra) in this data field. IV vancomycin is captured separately. Trimethoprim/Sulfamethoxazole (Bactrim, Septra) is given as PJP prophylaxis and captured below.

Report the antibacterial drug start date and ensure the date reflects the first date when the drug was administered. If the start date is prior to the start of the preparative regimen *and* the date is unknown, report the start date as seven days prior the start of the preparative regimen. Refer to the medical administration record to confirm the start date.

If no antibacterial drugs were given as prophylaxis, including prior to the start of the preparative regimen and no later than day +45, select **None**. Do not report antibacterial agents given empirically for neutropenic fever. Additionally, do not report penicillin if given as splenic prophylaxis.

Example 2: If both amoxicillin and levofloxacin were started as prophylaxis on the same day the preparative regimen was started, the center should report whichever agent is considered standard for prophylaxis at their institution. However, if amoxicillin was administered at the start of the preparative regimen and levofloxacin was started two days later, the center should only report amoxicillin as the first antibacterial infection prophylaxis drug.

Questions 192 – 193: Was vancomycin IV also given as prophylaxis?

Indicate if vancomycin IV was also given for prophylaxis at the *same time as the first antibacterial drug reported above*. If **Yes**, report the start date of vancomycin IV. It is uncommon that vancomycin is used as prophylaxis, therefore, please confirm with the physician that the intent of vancomycin IV was prophylaxis.

Example 3: Amoxicillin was started as prophylaxis on the same day the preparative regimen was started, and then vancomycin IV was started on day +1 post-infusion. If the amoxicillin was continued while the recipient remained on vancomycin, select **Amoxicillin** in the antibacterial section and report the start date and also report **Yes**, vancomycin IV was also given as prophylaxis with the start date (these will have separate start dates). Vancomycin IV was given *at the same time (in addition to)* as the first antibacterial drug, amoxicillin. However, if amoxicillin was stopped prior to or on the same day when vancomycin was started, **No** would be reported.

Questions 194 – 196: Specify the first antiviral drug given *(select one)*

Report the *first* antiviral drug administered for prophylaxis and closest to the start of the preparative regimen / infusion and started no later than day +45. This may include antiviral drugs started prior to the start of the preparative regimen as long as they were continued at the start of the preparative regimen. If the start date is prior to the start of the preparative regimen *and* the start date is unknown, report the date as seven days prior the start of the preparative regimen. Only one antiviral drug may be reported.

If **Other antiviral drug** is selected, specify the drug. *Do not include letermovir in this data field.*

If no antiviral drugs were given, including prior to the start of the preparative regimen and no later than day +45, select **None**.

Questions 197 – 198: Was letermovir (prevymis) given as prophylaxis?

Letermovir is given to prevent CMV reactivation and is generally started between Day 0 and Day +28 post-HCT.

Indicate if letermovir was also given for prophylaxis at the *same time (in addition to) as the first antiviral drug reported above*. If **Yes**, report the start date of letermovir.

Questions 199 – 201: Specify the first antifungal drug given *(select one)*

Report the *first* antifungal drug administered for prophylaxis and closest to the start of the preparative regimen / infusion and started no later than day +45. This may include antifungal drugs started as prophylaxis prior to the start of the preparative regimen as long as they were continued at the start of the preparative regimen. Only one antifungal drug may be reported. If the start date is prior to the start of the preparative regimen *and* the start date is unknown, report the date as seven days prior to the start of the preparative regimen.

If **Other antifungal drug** is selected, specify the drug. Do not report Nystatin in this data field.

If no antifungal drugs were given, including prior to the start of the preparative regimen and no later than day +45, select **None**.

Questions 202 – 204: Specify the first anti-pneumocystis (PJP) drug given *(select one)*

Report the *first* anti-pneumocystis (PJP) drug administered for prophylaxis and closest to the start of the preparative regimen / infusion and started no later than day +45. This may include anti-pneumocystis (PJP) drugs started prior to the start of the preparative regimen as long as they were continued at the start of the preparative regimen. Only one anti-pneumocystis (PJP) drug may be reported.

If **Other anti-pneumocystis** is selected, specify the drug.

If no anti-pneumocystis (PJP) drugs were given, including prior to the start of the preparative regimen and no later than day +45, select **None**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q205 – 221: Infection

Infections occur frequently in transplant patients. The following questions are intended to capture detailed information on *clinically significant* infections diagnosed during the reporting period. A single infection may be found on multiple cultures or at multiple sites. Infections may recur following resolution of symptoms and negative testing. Use the instructions provided in this section to determine when an infection should be considered clinically significant, and therefore reported, as well as when to report new and / or recurrent infections.

Combined Follow-Up
In scenarios where a cellular therapy is given after a HCT and this form is being completed based on the subsequent cellular therapy, these questions do not apply and are disabled.

Reporting Multiple Infections
Complete *Organism* through *Date of infection diagnosis* for each reported infection by adding an additional instance in the FormsNet application to report the organism, site, and date of diagnosis.

Possible COVID-19 Reporting Scenarios:
Do NOT report an infection in the following scenarios:

- A recipient has a positive antibody result.
- The recipient was symptomatic and treated but COVID-19 testing was not performed and / or COVID-19 diagnostic testing was performed and negative

DO report an infection in the follow scenarios:

- A recipient has a positive COVID-19 diagnostic result (PCR or antigen), regardless of if treatment was given or if the recipient was asymptomatic
- A recipient has a positive antibody result *and* a positive COVID-19 diagnostic test (PCR or antigen)

Questions 205 – 213: Did the recipient develop a clinically significant infection?

Indicate whether the recipient developed a clinically significant bacterial, viral, or fungal infection during the reporting period. For the purpose of this manual, the term "clinically significant" refers to any infection requiring treatment. Surveillance cultures in which normal flora is present and the recipient is asymptomatic do not need to be reported. If no clinically significant infections occurred during the reporting period, report **No**.

Do **not** report the following scenarios:

- Culture-negative neutropenic fever without clear source;
- Upper respiratory infections which are presumed viral, but no virus has been identified;
- Candida detected in oral or stool samples (includes oral thrush);
- Toenail fungus;
- Yeast infection in the groin, vagina, or under the breasts;
- Surveillance cultures in which normal flora is present and the recipient is asymptomatic;
- Infections persisting from a prior reporting period (including infections which have progressed to new sites since the last report); or
- Infections recurring within the time frames specified in the Definitions for Same Infection table below.

Systemic inflammatory response syndrome and septic shock may be diagnosed with or without an organism identified by relevant testing. In either case, a clinical diagnosis of these complications will be reported in the following section. If an organism is identified by molecular report, laboratory report, or other physician documentation, the infection should be captured in this section. If no organism is identified, the center should use the following guidelines to determine whether to report an infection:

- If a fungal infection is suspected (per radiology assessments) and treated, but no organism is isolated during the reporting period, select **Suspected fungal infection**.
- If a bacterial or viral infection is suspected and treated, but not confirmed, select **Suspected bacterial infection** or **Suspected viral infection**, respectively.
- If no particular organism group is identified or suspected, **do not** report an infection in this section.

For each infection, report the organism, site, and date of diagnosis.

If there are multiple positive tests within the specified timeframes listed below, the infection is considered the 'same' and should not be reported multiple times.

Definitions for *Same* Infection

Bacteria	Virus	Fungal
≤ 7 Days • Any bacteria ≤ 30 Days • Clostridium difficile ≤ 365 Days • Helicobacter pylori	≤ 14 Days • Adenovirus • Enterovirus • Herpes zoster • Influenza • Parainfluenza • Rhinovirus • Respiratory syncytial virus • Varicella zoster ≤ 21 Days • COVID-19 ≤ 30 Days • Human Herpes Virus – 6 ≤ 60 Days • Cytomegalovirus • Epstein-Barr virus • Herpes simplex • Polyomavirus	≤ 14 Days • Any yeasts ≤ 90 Days • Any molds

Organism

Select the identified or suspected organism as reported on the microbiology report, laboratory report, or other physician documentation.

If the specific organism is not listed, use the code **Other organism** and report the name of the organism in the space provided.

In some cases, an infection may be suspected but significant enough to be treated. If a fungal, bacterial, or viral infection is suspected, but not identified, report **Suspected bacterial infection, Suspected fungal infection** or **Suspected viral infection**. As noted above, only report infections which are *clinically significant*.

Reporting the following infections, will cause a Fungal Infection Post-HCT Data (2146) form to come due:

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus niger
- Aspergillus, NOS
- Aspergillus terreus
- Aspergillus ustus
- Blastomyces (all species, including dermatitidis)
- Candida albicans
- Candida auris
- Candida parapsilosis
- Candida non-albicans
- Coccidioides
- Cryptococcus gattii
- Cryptococcus neoformans
- Fusarium (all species)
- Histoplasma (all species, including capsulatum)
- Lomentospora prolificans
- Mucorales (all species including Rhizopus, Mucor, Rhizomucor, Absidia, Lichtheimia, Cunninghamella species)
- Pneumocystis (PCP / PJCP)
- Scedosporium (all species)
- Suspected fungal infection

Reporting the following infections will cause a Hepatitis Serology Post-HCT Data (2147) form to come due:

- Hepatitis B Virus
- Hepatitis C Virus

Reporting the following infections will cause a Human Immunodeficiency Virus Post-HCT Data (2148) form to come due:

- Human Immunodeficiency Virus 1 or 2

Site

Infections can occur virtually anywhere. In order to capture sufficient detail without excess burden, there is a list for the potential sites. An infection may occur in more than one site at the same or at different times.

- If the infection is identified at multiple sites with the same organism and within the recurrence interval to be considered the same infection (Definitions for Same Infection table), please report all sites the organism was identified.
- If the infection is identified at multiple sites with an organism already reported but is outside of the recurrence interval to be considered the same infection, please report as a new infection.

Select the site(s) of the infection from the options provided on the form. Report all sites of infection which were confirmed by microbiology, laboratory report, or other physician documentation during the reporting period. This includes any new sites identified after the date of diagnosis as well as after treatment has been initiated.

For clarification, the following site definitions are provided:

- **Blood:** includes blood or serum obtained from a central IV-line, catheter tip, or from a direct needle stick (Peripheral draw). Blood should be the reported site for infections identified in the bone marrow.
- **Bone:** an infection in the bone itself (Osteomyelitis)
- **CNS:** includes CSF (cerebrospinal fluid) specimens as well as abscesses and/or inflammation noted on brain imaging (encephalitis, meningitis)
- **Eyes:** includes infection in any part of the eye (i.e. retinitis)
- **Genital:** includes vagina, penis, perineum, ovaries, scrotum, testes, uterus
- **GI tract, lower:** includes jejunum, ileum, colon, rectum, and stool
- **GI tract, upper:** includes mouth, dentition, esophagus, stomach, and duodenum
- **Joints:** includes fibrous connective tissue and cartilage at any site of bone articulation, typically isolated to a single area (i.e., not a diffuse infection) such as the knee, elbow, or shoulder
- **Liver / Spleen:** includes the gallbladder and biliary tract
- **Lung:** also known as the lower respiratory tract
- **Sinus and/or upper respiratory tract:** all areas from the nose to the throat and sinuses, does not include lungs (report as “Lung”), mouth, or dental infections (report mouth and dental as “GI tract, upper).
- **Skin, cellulitis:** a spreading bacterial or viral infection of the skin and tissues beneath the skin
- **Skin, necrotizing fasciitis:** a severe bacterial infection of the fascia, the tissues that line and separate muscles, that causes extensive tissue death including damage to skin and overlying tissues
- **Urinary tract, lower:** includes urinary tract infections and cystitis (bladder inflammation)
- **Urinary tract, upper:** includes the kidneys and ureters

Date of Diagnosis

Report the specimen collection date of the positive microbiology culture or laboratory report as the diagnosis date. For suspected fungal infections, enter the date of a radiological test or the date treatment was started. If multiple sites of infection are

identified during the reporting period, report the collection date of the first positive microbiology culture or laboratory report.

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

Infection Reporting Scenarios:

A. A recipient's post-HCT CMV testing was consistently negative until 1/10/2015 when CMV PCR testing found 15,000 copies of the virus in the recipient's peripheral blood. On 1/20/2015, the CMV PCR detects 2000 copies. The CMV PCR is still positive on 1/30/2015 but is documented as "detected but not quantifiable". From 2/7/15, all subsequent CMV PCRs are negative until 6/3/2015 when the CMV PCR demonstrates 1300 copies.

The center should report one instance of infection to capture the CMV infection first documented on 1/10/2015. A second instance should also be reported to capture a recurrent CMV infection documented on 6/3/2015. This is >60 days after PCR testing reverts to negative and is therefore considered a recurrence and not the same infection per the guidelines in the Definitions for the Same Infection table above. The recurrent infection would be reported on a subsequent Post-Infusion Data Form if it is diagnosed after the date of contact for the form being completed.

B. A recipient with concerning respiratory symptoms undergoes a bronchiolar lavage on 10/1/2014. A culture performed on the sample collected from the procedure revealed a Streptococcus, Group B infection. The recipient received systemic antibacterial antibiotics, but the infection progressed to their blood as demonstrated by a culture performed on sample collected 10/3/2014. The recipient did not have any repeat cultures performed between their initial diagnosis and testing performed on 11/1/2014. The center should report one instance to capture the Streptococcus, Group B infection. The diagnosis date is the date of the first positive culture performed on the sample collected 10/1/2014.

- If the positive culture from 10/3/2014 was collected during the same reporting period, "lung" and "blood" should both be reported as sites of infection.
- If the positive culture from 10/3/2014 was collected after the date of contact for the current reporting period, do not report "blood" as a second site of infection.

C. A recipient is empirically diagnosed with septic shock on 8/15/2013, though cultures and viral tests are consistently negative. The recipient is treated with multiple antimicrobial agents which eventually leads to a resolution of all symptoms / complications. The organism responsible for the suspected infection is never identified.

As no organism was identified, the only scenario in which the center should report this as an infection is if there is documentation confirming a suspected fungal infection. In any case, the clinical diagnosis of septic shock will be reported in a following question.

Questions 214 – 215: Did the recipient develop Systemic Inflammatory Response Syndrome (SIRS)?

Systemic inflammatory response syndrome refers to unregulated inflammation which may or may not be related to an infection. Using the criteria below, indicate if the recipient developed SIRS in the reporting period. If **Yes**, report the diagnosis date.

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

When determining the development of SIRS, the following criteria should be used and do not use the transplant center's own criteria:

SIRS Criteria (adults and pediatrics):

Requires at least one or more of the following:

- Core temperature > 38.5 C or < 36 C, *and / or*
- Leukocytosis or leukopenia for age (not secondary to chemotherapy) or >10% bands

Additional symptoms may include:

- Tachycardia, otherwise unexplained persistent in absence of external stimulus, chronic drugs or painful stimuli **or** bradycardia, in < 1 year old, otherwise unexplained persistent
- Tachypnea or mechanical ventilation for an acute process not related to underlying neuromuscular disease or general anesthesia

As long as **two symptoms** are present and one of the symptoms is from the first group above, SIRS should be reported.

Questions 216 – 217: Did the recipient develop septic shock?

Septic shock refers to the failure to maintain sufficient mean arterial pressure without intervention with vasopressors. It results from vasodilation associated with infection. If septic shock was clinically diagnosed during the reporting period, report **Yes** and indicate the diagnosis date.

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

Questions 218 – 221: Did a fecal microbiota transplant (FMT) occur?

Fecal microbiota transplant (FMT) refers to the procedure involving collecting fecal matter from a pre-screened donor and transferring it to a recipient by the oral or rectal

route (for example by nasogastric tube or enema) in order to restore intestinal microbial flora. FMT is commonly used as treatment for C difficile colitis or as treatment / prevention for GVHD.

If a FMT occurred during the reporting period, report **Yes**, indicate the date of FMT and specify the indication. If the indication is not listed on the form, select **Other** and specify the indication.

If multiple FMT's were received during the reporting period, report the first date of FMT performed in the reporting period. Use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms if the exact collection date is not known.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q222: New Malignancy, Lymphoproliferative or Myeloproliferative Disease/ Disorder

Combined Follow-Up
In scenarios where a cellular therapy is given after a HCT and this form is being completed based on the subsequent cellular therapy, these questions do not apply and are disabled.

Question 222: Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the infusion was performed? *(include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)*

Indicate whether a new or secondary malignancy, lymphoproliferative disorder, or myeloproliferative disorder was diagnosed during the reporting period. Do not report recurrence, progression, or transformation of the recipient's primary disease (disease for which the transplant was performed) or relapse of a prior malignancy.

Report relapse of the recipient's primary disease on the appropriate post-infusion disease-specific data form. Relapse of a prior malignancy will not be captured by the CIBMTR.

New malignancies, lymphoproliferative disorders, and myeloproliferative disorders include but are not limited to:

- Skin cancers (basal, squamous, melanoma)
- New leukemia
- New myelodysplasia
- Solid tumors
- PTLD (post-transplant lymphoproliferative disorder) (report as NHL)

The following should not be reported as new malignancy:

- Recurrence of primary disease (report as relapse or disease progression)
- Relapse of malignancy from recipient's pre-HCT medical history
- Breast cancer found in other (i.e., opposite) breast (report as relapse only if the infusion was for breast cancer)
- Post-infusion cytogenetic abnormalities associated with the pre-HCT diagnosis (report as relapse)
- Transformation of MDS to AML post-HCT (report as disease progression)

Post-Transplant Lymphoproliferative Disorder (PTLD)
PTLD should be reported as a new malignancy if it was confirmed via a biopsy (treatment not required) or suspected to be PTLD and treated

Recurrent Non-Melanoma Skin Cancers
If there is a recurrence of non-melanoma skin cancers in the reporting period, select **Yes** for *Did a new malignancy, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed* and a single Subsequent Neoplasms (3500) will come due, allowing the total number of non-melanoma skin cancer lesions diagnosed during the reporting period to be reported. If additional non-melanoma skin cancer lesions are diagnosed in the reporting period, update the reported total number of non-melanoma skin cancer lesions diagnosed in the reporting period on the Subsequent Neoplasms (3500). Do not create separate Subsequent Neoplasms (3500) forms for each discrete lesion diagnosed in the reporting period. If a non-melanoma skin cancer is diagnosed again in a future reporting period, repeat the process for that reporting period.

If a new malignancy, lymphoproliferative disorder, or myeloproliferative disorder was diagnosed during the reporting period, report **Yes** and the Subsequent Neoplasm (3500) form will come due.

The **Previously reported** option should only be used if the same malignancy has already been reported on a Subsequent Neoplasms (3500) form that was made due on demand. See examples below. If it is unclear whether or not to use of this option, contact CIBMTR Center Support if there are questions.

- Example 1**.** A recipient developed a new malignancy at Day +68 and is reported at the time the Day 100 Post-Infusion Follow-up (2100) form is completed. In this scenario, report **Yes**, the recipient developed a new malignancy and a Subsequent Neoplasms (3500) form will be completed to report the new malignancy information. For all future reporting periods, select **No**.

- Example 2. A recipient developed a new malignancy during the seven-year reporting period and the transplant center decided to create the Subsequent Neoplasms (3500) form as an unscheduled form in FormsNet3^{SM} to report the new malignancy information immediately since a Post-Infusion Follow-Up for seven-year reporting period will not come due. When the eight-year Post-Infusion Follow-Up (2100) form is completed, **Previously reported**, will be reported since a prior Subsequent Neoplasms (3500) form has already been submitted for the new malignancy.

- Example 3. A recipient was diagnosed with basal cell skin cancer on the neck in the one-year reporting period and two months later, within the same reporting period, there was a diagnosis of basal cell located on the nose. The lesion on the nose is not considered a metastasis from the neck, but a new discrete lesion. In the two-year reporting period, the recipient was diagnosed with an additional basal cell skin cancer on the arm. For the one-year reporting period, report **Yes**, there was a new malignancy on the Post-Infusion Follow-Up (2100) Form, a single Subsequent Neoplasms (3500) Form will come due, and report **2** for the total number of non-melanoma lesions diagnosed in the reporting period on the Subsequent Neoplasms (3500). For the two-year reporting period, report **Yes**, there was a new malignancy on the Post-Infusion Follow-Up (2100) Form, a single Subsequent Neoplasms (3500) Form will come due, and report **1** for the total number of non-melanoma lesions diagnosed in the reporting period on the Subsequent Neoplasms (3500).

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q223 – 247: Functional Status

Combined Follow Up and Functional Status
In scenarios where a cellular therapy is given after a HCT and this form is being completed based on the subsequent cellular therapy, these questions do apply and should be answered.

Question 223: Was the intent to complete the HCT procedure (conditioning, infusion, and period of recovery from neutropenia) as an outpatient?

Report **Yes** if the plan was to complete all conditioning, infusions, and recovery in the outpatient setting. If the plan was to admit the patient for any part of the transplant, report **No**.

Report **Yes** even if the recipient required an unplanned admission.

This question can only be answered for the Day 100 reporting period.

Question 224: Did the recipient require an unplanned admission?

Report whether the recipient required an unplanned admission during the reporting period. This includes unplanned admissions for the purpose of completing an infusion as well as admissions to address any post-infusion complications. Report **Yes** if an unplanned admission was required. If the recipient did not require an unplanned admission, report **No**.

This question can only be answered for the Day 100 reporting period.

Questions 225 – 226: Was the recipient discharged prior to the date of contact?

If the recipient was discharged from the hospital during the reporting period, report **Yes** and report the date the recipient was discharged. If the recipient was admitted to the hospital multiple times during the reporting period, report first discharge date. If the recipient was not discharged from the hospital during the reporting period, report **No**.

If the recipient died without ever being discharged from the hospital, report **No**.

This question can only be answered for the Day 100 reporting period.

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

Question 227: Total number of inpatient days (day 0 to day 100) in first 100 days post-infusion

Enter the total number of inpatient days (including day 0). If the recipient was discharged and readmitted during the first 100 days, the total should include days hospitalized after being readmitted. In the scenario of readmission, when counting the total number of inpatient days, count either the day of admission or the day of discharge; do not count both.

If the recipient receives a subsequent infusion prior to day 100, do not include the start date of the preparative regimen for the subsequent infusion (or the date of the subsequent infusion if no preparative regimen was given).

This question can only be answered for the Day 100 reporting period.

Questions 228 – 230: Recipient height *(most recent)*

These questions will only be enabled / answered for pediatric patients (≤ 16 years old) when the form visit ID is 6 months or greater. These questions will be disabled / not answered for all recipients on the day 100 follow-up form.

Indicate whether the recipient's height is known. If **Known**, report the recipient's most recent height, specify the units, and report the date the height was measured. If the recipient's height was not measured during the reporting period, report **Unknown**. For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 231 – 233: Recipient weight *(most recent)*

Indicate whether the recipient's weight is known. If **Known**, report the recipient's most recent weight, specify the units, and report the date the weight was measured. If the recipient's weight was not measured during the reporting period, report **Unknown**. For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 234 – 237: Functional status *(check all that apply)*

The CIBMTR uses the Karnofsky / Lansky scale to determine the functional status of the recipient on the date of contact. The Karnofsky Scale is designed for recipients aged 16 years and older and is not appropriate for children under the age of 16. The Lansky Scale is designed for recipients one year old to less than 16 years old. If the recipient is less than one year old, leave KPS data fields blank. An ECOG score may be reported for recipients of all ages.

Acceptable performance scores include those recorded within 14 days prior to 100 Day and Six-Month contact dates. For the annual reporting periods, performance scores may be reported if dictated within one month of the contact date. If the recipient passed away during the reporting period, this question will be disabled.

If a performance score was documented within the applicable timeframes, select the appropriate performance scale. Using Karnofsky or Lansky scale, select the score (10-100) that best represents the recipient's activity status immediately prior to the date of last actual contact. The only valid scores are 10-100; zero is not a valid response for this scale, nor are values not ending in zero, such as "85." The Karnofsky / Lansky scale can be found in Appendix L. For ECOG, the only valid scores are 0 – 4.

Review the guidelines below to determine which score to report:

- If both a Karnofsky / Lansky and an ECOG score is documented within the applicable time frames, the center may choose which score or if both scores are reported.
- If only a Karnofsky / Lansky score is documented within the applicable time frame, only report a KPS – converting the KPS to an ECOG is not required.
- If only an ECOG is documented within the applicable time frames, only report an ECOG – converting the ECOG to a KPS is not required.

Recipient performance status is a critical data field that has been determined to be essential for all outcome-based studies. Determination of performance status is ideally performed by a healthcare provider. Centers are encouraged to put tools in place to facilitate this collection. If a performance score is not documented in the source documentation (e.g., inpatient progress note, physician's clinic notes), data professionals are encouraged to discuss a determination with the physician or mid-level health care provider (NPs and PAs) rather than make an assignment themselves, based on inadequate information. Documentation from an RN who has been trained and authorized to determine performance scores may also be used.

Pregnancy Questions
The pregnancy questions will only be answered for recipients between the ages of 10 and 60.

Combined Follow Up and Pregnancy
In scenarios where an HCT was given after a cellular therapy and this form is now being completed based on the subsequent HCT date, pregnancy questions do not apply and are disabled.

Question 238: Did the recipient become pregnant? *(Female only)*

Indicate whether the recipient was pregnant at any time during the reporting period. Skip this question for male recipients.

If **Yes**, complete the Pregnancy (3501) form also. The **Previously reported** option should only be used if the same pregnancy instance has already been reported on a Pregnancy (3501) form that was created as an unscheduled form (on-demand). See examples below.

Contact CIBMTR Center Support with questions.

Question 239: Did the recipient's female partner become pregnant? *(Male only)*

Indicate whether the recipient's female partner was pregnant at any time during the reporting period. Skip this question for female recipients.

If **Yes**, complete the Pregnancy (3501) form also. The **Previously reported** option should only be used if the same pregnancy instance has already been reported on a Pregnancy (3501) form that was created as an unscheduled form (on-demand). See examples below.

Contact CIBMTR Center Support with questions.

Example 1. A recipient or recipient's female partner becomes pregnant at Day +68 and is reported at the time when the Day 100 Post-Infusion Follow-Up (2100) form is completed. The recipient or recipient's female partner is still pregnant at the six-month reporting period and then delivers the baby during the one- year reporting period. The recipient / recipient's female partner does not become pregnant again.

For the Day 100 reporting period, the pregnancy questions should be reported as **Yes** and the Pregnancy (3501) form will be completed to report the pregnancy information. For the six-month and one-year reporting periods, **Previously reported** should be selected since the recipient / recipient's female partner was still pregnant during the reporting period and a prior Pregnancy (3501) form has already been submitted for the pregnancy. For all future reporting periods, select **No**.

Example 2. A recipient or recipient's female partner becomes pregnant during the seven-year reporting period and the transplant center decided to create the Pregnancy (3501) form as an unscheduled form in FormsNet3^{SM} to report the pregnancy information immediately since a Post-Infusion Follow-Up for seven-year reporting period will not come due. When the eight-year Post-Infusion Follow-Up (2100) form is completed, **Previously reported**, will be reported since a prior Pregnancy (3501) form has already been submitted for the pregnancy.

Questions 240 – 242: Has the recipient smoked tobacco cigarettes since the date of last report?

The intent of this question is to determine the recipient's history of smoking cigarettes only. Do not report the use of cigars, pipe tobacco, chewing tobacco, electronic cigarettes, vaping or other drugs. Report **Yes** if the recipient has smoked tobacco cigarettes since the date of the last report and capture the average number of packs (20 cigarettes per pack) smoked a day, if known. If the recipient has not smoked tobacco cigarettes since the date of the last report, or their smoking history is not known, report **No** or **Unknown**.

Questions 243 – 244: Specify the category which best describes the recipient's current occupation

Select the category that best describes the recipient's current occupation. If the recipient is younger than school-aged, select **Under school age**. If the recipient is a student, select **Not employed**. If **Other** is selected, specify the recipient's occupation.

Only one work status may be reported. If a recipient has multiple work opportunities during the current reporting period, report the highest level of work being performed. For example, full time work would be reported over part time work.

Questions 245 – 247: What is the recipient's current or most recent work status?

Select the work status that best describes the recipient's current or most recent employment during this reporting period. If the recipient is **Retired**, specify their retirement status. If the recipient's status is anything other than **Full time**, indicate if the recipient claimed and received medical disability due to any illness.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)