Instructions for Fungal Infection Pre-Infusion Data (2046)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Fungal Infection Pre-Infusion Data (2046).

Fungal Infection Pre-Infusion Data (2046)

Fungal infections are significant opportunistic infections affecting transplant patients. Because these infections are quite serious, it is important to collect additional information on them. The Fungal Infection Pre-Infusion Data (2046) Form captures information regarding the diagnosis, treatment, and response to treatment of any proven or suspected fungal infections diagnosed prior to receiving a HCT or cellular therapy. This form must be completed when one of the fungal infections listed below has been reported on the Recipient Baseline (2000) Form. One form will be completed for each applicable infection reported.

The following infections will cause a Fungal Infection Pre-Infusion Data (2046) Form to come due when reported on the Recipient Baseline (2000) Form:

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus niger
- Aspergillus terreus
- Aspergillus ustusAspergillus, NOS
- Blastomyces (dermatitidis)
- Candida albicans
- Candida non-albicans
- Cryptococcus gattii
- Cryptococcus neoformans
- Fusarium (all species)
- Histoplamsa (capsulatum)
- Mucorales (all species)
- Rhizopus (all species)
- Scedosporium (all species)
- Zygomycetes, NOS
- Suspected fungal infection

For reference, definitions of some common terms concerning fungal infections are provided below. These definitions are for clarification only and should not be considered to be reporting criteria or instructions.

- Fungemia: The presence of fungus (mold or yeasts) in blood cultures
- Proven invasive fungal infections: Based on EORTC published recommendations as follows:
    - Histopathologic, cytopathologic, or direct microscopic examination of a specimen obtained by needle aspiration or biopsy in which hyphae or melanized yeast-like forms are seen accompanied by evidence of associated tissue damage (molds) or showing encapsulated budding yeasts or Candida species showing pseudohyphae or true hyphae (yeasts); or
    - Cultures of specimens obtained by a sterile procedure from a normally sterile site (excludes bronchial lavage, sinus specimen, and urine) with clinical or radiologic evidence of abnormal growing mold, 'black yeast', or yeast.
- Probable invasive fungal infections: Based on EORTC published recommendations[1] requires presence of one each of host factors, clinical features, and mycological features:

Host Factors

- Receipt of allogeneic HCT
- Treatment with steroids of at least 0.3mg/kg/day prednisone equivalent for three weeks or longer
- Treatment with T-cell immunosuppressants (cyclosporine, tacrolimus), monoclonal antibodies (alemtuzumab), or nucleoside analogues (fludarabine) in the past 90 days

Clinical Features

- Lower respiratory tract disease includes CT findings of one of the following:
    - Dense, well-circumscribed lesions with or without a halo
    - Air-crescent sign
    - Cavity
- Tracheobronchitis with evidence of ulceration, nodule, pseudomembrane, plaque, or eschar on bronchoscopy
- Sinonasal infection with; CT documenting acute sinusitis and at least one of the following:
    - Acute localized pain (including radiation to the eye)
    - Nasal ulceration with black eschar
    - Bone destruction of the sinuses.

Mycological Features

- Direct: Fungal elements of mold or culture of specific mold from sputum, bronchoalveolar lavage, bronchial brushings, or sinus aspirate.

- Indirect: Galactomannan antigen detected in serum, plasma, bronchial lavage fluid, or cerebrospinal fluid or Beta-D-glucan detected in serum.

Disseminated infections with Histoplasmosis, Blastomycosis, or Coccidiomycosis:

- Culture of any of these organisms from an affected site or from the blood
- Histopathology or direct microscopic demonstration of the appearance characteristic of these dimorphic (can exists in both a yeast and mold (hyphae) form based on external conditions) fungi
- Demonstration of coccidioidal antibody in CSF or a 2-dilution rise in two consecutive blood samples in the appropriate setting; or
- Presence of a host factor (see above) plus an appropriate clinical picture with mycological evidence such as a positive *Histoplasma* antigen test from urine, blood, or cerebrospinal fluid

Disseminated *Cryoptococcus*: Crypotococcal antigen detected in the cerebrospinal fluid.

Links to Sections of Form:
Q1-25: Infection Episode
Q26-31: Treatment of Infection

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
2/27/2026	2046: Fungal Infection Pre-Infusion Data	Modify	Version 3 of the 2046: Fungal Infection Pre-Infusion Data section of the Forms Instructions Manual released. Version 3 corresponds to revision 6 of the Form 2046.

Q1 – 25: Infection Episode

Question 1: Organism

This field is auto-populated to match the fungus reported on the Recipient Baseline (2000) Form. Review the value to ensure it is accurate. A Fungal Infection Pre-Infusion Data (2046) Form will come due for each applicable infection reported on the Recipient Baseline (2000) Form so it is imperative to identify the fungal infection to which this form will correspond.

If multiple infections of the same fungus are reported during the same reporting period, a Fungal Infection Pre-Infusion Data (2046) Form must be completed for each infection instance, or episode, reported.

Question 2: Date of infection diagnosis

This field is auto-populated to match the date reported on the Recipient Baseline (2000) Form. Review the value to ensure it is accurate. See the Recipient Baseline (2000) section of the manual for further instructions on reporting the date of diagnosis.

If multiple infections of the same fungal organism are reported in the same reporting period, the diagnosis date reported will clarify for which infection episode the form is being completed.

Diagnostic Results
Report all testing that had positive results and which indicated the fungal infection was present. Do not report negative or indeterminate / equivocal testing.

Questions 3 – 25: Diagnostic testing

If multiple fungal infections were diagnosed, a separate Fungal Infection Pre-Infusion Data (2046) Form must be completed for each organism. Ensure that the test results reported below reflect only the assessments used to identify the infection or organism for the form being completed.

Only report methods performed and samples collected (or sites assessed for radiological findings) within 14 days (+ / -) of the diagnosis date reported above.

For each assessment, specify if the results were positive for the fungal infection using the following guidelines:

- **Yes**: Assessment was completed within 14 days (+ / -) of the infection diagnosis date and was positive for signs of the fungal infection being reported. If **Yes**, specify the site(s) of where the infection was detected. If the site is not listed, select the ‘other’ option and specify.
- **No**: Assessment was not performed within 14 days (+ / -) of the infection diagnosis date, was completed but not positive for the reported fungal infection or the results were ‘equivocal’ or ‘indeterminate.’

- **Unknown**: This option should be used sparingly and only when there is no information on whether the assessment was performed.

If the significance of the test result is unclear, seek clinician clarification.

Diagnostic Assessments

- Radiographic findings (e.g., x-ray, CT, or MRI): Includes imaging such as x-ray, CT, PET, or MRI. These assessments can show infection but do not identify the organism.
- Pathology: Biopsy or fine needle aspirate samples are evaluated by microscopy (without incubation). If culture or staining was performed, report under those methods. Review the results and / or interpretation section of the pathology report.
- Culture: Samples are incubated in media to detect fungal growth. Results are generally found in the microbiology / virology section of the medical record and are determined based on colony formation and growth, in addition to microscopic assessment. If staining was done after incubation, report under the staining method below.
- KOH / Calcofluor / Giemsa stain: Samples, usually fluids like sputum or wash samples, are stained and examined under microscopy to determine if fungal cells are present (positive) or absent (negative).
    - KOH: Potassium hydroxide (fungal wet prep)
    - Calcofluor: Binds fungal cell walls
    - Giemsa: Often used for Histoplasma
- Galactomannan assay: Uses ELISA method to detect galactomannan (specific to Aspergillus genus) in a sample. This test does not determine the Aspergillus subtype and additional testing is required.
- 1,3-Beta-D-glucan (Fungitel) assay: Uses ELISA method to detect beta-D-glucan (found in Candida, Aspergillus, and others). This test does not determine the fungal subtype and additional testing is required.
- PCR assay: Detects fungal DNA using polymerase chain reaction (PCR). Presence and classification of fungi are assessed by identifying DNA sequences unique to specific fungi. Results are generally found in the microbiology / virology or the molecular pathology section of the medical record.

Section Updates

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

Q26 – 31: Treatment of Infection

Question 26: Did the recipient receive any therapy between 7 days prior to the date of infection diagnosis and the date of infusion?

Specify if any antifungal drugs were given between seven days prior to the infection diagnosis date and the infusion date (i.e., Day 0 of the HCT or cellular therapy).

If the dose of fungal prophylaxis increased between seven days prior to the infection diagnosis date and the infusion date, select **Yes**.

If antifungal drugs were not given between seven days prior to the infection diagnosis date and the infusion date, or it is unknown if given, select **No**.

Reporting Multiple Antifungal Drugs
Complete *Antifungal drugs* through *Date started* questions to report all antifungal drugs given between seven days prior to the diagnosis date and the infusion date by adding an additional instance in the FormsNet3^{SM} application.

Questions 27 – 30: Antifungal drugs

Specify the antifungal drug given seven days prior to the infection diagnosis date and the infusion date and the therapy start date. If an antifungal drug was given but not listed, select **Other antifungal drug** and specify.

If an antifungal drug was started greater than seven days prior to the date of infection diagnosis and continued within seven days of the diagnosis date, report the therapy start date as seven days prior to the infection diagnosis.

If the exact start date is not known, use the guidelines for reporting estimated dates in General Instructions, General Guidelines for Completing Forms.

Infection Status
The **Unknown** option should never be used to report the status of the infection. The options on the form will be revised with next revision of this form.

Question 31: What was the status of the infection? *(at the last evaluation prior to the start of the preparative regimen)*

Report the status of the fungal infection immediately prior to the start of the preparative regimen / lymphodepleting therapy (or infusion if no preparative regimen / lymphodepleting therapy was given) based on the primary care provider's clinical judgement.

If the status of the infection is not documented prior to the start of the preparative regimen / lymphodepleting therapy, seek clinician clarification.

Select **Ongoing** if the infection is still present but cannot be considered improved or resolved.

Section Updates

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