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Organ Function / Late Effects (3504 R1)

The Organ Function / Late Effects (3504) Form is a new data collection form to be used for cell therapy and HCT recipients. This new form was created by removing the Organ Function section from the Post-Infusion Follow-up (2100) Form. The content of the new form is largely unchanged but restructured to align with current reporting instructions. The new structure will clearly capture these reporting scenarios:

- Experienced (Yes/No)
- Diagnosed in this post-infusion reporting period
- Diagnosed pre-infusion and persisted into this reporting period
- Diagnosed post-infusion and persists
- Occurred and resolved, occurred again as a new instance in this reporting period

This form will come due:

- For CT recipients on the CRF track: after the F4100 & F4101 are completed, the F3504 will populate beginning at 1-year post-infusion time point.
- For HCT recipients on the CRF track: after the F2400 & F2402 are completed, the F3504 will be paired with the F2100 at all time points.

Recipient Baseline Data (2000 R7) / Post Infusion Follow-up (2100 R10)

2000R6	Data Change Description	2000R7	Rationale
Organism (Q36)			
Blastomyces (dermatitidis)	Update: retire and add new	Blastomyces (all species, including dermatitidis)	Updated the option text to standardize across the forms.

Candida non-albicans	Update: retire and add new entries	Candida auris Candida parapsilosis	Added 2 new individual entries for important candida species in HCT / cellular therapy.
		Candida non-albicans (excluding C. parapsilosis and C. auris)	Updated the option to account for the two new entries.
	Addition	Coccidioides (all species)	Align with Post-Cellular Therapy Essential Data (F4100R10).
Histoplasma (capsulatum)	Update: retire and add new	Histoplasma (all species, including capsulatum)	Updated the option text to standardize across the forms.
	Addition	Lomentospora prolificans	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Mucorales (all species)	Replacement	Mucorales (all species including Rhizopus, Mucor, Rhizomucor, Absidia, Lichtheimia, Cunninghamella species)	Updated the organisms to list the words that data managers are likely to see in the lab report.
Rhizopus (all species)	Removal		'Rhizopus' is part of the option "Mucorales"

Zygomycetes, NOS	Removal		This was an old term for "Mucorales", but won't be used by any labs now.
	Addition	Pneumocystis (PCP / PJP)	Align with Post-Cellular Therapy Essential Data (F4100R10).
Prior viral exposure / infection (check all that apply) (Q38)			
Anti-EBV (Epstein-Barr virus antibody)	Replacement	Anti-EBV (Epstein-Barr virus IgG and / or EBNA antibody)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Hepatitis B surface antibody	Replacement	HbsAb (hepatitis B surface antibody)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.

Toxoplasmosis antibody	Replacement	Toxoplasma IgG (Toxoplasma antibody)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Not applicable (all viral testing negative)	Replacement	Not applicable (all baseline serology/NAATs negative)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Socioeconomic Information Section			
Is the recipient an adult (18 years of age or older) or emancipated minor? (Q104)	Removal		Data is captured on Pre-Transplant Essential Data (F2400).
Specify the recipient's marital status (Q105)	Removal		Data is captured on Pre-Transplant Essential Data (F2400).
What is the highest educational grade the	Removal		Data is captured on Pre-Transplant

recipient completed? (Q109)			Essential Data (F2400).
Is the recipient covered by health insurance? (Q111)	Removal		Data is captured on Pre-Transplant Essential Data (F2400).
Specify type of health insurance (check all that apply) (Q112)	Removal		Data is captured on Pre-Transplant Essential Data (F2400).
Specify other government program (Q113)	Removal		Data is captured on Pre-Transplant Essential Data (F2400).
Specify other health insurance (Q114)	Removal		Data is captured on Pre-Transplant Essential Data (F2400).
Specify the recipient's combined household gross annual income (include earnings by all family members living in the household before taxes) (For U.S. residents only) (Q115)	Removal		Data is no longer essential for research.
Number of people living in the household (Q116)	Removal		Data is no longer essential for research.
Number of people living in the household under the age of 18 (Q117)	Removal		Data is no longer essential for research.

F2100R9	Data Change Description	F2100R10	Rationale
Vital status section (Subsequent HCT/CT Q4 – Q9)	Removal		Data is captured on Indication for CIBMTR Data Reporting (F2814R5).

Chimerism studies section (Q58 – Q74)	Removal		Data is captured on Chimerism Essential Data (F2451R3).
Infection section (Q245 – Q249)	Removal		Data is no longer required for research.
Organ Function section (Q250 – Q382)	Removal		Data is captured on Organ Function / Late Effects (F3504R1).
Subsequent HCT section (Q409 – Q412)	Removal		Data is captured on Indication for CIBMTR Data Reporting (F2814R5).
Organism (Q229)			
	Addition	Achromobacter xylosoxidans	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
	Addition	Actinomyces (all species)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in

			laboratory reports.
	Addition	Bacillus cereus	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
	Addition	Bacteroides fragilis	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Pseudomonas or Burkholderia cepacia	Replacement	Burkholderia cepacia	The old name of Pseudomonas cepacia was dropped in 1992, so this entry is to simplify to minimize incorrect selections
Citrobacter (freundii, other species)	Replacement	Citrobacter (all species, including freundii)	Updated the option text to standardize across the forms.

Clostridium difficile	Replacement	Clostridioides difficile (previously Clostridium difficile)	Updated the option due to name change in 2016.
	Addition	Cutibacterium acnes (previously, Propionibacterium acnes)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports
Lactobacillus (bulgaricus, acidophilus, other species)	Replacement	Lactobacillus (all species, including bulgaricus, acidophilus)	Updated the option to standardize across the forms.
	Addition	Moraxella catarrhalis	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
	Addition	Rothia (all species)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant

			organisms commonly identified in laboratory reports.
	Addition	Staphylococcus coagulase negative (excluding Staphylococcus epidermidis)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Streptococcus, alpha-hemolytic	Update: retire and add new	Streptococci, viridans group (all species including mitis, anginosus, mutans, salivarius, bovis)	This updated option is matching the most likely way the organism will be reported by the lab, these are frequently reported currently in "other"
	Addition	Streptococcus, Group A (Streptococcus pyogenes)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.

Streptococcus, Group B	Replacement	Streptococcus, Group B (Streptococcus agalactiae)	The option is updated because labs sometimes report the species in place of the group.
	Addition	Yersinia enterocolitica	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Blastomyces (dermatitidis)	Update: retire and add new	Blastomyces (all species, including dermatitidis)	Updated the option text to standardize across the forms.
Candida non-albicans	Update: retire and add new entries	Candida auris Candida parapsilosis	Added 2 new individual entries for important candida species in HCT / cellular therapy.
		Candida non-albicans (excluding C. parapsilosis and C. auris)	Updated the option to account for the two new entries.
Histoplasma (capsulatum)	Update: update and retire new	Histoplasma (all species, including capsulatum)	Updated the option text to standardize across the forms.
	Addition	Lomentospora prolificans	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment

			with clinically relevant organisms commonly identified in laboratory reports.
Mucorales (all species)	Replacement	Mucorales (all species including Rhizopus, Mucor, Rhizomucor, Absidia, Lichtheimia, Cunninghamella species)	Updated the organisms to list the words that data managers are likely to see in the lab report.
Rhizopus (all species)	Removal		The option is removed because 'Rhizopus' is part of the option "Mucorales"
Zygomycetes, NOS	Removal		This was an old term for "Mucorales", but won't be used by any labs now.
	Addition	Astrovirus	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Enterovirus (ECHO, Coxsackie)	Update>>change to new option, retire old and create new	Enterovirus except polioviruses and D68 (including echoviruses and coxsackieviruses)	These options are now grouped together under updated Enterovirus entry
Enterovirus, NOS			
Enterovirus (polio)	Replacement	Polioviruses	This option is a group of

			species. Most accurate to call it "Polioviruses"
Hepatitis E	Replacement	Hepatitis E virus	Updated the organism to account for virus terminology.
	Addition	Parvovirus B19	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.
Rhinovirus (all species)	Update – retire general listing and add two new options	Rhinovirus (all species except Rhinovirus / enterovirus (not differentiated))	Updated to account for new entry for the non-differentiated group.
		Rhinovirus / enterovirus (not differentiated)	Added option to account for testing that does not differentiate between Rhinovirus and Enterovirus
	Addition	Sapovirus	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in

			laboratory reports.
Trypanosoma cruzi (Chaga)	Replacement	Trypanosoma cruzi (Chagas Disease)	The organism list is revised in accordance with recommendations from the Infection working committee, to ensure alignment with clinically relevant organisms commonly identified in laboratory reports.

Thalassemia Pre-Infusion (2058 R3)

Existing Organ Impairments

- **Q95 (“Specify co-existing diseases or organ impairments any time prior to start of preparative regimen”)**
 - Update: “Hypogonadism / gonadal dysfunction” and “Osteonecrosis” were added to the option list.
 - Rationale: These conditions are often seen in individuals with thalassemia; capturing these data is applicable to individuals with thalassemia in general and is necessary for current studies.

Thalassemia Post-Infusion (2158 R3)

Existing Organ Impairments

- **Q102 (“Specify organ impairments or disorders developed”)**
 - Update: “Hypogonadism / gonadal dysfunction” and “Osteonecrosis” were added to the option list.
 - Rationale: These conditions are often seen in individuals with thalassemia; capturing these data is applicable to individuals with thalassemia in general and is necessary for current studies.