Sepsis Data Collection Instructions:
Please read carefully
***Very important Notes** *

- Please document **ALL donor charts reviewed during this period** (*not only those with Sepsis mentioned*). This is a prospective data collection, so please do not include any charts that have been previously reviewed. Please ensure you include the review date.
- Please only document review at **Medical Director level**, not screening/quality assurance/etc. level.

Instructions for Data Entry by Column:
A: # - Starting with number 1
B: Date- Date chart review completed. Note: click on cell and then click on the date in the calendar and it will auto-fill the date selected.
C: Donor ID - Organization's Donor ID. This information will NOT be submitted to FDA.
D: Sepsis Diagnosed During Hospital Stay (in Problem list or discharge diagnosis)- (Drop down Yes, No) This does not include solely the mention of the word "sepsis" in the chart. There are many reasons why the word "sepsis" may appear in the chart without it being diagnosed. We are interested in a problem list diagnosis or a discharge diagnosis here.
E: SIRS (or SOFA) + Suspicion of Infection criteria met? - (Drop down Yes, No, N/A) The SIRS or SOFA criteria PLUS any suspicion of infection. For purposes of this data collection, we will use the Sepsis-2 and/or Sepsis-3 definitions, which essentially are either SIRS or SOFA (or qSOFA) criteria being met PLUS any suspected infection. If SIRS alone and no documentation in record of diagnosis or suspicion of infection or sepsis, please do not mark YES
Please refer to the SIRS/SOFA criteria at the end of this document.
F: If yes, Sepsis later "Ruled Out" by treating MD? (Drop down Yes, No, N/A) – Please mark yes if it is specified in the chart that Sepsis was initially diagnosed but later "ruled out".
G: Sepsis is NOT diagnosed in the chart, but Medical Director believes that there IS potential for transmissible infection. (Drop down Yes, No, N/A) (Examples: suspicion of local infection to tissue recovered, culture result obtained after death indicates potential infection, hospice death without sufficient labs/vitals to document sepsis, etc). This is important in identifying infection transmission risks that are not captured by Sepsis criteria alone.
H: Transmissible/ suspected infection treated appropriately and not a concern at time of death (TOD) (*describe in notes) – (Dropdown Yes, No) If a potentially transmissible infection was identified in the hospital course, but was treated appropriately per guidelines, please mark yes **and** also describe the circumstances briefly in the Notes* section (last column).
I: Medical Director believes true risk of transmissible infection present? (Dropdown Yes, No) This is the discretion of the reviewing tissue banking Medical Director based on full-chart review (whether or not the tissue is accepted).
J: Cause of Death? Free text. Medical Director determination of actual cause of death. Note: if this differs from the COD listed in official records (death certificate, medical examiner, etc.) please include the COD from official records in the Notes* column.
K: **Notes*** Free text. Please describe if yes to column H or if official COD differs from medical director's determination of COD, or for any other interesting or unusual circumstances.

Sepsis-2 (SIRS+ Suspected Infection)

Clinical evidence of infection; and
Two or more of the following systemic responses to infection if unexplained:
o Temperature of >100.4º F (38º C);
o Heart rate >90 beats/min;
o Respiratory rate >20 breaths/min or PaCO2 <32; or
o WBC >12,000 cells/mm^3, < 4,000 cells/mm^3, or >10% immature (band) forms.
More severe signs of sepsis include unexplained:
Hypoxemia
Elevated lactate
oliguria
altered mentation
hypotension

Sepsis-3

Suspected or documented infection and

an acute increase of ≥2 SOFA points (a proxy for organ dysfunction)

qSOFA (Quick SOFA) Criteria	**Respiratory rate ≥22/min**
	Altered mentation
	Systolic blood pressure ≤100 mm Hg

OR

SOFA (see below chart)

Table 1

Sequential [Sepsis-Related] Organ Failure Assessment Score[a]

	Score				
System	**0**	**1**	**2**	**3**	**4**
Respiration					
PaO_2/FIO_2, mm Hg (kPa)	≥400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) with respiratory support	<100 (13.3) with respiratory support
Coagulation					
Platelets, $\times 10^3/\mu L$	≥150	<150	<100	<50	<20
Liver					
Bilirubin, mg/dL (μmol/L)	<1.2 (20)	1.2–1.9 (20–32)	2.0–5.9 (33–101)	6.0–11.9 (102–204)	>12.0 (204)
Cardiovascular	MAP ≥70 mm Hg	MAP <70 mm Hg	Dopamine <5 or dobutamine (any dose)[b]	Dopamine 5.1–15 or epinephrine ≤0.1 or norepinephrine ≤0.1[b]	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1[b]
Central nervous system					
Glasgow Coma Scale score[c]	15	13–14	10–12	6–9	<6
Renal					
Creatinine, mg/dL (μmol/L)	<1.2 (110)	1.2–1.9 (110–170)	2.0–3.4 (171–299)	3.5–4.9 (300–440)	>5.0 (440)
Urine output, mL/d				<500	<200

Abbreviations: FIO_2, fraction of inspired oxygen; MAP, mean arterial pressure; PaO_2, partial pressure of oxygen.

[a]Adapted from Vincent et al.[27]

[b]Catecholamine doses are given as μg/kg/min for at least 1 hour.

[c]Glasgow Coma Scale scores range from 3–15; higher score indicates better neurological function.