

TT-CMV: Prevention of transfusion-transmitted CMV in low birth-weight infants

Scheduled Forms Checklist

LBWI ID: - -

Date enrolled:
month day year

All Required and Optional Scheduled Forms

Optional form needed if...

DOB

- ☐ LBWI: Blood Collection Form
- ☐ LBWI: Urine Collection Form
- ☐ MOC: Blood Collection Form
- ☐ LBWI: Demographic and Birth Data Form
- ☐ MOC: Demographic and Medical Record Review Form
- ☐ MOC: Placental Infection and Pathology
- ☐ SNAP Form
- ☐ LBWI: Medical Record Review and Laboratory Results

DOL 4

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ SNAP II Form

DOL 7

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ SNAP II Form
- ☐ Breast Milk Collection *If LBWI is being fed breast milk*
- ☐ Summary Form

DOL 14

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ SNAP II Form
- ☐ Summary form

DOL 21

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ LBWI: Blood Collection Form
- ☐ SNAP II Form
- ☐ Breast Milk Collection *If LBWI is being fed breast milk*
- ☐ Summary Form

DOL 28

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ SNAP II Form
- ☐ Breast Milk Collection *If LBWI is being fed breast milk*
- ☐ Summary Form

DOL 40

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ LBWI: Blood Collection Form
- ☐ SNAP II Form
- ☐ Breast Milk Collection *If LBWI is being fed breast milk*
- ☐ Summary Form

DOL 60

- ☐ LBWI: Medical Record Review and Laboratory Results
- ☐ LBWI: Blood Collection Form
- ☐ SNAP II Form
- ☐ Summary Form

End of Study / DOL 90

- ☐ End of Study
- ☐ LBWI: Blood Collection Form
- ☐ LBWI: Urine Collection Form *if LBWI blood is not available at end of study*
- ☐ MOC: Blood Collection Form *if MOC tested CMV seronegative at enrollment*
- ☐ Summary Form

Post-Discharge

- ☐ LBWI: Blood Collection Form *If LBWI recv'd txn in 7 days before d/c*

As-Needed Forms Checklist (page 1 of 2)

LBWI ID: - -

Date enrolled:
month day year

Logs (updated regularly)

Concomitant Medications Log
Vasopressor Log
Breast Milk Feeding Log
Mechanical Ventilation Log

Outcome Forms*

Optional form needed if...

☐ Suspected CMV (case #1)

☐ Investigation of Suspected CMV Disease

☐ Breast Milk Collection Form *If LBWI is being fed breast milk*

Suspected CMV (case #2)

☐ Investigation of Suspected CMV Disease

☐ Breast Milk Collection Form *If LBWI is being fed breast milk*

☐ NEC (case #1)

☐ Necrotizing Enterocolitis (NEC) Form

☐ SNAP II Form

☐ NEC Parenteral Nutrition Log

NEC Imaging Form ☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5

☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10 *If image taken*

☐ NEC (case #2)

☐ Necrotizing Enterocolitis (NEC) Form

☐ SNAP II Form

☐ NEC Parenteral Nutrition Log

NEC Imaging Form ☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5

☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10 *If image taken*

☐ IVH

☐ Intraventricular Hemorrhage (IVH) Form

☐ SNAP II Form

IVH Imaging Form ☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5

☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10 *If image taken*

☐ BPD

☐ Bronchopulmonary Dysplasia (BPD) Form

☐ ROP

☐ Retinopathy of Prematurity (ROP) Form

☐ PDA

☐ Patent Ductus Arteriosus (PDA) Form

☐ Infection / Sepsis Form #1

☐ Infection / Sepsis Form #2

☐ Infection / Sepsis Form #3

☐ Infection / Sepsis Form #4

☐ Infection / Sepsis Form #5

* Outcome forms are not pre-loaded in this binder. They can be downloaded and printed from the study web site.
(<https://cfusion.sph.emory.edu/BMI/PPG/login.cfm>)

As-Needed Forms Checklist (page 2 of 2)

LBWI ID: - -

Date enrolled:
month day year

Transfusion Forms

Red Blood Cell Transfusion Record

☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5 ☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10
☐ #11 ☐ #12 ☐ #13 ☐ #14 ☐ #15 ☐ #16 ☐ #17 ☐ #18 ☐ #19 ☐ #20

Platelet Transfusion Record

☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5 ☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10
☐ #11 ☐ #12 ☐ #13 ☐ #14 ☐ #15 ☐ #16 ☐ #17 ☐ #18 ☐ #19 ☐ #20

Fresh Frozen Plasma Transfusion Record

☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5 ☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10
☐ #11 ☐ #12 ☐ #13 ☐ #14 ☐ #15 ☐ #16 ☐ #17 ☐ #18 ☐ #19 ☐ #20

Cryoprecipitate Transfusion Record

☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5 ☐ #6 ☐ #7 ☐ #8 ☐ #9 ☐ #10

Granulocyte Transfusion Record

☐ #1 ☐ #2 ☐ #3 ☐ #4 ☐ #5

Adverse Event & Reaction Forms*

- ☐ Transfusion Reaction #1
- ☐ Transfusion Reaction #2
- ☐ Transfusion Reaction #3
- ☐ Expected Adverse Event Resulting in Death Form
- ☐ Unexpected Serious Adverse Event Form #1
- ☐ Unexpected Serious Adverse Event Form #2
- ☐ Unexpected Serious Adverse Event Form #3
- ☐ Unexpected Serious Adverse Event Form #4
- ☐ Unexpected Serious Adverse Event Form #5

** AE/Reaction forms are not pre-loaded in this binder. They can be downloaded and printed from the study web site.
(<https://cfusion.sph.emory.edu/BMI/PPG/login.cfm>)*

Other Forms*

- ☐ Transfer
 - ☐ Transfer Form
 - ☐ Summary Form (Unscheduled #1)
 - ☐ Summary Form (Unscheduled #2)
 - ☐ Summary Form (Unscheduled #3)
 - ☐ Summary Form (Unscheduled #4)
 - ☐ Summary Form (Unscheduled #5)
 - ☐ Summary Form (Unscheduled #6)
- ☐ Protocol Deviation #1
- ☐ Protocol Deviation #2
- ☐ Protocol Deviation #3
- ☐ Protocol Deviation #4
- ☐ Protocol Deviation #5

** Other forms are not pre-loaded in this binder. They can be downloaded and printed from the study web site.
(<https://cfusion.sph.emory.edu/BMI/PPG/login.cfm>)*