### Key Fields

- **Sequence Number**
- **Date Received:** __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ 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Form 3010 R3.0: Product Complaint Form

Center: CRID:

28 Was there a problem with transport or handling?
   ☐ Yes ☐ No

29 Was there a problem with product labeling and/or accompanying records?
   ☐ Yes ☐ No

30 Was product contaminated?
   ☐ Yes ☐ No

31 Was there a problem with product appearance (e.g. clots, color, particulates)?
   ☐ Yes ☐ No

32 Was the cell count/viability significantly lower than expected or agreed upon?
   ☐ Yes ☐ No

33 Was there a problem of a nature not listed in questions 26-32?
   ☐ Yes ☐ No

34 When was problem/complaint discovered?
   ☐ Upon receipt (i.e. when your site inspected and took possession of the product)
   ☐ After receipt

35 Specify:

36 Describe problem/complaint and when and how it was discovered:

37 Describe immediate action taken:

38 Was product infused?
   ☐ Yes ☐ No

39 Date of infusion: __ __ __ __ __ __ __ __

40 Was there a serious recipient adverse event caused by, or probably caused by, the product?
   ☐ Yes – Complete an Adverse Event form to report details
   ☐ No

Person Completing Form
First Name: ___________________________ Last Name: ___________________________
Date: __ __ __ __ __ __ __ __
Preferred method of contact: (phone number or email address) ___________________________

To Be Completed By NMDP/CIBMTR Reviewer

Questions: 41 - 47

Product Complaint: Failure/possible failure of a drug (includes biological products) to meet any of its specifications. This includes complaints that may potentially impact the safety, quality, identity, purity, or potency of the product.

41 Will NMDP/CIBMTR be initiating a product complaint investigation?
   ☐ Yes ☐ No

42 Rationale:
   ☐ Licensed Cord Blood Unit
   ☐ Not on NMDP sponsored Cord Blood IND
   ☐ Product (Marrow, PBSC, Therapeutic Cells) not facilitated by NMDP
   ☐ Does not meet "product complaint" definition, but will be forwarded to appropriate NMDP department for follow-up
   ☐ Other

43 Comment:

44 Will NMDP/CIBMTR be notifying the Cord Blood Bank?
   ☐ Yes ☐ No

45 Will NMDP/CIBMTR be notifying the non-NMDP Cord Blood IND Sponsor?
   ☐ Yes ☐ No

46 Non-NMDP Cord Blood IND Sponsor email: ___________________________

47 Additional comments: (optional)

Person Completing Review Section of Form
First Name: ___________________________ Last Name: ___________________________
Date: __ __ __ __ __ __ __ __