## LD-Delivery Mother Flowchart for Zika Virus Addendum

## Questions at Z3ab.

**Donor Eligibility:** Policies regarding donor assessment for Zika Virus (ZIKV) risk should be established using current guidance. A donor of Birth Tissue (BT) is not eligible if she had sexual intercourse during this pregnancy with a male who was known to have a medical diagnosis of ZIKV infection and he was diagnosed with it within 6 months prior to having sexual intercourse with the donor; see FDA/CBER <u>Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry.</u> To capture scenarios where the woman is not aware of the earliest onset of pregnancy, the time period "during this pregnancy," could be expanded to address risk during the past ten (10) months. Additionally, for a donor or Birth Tissue (BT), the donor is not eligible if she had sex during this pregnancy with a male who is known to have resided in, or travel to, an area with active ZIKV transmission and he traveled to or lived in a risk area within 6 months prior to having sex with the donor. An area with "active ZIKV transmissions" means an area where vector-borne (i.e., mosquito-acquired) transmission of ZIKV has occurred. The preamble to this question must be read to the delivery mother or bolded if she reads it to facilitate comprehension of what the term sex refers to ("**For the next question, sex refers to any method of sexual contact including vaginal, anal, and oral").** For **current ZIKV guidance** regarding areas with active ZIKV transmission areas/maps. Local policy and/or international requirements can be stricter.

