

PROTOCOL FOR SAMPLE COLLECTION
PART VI. PLACENTA FROM STILLBIRTHS AND NEONATAL LIVE BIRTHS

1. Check consent form* to ensure that consent was obtained for specimens to be collected.

Note: HIV infected placental tissue will be collected, stored and analyzed in South Africa. HIV-infected placental tissue will not be collected in the Northern Plains due to potential risk of infection to Clinical Staff.

***The Clinical Coordinator is responsible for performing this check.**

2. Refer to Part IB for general considerations for collection and storage of pathologic specimens.

3. Label* one small 10% formalin specimen container and one freezer bag with study Participant ID labels accompanying the specimen. No other participant identifiers (i.e., name and any other PHI) should be used.

***Specimen collection media may be pre-labeled or labeled after collection depending on best practices at each clinical site.**

4. Perform usual diagnostic examination

Weight, dimensions of disk and cord, description and photography of lesions, microbiologic cultures (if clinically indicated) (refer to the Placental Examination Procedures available on the study website).

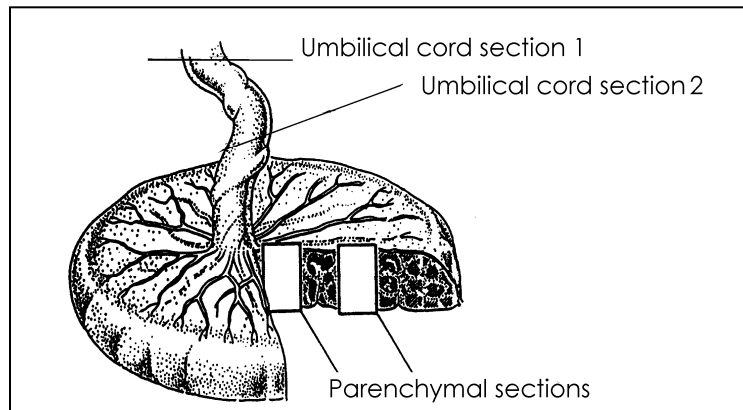
5. Collect the following diagnostic and research samples:

- a) 2 sets of the following sections (see diagram) One set will be for your institution's diagnostic needs, and one set of adjacent sections will be for the Safe Passage Study. Each set will be placed in a formalin container.

Alternatively, paraffin blocks of these fixed tissues may be sent:

- i. Membranes: removed from disc, rolled, and cross-sectioned
- ii. Cord sections: placed in 1 cassette
- iii. Parenchymal sections (at least 2), including any lesions

- b) 2 parenchymal cubes: frozen at -70°C (for Safe Passage Study)



6. Store the specimens collected as follows:

- a) Store the following specimens at room (ambient) temperature:

- i. Paraffin blocks of placenta (membranes, cord, parenchyma, adjacent to diagnostic blocks)
- ii. "Wet" tissues in 10% formalin-soaked gauze in sealed plastic bags or containers
 1. Placenta blocks (if paraffin embedding not available)
- iii. Copies of photographs
 1. Placenta (any abnormalities)
- iv. Copies of final diagnostic reports
 1. Placenta (including results of microbiology)

- b) Store the frozen Placental blocks in a secure location and at -80°C.

7. Complete the Specimen Collection Information Form for the specimen obtained. Enter the information recorded on the Specimen Collection Information Form in the PASS EDC System (www.dmstat.com/p2).
8. Refer to the "Specimen Collection Summary" document for a complete list of all current shipment destinations.
9. Complete the appropriate Specimen Shipment Log for the specimen obtained. Enter the information recorded on the Specimen Shipment Log in the PASS EDC System (www.dmstat.com/p2).
10. Send placental tissue * according to procedures outlined in Part VIII– Protocol for Packaging and Shipping Large Ambient Specimens and Part X – Protocol for Packaging and Shipping Refrigerated/Frozen samples.

****HIV+ placental tissue collected in South Africa must be stored and analyzed in the Pathology Department at Stellenbosch University.***

Contact the Primary Contact at the DBPC and the Project Manager at the DCAC if you have any questions or concerns regarding the procedures outlined in this document.