SUBJECT: Placenta and Cord Blood Distribution Policy for the Labor and Delivery (L&D) Unit at the Hospital of the University of Pennsylvania (HUP)

PURPOSE

The purpose of this guideline is to establish a process for collecting cord blood and placenta specimens for distribution for research purposes from all deliveries that take place at the Hospital of the University of Pennsylvania.

SCOPE

This guideline will apply to all L&D delivery staff including, but not limited to, Nurse Managers, RNs and residents, and investigators who wish to utilize cord blood and placenta specimens for research and clinical research coordinators handling the collected specimens.

Refer to the Labor and Delivery Biospecimen Protocol for detailed information on the collection and storage of cord blood and placental tissue.

IMPLEMENTATION

This policy will be implemented by the Director of the Labor and Delivery unit and Director of the Maternal Child Health Research Program.

PROCESS AND PROCEDURE

I. Statement of Purpose
Our goal is to enhance research capabilities within the Department of Obstetrics and Gynecology by offering efficient, accurate and cost effective specimen collection for researchers without the interruption of clinical activities on L&D.

Investigators within or external to the Department conducting research requiring cord blood and/or placenta specimens will be accommodated through this new process that utilizes clinical staff to label, obtain, and properly store specimens. Our goal is to maintain high ethical standards and good clinical practice while making cord blood and placenta samples more readily available for research approved by the Institutional Review Board, Women’s Health Clinical Research Center and MCHRP.

II. Feasibility Review and Approval Process
Any investigator wishing to use biologic specimens collected and banked on L&D is required to submit a request consisting of a Research Study Feasibility Assessment form, a copy of the protocol summary, and any budgetary documents pertinent to the request. Additionally, all investigators requesting this service will complete the appropriate forms required for placenta and cord blood procurement. Requests will be reviewed by the Director of the Maternal Child
Health Research Program (MCHRP) in concert with the Women’s Health Clinical Research Center. Submissions will be acknowledged as received. Initial review will occur within 14 days. More time may be required to convene a review committee and render a decision, depending on the complexity of the project.

The Department Chair has the final authority to approve requests for use of departmental resources and to cease biospecimen collection on L&D.

All approvals will be contingent upon the receipt of IRB approval documentation, and relevant staff training and education. All approved research must be in compliance with other applicable requirements, such as research billing compliance, research staff training in human subject research, and Good Clinical Practices.

III. Feasibility Amendments
Investigators making minor amendments to their protocol or recruitment plan must notify the WHCRC of such changes. Written acknowledgement will be provided. Major changes will require the resubmission of a Research Study Feasibility Assessment Form. This form will be reviewed in the manner outlined in Section II of this document, with a formal response letter to follow.

IV. Staff Training and Education
Investigators must ensure that the Research Coordinators (defined as nurse, student, post docs etc.) responsible for collection, processing and disposal of specimens on L&D must provide evidence of competency completion that includes, but is not limited to, the following:

1. CITI Certification
2. HIPPA Privacy Training
3. Blood Borne Pathogens Training (Knowledge Link)
4. Hep B vaccination
5. Review of usage of L&D research lab refrigerators and soiled utility room

Investigators and Research Coordinators utilizing specimens will be trained on usage of the L&D research lab and refrigerator. This training will be documented in a training log in the lab.

V. Research Conduct
Investigators approved to utilize biospecimens in the Department of Obstetrics and Gynecology agree to abide by the Department’s standards and guidelines for the conduct of clinical research. Failure to do so will result in a review by the Director of the MCHRP and possible termination of the agreement. Investigators will be asked to provide annual updates on the status of the project and notify the Director of changes to the project that may affect use of resources, including IRB correspondence describing these changes.

VI. Cost of Research Resources
In some cases, an investigator may be asked to cover the cost of the requested resources. Examples of budgetary items include but are not limited to support of MCHRP research staff,
space, equipment. These costs will vary based on the complexity of the protocol and study needs.