POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M95-9 (rev.) 5 June 2009

MANUAL TRANSMITTAL SHEET

POLICY: Guidelines for Limits of Blood Drawn for Research Purposes in the Clinical Center

1. Explanation of Material Transmitted: This issuance directs the drawing of blood for research purposes from adult and pediatric subjects. The policy was reviewed by the Medical Executive Committee (MEC) on 5 May 2009 and approved with changes in keeping with current regulations and practice. Further amendments were approved at the 2 June 2009 MEC meeting with regard to daily limits for blood drawn from pediatric patients for research purposes.

2. Material Superseded: MAS No. M95-9, dated 19 May 2009

3. Filing Instructions: Provision of Care Section

   Remove: No. M95-9, dated 19 May 2009

   Insert: No. M95-9 (rev.), dated 5 June 2009

DISTRIBUTION

Physicians, Dentists, and Other Practitioners Participating in Patient Care

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M95-9 (rev.) 5 June 2009

SUBJECT: Guidelines for Limits of Blood Drawn for Research Purposes in the Clinical Center

PURPOSE

This statement codifies the policy of the NIH Clinical Center regarding the volume of blood drawn for research purposes from adult and pediatric patients, including normal volunteers, in the inpatient units and outpatient clinics of the Clinical Center.

POLICY

Under most circumstances, the amount of blood that may be drawn from adults or children at the Clinical Center shall not exceed specified limits. These limits have been set by total volume in the case of adults, and by body weight in the case of children.

CONSIDERATIONS

The Institutional Review Board (IRB) shall consider how much blood would be taken, with what frequency, and the risks involved, to assure that the volume and frequency of collection (as specified in the protocol) are within safe limits. The Chief of the Clinical Center's Department of Transfusion Medicine, or his/her designee, may be consulted in cases of uncertainty. It is ultimately the responsibility of the Principal Investigator to ensure that blood drawing limits are observed and adhered to.

Adult Patients and Volunteers: Blood Drawing Limits for Research Purposes

The amount of blood that may be drawn from adult patients and volunteers (i.e., those persons 18 years of age or older) for research purposes shall not exceed 10.5 mL/kg or 550 mL, whichever is smaller, over any eight week period. The amount of blood to be drawn from volunteers and the frequency of collection shall be specified in the clinical research protocol, and exceptions to the 10.5 mL/kg or 550 mL limitations shall be approved by the IRB.

Pediatric Patients: Blood Drawing Limits for Research Purposes

For pediatric patients, no more than 5 mL/kg may be drawn for research purposes in a single day, and no more than 9.5 mL/kg may be drawn over any eight-week period.

Exceptions to Blood Drawing Limits

In any patient whose clinical condition might be adversely affected by removal of the volumes stated above, for example, patients with significant anemia or compromised cardiac output, investigators should consider further limiting the volume of blood withdrawn for research purposes.

In instances of clinical need, it is the responsibility of the patient's attending physician to determine if phlebotomy in excess of the above limits may be permitted.

Because blood samples in excess of those mandated by the protocol may be taken in the course of providing patient care, health care providers will ensure that all instances of blood collection in excess of permitted volumes are recorded and justified in the patient's record.

Exceptions shall not be permitted for phlebotomy intended solely for research purposes unless the limits have been explicitly increased in a research protocol that has received full IRB approval.