



## **BLOOD DRAWING FOR HUMAN SUBJECT RESEARCH**

1/17/2008

The Duke University Health System Institutional Review Board (DUHS IRB) endorses the recommendations of the American Association of Blood Banks.

### **A. Blood Drawing Limits for Protocols Reviewed Using the Expedited Procedure**

“Categories of Research that May Be Reviewed by the IRB through an Expedited Review Procedure,” 63 FR 60364-60367, November 9, 1998, Section (F)(2):

“Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.”

### **B. Blood Drawing Limits for Protocols Reviewed by a Convened Board**

The convened IRB may approve a volume of blood drawn for research purposes that exceeds the limits shown above in Section A. To qualify for approval by a convened board, blood drawn for research purposes must not exceed the following volumes unless specifically justified in the research protocol:

#### **1. Adults**

a. Healthy Non-Pregnant Adults: The volume of blood to be drawn must be stated specifically in the protocol. The maximum is 550 ml at any one time, 550 ml in an eight week period, and not more than 5 such amounts of 550 ml per year. Whole blood donations must be deferred for at least 48 hours after plasmapheresis.

b. Adults Who Are Pregnant or Being Treated: The volume of blood to be drawn must be stated specifically in the protocol. If an individual collection will exceed 100 ml at any one time, or will exceed 550 ml in an eight week period, or will

exceed more than 5 such amounts per year, or if subjects fall into the following categories, a specific justification must be given and the noted precautions taken.

(1) Adults Who Are Pregnant or Being Treated for a Physical Condition:

If on the day of donation the volume is greater than 100 ml:

(a) The donor's history must be evaluated and the donor examined by a qualified person.

(b) Determination of the hemoglobin concentration must be done.

Unless specifically approved in the protocol:

- The hemoglobin must be no less than 12.5 g per dl for female donors, and no less than 13.5 g per dl for male donors; or
- The packed cell volume must be no less than 38 percent for females, and no less than 41 percent for males.

(c) Unless specifically approved in the clinical protocol:

- The pulse shall reveal no pathological cardiac irregularity.
- The systolic blood pressure (untreated) should be between 90 and 180 mm of mercury.
- The diastolic pressure (untreated) should be between 50 and 100 mm of mercury.

(2) Non-Pregnant Adults Being Treated for a Non-Physical Condition:

Up to 3 ml/kg (not to exceed 300 ml) may be collected at any one time, or the above precautions for subjects being treated for a physical condition or who are pregnant must be taken for a larger collection.

(3) Adults Not Meeting Any of the Above Criteria:

The volume drawn may not exceed the lesser of 50 ml or 1 ml/kg on any day.

## 2. Children

a. Healthy Infants, Children, and Adolescents: The volume of blood to be drawn must be stated specifically in the protocol. The maximum is 2 ml/kg (not to exceed 200 ml) at any one time, 7 ml/kg (not to exceed 550 ml) in an eight week period, and not more than 5 such amounts of 7 ml/kg per year.

b. Children Who Are Being Treated: The volume of blood to be drawn must be stated specifically in the protocol. If the volume exceeds 2 ml/kg (not to exceed 200 ml) at any one time, 7 ml/kg (not to exceed 550 ml) in an eight week period, or more than 5 such amounts of 7 ml/kg per year, or if children fall into any of the following categories, specific justification must be given and the noted precautions taken.

(1) Children Being Treated for a Physical Condition: On the day of donation of a volume greater than 2 ml/kg:

(a) The donor must be examined by a qualified person.

(b) Determination of the hemoglobin concentration must be done.

Unless specifically approved in the protocol:

- For pre-adolescent children:

- the hemoglobin must be no less than 11 g/dl,

- the packed cell volume must be no less than 33 percent.

- For adolescent children, use the above adult subject standards.

(c) The child's blood pressure must be within the normal range for age.

(2) Children Being Treated for a Non-Physical Condition: Up to 3 ml/kg (not to exceed 300 ml) may be collected at any one time, or the above precautions for children with medical conditions must be taken for a larger collection.

(3) Children Not Meeting Any of the Above Criteria: The volume drawn may not exceed the lesser of 50 ml or 1 ml/kg on any day.