Pennington Biomedical Research Center
Louisiana State University

G-011 - Guidance for Blood Drawing Limits for Research

As a general rule, investigators must not draw more blood from any research participant than is needed to answer the research question and should design the research to minimize that volume.

A. Blood Drawing Limits for Protocols that Qualify for Expedited Review
Guidelines for collection of blood samples by finger stick, heel stick, ear stick, or venipuncture are as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds, the amounts drawn may not exceed 550 ml (or about 37 tablespoons) total 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, the amount drawn may not exceed the lesser of 50 ml (3.4 tablespoons) or 3 ml per kg total in an 8 week period and collection may not occur more frequently than 2 times per week.

B. Blood Drawing Limits for Protocols that Require Full Board Review
The convened IRB may approve a volume of blood drawn for research purposes that exceeds the limits referred to above. As a general rule, blood drawn for research purposes must not exceed the following volumes:
For an adult, the amount of blood that may be drawn for research purposes shall not exceed 5 ml/kg in any one 24 hour period, and 7 mL/kg in any eight week period.
For a child, the amount of blood that may be drawn for research purposes shall not exceed 3 ml/kg in any 24 hour period, and 7 mL/kg in any eight week period.

C. Exceptions to Blood Drawing Limits
(a) Any exception to these above limits must be specifically justified in the research protocol. Protocols will be reviewed on a case by case basis by a convened IRB when blood volumes exceed these above limits.
(b) For protocols that involve participants whose clinical condition might be adversely affected by removal of the blood volumes stated above, for example, a person with significant anemia or compromised heart function, investigators should further limit the volume of blood withdrawn for research purposes so as to minimize harm to the subject.
(c) This policy was implemented to provide general guidelines to researchers as a standard rule to follow and include in their research protocols. The Medical Investigator (MI) provides medical oversight and may make changes or exceptions to the guidelines based on their clinical judgment to ensure the safety of a participant.

References
Duke University Health System, Human Research Protection Program. "Blood Drawing for Human Subject Research." 12/13/2012