



BLOOD DRAWING FOR HUMAN SUBJECT RESEARCH

9/28/2021

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

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

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

- (a) from healthy, non-pregnant 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. This should account for no more than 3% blood volume in a 24-hour period.

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 referred to above, taking into account the blood being collected as standard of care. 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. Any exception to these limits must be specifically justified in the research protocol and approved by a convened IRB.

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. Any exception to these limits must be specifically justified in the research protocol and approved by a convened IRB.

C. Exceptions to Blood Drawing Limits

For any subject whose clinical condition might be adversely affected by removal of the volumes stated above, for example, a person with significant anemia or compromised cardiac output, investigators should further limit the volume of blood withdrawn for research purposes so as to minimize harm to the subject.

A subject's attending physician may determine if phlebotomy for research purposes should be further restricted below the limits stated above. Also, the convened IRB in its review of a specific protocol may limit the blood volumes to be obtained for research to amounts lower than the upper limits provided above.

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 approval by a convened IRB.

References:

Blood drawing policies from the National Institutes of Health, OHRP, the European Union, WHO, and Children's Hospital of Philadelphia

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