

Institutional Review Board (IRB) Policies & Procedures Manual



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Research Blood Drawing Guidelines

Purpose

This policy provides guidelines for investigators to consider when designing a protocol that involves drawing blood from human subjects for research* purposes.

* For research conducted under approval by the Dana-Farber Cancer Institute (DFCI) IRB you may follow the DFCI IRB blood drawing guidelines.

Policy

Up to 5% of the whole blood volume may be removed over an 8-week period, on a single occasion or in divided portions, from human subjects in good health and with a hematocrit of not less than the low normal value for age.

The table below shows values for mean blood volume based on age (Geigy Scientific Tables, 7th Ed.), and an example of the body weight in Kg for a low weight female (10th percentile, CDC growth chart) and corresponding reasonable maximal blood draw volume in cc

Age	Mean blood volume per weight (mL/kg)	Low Weight Female (CDC 10 th percentile) Weight in Kg	Reasonable Max Blood Draw volume (cc)
Premie	75	1	4
Newborn, 15-30 minutes of age	76.5	2.7	10
Newborn, 24 hours	83.3	2.8	12
Children, 3 months	87	5.4	23
Children, 6 months	86	6.9	30
Children, 1 year	80	7.6	30
Children, 6 years	80	17.3	69
Children, 10 years	75	29.4	110
Children, 15 years	71	51	181
Men	71		
Women	70	58	203

Examples:

1. Determine *Mean blood volume per weight* based on age of child
e.g. A 3-month-old child will have a *Mean blood volume per weight* of 87 mL/kg
2. Multiply the *Mean blood volume per weight* times the child's weight
e.g. For a 3 kg child, multiply 87mL/kg x 3 kg = 261mL (261mL is the child's total blood volume)
3. Multiply the child's total blood volume by 5% (0.05) to obtain *5% of the total blood volume*
e.g. 261mL x 0.05 = 13.05 mL

Thus, 13.05 mL is the total amount of blood which may be removed from a 3-month-old child who weighs 3kg.

Investigators should note that it may be problematic to remove 100 mL or more from a small child who may not sit still for the amount of time required to do so.

1. Additional volumes of blood may be removed in subsequent 8-week periods using the same criteria, if the subject remains in good health and maintains a hematocrit level of not less than the low normal value for age.
2. If blood samples for research purposes are to be obtained at the same time a clinical sample is drawn, or if it is expected that additional clinical samples will be taken during the 8 week period, the total amount of blood (research and clinical) should not exceed 5% of whole blood volume, unless specifically approved by the IRB. For this reason, investigators must know and take into consideration clinically indicated blood drawing requirements for potential subjects.
3. The amount of blood drawn should be limited to that needed to meet the goals of the particular study.
4. Whenever the volume of blood to be removed will exceed 1% of whole blood volume of the subject, hematocrit should be checked in advance to determine that it is not less than the low normal value for age. The frequency of monitoring hematocrit levels should be commensurate with the volume of blood to be removed, and the estimated vulnerability of the subject to blood loss.
5. If a subject may not be in good health, and in particular, has a cardiovascular, pulmonary or hematopoietic problem, the volume of blood to be removed should be adjusted accordingly.

6. If the study protocol necessitates that the volume of blood to be removed exceeds the above criteria recommended for subjects in good health, or that the volume cannot be reduced in consideration of poor health or low hematocrit level, the IRB will consider approving the project only if the added risk can be justified by the expected direct benefit to the subjects.

7. Whenever possible, blood should be taken at the same time that a clinically indicated blood draw is performed.

8. The estimated volume and frequency of blood to be removed, risks associated with blood removal, and the measures to be taken to minimize those risks should be included in the research consent form.

9. Measures to minimize the risk of a potential reaction to a blood draw should be taken. Such measures may include the following.
 - Research staff should make sure that subjects have eaten and had something to drink before a blood draw.
 - Subjects should be asked to remain in the blood draw area for at least 10 minutes after a blood draw. They should be encouraged to drink, eat, and report symptoms and should be observed for any problems.
 - A nurse or trained health care provider should always be on site to deal with any reactions.
 - Use of EMLA cream is recommended to minimize pain (optional).

Related Content

None Identified

Document Attributes

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