

BLOOD SAMPLING GUIDELINES

GENERAL GUIDELINES:

In general, the collection of blood samples meeting the following criteria can be approved by expedited review if the Human Research Committee finds that the blood collection poses only minimal risk to subjects. Although the removal of blood in these amounts is acceptable, the amount of blood withdrawn should be limited to that needed to meet the goals of the particular study.

Collection of blood samples by finger stick, heel stick, or venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds poses minimal risk. For these subjects, blood may be drawn not more than twice per week, total amount not to exceed 550 cc in an 8-week period.

Collection of blood samples from all other adults (e.g., individuals who are ill or pregnant) and children must take into consideration 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, blood may be drawn not more than twice per week, total amount not to exceed the lesser of 550 cc or 3 cc per kg in an 8-week period.

- + **Adults - Blood sampling in amounts of up to 250 cc, drawn at one time**
 - o In general, blood sampling in amounts totaling up to 200 cc may be removed from a volunteer subject that upon examination appears healthy, without further precaution.
- + **Adults - Blood sampling in amounts exceeding 250 cc, drawn at one time**
 - o The following guidelines apply when blood sampling in amounts exceeding 200 cc at one time is proposed:
 - + WEIGHT must be greater than 110 lbs (50 kg);
 - + PULSE must be between 55 and 100 beats/minute with no cardiac irregularity;
 - + TEMPERATURE must not exceed 37.5°C or 99.5°F;
 - + CBC should be drawn before sampling (and at the end of the sampling period if relevant; see below);
 - + HEMATOCRIT must be between 0.35 - 0.45 for females and 0.38 - 0.54 for males;
 - + or HEMOGLOBIN must be between 12.5 and 16;
 - + TOTAL VOLUME from one subject must not exceed 550 cc for any one sample;
 - + THERE MUST BE 6 WEEKS between samples, if multiple samples of 550 cc are required from one subject.

Monitoring

Subjects should be monitored after large volume phlebotomy to ensure that they are feeling well and able to resume regular activities, as happens after donation at a blood bank, i.e., check vital signs and ensure volume repletion with oral fluids.

Iron Supplementation

Iron therapy is not required for healthy adults with normal diets who donate blood infrequently; this is not recommended or required by blood banks. If an individual repeatedly donates blood up to the limits of 550 cc in 8 weeks, or there is other reason to believe it would be medically advisable, the investigators should consider rechecking CBC or hemoglobin at the conclusion of blood drawing (after repletion of volume status). If hemoglobin at the end of the sampling period is at or below the lower end of the normal range, iron therapy should be considered. Usually 320 mg ferrous sulfate or equivalent three times per day for one month should suffice. If iron therapy is offered, the consent forms and discussions with the subject should include discomforts and risks of iron therapy (i.e., GI upset, constipation, and black stools). Research funds should pay for repeat lab studies and iron therapy, if needed.

Human Blood Sampling Guide

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Table of Contents Human Blood Sampling Guide

1. Understanding the eBook Human Blood Sampling Guide
 - The Rise of Digital Reading Human Blood Sampling Guide
 - Advantages of eBooks Over Traditional Books
2. Identifying Human Blood Sampling Guide
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Human Blood Sampling Guide
 - User-Friendly Interface
4. Exploring eBook Recommendations from Human Blood Sampling Guide
 - Personalized Recommendations
 - Human Blood Sampling Guide User Reviews and Ratings
 - Human Blood Sampling Guide and Bestseller Lists
5. Accessing Human Blood Sampling Guide Free and Paid eBooks

- Human Blood Sampling Guide Public Domain eBooks
- Human Blood Sampling Guide eBook Subscription Services
- Human Blood Sampling Guide Budget-Friendly Options
- 6. Navigating Human Blood Sampling Guide eBook Formats
 - ePub, PDF, MOBI, and More
 - Human Blood Sampling Guide Compatibility with Devices
 - Human Blood Sampling Guide Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Human Blood Sampling Guide
 - Highlighting and Note-Taking Human Blood Sampling Guide
 - Interactive Elements Human Blood Sampling Guide
- 8. Staying Engaged with Human Blood Sampling Guide
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Human Blood Sampling Guide
- 9. Balancing eBooks and Physical Books Human Blood Sampling Guide
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Human Blood Sampling Guide
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Human Blood Sampling Guide
 - Setting Reading Goals Human Blood Sampling Guide
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Human Blood Sampling Guide
 - Fact-Checking eBook Content of Human Blood Sampling Guide
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development

- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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