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 Although the removal of blood in these amounts is acceptable, the amount of blood withdrawn should be limited to that needed to meet the goals of the particular study.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 50 cc or 3 cc per kg in an 8 week period.

- **Adults - Blood sampling in amounts of up to 200 cc, drawn at one time**
    - 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 200 cc, drawn at one time**

    - 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 50 and 100 beats/minute with no cardiac irregularity;
        - TEMPERATURE must not exceed 37.55^{o}C or 99.5^{o}F;
        - CBC should be drawn before sampling (and at the end of the sampling period if relevant; see below).
        - HEMATOCRIT must be between: 0.36 - 0.48 for females and 0.38 - 0.54 for males;
        - or HEMOGLOBIN must be between 12.5 and 20;
        - TOTAL VOLUME from one subject must not exceed 550 cc for any one sample;
        - THERE MUST BE 8 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.

- **Children**

  Federal regulations do not allow children to participate in research unless the research involves minimal risk or, if more than minimal risk, the research presents the prospect of direct benefit to the subject. Blood sampling is considered a risk, albeit small. Blood volume taken from children must be less than 3 cc/kg body weight per 8 week period. In studies where the direct benefit far outweighs this volume restriction, a full protocol must be submitted for review of the full committee, and the following guidelines will apply:

  - If more than 3 cc/kg body weight per 8 week period is required and justified by the potential benefits, up to 9 cc venous blood/kg body weight/8 week period may be considered in older children (e.g., not neonates, toddlers, etc.), with the latter figure being the absolute upper limit.

  - Any child involved in a study involving removal of venous blood in the range of 3-9 cc/kg body weight per 8 wk period should be placed on iron supplementation therapy. It is recommended that a dose of 30 mg ferrous sulfate/kg/day in 3 divided doses be given. Such therapy should continue for at least 8 weeks and should be monitored by hemoglobin measurements.

Recommendations

- The use of EMLA cream is recommended to minimize pain related to blood draws in young children.
- Whenever possible, blood should be taken from children at the same time that a clinically needed blood draw is performed to avoid "extra" needle sticks

Consent/Assent

- Children, ages 7-17, must assent verbally to blood draws for research purposes and this should be documented in research and clinical records.
- Children, ages 14-17, may co-sign the parental consent form, if desired by the investigator or parent.
- All minors (anyone under 18) must have a parent or guardian sign a consent form giving permission to draw blood from their child for research purposes.