

HUMAN RESEARCH AFFAIRS
BLOOD SAMPLING GUIDELINES

BACKGROUND

The collection of blood samples in the course of research studies is a common practice. Institutional Review Boards (IRBs) are charged with evaluating the rationale, methodology, and risk/benefit ratio to research participants in the collection of these samples.

In some instances, the collection of blood samples may be considered to present no more than minimal risk to research participants and may be reviewed through an expedited review process (45 CFR 46.110). In other instances, the collection of blood samples may be considered as greater than minimal risk and must be given full board review.

The following IRB guidance outlines general and specific guidelines for the collection of blood samples from adults and children for research purposes.

GENERAL GUIDELINES

In general, the collection of blood samples meeting the following criteria can be approved by expedited review if the IRB finds that the blood collection poses only minimal risk to participants. Although the removal of blood in these amounts is acceptable, the amount of blood withdrawn should be limited to that needed to meet the goals of the particular study.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 if the following parameters are met: 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. To be considered minimal risk for these participants, blood may be drawn not more than twice per week, and the total amount must not 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 participant that upon examination appears healthy, without further precaution.
- **Blood sampling in amounts exceeding 200 cc, drawn at one time:**
 - The following guidelines are suggested when blood sampling in amounts exceeding 200 cc at one time is proposed and should be described in the research protocol as applicable:

- 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°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: 0.36 - 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 protocol should describe this as a study procedure, and 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 participant. Blood sampling is considered a risk, albeit usually a small one. To be considered minimal risk, blood volume taken from children must be either less than 50 cc or less than 3 cc/kg body weight, whichever is smaller, in an 8-week period and collection may not occur more frequently than 2 times per week. In studies where the direct benefit outweighs this volume restriction, the full IRB committee can consider approval as a more than minimal risk study. The full IRB committee will consider the blood volume, frequency of blood draws, and age, weight, and health of children and make determinations regarding approval on a case-by-case basis.

Recommendations

- The use of EMLA cream is recommended to minimize pain related to blood draws in young children. When used, this should be described in the protocol, consent documents, and it should be listed as an ancillary drug in Insight.
- 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

As for all research procedures, assent of children for research blood draws needs to be collected and documented per the Informed Consent of Research Subjects Policy and as outlined in your IRB application and IRB approved protocol.