

Wayne State University Human Investigation Committee	
SUBJECT	Research Studies Involving the Collection of Blood Samples
Section	
Form Date	11/01/06
Approvals	Steering Committee: 7/9/97, 1/16/02, 8/8/02, 7/18/07, All IRB Committees 8/8/02, Administrative Approval 4/25/98, 7/25/07

Background

The collection of blood samples in the course of clinical 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 WSU Human Investigation Committee policy outlines general and specific guidelines for the collection of these blood samples for research purposes for adults and children.

HIC Policy

1. **Consent** - Oral consent is sufficient to collect additional volume (within the limits specified above for minimal risk) from patients in whom blood is being drawn for clinical purposes.
2. **Cord Blood** -Cord blood can be used, following IRB review and approval, when blood is extracted from the placental side of the cord after it has been clamped and severed.
3. **Stored Blood** - Sera, plasma and other blood components that have been previously collected for clinical or research purposes are considered stored specimens. The use of stored specimens may be exempted, expedited or require full board review depending on the nature of the proposed investigation. (See WSU Policy/Procedure: "Use of Biological Specimens for Research".)
4. **In general** the following requirements must be met:
 - a. There are no special health reasons (e.g., severe anemia) to contraindicate blood withdrawal.
 - b. In patients from whom blood is already being drawn for clinical purposes, there are no other

health reasons to preclude additional blood collection.

- c. In subjects from whom blood is *not* already being drawn for clinical purposes, the withdrawal method is by cutaneous sticks (e.g., heel, ear or finger) or by standard venipuncture in a reasonably accessible peripheral vein.
- d. Experienced professional or technical personnel carry out all blood withdrawals and collections.

Adults

In Michigan, state law defines adults as individuals 18 years of age or older.

Minimal Risk Blood Collection

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

- a. Blood samples may be collected for research purposes from healthy 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, 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 (45 CFR 46.110).

Greater than Minimal Risk Blood Collection

Collection of blood samples that involves greater than minimal risk (such as pharmacokinetic or other monitoring studies) must be evaluated by the full IRB Committee on a case by case basis.

Children

Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a). In Michigan, a person under the age of 18 years is considered to be a child. (See WSU Policy/Procedure: "Vulnerable Participants: "Children as Research Participants (Subjects)" with regard to emancipated minors.)

Minimal Risk Blood Collection

Blood samples may be collected under the following conditions:

- a. No more than three (3) skin punctures are to be made in any single attempt to draw blood solely for research purposes.
- b. The volume drawn per specimen, including blood drawn for clinical purposes should not exceed one per cent (1%) of the child's total blood volume. A child's blood volume is usually

estimated to be 80cc/kg, thus volume drawn per specimen should generally be $\leq 0.8\text{cc/kg}$. (For example, for a child weighing 20kg, the maximum volume of blood that could be drawn for research as well as for clinical purposes would be $20 \times 0.8 = 16\text{cc}$).

- c. The cumulative volume of blood withdrawn for clinical or research purposes over an eight week period should not exceed ten percent (10%) of the child's total blood volume. A child's blood volume is usually estimated to be 80cc/kg, thus volume drawn should be $\leq 8\text{cc/kg}/8\text{weeks}$. (For example, for a child weighing 20kg, the maximum volume of blood that could be drawn for research and clinical purposes together over 8 weeks would be $20 \times 8 = 160\text{cc}$).

Note: 5 cc = 1 teaspoon
15 cc = 1 tablespoon
60 cc = 1/4 cup or 4 Tablespoons
240 cc = 1 cup

Greater than Minimal Risk Blood Collection

For pharmacokinetic or other monitoring studies done for research purposes that require frequent blood sampling over a short period of time (e.g. multiple samples over 24-48 hours), the requests will be evaluated by the HIC on an individual basis.

For studies requiring multiple blood draws from children who cannot give written assent (typically all children <13 years) when there is no (or little) direct benefit to the child:

If four or more blood samples are required in 13 hours or less, a peripheral venous heplock is highly recommended. However, in no case may more than eight cutaneous punctures (*including missed attempts*) be performed solely for research purposes in this time period.