VENIPUNCTURE BLOOD COLLECTION	SOP 6.4.01

1. Purpose & Policy

This SOP provides guidance on the establishment of a safe and appropriate location and method for obtaining human blood and human blood products via venipuncture collection. See Policy *Section 6.4.*

2. General Information

Venipuncture blood collection involves using a needle to extract blood from a vein and is typically performed on the inside of the elbow or back of the hand. Research studies may require the use of venipuncture blood collection when samples must be used within a couple hours of donation.

Venipuncture blood collection may only be performed by a licensed and insured phlebotomist under contract with Caltech. The Principal Investigator is responsible for verifying that the contracted phlebotomist is properly licensed and insured.

3. Training Requirements

In addition to the regular IRB CITI training requirements, investigators that work with blood samples must complete the required Biosafety and Bloodborne Pathogens training offered by the Biosafety Officer, as well as any other biosafety lab training elements provided by the PI. Investigators should also carefully read and follow this guidance.

4. Procedure

A. Blood Collection Risk Assessment

Venipuncture blood collection presents minimal risk to adult participants under the following conditions and guidelines (45 CFR 46.110):

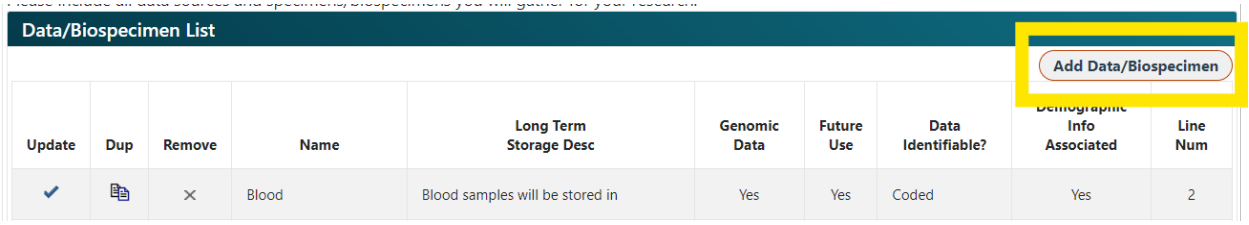
1. Blood samples may be collected for research purposes from healthy, non-pregnant adults who weigh at least 110 pounds. The amount drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
2. Blood samples may be collected for research purposes from other adults (not designated in 1. above), after considering the following: age, weight, and health of the participants, the collection procedures, the amount of blood to be collected, and the frequency of collection. For these participants, 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.

Venipuncture blood collection presents greater than minimal risk to adults participants when the collection of blood samples falls outside of the above parameters or is to be done in research that involves greater than minimal risk to adult participants. Studies with venipuncture blood collection will be reviewed via FCR for the first review and can be reviewed via Expedited Review for subsequent reviews.

Greater than minimal risk studies must undergo Full Committee Review at a convened IRB meeting.

B. Full Application

In the Samples and Data section, add blood as a sample by clicking on the *Add Data/Biospecimen* button.



Complete all required fields found on the next screen. The requirements outlined in 4 C-E of this SOP must be included in this section. The remaining questions found in the Samples and Data section, outside of the Data/Biospecimen List table, must also be answered.

In the Participant Selection Criteria section, participants with a history of fainting during blood draws and participants who are on blood thinners should be excluded.

In the Study Participation section, include the blood collection procedure in the Description of Participation, Physical Discomfort (discomfort at time of needle insertion, infection, bleeding after draw, and soreness or bruising after the procedure), Psychological Discomfort and Physical Contact sections.

In the Risks and Benefits section, include how the risks of venipuncture blood collection will be mitigated.

C. Procedure Room

Any location where blood is drawn must meet biosafety standards for bloodborne pathogens and must have sufficient privacy and safety safeguards for participants. The Caltech Biosafety Officer must inspect and review the room prior to use. The room where the venipuncture blood draw will be performed:

- Does not contain any hazardous chemicals or equipment,
- Has furniture that is easily disinfectable,
- Does not have carpeted floors (If the only option is a carpeted space, plastic or other impervious or cleanable material must be used to cover the carpet),

- Has a chair with back support for the participants to sit during the blood draw,
- Contains a sink for hygiene, or identify a nearby hand washing location,
- Contains an appropriate sharps/biohazard disposal receptacle,
- Contains appropriate disinfectant for the procedure area, and
- Contains a phone for emergency contact (can be a cell phone).

D. Post Blood Draw / Participant Observation

A sterile bandage should be placed over the draw site following the procedure. The investigator must observe the participant for any lightheadedness, bruising, or bleeding during and after the procedure. If the participant is lightheaded, they should be reclined and monitored until symptoms resolve. Water should be offered to all participants and juice or a small snack should be provided for blood draws over 50 ml.

If the participant is asymptomatic after the procedure, they can be released.

Any participant who requires more than three attempts to access a vein cannot be used in the study. Any participant who experiences side effects during or after the procedure will not be eligible to participate in the study or other future studies that include venipuncture.

E. Sample Storage
Blood storage will follow the laboratory's IBC and IRB-approved protocols.

5. Informed Consent (IC)

Participants must be notified of the venipuncture blood collection in the Informed Consent document. The PI must include appropriate procedure and risk language, including the most common adverse side effects.