



Human Subject Protection Program
Investigator Guidance
February 18, 2020

ACCEPTABLE BLOOD VOLUMES DRAWN FOR CHILDREN IN RESEARCH STUDIES

CHLA IRB Blood Draw Volume Policy

CHLA IRB policy is to limit the maximum acceptable blood volumes drawn for research at CHLA as follows:

1. No more than 2.5% of total blood volume may be drawn solely for research purposes within a 24 hour period. This is generally 2ml/kg.
2. No more than 5% of total blood volume may be drawn solely for research purposes within a 30-day period. This is generally 4ml/kg.
3. If the investigator requests blood in excess of this amount, he/she must provide a detailed justification for this and describe what safeguards are in place to protect the subjects from undue risk.

Age	Total Blood Volume	Allowable Within 24-hours	Allowable Within 30-days
Preterm Infant	105 ml/kg	2.5 ml/kg	5 ml/kg
Term Infant	85 ml/kg	2 ml/kg	4 ml/kg
3 months to Adult	75 ml/kg	2 ml/kg	4 ml/kg

The CHLA IRB will comply with Federal Regulations that limit the volume of blood drawn for research purposes under expedited review.

The NIH guidelines for adults allow no more than 7 ml/kg per 6-week period. The Committee has adopted these guidelines for adults (18 and older) with a hemoglobin level of at least 11.5 (within normal limits).

Definitions

Blood Draws for Research - are those blood draws conducted solely for the use of research. If a blood test would be conducted for clinical purposes but is also recorded for research purposes, this blood draw would not be considered part of the blood volume limits for research.

Discard volume - is the blood drawn (from IVs and central lines) in advance of the blood drawn for research purposes. This amount of blood *should be* included in the calculations for research blood volumes.

Procedures

Minimal Use

The application should include plans for collecting the quantity of blood required in order to answer the research question and no more, even if the amount is under the maximum amount allowed under this policy.

Exceeding the local CHLA IRB blood volume policy

If an investigator wishes to draw more blood than is allowed under local CHLA IRB policy, the following information must be included in the application:

- Scientific justification that this amount is necessary.
- Safety plans in place for monitoring subjects during the period in which the local CHLA blood volume limits will be exceeded (for risks associated with blood loss).

Blood volumes acceptable under expedited review category (2)

- Healthy, non-pregnant adults who weigh at least 110lbs
 - The amount drawn may not exceed 550 ml in an 8 week period
 - Collection may not occur more frequently than 2 times per week
- Other adults and children:
 - The amount drawn may not exceed the lesser of 50ml or 3ml/kg in an 8 week period
 - Collection may not occur more frequently than 2 times per week