

Maximum Blood Draw Limits

Review Procedures:

EXPEDITED REVIEW: Per OHRP (45 CFR 46.110) the following can be reviewed through an expedited review procedure: (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, non-pregnant 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 and children², 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.

FULL BOARD REVIEW: Blood collection that does not meet the expedited review requirements will be reviewed at the full board for risk category determination. The established guidelines below will aid reviewers in determining the risk category of the study.

1. Total Blood Volume Estimates for Various Age Ranges:

Age	Total Blood Volume Range* (ml/kg)
Preterm infant	90 - 105
Term infant	80 - 85
1-12 months	75 - 80
1 – 3 years	70 - 80
Older children and teens	65 - 80

*This range was compiled from various institutions and sources.

2. Allowable Blood Draw Limits for Pediatric Research:

If the subject is:

- a. Healthy and having no or minimal blood draws for clinical purposes the total blood volume withdrawal allowance would be:
 - 3% total blood/24 hour period
 - 10% total blood/month
- b. Affected or having large amounts of blood drawn for clinical purposes the total blood volume withdrawal allowance would be:
 - 2.5% total blood/24 hour period
 - 5% total blood/month

-For these subjects, the allowable limit is decreased because it may affect the number of blood transfusions needed.

Note:

- Amounts in excess of the above limits should be evaluated on a case-by-case basis. If the study protocol requires that the volume of blood exceeds the max limit criteria, investigators must provide detailed justification and describe what safeguards are in place to protect subjects from undue risk (CHLA IRB/CCI).
- Subjects who are having large amounts of blood drawn or are receiving blood transfusions for medically necessary purposes or on transfusion protocols may require a larger blood withdrawal volume.
- An acceptable amount of blood drawn for research may depend on the population being studied. For example, affected children may generally have more blood drawn because they are already being evaluated for a disease or condition. For healthy children, drawing large amounts of blood for which there is no direct benefit may not be acceptable or may need further review by Secretary of the Department of Health and Human Services as per (§45CFR46.407).

Maximum Allowable Total Blood Draw Volumes Chart

Body Wt. (kg)	Body Wt. (lbs)	Total blood volume (ml)	Max allowable volume in a 24 hour period**		Total volume drawn in a 30-day period**	
			2.5% of total blood volume (ml)	3% of total blood volume (ml)	5% of total blood volume (ml)	10% of total blood volume (ml)
1	2.2	100	2.5	3	5	10
2	4.4	200	5	6	10	20
3	6.6	240	6	7.2	12	24
4	8.8	320	8	9.6	16	32
5	11	400	10	12	20	40
6	13.2	480	12	14.4	24	48
7	15.4	560	14	16.8	28	56
8	17.6	640	16	19.2	32	64
9	19.8	720	18	21.6	36	72
10	22	800	20	24	40	80
11 – 15	24-33	880-1200	22-30	26.4-36	44-60	88-120
16 – 20	35-44	1280-1600	32-40	38.4-48	64-80	128-160
21 – 25	46-55	1680-2000	42-50	50.4-60	64-100	168-200
26-30	57-66	2080-2400	52-60	62.4-72	104-120	208-240
31-35	68-77	2480-2800	62-70	74.4-84	124-140	248-280
36-40	79-88	2880-3200	72-80	86.4-96	144-160	288-320
41-45	90-99	3280-3600	82-90	98.4-108	164-180	328-3600
46-50	101-110	3680-4000	92-100	110.4-120	184-200	368-400
51-55	112-121	4080-4400	102-110	122.4-132	204-220	408-440
56-60	123-132	4480-4800	112-120	134.4-144	224-240	448-480
61-65	134-143	4880-5200	122-130	146.4-156	244-260	488-520
66-70	145-154	5280-5600	132-140	158.4-168	264-280	528-560
71-75	156-165	5680-6000	142-150	170.4-180	284-300	568-600
76-80	167-176	6080-6400	152-160	182.4-192	304-360	608-640
81-85	178-187	6480-6800	162-170	194.4-204	324-340	648-680
86-90	189-198	6880-7200	172-180	206.4-216	344-360	688-720
91-95	200-209	7280-7600	182-190	218.4-228	364-380	728-760
96-100	211-220	7680-8000	192-200	230.4-240	384-400	768-800

The total blood volume listed refers to the total blood volume that can be drawn for **both clinical care and research procedures.

Minimum Hgb required at time of blood draw = 7.0

Minimum Hgb required at time of blood draw if subject has respiratory/CV compromise = 9.0-10

The above chart information with the 2.5% of blood volume columns has been adopted by Children’s Memorial Research Center IRB.

Points to consider when drawing blood from children for research purposes:

- Investigators (with input from overseeing physicians) should consider further limiting blood draws for research in subjects who may not be in good health (e.g. anemia, low cardiac output, pulmonary or hematopoietic problem) (Dr. Greene & UMich IRB).
 - Note that the overseeing physician has the ultimate authority to discontinue research blood draws. The investigator should consult with the overseeing physician on a constant basis for information about any health status changes.
- Iron supplementation therapy may be required for children involved in studies that draw a large amount of blood, with subsequent monitoring via hemoglobin measurements (Partners).
- Extra sticks should be minimized. Drawing extra blood during the time of standard blood draws (or when there is already an IV or lines in place that allow for small withdrawal amounts) is recommended. It is recommended that no more than 3 venipunctures (including missed attempts) be performed in this population. Note that central lines may have restricted access for blood draws.
- Estimated volume, frequency of blood draws, and risks of blood removal should be listed in the consent form.
- Consider other risks from a large blood withdrawal from pediatric subjects such as extra blood transfusions, fainting, etc.
- For studies where there is no direct benefit to the subject, it is pertinent that the amount of blood withdrawn does not exceed the limit so that it will not impact the subject's clinical condition.

References/Sites

Children's Hospital Los Angeles IRB blood draw policy. Click on investigator's manual and then go to page 57. Web site: <http://www.childrenshospitala.org/body.cfm?id=237>

City of Hope National Medical Center – Beckman Research Institute of the City of Hope Institutional Review Board. Blood Drawing Guidelines. Link: <http://resadmin.coh.org/doc/irb3250.doc>

CMRC IRB Maximum Allowable Total Blood Draw Volumes. (2006). Link: http://192.206.213.50/docs/Maximum_Allowable_Blood_Draws.doc

Dr. Greene's How Much Blood is Too Much Guideline. (2003). Web site: <http://www.drgreene.org/body.cfm?id=21&action=detail&ref=1616>

FDA Checklist of Pediatric Points to Consider. Link: www.fda.gov/oc/opt/Checklist.pdf

Partners Human Research Committee. Blood Sampling Guidelines. Web site: <http://healthcare.partners.org/phsirb/bldsamp.htm>

University of Arkansas for Medical Sciences IRB Investigator's Handbook for Human Studies. Appendix R: Guidelines for Blood Draws in Pediatric and Adult Populations. Link: <http://www.uams.edu/ora/irb/files/Investigator's%20Handbook%20ver%2018.doc>

University of Michigan Medical School – IRB Med. Guidance: Blood Draw Guidelines. Web site: http://www.med.umich.edu/irbmed/guidance/blood_draw.htm

University of Pittsburgh IRB Chart for Maximum Allowable Blood Draw Volumes. Web site: <http://www.irb.pitt.edu/irbmailings/listbot6-20-05.htm>



Human Subject Protection Program Guidance Document

University of Pittsburgh IRB Guidelines for Blood Withdrawal GCRC Policies. (2005). Link:
www.irb.pitt.edu/Guidance/Bloodwithdrawpediatrics.pdf

Wayne State University Human Investigation Committee Policy on Research Studies Involving the Collection of Blood Samples. (2002). Web site: <http://www.hic.wayne.edu/hicpol/blood.htm>