



**CHILDREN'S & WOMEN'S HEALTH
CENTRE OF BRITISH COLUMBIA**

AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

University of British Columbia – Children's & Women's Health Centre of BC
Research Ethics Board
(UBC C&W REB)

UBC C & W Research Ethics Board

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PEDIATRIC BLOOD VOLUME DRAW GUIDANCE

The table below provides guidance for clinical researchers and REB reviewers for assessing the risk level associated with total blood volumes collected in pediatric research participants for both research and clinical purposes. Blood volumes falling within the limits outlined below may be considered minimal risk and may undergo expedited review by the REB. Blood volumes above these limits or collected more frequently will undergo full board review and the higher blood volume requirements should be adequately justified in the REB application. Note: Blood draws in infants with a body weight of less than 3 kg will always be reviewed at the full board. To be considered minimal risk, maximal blood draws (5% TBV monthly) should not occur more than three consecutive months.

MAXIMUM ALLOWABLE TOTAL BLOOD DRAW VOLUMES (CLINICAL + RESEARCH)				
CONSIDERED MINIMAL RISK (adapted from (1))				
Body Weight (Kg)	Body Weight (lbs)	Total blood volume (mL)	Maximum allowable volume (mL) in one blood draw (= 2.5% of TBV)	Maximum allowable volume (mL) drawn over a 30 day period (= 5% of TBV) for outpatients only *note: must occur no more than 3 consecutive months
3	6.6	240	6	12
4	8.8	320	8	16
5	11	400	10	20
6	13.2	480	12	24
7	15.4	560	14	28
8	17.6	640	16	32
9	19.8	720	18	36
10	22	800	20	40
11-15	24-33	880-1200	22-30	44-60
16-20	35-44	1280-1600	32-40	64-80
21-25	46-55	1680-2000	42-50	64-100

26-30	57-66	2080-2400	52-60	104-120
31-35	68-77	2480-2800	62-70	124-140
36-40	79-88	2880-3200	72-80	144-160
41-45	90-99	3280-3600	82-90	164-180
46-50	101-110	3680-4000	92-100	184-200
51-55	112-121	4080-4400	102-110	204-220
56-60	123-132	4480-4800	112-120	224-240
61-65	134-143	4880-5200	122-130	244-260
68-70	145-154	5280-5600	132-140	264-280
71-75	156-185	5680-6000	142-150	284-300
76-80	167-176	6080-6400	152-160	304-360
81-85	178-187	6480-6800	162-170	324-340
86-90	189-198	6880-7200	172-180	344-360
91-95	200-209	7280-7600	182-190	364-380
96-100	211-220	7680-8000	192-200	384-400

Based on charts from the Children's Memorial Research Centre (Chicago, IL) (1) adapted by Rhona Jack, Ph.D. Children's Hospital and Regional Medical Center Laboratory Seattle WA and used by the Committee on Clinical Investigations, Children's Hospital in Los Angeles, CA; Baylor College of Medicine, Dallas, TX; Cincinnati Children's Hospital Institutional Review Board, OH; North Shore Long Island Jewish Health System, NY; University of California Davis.

ABOVE-MINIMAL RISK

The REB considers above-minimal risk to involve total (clinical + research) blood draw volumes higher than the limits outlined in the table above and/or procedures that expose the participant to risk of the following:

- Putting a child at risk of symptoms or signs of anemia, including light-headedness, fatigue, tachycardia, etc.
- Requiring a blood transfusion²
- Experiencing a clinically important drop in hemoglobin levels (i.e. below 8 g/dL)²
- Requiring volume replacement and/or iron supplementation²
- Infants with a body weight of less than 3 kg
- Significant number of needle pricks or accessions to central lines/catheters²

Additional caution should be exercised in children with concurrent acute or chronic medical conditions that are associated with inhibition of erythropoiesis, low hemoglobin level or blood volume depletion either as part of the illness or as a result of treatment. This includes conditions such as renal failure, bone marrow dysfunction, severe malaria, severe sepsis with disseminated intravascular coagulation, anemia and patients undergoing chemotherapy².

REFERENCES

1. Children's Memorial Research Center (CMRC) IRB allowable blood limits. Chicago, IL. Adopted 9/18/06. Accessed May 9 2012.
[http://www.childrensmrc.org/uploadedFiles/Research_Administration/Office_for_Research_Integrity_and_Compliance_\(ORIC\)/Institutional_Review_Board_\(IRB\)/Maximum_Allowable_Blood_Draws.doc](http://www.childrensmrc.org/uploadedFiles/Research_Administration/Office_for_Research_Integrity_and_Compliance_(ORIC)/Institutional_Review_Board_(IRB)/Maximum_Allowable_Blood_Draws.doc)
2. Howie, SRC. Blood sample volumes in child health research: review of safe limits. Bulletin of the World Health Organization; ID: BLT.10.080010. September 2010. p. 1-17.