# PEDIATRIC BLOOD DRAW VOLUME 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.

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| **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 |

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| 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_%28ORIC%29/Institutional_Review_Board_%28IRB%29/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.