Maximum Allowable Blood Draw Volumes

IRB Review Procedures

Criteria for Review under Expedited Category 2 (45 CFR 46.110)
Research can be reviewed under expedited category 2 when collection of blood meets specific criteria:

1. **Procedure/Method:** Collection of blood via finger stick, heel stick, ear stick, or venipuncture. *Note:* arterial collection is not included.
2. **Volume in the Targeted Population(s):**
   a. Healthy, non-pregnant adults who weigh at least 110 pounds: the amount drawn may not exceed 550 ml
   b. Other adults and children considering the age, weight, and health of the subjects: the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg
3. **Timing:** The amount may not exceed the volume limit above (see item 2) in an 8 week period
4. **Frequency:** Collection may not occur more frequently than 2 times per week;

All of the above as well as risks of blood collection should be outlined in the protocol and consent for the IRB’s review and consideration.

If the above criteria is not met, convened board review is required to determine the risk of the study (minimal or greater than minimal).

The established guidelines below aid in determining the risk category of the study.
- **Healthy:** having no or minimal blood draws for clinical purposes
- **Affected:** having large amounts of blood drawn for clinical purposes
  - For these subjects, the allowable limit is decreased because it may affect the number of blood transfusions needed.

### Maximum Allowable Total Blood Draw Volumes Chart

<table>
<thead>
<tr>
<th>Body Wt. (kg)</th>
<th>Body Wt. (lbs)</th>
<th>Total blood volume (ml)</th>
<th>Maximum allowable volume (ml) to be collected for both clinical care and research procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>in a 24 hour period...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Affected</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.5% of total blood volume</td>
</tr>
<tr>
<td>1</td>
<td>2.2</td>
<td>100</td>
<td>2.5</td>
</tr>
<tr>
<td>2</td>
<td>4.4</td>
<td>200</td>
<td>5</td>
</tr>
</tbody>
</table>
Minimum Hgb required at time of blood draw
- Given no respiratory/CV compromise = 7.0
- If subject has respiratory/CV compromise = 9.0-10

Notes:
- Amounts in excess of the 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 rationale and describe what safeguards are in place to protect subjects from undue risk.
- This is based on blood volume estimates for various age ranges:

<table>
<thead>
<tr>
<th>Age</th>
<th>Total Blood Volume Range* (ml/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm infant</td>
<td>90 - 105</td>
</tr>
<tr>
<td>Term infant</td>
<td>80 - 85</td>
</tr>
<tr>
<td>1-12 months</td>
<td>75 - 80</td>
</tr>
<tr>
<td>1 – 3 years</td>
<td>70 - 80</td>
</tr>
<tr>
<td>Older children and teens</td>
<td>65 - 80</td>
</tr>
</tbody>
</table>
Blood Volume Calculators

- www.endmemo.com/medical/bloodvolume.php

Methods for Minimizing Risk

1. **Limiting Blood Draws in Severely Sick Patients**: 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)
   a. An overseeing physician has the authority to discontinue research blood draws. The investigator should consult with the overseeing physician about any health status changes.

2. **Minimize Extra Sticks**: Extra sticks should be minimized whenever possible. 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.

3. **Iron supplementation and hemoglobin monitoring** may be required for children involved in studies that draw a large amount of blood.

4. **No Direct Benefit**: For studies where there is no direct benefit, it is pertinent that the amount of blood collected does not exceed the limit so that it will not impact the subject's clinical condition.
   a. When the study involves children there must be rationale as to how the study is likely to yield generalizable knowledge which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, and the risk must represent a minor increase over minimal risk.

References
