

Title: Guidelines for Blood Collection in Research	*Applicable to: Beaumont Health	Effective Date: 01/12/2018
		Last Periodic Review Date: 01/12/2018
Policy Owner: Administrative Director	Document Type: Policy	Functional Area: IRB and Clinical Research, Research Institute

***For This Document, Beaumont Health Includes:**

- Beaumont Corporate Shared Services
- Beaumont Hospital, Dearborn
- Beaumont Hospital, Farmington Hills
- Beaumont Hospital, Grosse Pointe
- Beaumont Hospital, Royal Oak
- Beaumont Hospital, Taylor
- Beaumont Hospital, Trenton
- Beaumont Hospital, Troy
- Beaumont Hospital, Wayne
- Beaumont Medical Group
- Beaumont Pharmacy Solutions
- Post Acute Care

I. PURPOSE:

The purpose of this policy is to provide guidelines for collection of blood samples from research participants for research conducted at Beaumont Health (BH).

II. SCOPE:

This policy applies to investigators, key research personnel, IRB members and IRB staff. This policy is not intended to conflict with or replace any policies of Beaumont Laboratory Services, nor apply to Beaumont Laboratory staff clinical operations.

III. BACKGROUND:

The Beaumont Health Institutional Review Board (IRB) serves as the local IRB for human subjects research conducted at Beaumont. Beaumont may authorize the use of an Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredited external IRB for studies meeting established criteria (IRB Policy [Review by an External Institutional Review Board](#)). In accordance with federal regulations, IRB review and approval is required to protect the rights and welfare of human subjects.

The IRB is charged with evaluating the rationale, methodology and risk/benefit ratio to research participants when blood samples are collected for research purposes. At times, the collection of blood samples for research purposes may be considered to present no more than minimal risk to research participants and may be reviewed through an expedited review process (IRB Policy

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[Expedited Review of Research](#)). In other instances, the collection of blood samples for research purposes may be considered as greater than minimal risk and must undergo full board review.

IV. **POLICY:**

IRB review and approval is required to protect the rights and welfare of research participants. The following conditions apply to requests for blood collection for research purposes:

1. The participants have no specific health conditions (e.g., severe anemia) to contraindicate the withdrawal of blood.
2. In participants from whom blood is *not* already being drawn for clinical purposes, the withdrawal method is by cutaneous sticks (e.g., heel, ear or finger) or by standard peripheral venipuncture.
3. Drawing of blood is carried out by experienced professional or technical personnel.

A. **Minimal Risk Blood Collection** - According to federal guidelines, blood sampling under the following circumstances may be reviewed by the IRB under an Expedited Review procedure.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. Blood samples may be collected for research purposes from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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**
2. From other adults and children* (<18 yrs of age in Michigan), considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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. (See IRB Policy [Vulnerable Populations: Children as Research Participants](#).)

B. **Blood Sampling Volumes in Children** - Blood samples may be collected under the following conditions in children participating in research:

1. The volume drawn at one time (including blood drawn for clinical purposes) should not exceed one percent (1%) of the child's total blood volume. A child's blood volume is usually estimated to be 80ml/kg. Therefore, the volume of blood drawn per specimen should be less than or equal to 0.8ml/kg.
Example: A 30kg child's maximum blood draw volume for research (and clinical) purposes would be 30 x 0.8 = 24ml.

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2. The total blood volume withdrawn for research (and clinical) purposes over an eight-week period should not exceed ten percent (10%) of the child’s total blood volume. Using the 80ml/kg blood volume for a child, the maximum volume of blood drawn should be less than or equal to 8ml/kg over the 8week period.
Example: A 30 kg child’s maximum blood draw volume for research (and clinical) purposes over 8 weeks would be 30 x 8 = 240ml).

C. **Blood Spot/Heel Stick Research** - Blood spots are routinely taken from newborns for screening purposes at Beaumont and throughout the state of Michigan and are sent to the Michigan Neonatal Biobank. The Michigan Neonatal Biobank obtains consent from the parents to use the screening blood spots for future research. Beaumont researchers may use blood spots obtained from the Michigan Neonatal Biobank for Beaumont research. In such cases, the Beaumont researcher and the Michigan Neonatal Biobank must be parties to a Material Transfer Agreement, per the Public Health Code. When the Michigan Neonatal Biobank has obtained blood spots from states other than Michigan, where state law does not require parental consent, the researcher must justify the need to use these specimens (obtained from outside Michigan) in the IRB application. Additionally, a Beaumont researcher may request IRB approval to obtain an additional blood spot from newborn/neonatal Beaumont patients. IRB approval and parental consent are required prior to the collection.

D. **Greater than Minimal Risk Blood Collection** - Blood sampling procedures that involve greater than minimal risk (e.g., excessive volume, methodology) must undergo review by the fully convened IRB or approved external IRB.

E. **Informed Consent and Authorization** - Blood sampling for research purposes may not occur prior to obtaining the research participant’s informed consent and authorization to take part in the research. The estimated volume and frequency of blood to be drawn, risks associated with drawing blood, and the measures taken to minimize those risks should be included in the information given to the participant in a written informed consent and authorization document. When listing amounts in the informed consent and authorization document, volumes should be translated into U.S. measurements as follows:

- 5ml = 1 teaspoon
- 15 ml = 1 tablespoon
- 60 ml = ¼ cup or 4 tablespoons
- 240 ml = 1 cup

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V. REFERENCES:

21 CFR 50 Subpart B Informed Consent Requirements
 21 CFR 56.108 IRB Functions and Operations
 45 CFR 46.111(b) Criteria for IRB Approval and Research
 45 CFR 46.108 IRB Functions and Operations
 45 CFR 46.116 Requirements for Informed Consent
 Public Law No: 113-240
 Michigan Biotrust for Health
 Michigan Public Health Code Act 368 of 1978, MCL 333.5431

VI. ASSOCIATED POLICIES:

IRB Policy [Expedited Review of Research](#)
 IRB Policy [IRB Initial Review of Research Protocols](#)
 IRB Policy [Informed Consent and Authorization in Research](#)
 IRB Policy [IRB Review of Research Involving Biospecimen Banking](#)
 IRB Policy [Review by an External Institutional Review Board](#)
 IRB Policy [Vulnerable Populations: Children as Research Participants](#)

CORPORATE AUTHORITY:

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.