

Title: <b>Criteria for Determining Frequency of Review by the IRB</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>03/16/2018</b>
		Last Periodic Review Date: <b>03/16/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Functional Area: <b>IRB and Clinical Research, Research Institute</b>

**\*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 determine whether a protocol requires review by the Institutional Review Board (IRB) more frequently than on an annual basis.

**II. SCOPE:**

This policy applies to investigators, research staff, IRB members and IRB staff.

**III. GENERAL:**

**The Beaumont Health (Beaumont) IRB serves as the primary Institutional Review Board for human participant research conducted at Beaumont (for information about the use of external IRB’s, see policy [Review by an External Institutional Review Board](#)). In accordance with federal regulations, the protection of the rights and welfare of participants requires an IRB oversight, at the time of protocol review and approval, to determine whether or not a protocol requires review on a more frequent than annual basis.**

**IV. POLICY:**

The following criteria may be used by IRB members or the IRB Chairperson, when reviewing protocols to determine the frequency of review:

1. The probability and/or magnitude of the anticipated risks to participants.
2. The vulnerability of the population being studied.

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3. The potential for serious risk to participants when the research involves new treatments whose risk is unknown, i.e., no history on which to base anticipated risks.
4. The medical condition of the proposed research participants and their susceptibility to problems as a result of protocol participation.
5. The qualifications and research experience of the principal investigator (PI) and key personnel.
6. Past history of PI and research team in adherence to IRB requirements.
7. The nature and frequency of unanticipated problems observed in similar research at this and other facilities.
8. Any other factors deemed relevant by the IRB.
9. Funding requirements per the funding agency.

For each research protocol, at the time of initial and continuing review, the IRB determines the length of the approval period. The IRB may specify an approval period of less than annual, defined with either a time interval or a maximum number of participants. These IRB determinations will be clearly stipulated in the IRB meeting minutes and in the approval letters sent to the investigator.

**V. APPLICABLE REGULATIONS AND GUIDELINES:**

- 45 CFR 46.103(b)(4) Assuring Compliance,
- 45 CFR 46.108(b) IRB Functions and Operations
- 45 CFR 46.109(e) IRB Review of Research
- 45 CFR.111 Criteria for IRB Approval of Research
- 21 CFR 56.103(a) Circumstances in which IRB Review is required
- Grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research
- Grants.nih.gov/grants/guide/notice-files/ Notice Number: NOT-OD-16-094

**VI. REFERENCES TO OTHER APPLICABLE POLICIES:**

- IRB Policy [\*Continuing Review and Renewal of a Protocol\*](#)
- IRB Policy [\*IRB Initial Review of Research Protocols\*](#)
- IRB Policy *Review by an External Institutional Review Board*

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**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.