Title: **Research Exempt from Full IRB Review**	*Applicable to: **Beaumont Health**	Effective Date: **03/19/2018** Last Periodic Review Date: **03/19/2018**
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 determine which research protocols *may* qualify for the category of Exempt research. Under federal regulations, certain categories of research activities are considered research but can be declared Exempt from further review by the Institutional Review Board (IRB).

II. SCOPE:

This policy applies to investigators, key personnel, IRB members and 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 IRB policy *Review by an External Institutional Review Board*). Human participant research is activity meeting the definition of "research" and involving "human participants." Projects which do not meet the criteria for human participant research are not reviewed under the federal regulations (see IRB policy 251 *Defining Human Participant Research*).

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IV. POLICY:

A. Under federal regulations, certain categories of research may be exempt from further review by the IRB. The Beaumont IRB is the only body authorized to review and grant Exemptions for qualified Exempt human participant research conducted at Beaumont. **Researchers may not independently make Exemption determinations or obtain such a determination from an external IRB.**

In order for a project to qualify as exempt from further review, the entire research project must fall within one or more of the six (6) specific regulatory categories of Exemption, provided below. Exempt research cannot involve prisoners as participants. Research regulated by the Food and Drug Administration (FDA) does not qualify as Exempt research.

If an investigator believes his/her protocol qualifies for an Exemption, an iMedRIS initial application must be submitted to the IRB for review. Exemptions may not be requested in person or by telephone. The IRB chairperson or a designated member of the IRB must "concur" the protocol qualifies for exemption. **Investigators cannot exempt their own projects.** A research project cannot start until after written concurrence is granted by the IRB. Retroactive "concurrence" or review is not permitted, per regulations. Data collected prior to IRB Exemption concurrence may not be used and must be destroyed.

B. **Exemption Categories** - Research activities are exempt from further review by the IRB when the only involvement of human participants will be in one or more of the following Exemption categories:
   1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
      a. research on regular and special education instructional strategies, or
      b. research on the effectiveness of or the comparison among instructional techniques, curricular, or classroom management methods.
   2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
      a. information obtained is recorded and retained in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
      b. any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior which is not exempt under the part 2 of this section, if:
   a. the human participants are elected or appointed public officials or candidates for public office; or
   b. federal law require(s) without exception all confidential or personally identifiable information will be maintained throughout the research thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner which participants cannot be identified, directly or through identifiers linked to the participants.
   Note: **To qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins.**
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and are designed to study, evaluate or otherwise examine:
   a. public benefit or service programs e.g. financial or medical benefits as provided under the Social Security Act or service (social, supportive, or nutrition services as provided under the Older Americans Act);
   b. procedures for obtaining benefits or services under these programs is conducted pursuant to specific federal statutory authority;
   c. possible changes in or alternatives to those programs or procedures or;
   d. possible changes in methods or levels of payment for benefits or services under those programs;
   e. there is no statutory requirement an IRB review the research;
   f. the research does not involve significant physical invasions or intrusions upon the privacy of participants.
6. Taste and food quality evaluation and consumer acceptance studies:
   a. wholesome foods without additives are consumed; or a food consumed containing a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the Environmental Protection Agency or the Food Safety and
   b. inspection of the U.S. Department of Agriculture.

C. **IRB Responsibility -** The IRB will review the protocol to determine if all aspects of the protocol meet one or more of the six (6) Exemption categories listed above. During the review process, careful consideration is given to review of the risks, benefits, provisions for confidentiality, participant's voluntary participation, and the process of informed consent.

Exempt research must comply with Beaumont's ethical standards, including:

1. The research holds out no more than minimal risk to participants.
2. Selection of participants in equitable.
3. Research data to be shared outside of the institution must be provided using a de-identified data set. A formal data sharing agreement must be executed prior to data being shared.
4. If there are interactions with participants, there should be a consent process to disclose the following:
   a. The activity involves research.
   b. A description of the procedures involved in the study.
   c. Participation is voluntary.
   d. Name and contact information for the researcher.
5. There are adequate provisions to maintain the privacy interests of participants.
6. **An investigator cannot exempt his/her own research project from review by the IRB**. Written "concurrence" from the IRB must be received prior to initiating any research activity.
7. The investigator is required to inform the IRB when they propose to change key personnel, increase enrollment numbers, or change dates for an Exempt research project. This is done via the Amendment request form in iMedRIS. Such changes are acknowledged by the IRB and an acknowledgement letter issued. The investigator is required to notify the IRB if any proposed study modifications would result in the protocol no longer meeting the Exemption status. In such cases, the investigator must submit an Amendment request form in iMedRIS before changes are implemented. If the modifications result in the project no longer meeting the Exemption status, the IRB will re-review the study under the appropriate review category (expedited or full board) and issue an appropriate approval letter. All key personnel listed on the project must complete the CITI Biomedical Investigators and Key Personnel Course and a conflict of interest disclosure (COID) prior to being added to the study.
8. Projects involving **genetics** may be referred for a higher level of review and approval.

D. **Exemption Concurrence/IRB Correspondence -** When the IRB determines a submission meets criteria for Exemption status, a letter will be sent to the investigator indicating the IRB acknowledges the Exemption request, and states the category number under which the Exemption status was granted. This information becomes part of the minutes of the next IRB meeting.

If the protocol does not meet the criteria for Exemption status, the investigator will be notified and given the reasons for the IRB's decision. The investigator will be instructed to resubmit the protocol under the appropriate Expedited or Full Board review status. If an investigator does not agree with the opinion of the IRB, he/she may appeal to the IRB chairperson.

Exemption status is granted for the life of the project, providing no changes are made to the protocol. Annual progress reports/final reports submissions are not required. However, a Study Closure form or study correspondence must be submitted to the IRB upon project completion. Alternately, Exempt studies may be closed administratively.

V. REFERENCES:

45 CFR 101(b) Exemption Categories
21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigation Device Exemptions
Federal Register, Vol. 56, No. 117 (June 18, 1991), #101b) (1)-(6).

VI. ASSOCIATED POLICIES:

IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *HIPAA and Research*
IRB Policy *Defining Human Participant Research*

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.