| Title: **Expedited Review of Research** | *Applicable to: **Beaumont Health** | Effective Date: **03/16/2018** |
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| | | Last Periodic Review Date: **03/16/2018** |
| 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 define the criteria for the Expedited Review procedure used by the Beaumont Health (Beaumont) Institutional Review Board (IRB). The 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*.

## II. SCOPE:

This policy applies to investigators, key personnel, IRB members and staff.

## III. DEFINITIONS:

A. **Expedited Review -** Review of research involving human participants by the IRB chairperson or designee, which meets the criteria outlined in this policy, in accordance with federal regulations. Expedited review may not be used when the research is classified.

B. **Expedited Reviewer -** An experienced IRB member is defined as an IRB voting member who has undergone IRB training which consists of meeting with the IRB manager to discuss regulatory criteria, IRB meeting packet, and IRB member expectations, including holding current CITI human participant protection training and observing a minimum of three IRB meetings prior to performing an expedited review. An expedited reviewer cannot have a project

specific conflict of interest as documented on the reviewer checklist. The expedited review may be conducted by the IRB chairperson, IRB manager, IRB research nurse clinician, IRB coordinator or other IRB member as deemed appropriate by the IRB chairperson. The expedited reviewer may consult with other IRB member(s) or a non-IRB member consultant with special expertise in the scientific area or discipline or special population being studied. The expedited reviewer receives the full study application and all related materials to complete their review and make the expedited determination. However, the reviewer remains responsible for their review and approval of research using the expedited procedure. When a consultant is to be used, the expedited reviewer follows the procedures described in *IRB Initial Review of Research Protocols* policy.

C. **Children -** Per the Department of Health and Human Services (HHS) "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

D. **Minimal Risk -** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

## IV. POLICY:

A. The Beaumont IRB serves as the Institutional Review Board for all human participant research conducted at Beaumont facilities. In accordance with federal regulations, IRB review and approval is required to protect the rights and welfare of human participants. Expedited review may occur with: 1) minimal risk new protocols, 2) continuations of previously approved protocols, and 3) amendments to approved protocols if the following criteria are met.

B. **Initial Review**

1. Expedited Review is appropriate only when all protocol required research activities present no more than minimal risk to human participants, **and** involve only procedures listed in one or more of the Expedited Review Categories listed below.
2. The listed activities should not be considered minimal risk simply because they are included on this list. Inclusion implies the activity is **eligible** for review through the Expedited Review procedure when the specific circumstances of the proposed protocol involve no more than minimal risk to human participants. The Categories in this list apply regardless of the age of participants, except as noted.
3. The Expedited Review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation,

or be stigmatizing, unless reasonable and appropriate protections will be implemented so risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

C. **Expedited Review Categories -** Categories one (1) through seven (7) pertain to both initial and continuing review conducted by the IRB.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug (IND) application [(21 CFR 12) - FDA Guidelines] is not required.
   ***Note:*** *Research on marketed drugs which significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.*
   b. Research on medical devices for which (i) an investigational device exemption (IDE) application [(21 CFR 812) - FDA Investigational Device Guidelines] is not required; or (ii) the medical device is approved for marketing and is being used in accordance with its approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. 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
   b. from other adults and children, 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.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   a. hair and nail clippings in a non-disfiguring manner;
   b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. permanent teeth if routine patient care indicates a need for extraction;
   d. excreta and external secretions (including sweat);
   e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f. placenta removed at delivery;
   g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

   h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   j. sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of a medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples:
   a. physical sensors applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participants privacy;
   b. weighing or testing sensory acuity;
   c. magnetic resonance imaging;
   d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) which have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). ***Note****: Some research in this category may be exempt from HHS regulations for the protection of human subjects (45 CFR 46.101 (b)(4)). This listing refers only to research which is not exempt.*
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
   ***Note:*** *Some research in this category may be exempt from HHS regulations for the protection of human subjects (45 CFR 46.101 (b)(2) and (b)(3)). This listing refers only to research that is not exempt.*

D. **Continuing Review -** Expedited continuation review is appropriate for studies which were initially reviewed by an Expedited Review or meet the Expedited Review categories below.

E. **Expedited Categories for Continuation**

1. Continuing review of research previously approved by the convened IRB as follows:
   a. where: i) the research is permanently closed to the enrollment of new participants; ii) all participants have completed all research-related interventions; and iii) the research remains active only for long-term follow-up of participants; or
   b. where no participants have been enrolled (at this site) and no additional risks have been identified (at any site); or
   c. where the remaining research activities are limited to data analysis.
2. Continuing review of research, not conducted under an IND or IDE where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting the research involves no greater than minimal risk and no **additional risks have been identified.**

F. **Amendments -** For minor modifications to an IRB approved protocol or informed consent and authorization document, an Expedited Review may be performed. A minor modification is defined as a change(s) which does not affect regulatory criteria for approval, including changes which do not materially affect an assessment of the risks and benefits of the protocol, and do not substantially change the specific aims or design of the protocol.

**G. IRB Responsibility -** Within these categories of research, the IRB expedited reviewer may exercise all of the authority of the IRB, except expedited reviewer may not disapprove the research. The reviewer may approve, require modifications or refer the research protocol to the convened IRB for full board review in accordance to the federal regulations. IRB documentation must include: 1) the categories justifying the Expedited Review, 2) date of the IRB action, and 3) the actions taken by the expedited reviewer. The investigator and individual completing the amendment request form will be sent a letter indicating the actions taken for each submitted amendment. These actions will be documented in the IRB minutes of each meeting.

**H. Procedures for Submission -** A researcher may submit an application for IRB expedited review via the iMedRIS system at any time. If consent is required for the research participation, a consent and authorization document and full board IRB application must be submitted for IRB review. The full IRB application is utilized even if the research study meets the expedited criteria in order to capture information regarding the consent procedure, privacy and confidentiality. The proposed consent document must include the components found in the consent template posted on the IRB website**.** If another form of consent is required (e.g., phone consent, information sheet, etc.) the researcher must submit the form of

consent proposed for use to the IRB. Each person listed as key personnel must have a completed annual Conflict of Interest Disclosure (COID) on file. A Waiver of Authorization is required if medical records will be accessed to screen and identify potential research participants. Data collection forms, CRFs, questionnaires, and any other study materials must be submitted to the IRB for initial approval. An Amendment request is required if there are any changes to the study or study materials, following IRB approval, prior to the change being implemented.

I. **Informing IRB Members** - The IRB members will be informed of all expedited approvals for initial review, continuing review and amendment to previously approved research, via the IRB meeting minutes.

## V. APPLICABLE REGULATIONS AND GUIDELINES:

45 CFR 46.110 Expedited Review Procedures
45 CFR 46.402(a) Definition of Children
21 CFR 56.110 Expedited Review Procedures
Protection of Human Participants: Categories of Research that may be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure, from the Federal Register: November 9, 1998 (Volume 63, Number 216)]

## VI. REFERENCES TO OTHER APPLICABLE POLICIES:

IRB Policy *Amendment Requests to the IRB Approved Studies*
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*

## 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.