Title: **Planned Emergency Research**	*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 establish a procedure for the review and approval of planned emergency research studies at Beaumont Health.

II. SCOPE:

This policy applies to investigators, key research personnel, Institutional Review Board (IRB) members and staff involved in the oversight and implementation of planned research in emergency situations in which participants are unable to give informed consent due to a life-threatening medical condition and for which the legally authorized representative or other appropriate surrogate cannot be reached within the therapeutic window.

III. POLICY:

It is the policy of Beaumont to protect the rights of all research participants, including those who may be unable to provide informed consent for emergency research. It is the responsibility of the IRB to review, approve, and provide guidance on the special ethical considerations inherent to conducting planned emergency research. **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*).**

A. **Informed Consent and Authorization Requirements for Planned Emergency Research** The IRB is responsible for the initial review and continuing review and approvals of clinical

investigations involving planned emergency research and may approve such an investigation without requiring informed consent from all research participants prior to study intervention. A waiver of informed consent may occur if the IRB, with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation finds and documents **each** of the following:

1. The human participants are in a life-threatening situation, available treatments are either unproven or unsatisfactory, **and** the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
2. Obtaining informed consent is not feasible because:
   a. The participants will not be able to give their informed consent as a result of their medical condition; **and**
   b. The intervention under investigation must be administered before consent from the participants' legally authorized representative (LAR) is feasible; **and**
   c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
3. Research participation holds out the prospect of direct benefit to the participants because:
   a. Participants are facing a life-threatening situation which necessitates intervention; **and**
   b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual participants; **and**
   c. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
4. The clinical investigation could not practicably be carried out without the waiver of consent.
5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a LAR for each participant within the window of time and, if feasible, to ask the LAR for consent within the specified window rather than proceeding without consent. The PI will summarize efforts made to contact the LAR and make this information available to the IRB at the time of continuing review.
6. The IRB has reviewed and approved informed consent procedures and an informed consent and authorization document consistent with 21 CFR 50.25, 21 CFR 50.24, 45 CFR 46.116(a) and (b) and 46.408 These procedures, and the consent document, are to be used with participants or their LAR in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when

providing an opportunity for a family member or LAR to object to a participants' activity in the clinical investigation consistent with the paragraph below.

7. The research activity is subject to regulations codified by the Food and Drug Administration (FDA) investigational new drug application (IND) or an FDA investigational device exemption (IDE).
8. The application clearly identifies the protocols which will include participants who are unable to consent.

B. **Community Consultation and Public Disclosure -** Additional protections of the rights and welfare of the participants are also required, including minimally **all** of the following:

1. Consultation (including consultation carried out by the IRB, where appropriate) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be enrolled; **and**
2. Public disclosure prior to the initiation of the clinical investigation, to the communities in which the research will be conducted and from which the participants will be enrolled. This disclosure will include plans for the investigation and its' risks and expected benefits; **and**
3. Public disclosure of sufficient information, following completion of the clinical investigation, to apprise the community and researchers of the study results including the demographic characteristics of the research population and its' results; **and**
4. Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; **and**
5. If obtaining informed consent is not feasible and a LAR is not reasonably available, the investigator has committed, if feasible, to make an attempt to contact the participant's family member who is not a LAR within the therapeutic window, in order to ask whether he or she objects to the subjects' participation in the clinical investigation. The PI will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

C. **Notification of Study Participation -** The IRB is also responsible for ensuring procedures are in place for the PI to:

1. Inform each participant at the earliest feasible opportunity (or an LAR of the participant if the participant remains incapacitated, or a family member if an LAR is not reasonably available) of the participant's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent and authorization document.
2. The IRB shall also ensure there is a procedure to inform the participant, (or LAR if the participant remains incapacitated, or a family member if an LAR is not reasonably

available) that he or she may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled.

3. If an LAR or family member is told about the clinical investigation and the participant's condition improves, the participant is also to be informed as soon as feasible. Informed Consent and Authorization will be performed when and if the participant is able to cognitively understand the information.
4. If a participant is entered into a clinical investigation with waived consent and the participant dies before an LAR or family member can be contacted, information about the clinical investigation is to be provided to the participant's LAR or family member, if feasible.

D. **IRB records -** IRB determinations and documentation requirements:

1. Documentation must be retained for at least 3 years after the completion of the clinical investigation, and the records shall be accessible for inspection and copying by the FDA in accordance with 21 CFR 51.115 (b).
2. Protocols involving an exception to the informed consent requirement under this section must be performed under a separate IND or IDE clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments under 21 CFR 312.30 or 812.35.
3. If an IRB determines it cannot approve a clinical investigation because the investigation does not meet FDA criteria (detailed above) or because of other relevant ethical concerns, the IRB must document and provide its findings in writing to the PI and study sponsor (if applicable). The sponsor is required to promptly disclose the information to the FDA, to the sponsor's other clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are asked to review this or a substantially equivalent investigation by the same sponsor.

E. **Department of Defense Sponsored Research** - An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

IV. REGULATORY REFERENCES:

21 CFR 50.24 Exception from Informed Consent Requirements for Emergency Research
21 CFR 50.25 Required Elements for Informed Consent
21 CFR 56.104(c) Exemptions from IRB requirement
45 CFR 46.116(a) and (b) and 46.408 Emergency Research Consent Waiver

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V. ASSOCIATED POLICIES:

IRB Policy *Informed Consent and Authorization in Research*
RI Policy *Research Supported by the Department of Defense*

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.