Title: FDA EXPANDED ACCESS PROGRAM (EAP)/FOR MEDICAL DEVICES	Policy Number: BC-IRB-414 Page: 1 of 5
SPONSORED BY: Sponsored Programs and Research Committee	**Issued for:** All BayCare, including without limitation: Bartow Regional Medical Center BayCare Alliant Hospital BayCare Hospital Wesley Chapel Mease Countryside Hospital Mease Dunedin Hospital Morton Plant Hospital Morton Plant North Bay Hospital South Florida Baptist Hospital St. Anthony's Hospital St. Joseph's Hospital Winter Haven Hospital
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Approved by: Keri Eisenbeis, Chief of Staff **Signature:**	

This policy is developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion by the health care provider warrants taking other actions.

This **FDA EXPANDED ACCESS PROGRAM (EAP)/FOR MEDICAL DEVICES** Policy applies to BayCare Health System, Inc., and any of its affiliated entities, including those entities listed above (collectively, "**BayCare**").

SCOPE:
BayCare Human Research Protection Program

PURPOSE:
This policy outlines the BayCare Institutional Review Board (BCHS-IRB) requirements when submitting Food and Drug Administration (FDA) Expanded Access Program (EAP) for Devices to BCHS-IRB when BCHS-IRB is the IRB of record. It describes the responsibilities of the Principal Investigator (PI) or treating physician for FDA EAP use of devices.

DEFINITIONS:
Investigational Medical Device is a device that has not been approved or cleared by the FDA for treatment outside clinical trials.

Expanded Access is a potential pathway for patients with a serious or life-threatening disease or condition to access an **investigational medical device** when no comparable or satisfactory alternative therapy options are available.

Emergency Use is the use of an investigational device (e.g., investigational drug, biologic, or device) in a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is insufficient time to obtain IRB approval.

Compassionate Use is the use of an investigational device to **treat or diagnose an individual patient or a small group of patients** with a serious disease or condition when there are no available alternative options.

Treatment Investigational Device Exemption (IDE) is expanded access use of an investigational device to **treat or diagnose a group of patients** with a serious or immediately life-threatening disease or condition when the device is also being studied for the same use under an approved IDE An approved IDE specifies the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in the study. During the course of the clinical trial, if the data suggests that the device is effective, then the trial may be expanded under a **new IDE** to include additional patients with life-threatening or serious diseases. This new IDE is referred to as a **Treatment IDE**.

Immediately life-threatening disease or condition is a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

Serious disease or condition is a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self- limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent.

There are Three Types of Expanded Access for Medical Devices:

- **Emergency Use**
- **Compassionate Use (Individual Patient/Small Group)**
- **Treatment Investigational Device Exemption (IDE)**

PROCEDURE:

A. Emergency Use of an Investigational Device in a Single Subject

1. Before administering the investigational device, the physician submits the following information to the IRB Office for review and confirmation for emergency use of an investigational device in a single subject:
    - IRB application that includes the words "EMERGENCY USE" and the name of the investigational device.
    - Physician letter or email with explanation that justifies administration of the investigational device (e.g., life-threatening situation, no standard acceptable treatment available, and not sufficient time to obtain IRB approval); and
    - Copy of the informed consent form.

2. If the immediate use of the investigational device is, in the physician's opinion, required to preserve the life of the patient and time is not sufficient to obtain assessment by the IRB Chair/Vice Chair, the physician submits a report in writing within five (5) working days following the emergency use as described in the sections below.

3. If the physician proposes to administer the investigational device in an emergency use situation without informed consent, the request to the IRB Office includes a statement certifying in writing that all of the conditions listed in Exception From General Requirements of Informed Consent are met. These conditions are as follows:
    - The subject is confronted by a life-threatening situation necessitating the use of the test article;
    - Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the subject;
    - Time is insufficient to obtain consent from the subject's legal representative; and
    - There is no alternative method of approved or generally recognized therapy available that will provide an equal or greater likelihood of saving the subject's life.

    If possible, this statement includes an evaluation by a physician who is not participating in the emergency use. However, if the immediate use of the investigational device without informed consent is, in the physician's opinion, required to preserve the life of the subject and time is not sufficient to obtain the independent determination by a nonparticipating physician, the independent evaluation is required in writing in the five (5) working days report described below.

4. Upon receiving an emergency use request, the IRB Staff assigns the submission review to the IRB Chair/Vice Chair.

5. The IRB Chair/Vice Chair assesses the request to determine whether it meets the regulatory requirements for emergency use and an IRB letter of concurrence is provided to the physician.

6. Within five (5) working days of the emergency use, the physician must submit a report to the IRB regarding the emergency use of the investigational device. That report is to include:
    - A brief description of the life-threatening situation;
    - Justification for use of the investigational device;
    - Signed informed consent form or justification for administration without informed consent;

- Statement of review and evaluation of the situation by a physician who is not participating in the emergency use (if administered without informed consent); and
- A description of the outcome of administration.

7. The IRB submits the case to the convened IRB meeting. The board acknowledges that the following expanded access emergency use criteria were met:
    - The subject was confronted by a life-threatening situation necessitating the use of the investigational drug, biologic, or device
    - No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the subject's life
    - Time was insufficient to obtain IRB approval

8. If a physician fails to submit a request involving emergency use of an investigational device to the IRB for review and confirmation prior to initiation, the IRB retrospectively reviews the situation to determine if the investigational device administration met the regulatory definition.

B. Compassionate Use of an Investigational Device (individual patient or small group)

1. Before using the device, if the device manufacturer agrees to provide the device under compassionate use, the PI or treating physician submits the following information to the IRB for review and confirmation for compassionate use of an investigational device:
    - IRB application that includes the words "COMPASSIONATE USE"
    - Prescription Letter from physician to test article manufacturer including the device(s) requested
    - Letter from manufacturer that authorizes use of the device
    - Letter from FDA or sponsor documenting the IDE number (when applicable)
    - Letter of concurrence for use of the device by an uninvolved physician
    - Description of the device e.g. Instructions for Use (IFU)
    - Informed consent document used in the consent discussion with the patient
    - Clearance from the PI or treating physician's institution to include:
        - Device and the procedure confirmation of Standard of Care (SOC)
        - Coverage by the Patient's Insurance
        - Administrative Review Approval letter

2. IRB staff pre-review and assign the submission review to the IRB Chair/Vice Chair.

3. The IRB Chair/Vice Chair reviews the submission and provides concurrence with the expanded access designation and considers the use to meet the federal statutory requirements and the criteria for compassionate use.

4. Following PI or treating physician submission to the FDA, he/she notifies the IRB by submitting the FDA response. The IRB Office acknowledges the FDA approval via submission correspondence and the PI or treating physician schedules the procedure.

Note: If the FDA denies the subsequent use of the device; the device is not used even if circumstances constitute a compassionate use.

5. The PI or treating physician provides the IRB with a copy of the patient or legally authorized representative signed informed consent as soon as obtained and prior to the procedure.

6. The case is presented at the convened IRB meeting. The board acknowledges that the following expanded access compassionate use criteria are met:
    - The patient has a life-threatening or serious disease or condition
    - There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition
    - Potential patient benefit justifies the potential risks of the investigational device

7. IRB Reporting Requirements following use of the device:
    1) Notification of Significant Deviation/Violation or any Serious/Unexpected Adverse Events within 5 working days of the event.

2) The final report within 45 calendar daysdays of device use or as required and approved by product manufacturer and FDA.

C. Treatment Investigational Device Exemption (IDE)

1. The physician submits the following information to the IRB Office:
   - Initial IRB application, including the Treatment IDE number;
   - Name of Treatment IDE holder/sponsor;
   - Sponsor protocol;
   - Letter from FDA or sponsor documenting the Treatment IDE number; and
   - The informed consent form.

2. The IRB staff pre-reviews the IRB submission to verify PI qualifications are met to use or administer the device and to confirm the following expanded access treatment IDE criteria are met:
   - The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;
   - There is no comparable or satisfactory alternative device available to treat or diagnose the disease or condition in the intended patient population;
   - The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or all clinical trials have been completed; and
   - The sponsor of the controlled clinical trial is pursuing marketing approval or clearance of the investigational device with due diligence.

3. The convened IRB reviews the protocol using the same procedure for Initial Application Full Board Review.

Appendix 1

This table provides a brief overview of the main differences among the types of expanded access for medical devices.

Type of Expanded Access	Brief Definition	IRB Action	FDA approval required?	Follow-up Reports to the FDA
Emergency use	Use of an investigational device when an **individual patient is in a life-threatening situation and needs immediate treatment** (there are no alternative options and no time to use existing procedures to get FDA approval for the use)	Chair Concurrence; Full Board Acknowledgment	No	Yes
Compassionate use	Use of an investigational device to **treat or diagnose an individual patient or a small group of patients** with a serious disease or condition when there are no available alternative options	Chair Concurrence; Full Board Acknowledgment	Yes	Yes
Treatment Investigational Device Exemption	Use of an investigational device to **treat or diagnose a group of patients** with a serious or immediately life-threatening disease or condition when the device is also being studied for the same use under an approved Investigational Device Exemption.	IRB Full Board Approval	Yes	Yes