Title: FDA EXPANDED ACCESS PROGRAM (EAP)/FOR DRUGS	Policy Number: BC-IRB-415 Page: 1 of 7
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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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 DRUGS** 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 FDA EAP submissions for Drugs 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 Expanded Access use of drugs.

DEFINITIONS:
Expanded Access is a mechanism to facilitate availability of investigational drugs, biologics, or devices (test articles) for patients with serious or immediately life-threatening diseases or conditions for which there are no satisfactory alternative treatments.

Compassionate Use is the use of a test article 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.

Emergency Use is the use of a test article (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 not sufficient time to obtain IRB approval.

A treatment Investigational New Drug (IND) is the use of an investigational drug to **treat or diagnose a group of patients** with a serious or immediately life-threatening disease or condition when the drug is also being studied for the same use under an approved Investigational New Drug Application.

I**mmediately 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.

A **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.

Forms:

FDA 3926 for Individual Patient Access, IND Application which is available for licensed physicians to use for expanded access requests for individual patient INDs.

FDA 1571 is a cover sheet and an agreement form for submitting an IND application to the FDA; it is also used for requesting individual patient expanded access to investigational drugs. The form indicates that the sponsor or sponsor-investigator agrees to conduct the research according to all appropriate FDA regulations.

Three Types of Expanded Access for Drugs:

- **Expanded access for individual patients, including for emergency use**
- **Expanded access for intermediate-size patient groups**
- **Expanded access for widespread treatment use**

PROCEDURE:

1. Use of Investigational Drugs for Individual Patients

A. Individual Patient IND

1. The physician submits the following for individual patient expanded access:
    - a completed IRB application with the phrase "INDIVIDUAL PATIENT IND" in the title
    - Letter from the pharmaceutical company agreeing to provide the drug
    - a copy of the FDA Form 3926 (for individual patient requests)
    - an individual patient IND approval letter from the FDA
    - an investigator's brochure, if applicable
    - a description of patient situation and treatment plan adequate to assess whether risks have been minimized and are reasonable in relation to anticipated benefits
    - a copy of the informed consent/authorization form which includes the statement indicating that although the primary use of the drug is for treatment, the drug is investigational, and FDA has not determined it is safe or effective for the condition of treatment.

2. If the IND was requested using Form 1571 or the waiver option on Form 3926 was not checked, the IRB schedule the submission for Full Board review.

3. If the IND was requested using Form 3926 and the waiver option was checked, the IRB staff send for review and concurrence by the IRB Chair/Vice Chair.

4. At the conclusion of treatment, the physician reports a written summary of the results of the expanded access use to the IND sponsor or the FDA and any safety related information or problems encountered to the IRB and IND sponsor or FDA (as applicable).

2. Emergency Use of a Investigational Drug in a Single Subject

In rare cases in which an emergency requires that the patient be treated before a written IND submission can be made, the physician obtains authorization for individual use from the FDA by telephone or electronic communication with subsequent submission of IND paperwork within 15 calendar days of the telephone/electronic authorization, in accordance with federal statute.

1. Before administering the investigational drug, the physician submits the following information to the IRB Office for review and confirmation for emergency use of an investigational drug in a single subject:
    - IRB application that includes the words "EMERGENCY USE" and the name of the investigational drug.
    - Physician letter or email with explanation that justifies administration of the investigational drug (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 drug 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 drug 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 investigational drug
    - Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective informed consent from the subject
    - Time is insufficient to obtain informed consent from the subject's legal representative
    - 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 drug 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 must be included 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 will be 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 drug. That report includes:
    - A brief description of the life-threatening situation
    - Justification for use of the investigational drug
    - Signed informed consent 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)
    - A description of the outcome of administration
    - FDA outcome letter regarding IND paperwork once available.

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 not sufficient to obtain IRB approval.

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

3. Intermediate or Widespread Population Treatment IND

1. The physician follows procedures for initial submission to the IRB with the following additions and provisions:
    - inclusion of the phrase "TREATMENT IND" in the title
    - documentation of FDA treatment IND approval (i.e., correspondence from the FDA or commercial sponsor, IND number printed on sponsor protocol)
    - related materials including the treatment protocol, investigator's brochure, informed consent/authorization form, and potential investigational drug costs.

2. IRB staff pre-review the IRB submission.

3. The convened IRB reviews the protocol according to federal regulations and internal policies.

4. At the conclusion of treatment, the physician reports a written summary of the results of the expanded access use (including any safety related information) to the IND sponsor or the FDA and submits a copy to the IRB.

4. Central IRB Approval

In cases where the expanded access protocol has received central IRB approval, BayCare IRB may defer responsibility for IRB review of the individual patient use to the central IRB where appropriate agreements and required approvals are obtained.

Appendix 1

The following table provides a overview of the types of expanded access requests for Investigational Drugs.

Type of Expanded Access	Brief Definition	IRB Action	FDA approval required?	Follow-up Reports to the FDA
Individual Patient Expanded Access IND (also referred to as a Single Patient IND)	Access to an investigational drug (including a biologic) for use by a single patient submitted as a protocol under a new IND. The investigational product may or may not be under development. Unless FDA notifies the sponsor that treatment may begin earlier, there is a 30-day waiting period before treatment with the drug may begin.	Full Board Review; Chair Concurrence with form 3926	Yes, from physician.	Yes
Individual Patient Expanded Access Protocol (also referred to as a Single Patient Protocol)	Access to an investigational drug (including a biologic) for use by a single patient submitted as a new protocol to an existing IND by the sponsor of the existing IND. Typically, several patients may follow the same protocol. The investigational product may or may not be under development. There is no 30- day waiting period before treatment with the investigational product may begin, but the protocol must be received by FDA and have approval by an IRB before treatment may begin.	Full Board Review	Yes, from IND holder.	Yes
Emergency IND	Individual Patient Access IND for Emergency use: Access to an investigational drug (including a biologic) for use by a single patient in an emergency situation (i.e., a situation that requires a patient to be treated before a written submission can be made) submitted as a protocol under a new IND. Treatment is initially requested and authorized by telephone or other rapid means of electronic communication, and may start immediately upon FDA authorization. The written submission (i.e., the individual patient expanded access IND) must be submitted within 15 business days of the telephone authorization	Chair Concurrence; Full Board Acknowledgment	Prior authorization, from physician.	Yes

Emergency Protocol	Individual Patient Expanded Access Protocol for Emergency Use: Access to an investigational drug (including a biologic) for use by a single patient in an emergency situation (i.e., a situation that requires a patient to be treated before a written submission can be made) submitted as a new protocol to an existing IND by the sponsor of the existing IND. Treatment is initially requested and authorized by telephone or other rapid means of communication, and treatment may start immediately upon FDA authorization. The written submission (i.e., the individual patient expanded access protocol) must be submitted within 15 business days of the telephone authorization.	Chair Concurrence; Full Board Acknowledgment	Prior authorization, from IND holder.	Yes
Intermediate-size Patient Population Expanded Access IND	Access to an investigational drug (including a biologic) for use by more than one patient, but generally fewer patients than are treated under a typical treatment IND or protocol, submitted as a protocol under a new IND. The investigational product may or may not be under development for marketing. Unless FDA notifies the sponsor that treatment may begin earlier, there is a 30-day waiting period before treatment may begin.	Full Board Review	Yes, from physician.	Yes
Intermediate-size Patient Population Expanded Access Protocol	Access to an investigational drug (including a biologic) for use by more than one patient, but generally fewer patients than are treated under a typical treatment IND or protocol, submitted as a protocol to an existing IND by the sponsor of the existing IND. The investigational product may or may not be under development for marketing. There is no 30-day waiting period before treatment with the investigational product may begin, but the protocol must be received by FDA and have IRB approval before treatment may begin.	Full Board Review	Yes, from IND holder.	Yes

Widespread Use Treatment IND	Access to an investigational drug (including a biologic) for treatment use by a large (widespread) population, submitted as a protocol under a new IND. The investigational product must be under active development for marketing. Unless FDA notifies the sponsor that treatment may begin earlier, there is a 30-day waiting period before treatment may begin.	Full Board Review	Yes, from physician.	Yes
Widespread Use Treatment Protocol	Access to an investigational drug (including a biologic) for treatment use by a large (widespread) population, submitted as a protocol to an existing IND by the sponsor of the existing IND. The investigational product must be under development for marketing. Unlike other access protocols submitted to existing INDs, there is a 30-day waiting period before treatment may begin, unless FDA notifies the sponsor that treatment may begin earlier.	Full Board Review	Yes, from IND holder.	Yes