| Policy and Procedure | |
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| Title: | **Expanded Access - Compassionate & Emergency Use of Test Articles - Research** |
| Maintained by: | Baylor St. Luke's Medical Center Research Office |
| Reviewed by: | Baylor St. Luke's Medical Center Research Office<br>Baylor St. Luke's Medical Center Research Pharmacy |
| Approved by: | Sr. Vice President and Chief Operating Officer |
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**REVISION SUMMARY**

| Date | Referenced Section(s) | Change |
|---|---|---|
| April 2017 | Whole Document | Major revisions |

**SCOPE**

Applicable to:
CHI St. Luke's Health–Baylor St. Luke's Medical Center (BSLMC)
Department(s): All groups involved in research activities at BSLMC

**DEFINITION(S)**

**Administrative Approval** – All research to be conducted at or in conjunction with a BSMLC facility must be approved by the designated chief officer, or an individual with delegated authority, prior to data collection or study initiation. The administrative approval process includes a review of each protocol to ensure protection of patients and staff, conduct feasibility, hospital compliance and compensation for resource utilization. See administrative approval policy and procedure *Protocol Administrative Review – Research* for approval process.

**Compassionate Use –** Limited use of a test article outside of a clinical trial for patients who have serious or life-threatening conditions and do not meet the enrollment criteria for a current clinical trial. However, the use does not meet the criteria for emergency use, and prior FDA approval and IRB concurrence or approval are required before the test article can be used (21 CFR 812.35; 21 CFR 312.1).

**Emergency Use –** According to the Food and Drug Administration (FDA), the use of a test article (unapproved drug, biologic, or device) in a life-threatening situation where no standard acceptable treatment is available and there is not sufficient time to obtain IRB approval (21 CFR 56.102(d)). Emergency use provision in the FDA regulations is an exemption from prior review and approval by an IRB. However, for drugs and biologics, FDA authorization is required prior to use (21 CFR 312.310(d)). For devices, prior FDA approval is not required; however, emergency use of a device must be reported to the FDA within 5 days (21 CFR 812.35(a)(2)). The IRB must be notified of emergency use within 5 working days (56 CFR 104(c)).

**Expanded Access –** The use of an investigational drug, biologic or device outside of a clinical trial for treatment of a patient. Compassionate Use (also called Individual Patient/Small Group Access) and Emergency Use are two mechanisms of expanded access.

**Institutional Review Board** – An Institutional Review Board (IRB) is a formal committee, governed by Food and Drug Administration (FDA) regulations, which is designated to review, approve, and monitor biomedical research involving human subjects.

## POLICY

Baylor St. Luke's Medical Center (BSLMC) permits compassionate and emergency use of test articles, in accordance with FDA regulations, and with appropriate reporting to the IRB of record and the hospital.

## PROCEDURES

A. All compassionate and emergency use of investigational drugs, biologics, or devices conducted at BSLMC must be compliant with FDA regulations and reported to the IRB of record as required.
    a. Obtaining FDA and IRB approval and completing reporting as required are the responsibility of the physician conducting the compassionate or emergency use.

B. Because FDA regulations do not consider compassionate or emergency use as research, submission of an application for BSLMC Administrative Approval is not required.

C. Physicians must notify the BSLMC Research Office of compassionate and emergency use for all investigational drugs, biologics and devices:

    a. Notification must occur **prior** to compassionate use.

    b. Notification must occur **as soon as possible and no later than three (3) calendar days** following emergency use.

    c. Notification should be sent via secure email and include:
        i. Expanded access mechanism (compassionate/emergency)
        ii. Treating physician's name
        iii. Patient name
        iv. Date of test article use
        v. Drug/biologic/device name
        vi. Drug/biologic/device manufacturer name
        vii. Name of uninvolved physician providing independent assessment

D. For drugs and biologics:

a. Physicians seeking compassionate or emergency use of a drug or biologic must comply with BSLMC policies regarding the receipt, storage, labeling, and dispensation of the drug/biologic.

b. Physicians must notify the BSLMC Research Pharmacy upon determination of the need for and **prior** to compassionate or emergency use of a drug or biologic, in order to allow the pharmacy to coordinate receipt and/or dispensation of the test article.
    i. BSLMC Research Pharmacy is not responsible for costs associated with procurement of the drug or biologic, including shipping costs, unless prior approval is obtained from the pharmacy. These costs are the responsibility of the physician conducting the compassionate or emergency use.

E. For devices:

a. Devices used for compassionate and emergency use must already be approved by BSLMC supply chain or be provided free of charge by the sponsor.
    i. This includes all modules, components and accessories required for the device.
    ii. Coverage of shipping costs is the responsibility of the physician conducting the compassionate or emergency use.

b. BSLMC Research Office will request or confirm the device code in coordination with supply chain for management of the device.

F. BSLMC Research Office will notify BSLMC Patient Financial Services of all compassionate and emergency uses of test articles.

G. BSLMC Research Office will create an Epic study record for the compassionate or emergency use. The Epic record will allow the hospital to identify the patient encounter as compassionate/emergency use of a test article.

a. Data fields entered in the Epic record will include:
    i. Study name: Compassionate/Emergency Use: <TEST ARTICLE NAME> - <PATIENT INITIALS>
    ii. Study code: Compassionate/Emergency Use: <TREATMENT DATE>
    iii. Status: Active
    iv. IRB Approval: *Left blank*
    *v.* NCT #: *As applicable*
    vi. Description: This is a compassionate/emergency use of <TEST ARTICLE NAME> for <PATIENT NAME> under treating physician <TREATING PHYSICIAN NAME>.
    vii. Guarantor contact: *Left Blank*
    viii. Study users: Treating physician name

ix. Guarantor type: Research[104] with non-review dummy charge to prevent it from routing to the research work queue
x. Reporting groupers: *Left blank*
xi. No fee schedule assignment

H. For emergency use, physicians must provide completion of the IRB notification to the BSLMC Research Office within 14 calendar days from the date of use.

I. The BSLMC Research Office will maintain a record of all Compassionate/Emergency Use for compliance purposes.

**RELATED DOCUMENTS**

Code of Federal Regulation – Title 21, Food and Drugs
Guide to Conducting Clinical Research at BSLMC

Document Metadata

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| Author(s): | Meddaugh, Hannah Marie<br>*Administrative Staff* |
| Approver(s): | Berger, David<br>*Senior Vice President* |