Patients Hospitalized with Investigational Drug from Another Institution/Investigator, Investigational Drug from a Boston Children's Hospital Outpatient Clinical Trial, or with Supply of Drug Not Approved in United States

Purpose

This policy describes the procedures for:

- Patients hospitalized with an Investigational Drug from Another Institution/Investigator
- Patients hospitalized with an Investigational Drug from a Boston Children's Hospital (BCH) Outpatient Clinical Trial
- Procedures for Patients Admitted with a Supply of a Drug that is Licensed in Another Country (Other than the US), and it is Determined that it is in the Best Interest of the Patient to Remain on the Drug While Under the Care of Boston Children's Hospital

Policy

Patients Hospitalized with Investigational Drug from Another Institution/Investigator

Patients may be admitted to BCH with an investigational drug prescribed by a physician outside of BCH as a result of enrollment on a research protocol at another institution. When this situation arises, investigators are urged to immediately call the IRB to discuss the specifics of the situation and come to a determination.

Patients Hospitalized with Investigational Drug from a Boston Children's Hospital Outpatient Clinical Trial

Patients may be admitted to BCH with an investigational drug prescribed by a BCH physician as a result of enrollment on a BCH outpatient research protocol. When this situation arises, the primary attending physician and investigators are to make the determination, based on the specifications of the protocol and clinical status of the patient, appropriateness to continue administering investigational drug in the inpatient setting.

The decision regarding continuation of therapy will be documented in the patient's medical record. If the decision is to continue therapy, the primary clinical team's physician will place the order in CHAMPS.

Procedures for Patients Admitted with a Supply of a Drug that is Licensed in Another Country (Other than the US), and it is Determined that it is in the Best Interest of the Patient to Remain on the Drug While Under the Care of Boston Children's Hospital

When a patient enters BCH with a drug supply that is not approved in the United States, it may be considered "a personal supply of the drug." This can occur only if the drug is in the possession of the patient. Future supply of the drug must also be through the patient. If more drug is required, it must be shipped directly to the patient and guidance is provided for this situation. See the ***Patient's Own Medication Policy*** for further information.

It is important that the BCH physician is aware that when the decision is made to use such a medication, there will be no interaction screening or dose range alerts fired in the CPOE system and they will be responsible for monitoring the patient for any adverse effects as part of providing clinical care to the patient.

Procedures

Patients Hospitalized with Investigational Drug from Another Institution/Investigator

The determination must be made as to whether the original Principal Investigator (PI) will continue to maintain responsibility for the patient on the research protocol, or whether this responsibility will be transferred to a physician at Boston Children's Hospital.

In the first case, as long as the follow-up and care of the patient remain the responsibility of an investigator at another institution, review and approval by the IRB is not usually required. In this situation, BCH and its investigators are not a participating research site. However, BCH physicians are to determine whether the patient signed an informed consent and the name of the physician responsible and are to obtain any information necessary to safely continue use of the investigational drug (e.g., information about possible adverse events). Documentation of administration of the investigational drug will be recorded in the patient's medical record as a "home medication" per the ***Patient's Own Medication Policy***

It is also recommended that the PI be contacted so that he or she may be advised about the hospitalization of the patient, and to obtain any information about the investigational drug.

If the care of a child on an investigational drug is being transferred to a Boston Children's Hospital physician, this request must go through the IRB.

For further and more detailed information about how this situation should be handled see ***FDA guidance. Use of Investigational Products When Subjects Enter a Second Institution***. This guidance may also be useful for investigators who enroll subjects at BCH but then wish to have treatment provided and or research assessments provided at another location that may be close to the patient's home.

Patients Hospitalized with Investigational Drug from a Boston Children's Hospital Outpatient Clinical Trial

The determination to continue a patient on investigational drug must be made by the primary attending physician on the inpatient service. The primary attending physician on service should communicate with the BCH PI for advice about the inpatient status of the patient and protocol

details, including information on how to treat a patient if they are hospitalized while on the protocol. Documentation of administration of the investigational drug will be recorded in the patient's medical record as a "home medication" per the ***Patient's Own Medication Policy***

Procedures for Patients Admitted with a Supply of a Drug that is Licensed in Another Country (Other than the US), and it is Determined that it is in the Best Interest of the Patient to Remain on the Drug While Under the Care of Boston Children's Hospital

If more drug is required, it must be shipped directly to the patient. If this situation occurs, the following guidelines are to be followed:

1. The Boston Children's Hospital physician is to contact the physician who prescribed the drug to discuss whether it is in the patient's best interest to remain on the drug. The physician who prescribed the drug is to be made aware of the therapy /testing that the patient will undergo. Both physicians are to agree that the patient will benefit by remaining on the drug while under the care of Boston Children's Hospital.
2. The Boston Children's Hospital physician is to obtain enough information about the drug, possible side effects, and drug interactions to feel comfortable that the patient can remain on the drug while undergoing treatment at Boston Children's Hospital. The required, appropriate monitoring must be able to occur. In many instances, drug interaction screening or dose range checking within the CPOE system will not be available.
3. Discussions with the physician responsible for prescribing the drug, and the rationale for continuing administration of the drug, are to be documented in the medical record.
4. Documentation of administration of the investigational drug will be recorded in the patient's medical record as a "home medication" per the ***Patient's Own Medication Policy***

Related Content

BCH Policy

Patient's Own Medication Policy

Federal Guidance

FDA: Use of Investigational Products When Subjects Enter a Second Institution

Document Attributes

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