# Patients Hospitalized with Investigational Drug from Another Institution/Investigator or with Supply of Drug Not Approved in United States

## Procedures

### Patients Hospitalized with Investigational Drug from Another Institution/Investigator

Patients may be admitted to Children's Hospital with an investigational drug prescribed by physician outside of Children's Hospital as a result of enrollment on a research protocol at another institution. When this situation arises, investigators are urged to immediately call the Clinical Investigation Office to discuss the specifics of the situation. 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 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 CIC is not usually required. In this situation, Children's Hospital and its investigators is not a participating research site. However, Children's Hospital 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). 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 Children's Hospital physician, this request must go through the CCI

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

***http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116334.htm***

This guidance may also be useful for investigators who enroll subjects at Children's hospital but then wish to have treatment provided and 0r research assessments provided at another location that may be close to the patients home.

# 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 Children's Hospital

When a patient enters Children's Hospital with a drug supply that is not approved in the United States, it may be considered "a personal supply of the drug." The Children's Hospital physician will not be considered responsible for the patient who receives 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. If this situation occurs, the following guidelines are to be followed:

1. The 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 Children's Hospital.
2. The 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 Children's Hospital. The required, appropriate monitoring must be able to occur.
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.

## Document Attributes

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| **Approved** | Susan Kornetsky<br>Director of Clinical Research Compliance<br><br>Carleen Brunelli, MBA, PhD<br>Vice President for Research Administration | | |