

Written: 12/16/13

Reviewed:

Revised:

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APPROVALS:

SLT: 04/11/14; BOD: 2Q-14

Scope: Medical Center Beckman Research Foundation

**Expanded
Access/Emergency Use to
Investigational Test
Articles for Treatment Use**

I. PURPOSE / BACKGROUND

This policy describes the requirements for the use of investigational test articles (drugs, biologics, or devices) when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition, also known as expanded access.

Expanded access can include a single patient, an intermediate sized patient population, treatment IND, or emergency use treatment protocols.

II. POLICY

- A. Research Investigators who require the expanded access use of investigational drugs, biologics or devices should determine the appropriate protocol for submission and/or notification to the Institutional Review Board (IRB), a single patient, an intermediate sized population, emergency use, etc.
- B. Research Investigators who submit for a single patient or an intermediate sized population should submit protocols to the IRB for review and approval. Administration of the investigational drug, biologic, or device cannot occur until IRB approval has been obtained.
- C. Research Investigators who require the emergency use of investigational drugs, biologics, or devices must notify the following departments listed below prior to the administration or use, regardless of the requirement for prospective IRB approval. Emergency use must meet the definitions as outlined in City of Hope's *HRPP manual* and federal regulations.
 - i. Office of Human Research Subjects Protection (OHRSP)
 1. OHRSP will determine if the IRB is able to convene in a timely manner to review the emergency use request. If the IRB is able to convene and review the submission, the Investigator is required to obtain IRB approval prior to administration of the agent. If IRB is unable to convene, FDA regulations allow for the administration without prospective IRB approval.
 - ii. Institutional Biosafety Committee (IBC)
 1. For any test article that involves the use of recombinant nucleic acids, involving gene transfer or gene therapy as defined in the *NIH guidelines for Research Involving Recombinant or Synthetic Nucleic Acid*, the IBC should be notified.

- iii. Office of IND and Regulatory Affairs (OIDRA)
 - 1. OIDRA assists the research Investigator in obtaining an IND, IDE, or emergency IND (EIND) from the FDA and submitting all subsequent reporting requirements.
- iv. Investigational Drug Service (IDS)
 - 1. IDS is responsible for receiving and dispensing the investigational agent according to institutional policy.
- v. Biomedical Instrumentation Services (BIS)
 - 1. BIS is responsible for receiving all medical devices according to institutional policy.
- D. Research Investigators must obtain approval from the following entities prior to obtaining the investigational drug, biologic or device:
 - i. Drug Manufacturer
 - ii. FDA
 - iii. IRB (if applicable).
- E. Investigational test articles must be shipped to the appropriate entities and follow institutional policies as listed below:
 - i. Investigational Drug Accountability
 - ii. Drug Storage and Preparation Areas
 - iii. Equipment Management Patient Care and Non-Patient Care Areas.
- F. Procedures for handling review, approval, and or notification of expanded access use of investigational agents must appropriately follow City of Hope’s *HRPP Manual*.

III. PROCEDURE

RESPONSIBLE PERSON(S)/DEPT.	PROCEDURE
Principal Investigators	<ul style="list-style-type: none"> 1. Determine the appropriate submission and/or notification mechanism for expanded access treatment protocols. <ul style="list-style-type: none"> A. Obtain the appropriate applicable approvals for the use and administration of test articles: <ul style="list-style-type: none"> 1. Drug Manufacturer 2. FDA 3. IRB (if applicable). 2. For emergency use treatment, notify the following departments, prior to the use of the test article: <ul style="list-style-type: none"> A. Office of Human Research Subjects Protection (OHRSP) B. Institutional Biosafety Committee (IBC), as applicable C. Office of IND Development and Regulatory Affairs (OIDRA) D. Investigational Drug Service (IDS)/Biomedical Instrumentation Services (BIS). 3. Ensure shipment, dispensing, and administration of test articles follow applicable institutional policies.

Owner: IRB Operations Director

Sponsor: Senior Vice President, Research Operations

References: 21 CFR 50, 21 CFR 56, 21 CFR 312 (312.305; 312.310) 21 CFR 812

Related Policies:

1. HRPP Manual
2. Investigational Drug Accountability
3. Drug Storage and Preparation Areas
4. Equipment Management Patient Care and Non-Patient Care Areas

Appendix One - Acronyms, Terms and Definitions Applicable to this Policy:

1. **City of Hope (“COH”)** - City of Hope National Medical Center (“COHNMC”), Beckman Research Institute (“BRI”), and City of Hope Medical Foundation (“COHMF”), collectively referred to as City of Hope (“COH”) for purposes of this policy.
2. **Emergency use** - Use of a test article on a human participant 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. 21 CFR 56.102 (d).
3. **HRPP** – Human Research Protections Program.
4. **IDE** - Investigational drug exemption.
5. **Immediately life threatening disease or condition** - A stage of disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. 21 CFR 312.300 (b).
6. **IND** - Investigational new drug.
7. **Medical Center** – Refers to all facilities covered by City of Hope National Medical Center’s hospital license.
8. **Serious disease or condition** - 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. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. 21 CFR 312.300 (b).
9. **Test article** - Any drug, biological product, or medical device for human use. 21 CFR 56.102 (1).