

<b>Title:</b> <b>Clinical Research Initiation</b>	<b>No.:</b>
	<b>Effective: mm/dd/2008</b>
	<b>Revised:</b>
<b>Approved By:</b>  <b>James Palermo, MD,VP/CQO, Health First</b>	<b>Page</b>

**Entity: Health First**

**I. OBJECTIVE**

The objective of this policy is to provide an overview of the processes associated with initiating a new clinical research study within Health First, and to provide additional detail on the feasibility assessment process that precedes IRB review.

**II. DEFINITIONS**

**Clinical Research:** Activities that are either a) Research, as defined in DHHS regulations, that involve Human Subjects, as defined in DHHS regulations; or b) Clinical Investigations, as defined by FDA regulations, that involve Human Subjects, as defined by FDA regulations. These definitions apply independently of the source of funding for the activity.

**III. POLICY**

In order to initiate clinical research in Health First Facilities, investigators must ensure that ALL of the following are in place:

- Successful completion of a Health First feasibility assessment;
- Review and approval of the clinical research protocol and associated study materials by the Health First IRB of Record in accordance with the Health First policy on “**The Authority and Independence of the Health First IRB of Record;**”
- A documented Medicare Coverage Analysis (MCA) for all clinical research studies anticipating third-party health insurance payments for particular items and services in accordance with the Health First policy on “**Medicare Coverage Analysis;**”
- Development of a comprehensive budget that is representative of all expenses emanating from a clinical research project at HF facilities, in accordance with the Health First policy on “**Budgeting For Clinical Research.**”
- Implementation of a contract between Health First and the investigator/practice, including a Master Services Agreement, Hospital Use agreement, and Clinical Research Service Request Form as

applicable, in accordance with the Health First policy on “**Contract Review, Negotiation, and Execution.**”

#### **IV. GENERAL OVERVIEW**

A. Attachment 1 provides a general overview of the processes associated with initiating new clinical research within Health First.

1. The flowchart illustrates the feasibility assessment process that is conducted upon submission of a complete set of materials.
2. Upon successful completion of the feasibility assessment process, the following four processes are conducted in parallel: 1) IRB review, 2) Contract negotiation, 3) Budget development, and 4) Medicare Coverage analysis.
3. Upon successful completion of these processes, a Study Initiation Memo informs the Investigator that the clinical research study may begin.

#### **V. SUBMISSION REQUIREMENTS FOR PROSPECTIVE CLINICAL RESEARCH**

A. Investigators who wish to conduct clinical research within Health First must submit the following materials to the Health First Research Administrative Liaison:

1. Clinical Research Feasibility Assessment Form A
2. Clinical Research Feasibility Assessment Form B, if applicable
3. WIRB Initial Review Submission Form
4. Study Protocol
5. Informed Consent Form
6. Principal Investigator’s CV and license
7. Clinical Research Contract (Clinical Research Services Request form or Clinical Trial Agreement, as applicable).

B. Submission materials can be submitted to the Research Administrative Liaison electronically at [Clinical.Research@Health-First.org](mailto:Clinical.Research@Health-First.org) or may be submitted in hard-copy to the RAL’s office.

#### **VI. FEASIBILITY ASSESSMENT PROCESS**

A. Upon receipt of materials for newly proposed clinical research, the Research Administrative Liaison (RAL) will review submitted clinical research materials for completeness in advance of a feasibility assessment.

B. In addition, the RAL verifies that:

1. All individuals involved in the conduct of the research have disclosed any significant financial interests or other potential conflicts of interest;
2. All individuals involved in the conduct of the research meet human subjects research education requirements;
3. The proposed research is compliant with the Health First policy on **“Clinical Research Suitability/Feasibility.”**

C. Submissions that are not considered complete by the RAL, or that do not meet the criteria listed in section B above, are not distributed for feasibility assessment. The RAL will notify the investigator/coordinator of the need to provide additional information or address any outstanding issues before proceeding.

D. Once the RAL determines that the submitted materials are complete and that the submission should undergo a feasibility assessment, the RAL identifies the individuals whose input is needed in assessing the feasibility of the proposed research. These individuals may include, but are not limited to, representatives from a subset of the following:

1. IO
2. Pharmacy
3. Cath Lab
4. Radiology
5. Patient Business Services
6. Nursing
7. Medical Records
8. Compliance
9. Legal Counsel

E. These individuals will receive email notification from the RAL as well as electronic copies of the relevant protocol submission materials and a suitability checklist.

F. Reviewers will review the submitted protocol materials and complete and submit the “suitability checklist” to the RAL within three business days.

1. Failure by a reviewer to respond with a completed checklist within three business days will be considered by the RAL to be an “approval” of the feasibility of the proposed research.

G. If a reviewer’s completed form identifies an issue that negatively impacts the feasibility of the proposed research, then the RAL will work with the reviewer(s) and the Investigator to coordinate an effort to resolve any issue(s) to the satisfaction of the reviewer.

1. An inability to resolve any outstanding issues to the satisfaction of the investigator will lead Health First to conclude that the proposed research is not feasible.

H. Either upon the conclusion of the 3-day feasibility review, or upon the conclusion of the effort to resolve any outstanding issues, the RAL will notify the Investigator of the outcome of the feasibility assessment.

1. Clinical research deemed “feasible” may proceed with submission to Western IRB for review.

2. Clinical research deemed not to be “feasible” will not proceed further within Health First.

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Owner: Health First Office of Quality Management

Attachments:

- Attachment 1: Clinical Research Initiation process Overview

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