

<b>Title: Clinical Research Suitability/Feasibility</b>	<b>No.:</b>
	<b>Effective: 5/20/2008</b>
	<b>Revised:</b>
<b>Approved By:</b>  <b>James Palermo, MD,VP/CQO, Health First</b>	<b>Page 1 of 3</b>

**Entity: Health First**

## **I. OBJECTIVE**

The Objectives of This Policy Are

- To identify any infrastructure, regulatory or financial issues that may impinge on Health First's (HF's) ability to conduct a proposed clinical research study
- To ensure that HF has adequate capacity to conduct a clinical research study and that unfair or unrealistic demand are not place on physicians, HF staff and facilities.
- To ensure that only clinical research consistent with HF's clinical care mission, risk tolerance, and overall strategy are conducted at HF.
- To avoid unnecessary IRB consideration of studies deemed not suited to HF.
- To assist investigators in their choice of studies to undertake at HF.

## **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 independent of the source of funding for the activity.

## **III. POLICY**

- A. It is the policy of the Health First (HF) to ensure that clinical research studies conducted at its facilities are consistent with its mission and strategy and are suitable to HF from an operational, compliance, ethical, financial, and risk-management standpoints. HF makes substantial efforts to create an environment where accurate assessments of clinical research studies are completed in an efficient and compliant manner. The analysis is designed to promote the thorough and timely evaluation of research opportunities that HF may pursue together with research investigators. Ultimately, it is the Chief Operating

Officer(s) of the facility (facilities) where the research will be conducted who will approve or disapprove a study based on the results of this assessment.

- B. It is the policy of HF *not* to conduct clinical research that falls into the following categories:
- a. Research on healthy volunteers;
  - b. Investigator-initiated post-marketing studies of drugs, biologics or medical devices;
  - c. Research projects involving investigators or other key personnel with significant unmanaged financial conflict of interest (as further described in the Health First Conflict of Interest Policy).
- C. The *Clinical Research Feasibility Assessment Forms A and B* are the designated tools for recording the results of a suitability assessment. The forms seeks to gather critical study and project data, as well as information regarding the operations of the research entity (e.g. Physician Group, PI, departments involved, etc.) and how the research project is expected to impact HF. It is important that all individuals and entities that intend to utilize HF to conduct research complete and send the assessment form to the Research Administration at HF for review and approval.
- D. This policy applies to all research projects where any HF resources might be used, including Medical Records. In addition to outlining the specifications of the study and the personnel that will be involved, the Research Application may answer questions about the capacity and/or suitability of available facilities and personnel and the prospect of enrolling a sufficient number of subjects. Part of the feasibility assessment is also an evaluation of the level of risk to the participants and to HF.
- E. The Principal Investigator is responsible for completing an accurate *Clinical Research Feasibility Assessment* form, but may delegate the activity as he or she sees fit. Incomplete applications will be returned to the PI if critical information is not included or if further explanation is necessary in order for the RA to determine the feasibility of carrying out the study. The application can assist the PI with determining if the research study is appropriate and must be submitted to Research Administration and a suitability analysis must be completed before the RA will expend resources on study set-up procedures. The approval of the suitability analysis will prompt the completion of a coverage review and a budget, as well as the initiation of IRB review and study negotiations. It is imperative that this be done within a reasonable time frame to ensure maximum efficiency.

#### **IV. PROCEDURE**

This is a Policy Statement only. Associated procedures are outlined on the attached Process Maps.

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Owner: Health First Office of Quality Management

Attachments: Clinical Research Initiation Process Overview Flowchart