



North Broward Hospital District

Institutional Review Board (IRB)
Human Research Protections

Steps for Submitting New Research Project(s)

Note: all forms and applications are located on this Web Site

New research projects require FACILITY pre-approval before submission to the IRB. Pre-approvals can be obtained at the facility where intended research will be conducted.

****Eligibility for Conducting Research****

Physicians: are required to register within the North Broward Hospital District Health Care System including approval of hospital privileges processed through Medical Staffing.

Non-Employees: are required to obtain sponsorship from the hospital's physician/employees. IRB will require a letter of acceptance from the sponsored employee who will enter into agreement with the IRB and the institution.

Acceptance of Research Projects

The Feasibility of research is a preliminary screening process required by the IRB and institution to ensure that the administrative teams (where research will be conducted) are able to facilitate research activities and that adequate provisions are in place to provide a safe research environment. Each new trial must receive Institutional approval prior to receiving IRB review.

STEP One

- a) Fill out IRB Initial Review Application

STEP Two

1. Submit the following documents to facility administrator for approval.
 - a) Initial Application / Institutional Clearance form. (See page 2 of initial review application).
 - b) Informed consent documents (if applicable)
 - c) Protocol information
 - d) Contract approval form (if applicable)
 - e) Research Budget
2. Submit the above referenced documents to the facility administrator where you intend to conduct research. The designated administrator(s) will review the protocol and determine if adequate provisions are in place to facilitate research activities. Once

approval is obtain forward research document(s) to the IRB for additional review and consideration. (See IRB initial review application for submission requirements).

STEP Three

1. After receiving facility approval next, submit the following completed documents to North Broward Hospital District IRB-Office of Human Research Protection.

- a) Initial Review Application
- b) Institutional Clearance form is located on page 2 of the IRB application.
- c) Protocol design
- d) Informed consent documents
- e) Form FDA 1572,
- f) Investigator CV's, licenses
- g) Central Laboratories listed on the 1572 – lab certificates for each must be forwarded to the IRB.
- h) Other required regulatory documents.
- i) Investigator's training certificate

STEP Four

Sponsored Research: Contract Approval Process

1. The Final step before initiating research activities is negotiation and execution of contractual agreement between the North Broward Hospital District, Sponsor and Investigator. Submit the following documents to the North Broward Hospital District Contracts Departments.

- a) Clinical Trial Agreement
- b) Contract Approval Form
- c) Budget(s)
- d) IRB approval letter
- e) Protocol document
- f) Other related documents

***STEP Five**

*Research that does not require a contract agreement omit step 4.

Questions or Assistance

Research Site

Contact facility Administration where you intend to conduct research activities

Institutional Review Board-Office Of Human Research Protections

(954) 355-4941 or (954) 355-4358

Contracts

954-355-5181 or (954) 355-5183