**Clinical Research Staff Job Descriptions**

1. **PURPOSE**

To establish guidelines and requirements for ensuring clinical site research personnel have a written job description on file.

1. **SCOPE**

Applies to all <name of Sponsor/Investigator> personnel involved in the implementation and coordination of clinical investigations.

## BACKGROUND

The Sponsor/Investigator is responsible for the overall conduct of a research study at the clinical site. As such, there will be on file a written job description for each employee who performs protocol required duties.

**In accordance with:**

21 CFR 312 and 812

ICH GCP Consolidated Guideline ‑ Part 4. Investigator

Applicable State and Local Laws concerning licensure of professional staff

Hospital or Medical Center Policies concerning physician staff privileges

Research Department Job Descriptions

Company policies concerning job duties and responsibilities

## PROCEDURE

* 1. Personnel employed by the Sponsor/Investigator will have a job description on file that specifies the job requirements for the position they hold.
  2. These job descriptions will be reviewed and signed by all personnel on the date of employment.
  3. Any updates to the job descriptions will be:
  + reviewed with the staff by the Sponsor/Investigator and <insert correct title>
  + signed and dated by the employee
  + filed in the personnel files for each employee
  1. Attachment(s):
  + Clinical Research Nurse Job Description
  + Clinical Research Coordinator Job Description
  + Research Assistant Job Description
  + Data Management Job Description
  + Laboratory Personnel Job Description(s)
  + Regulatory Personnel Job Description
  + Clinical Research Manager Job Description
  + Director of Research Job Description
  + *(Other)*