ClLINICAL RESEARCHER SKILLS CHECKLIST

Name_____ Date_____

Experience Since: _____

For each skill listed, indicate the number that best describes your experience:
0 = No Experience 1= Limited Experience 2 = Moderate Experience
3 = Experienced & Competent 4 = Able to Teach and Supervise
5 = Not Applicable

Designing, implementing and monitoring clinical studies _____

Direct investigator performance and adherence to protocol _____

Developing protocols and case report forms _____

Interact with data management personnel for data entry and planning purposes _____

Recruit/screen/select competent investigators _____

Monitor data for safety and efficacy trends by reviewing clinical data _____

Writing clinical reports upon completion or termination of studies _____

Prepare clinical portions of INDs, NDAs and BLAs _____

Plans clinical program and develop timetable for research _____

Supervise, design and write informed consent forms _____

Supervise and direct the design, implementation and monitoring of clinical trials _____

Reviewing case report forms _____

Assist in the determination of guidelines for the collection, compilation, documentation and analysis of clinical data _____

Coordinate and implement procedures to collect data from patients charts, medical records, interviews, questionnaires, diagnostic tests and other sources _____

Code, evaluate and interpret collected data_____

Prepare appropriate documentation _____

Obtain blood samples, cultures, tissues and other specimen for laboratory analysis _____

Ensure compliance with protocol guidelines _____

Knowledge of regulatory requirements _____

Identify problems, inconsistencies and monitor patients' progress to include documentation and reporting of adverse events _____

Evaluate and interpret collected clinical data in conjunction with principal investigator_____

Prepare oral/written presentations and analyses to set forth progress _____

Assist in the preparation of amendments to protocols and/or modifications _____

Coordinate the development of forms, questionnaires and the application of research techniques _____

Provide guidance to lower level personnel involved in study_____