I. PURPOSE

When permitted by State law, a laboratory may make available to a Physician’s office a phlebotomist who collects specimens from patients for testing by the outside Laboratory. However, the phlebotomist may not perform additional tasks that are normally the responsibility of the Physician's staff.

This protocol will define the allowable job tasks that may be performed by a Wake Forest laboratory employee at a phlebotomy draw-station located in a non-Wake Forest owned physician practice.

II. PROTOCOL

A. Services which may be performed:

1. Only those tasks directly related to the collection or processing of Laboratory specimens may be performed. These tasks include:
   a. Collection of specimens from patients for testing by the WFBH Laboratory
   b. Collection of specimens from patients for testing at a reference Laboratory affiliated with the WFBH Laboratory.
   c. On-line Order Entry of orders from a written requisition/script provided by the Physician’s office.
   d. Centrifugation of specimens
   e. Aliquoting of specimens
   f. Specimen preparation for transport
   g. Packaging of specimens for transport
   h. Preparation for disposal of medical waste directly related to specimen collection, e.i. needles

2. Only those clerical duties directly related to the handling and processing of laboratory specimens may be performed. These tasks include:
   a. Collection of Advance Beneficiary Notice (ABN) form.
   b. Mini-registration of the patient in the Laboratory Information System in the event of Hospital Information System downtime.
   c. Clerical duties directly related to the specimen being collected, ie. filing of requisitions, routing of ABN, and handling of test-specific forms.

B. Services which may not be performed

1. Performance of any tasks that are normally the responsibility of the physician office staff. Such tasks include, but are not limited to:
   a. Taking of vital signs or other nursing functions.
   b. Testing for the Physician’s office Laboratory.

2. Performance of clerical duties normally the responsibilities of the physician’s office staff. Such tasks include, but are not limited to:
Diagnostic Laboratories

a. Registration of patient's demographics into the physician’s computer system.
b. Preparation of paper requisitions for Laboratory test ordering.
c. Filling out and completion of test-specific forms.
d. Collating or filing results.
e. Answering the office phone for results or other matters. Calling patients for appointments.

3. Venipuncture or other specimen collection services for testing to be performed by the physician’s office laboratory.

4. Venipuncture or other specimen collection services for patients having exclusive insurance requiring that the specimen to be directed to a competitor's laboratory. The only exception to this is a written agreement between the parties.

C. COMPLIANCE:

1. It is the responsibility of the laboratory Phlebotomy Supervisor to closely monitor it’s phlebotomist-employees’ conduct to ensure that the lab-imposed bans on non-specimen collection related tasks are followed.

2. Initial failure by the phlebotomist-employee to comply with the policy will result in corrective action. Reoccurrence of the same type of infraction will result in progressive corrective action including termination.

3. Any additional job tasks requested by the physician’s office of the phlebotomist-employee must be submitted to the Phlebotomy Supervisor in writing for consideration.

4. A physician’s office that violates the above agreement will result in having this voluntary service terminated.

III. SCHEDULE FOR REVIEW
1. Annually

IV. DISTRIBUTION LIST
1. Laboratory Main Central Processing
2. WFBH Clinics
3. All In-office Phlebotomy Sites
V. Reference:

Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994)

Provision of Phlebotomy Services to Physicians

When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services. Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals. Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [of her] employer or where the contractual prohibition is not rigorously enforced.

The Stark laws allow the placement of computers as long as the computer is used solely to order tests and receive results, anything beyond that is a violation of Stark and subject to penalty including fines and exclusion from Medicare.

Other Inducements:

The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute:

- Free pick-up and disposal of bio-hazardous waste products (such as sharps) unrelated to the collection of specimens for the outside laboratory.
- Provision of supplies such as gauze or band-aids that can be used for other patients, computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.
- Provision of free laboratory testing for health care providers, their families and their employees.
- When one purpose of these arrangements is to induce the referral of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider may be liable under the statute and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.