DEFINITIONS:

1. **Indirect Activities**: Those costs that have been incurred for common or joint objectives, and thus are not readily subject to treatment as direct costs of research agreements or other ultimate or revenue producing cost centers, such as, but not limited to, depreciation, administrative and general, operation of plant, maintenance of plant, laundry and linen service, housekeeping, dietary, maintenance of personnel, and medical records and library.

2. **Instruction and Training**: The formal or informal programs of educating and training technical and professional health services personnel, primarily medical and nursing training.

3. **Investigator**: An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.

4. **Organized Research**: Means all research activities whether the support for such research is from a federal, non-federal, or internal source. Research activities includes any effort spent on a research agreement such as preparing and delivering special lectures about specific aspects of the ongoing research, writing research reports and articles, participating in appropriate research seminars, consulting with colleagues with respect to related research, and attending appropriate scientific meetings and conferences.

5. **Other hospital activities**: Means any organized activities of a hospital not immediately related to patient, care, research, and instructional and training functions which produce identifiable revenue from the performance of these activities.
6. **Patient care**: Means those departments or cost centers which render routine or ancillary services to in-patients and/or out-patients.

7. **Research Staff**: Individuals who assist in a research project overseen by an Investigator.

**RESPONSIBLE POSITIONS (TITLE):**
- Investigator
- Research Staff
- Research Compliance staff

**EQUIPMENT NEEDED:**
- None

**PROCEDURE STEPS, GUIDELINES, OR REFERENCE**

1. **APPLICABILITY**
   1.1. Palmetto Health employed Investigators and Research Staff whose salaries (all or a portion) are expended on federally sponsored research whether by a prime award, subaward, collaborative agreement, or contract or if required as a condition of participation in the research project should record their effort on the project(s). Only Research Staff (or those individuals that work at responsible levels of activities for the research project) whose salaries are directly chargeable should track their effort.
   1.2. All non-employed Investigators that utilize Palmetto Health’s Clinical Trial department Research Staff whose employer does not have an established effort reporting mechanism should track their effort.

2. **EFFORT REPORTING**

2.1. Investigators and Research Staff should track their effort on appropriate projects. The following outlines the information to be collected. A template *Effort Report Form* is available at [www.palmettohealth.org/ResearchCompliance](http://www.palmettohealth.org/ResearchCompliance). However, other similar documentation tools may be utilized.

2.1.1. **Full Name**: The full name of the Investigator or Research Staff, whose effort will be listed on the form.
2.1.2. **Department/Entity**: List the Palmetto Health department (employed) or affiliation (non-employed).
2.1.3. **Date Range of Effort**: It is suggested that a standard reporting period is established at the beginning of the project. This may be on a weekly basis, monthly basis, or a six month period, for example.
2.1.4. **Organized Research**: List study names and/or identifiers (e.g. IRB Pro number or account number). Provide the actual effort expended as a percentage of total work time (i.e. *Actual Effort Expended*). Individuals may also utilize estimates
as are typically noted in the project’s award (i.e. *Estimated Effort Expended*). *Estimated Effort Expended* determined before the performance of services (e.g. budget estimates) may be used as a guide for the individual completing the form to determine the *Actual Effort Expended*. Note, *Estimated Effort Expended* does not qualify as actual effort spent.

2.1.5. **Patient Care, Instruction and Training, Indirect Activities, and Other Hospital Activities**: Estimation of time as a percentage should be provided for these additional four broad functional categories.

2.1.6. **Certification**: The individual reporting their time or a responsible individual such as a supervisor or manager having first-hand knowledge of the services performed on each research agreement may sign the effort report to certify. Each department is responsible for establishing business processes to certify effort reports.

2.2. The total effort of all categories (Organized Research, Patient Care, Instruction and Training, Indirect Activities, and Other Hospital Activities) must not exceed 100%.

2.3. The effort reports may be submitted to Research Compliance and/or retained by the department. Research Compliance may request the effort reports periodically and when necessary to support financial and/or other reporting requirements if retained by the department.

2.4. Research Compliance will review submitted effort reports, file appropriately, and utilize, as necessary, for reporting purposes.

**REFERENCES**
Office of Management and Budget Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
45 CFR Part 74 Appendix E: Principals for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals