Summary
This course is a 2 credit elective for the Clinical and Translational Science Masters Program. Students enrolled in the course will participate in clinical research activities in either the Clinical Research Center (CRC) or the Pediatric Clinical Research Center (PCRC) of RWJMS under the guidance of Dr. Vivien Hsu or Dr. Sunanda Gaur, respectively (the Course Directors). Students will be exposed to all aspects of developing, implementing, and conducting clinical trials in the CRC and/or PCRC. In addition to the Course Directors, each student will be paired with a research coordinator/nurse in the CRC/PCRC who will help develop a plan for the student. Students must spend at least 30 hours per semester in the CRC or PCRC to earn 2 credits; however, hours are flexible and scheduled by agreement between the instructor and each student enrolled in the course.

Prospective Students must contact the course director(s) individually prior to enrolling in the course to determine the study opportunities and schedule for the planned semester.

Course Objectives
The goal of this course is to expose students to the entire process of implementing and conducting a clinical trial in an academic setting, especially an industry-sponsored trial. If possible, students will shadow a particular study from start to finish, including attendance in study activation meetings, site initiation meetings, and study monitor visits. In addition, students will shadow researchers in the CRC/PCRC as they consent and treat study participants. If following one particular study or research project in its entirety is not feasible, students will develop a plan with the Course Directors (with input from the appropriate research coordinators) so that the student can participate in all of the stages of clinical research conducted in the CRC/PCRC through the observation of a number of different studies. Students will also have the opportunity to observe site selection visits (where a potential study sponsor reviews and selects a site for a particular study), protocol meetings (staff meetings wherein all active and upcoming protocols in the unit are discussed), and Phase I meetings at the Cancer Institute of New Jersey (to discuss CINJ protocols performed in the CRC). Students may also participate in Research Utilization Group meetings at RWJUH and in an IRB meeting. If feasible and appropriate, students may participate in an investigator meeting wherein details of a new protocol and methodologies are explained to all investigators from participating study sites.

Although students cannot handle research subjects directly, students may observe the unit nurses, clinicians and lab personnel during their daily interactions with patients in the course of their research. Students will also be asked to observe and help with preparation of study samples in the research laboratory and the preparation of source documents and other items related to specimen collection, preparation, storage and analysis. In addition, students will shadow the Research Pharmacist as she collects, stores and dispenses study drugs. Students may also help CRC/PCRC personnel in the preparation of study documents, IRB submissions,
and other related regulatory documents as well as data collection and submission and adverse event reporting.

**Output/Evaluation**
At the end of the course, students will have completed CITI training and be HIPAA certified. Students must complete a written report (10-15 pages) describing a particular study in which they were involved. The report should detail the purpose of the study, the design (including clinical end points, sample size, and the biostatistics to support the study design), the implementation of the study, the conduct, data collection, and the outcomes of the study. Report topics may also be related to a specific aspect of the conduct of clinical trials, such as “Barriers to Enrollment in Clinical Trials” or “Conflicts of Interest in Clinical Trials Enrollment”. Topics may be selected by individual students and must be approved by the Course Directors.

The student will be evaluated by their attendance in the CRC (25%), their participation in various trial activities (25%), and their written report (50%). Students are expected to leave the course with a clear understanding of how a clinical study is initiated, conducted and closed, and each student will have hands on experience in the preparation of regulatory documents, patient samples, and other documents necessary for the conduct and completion of a compliant clinical study. Students will also witness first-hand the organizational structures and personnel functions required to carry out compliant clinical studies. Grading is Pass/Fail.

Students must undergo CITI Training:
[http://www.umdnj.edu/hsweb/Education/requirements.html](http://www.umdnj.edu/hsweb/Education/requirements.html)

Students must also be HIPAA certified (enter through MYUMDNJ.EDU).
[http://umdnj.hccs.com](http://umdnj.hccs.com)