

COLUMBIA UNIVERSITY POLICY ON TRAINING OF CLINICAL RESEARCH COORDINATORS

Effective Date: October 18, 2010

I. INTRODUCTION

This Policy applies to any employee or student at Columbia University (the “University”) who is acting as a Clinical Research Coordinator (as defined in Section II below) (“CRC”) on a clinical research study. Its purpose is to ensure, through mandatory training, that all CRCs are knowledgeable about the governmental regulations and institutional policies and guidelines that govern clinical research studies conducted at the University.

II. WHO IS GOVERNED BY THIS POLICY

For the purposes of this policy, a “Clinical Research Coordinator” is an individual who participates in clinical human subjects research that involves more than minimal risk and who is designated under “Personnel Staff” on any Rascal Human Subjects Protocol Data Sheet as employed in one of the following roles:

- Study Coordinator
- Research Coordinator
- Research Nurse
- Regulatory Coordinator
- Data Manager
- Research Assistant

III. EXEMPTIONS

An exemption from the requirements of this Policy may be granted by the IRB if an individual with one of the titles listed above does not in fact have CRC responsibilities.

IV. TRAINING REQUIREMENTS

A. The Clinical Research Training Program (the “Training Program”) will consist of the following elements:

1. Completion of the Rascal Training Course TC0098.
2. Completion of the online test in the Rascal Training Course with 80% of the questions answered correctly.

It is strongly recommended that all CRCs also review the Columbia University Clinical Research Handbook. <http://evpr.columbia.edu/content/clinical-research-handbook>

B. After January 1, 2011, no CRC listed on an IRB protocol, whether such protocol has been submitted to the IRB as an initial protocol or as a modification or renewal of an existing protocol, may be approved by the IRB unless such data sheet indicates that such CRC has completed the Training Program. No such CRC may commence conducting or continue to conduct any research activities under such protocol prior to obtaining IRB approval.