# Ethics and Regulations in Clinical Research [MCTS 5101S (3 credits)]

**Course Director:** Anna Petrova M.D., Ph.D., MPH  
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<th>Date</th>
<th>Instructor</th>
<th>Topic</th>
<th>Comments</th>
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| 09.06.16   | Anna Petrova MD, PhD, PH Professor, Pediatrics                              | Introduction to course, requirements and description. Lecture: Historical perspective of ethics and regulation in clinical research  
Description of the Rutgers RWJMS web-based CITI /HIPAA                                                                                 | CITI Training  
Exams must be completed by 10.04. 2016                                                                                                   |
| 09.13.16   | Anna Petrova MD, PhD, MPH Professor, Pediatrics                             | **Lecture:** Ethics and regulation in conducting the randomized clinical trials                                                                                                                      | 4:30-7:30                                                                                                                                |
| 09.20.16   | Anna Petrova MD, PhD, MPH Professor, Pediatrics                             | **Lecture:** Advanced Notice of Proposed Rulemaking (ANPRM):  
**Lecture:** Enhancing protections for research subjects & reducing burden, delay & ambiguity for researchers                                                                                 | 4:30-6:30  
6:45-7.:30  
Discussion  
Requirements for term presentation                                                                                                          |
| 09.27.16   | Marc Sturgill, Pharm.D.                                                      | **Lecture:** FDA regulations to perform pediatric drug research                                                                                                                                     | 4:30-7:30                                                                                                                                |
| 10.04.16   | Amisha Malhotra MD Associate Professor of Pediatrics  
Anna Petrova MD, PhD, MPH Professor, Pediatrics | **Lecture:** Ethical aspects for enrolment of HIV infected subjects in RCT  
**Lecture:** Ethical aspects for advertisement of participation in RCT                                                                  | 4:30-5:50  
6.00-7:30                                                                                                                                  |
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<th>Date</th>
<th>Speaker and Affiliation</th>
<th>Lecture:</th>
<th>Time</th>
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| 10.11.16 | Ambarina Faiz MD, PhD  
Instructor, Hematology  
ambarinaf@rwjms.rutgers.edu | Ethics and regulation in research on vulnerable population                     | 4:30-7:30   |
| 10.18.16 | John Crombie, Ph.D.  
Ethicon, Inc.  
jcrombi2@its.jnj.com | Ethics and regulation for using medical devices in clinical research         | 4:30-7:30   |
| 10.25.16 | Anna Petrova MD, PhD, MPH  
Professor, Pediatrics | Ethics and regulation in clinical data collection and storage                 | 4:30-7:30   |
| 11.01.16 | Anna Petrova MD, PhD, MPH  
Professor, Pediatrics | Misconduct, fraud, and integrity in clinical research. Discussion of cases. | 4:30-7:30   |
| 11.08.16 | Donna Hoagland, LPN, BS, CIP, CCRC, Director, IRB  
hoaglanddo@rwjms.rutgers.edu  
Anna Petrova MD, PhD, MPH  
Professor of Pediatrics | Requirements for approval of clinical research by the local IRB  
Violations of ethical principles in international clinical research. | 4:30-6:00  
6:30-7:30  |
| 11.15.16 | Eric Singer MD MA, FACS  
Assistant Professor of Surgery  
Anna Petrova MD, PhD, MPH  
Professor, Pediatrics | Ethics and regulation in conducting research on cancer patients  
Case presentations and discussion Preliminary presentation and discussion of Term Paper (Dr. Petrova) | 4:30-6:30  
6:30-7:30  |
| 11.22.16 | Donna Hoagland, LPN, BS, CIP, CCRC, Director, IRB RWJMS hoaglanddo@rwjms.rutgers.edu | Lecture: Analysis of research protocol from ethical point of view according to IRB criteria  
Lecture: Informed Consent: ethics and issues | 4:30-6:00  
6:00-7:30 |
| 11.29.16 | Anna Petrova MD, PhD, MPH Professor, Pediatrics | Lecture: Ethics and regulation in research data management  
Lecture: Discussion the published articles in association with fundamental ethical principals | 4:30-6:00  
6:00-7:30 |
| 12.06.16 | Anna Petrova MD, PhD, MPH Professor, Pediatrics | Formal Journal Club Presentations | Power-Point presentation  
20-25 min oral presentation with discussion (~ 5 minutes) |
| 12.13.16 | Anna Petrova MD, PhD, MPH Professor, Pediatrics | Formal term paper presentation 10 minute for presentation (PowerPoint) and 5 min for discussion | Power-Point presentation  
20 min oral presentation with discussion (~ 10 minutes) |

**Recommended Material**

**1. CITI Training/HIPAA Training**  
To enroll for CITI training:  
Students should go to [http://www.citiprogram.org/](http://www.citiprogram.org/) to enter the training.  
They will have to enter several questions to be able to enter CITI

They should select Rutgers RWJMS as their participating institution. Anyone can select any institution as their affiliated institution. They need to answer three questions:
1) Answer "YES. I would like to take the CITI Basic Course required by Rutgers RWJMS"
2) They have to select a "group". The options are noted below:
   (a) Biomedical/Clinical Research Investigators...
   (b) Social/Behavioral/Epidemiologic Research Investigators...
   (c) Data & Specimen only Research Investigators...
   (D) IRB MEMBER AND PROFESSIONAL HSP/IRB PROGRAM STAFF
   (e) Fogarty Global Infectious Disease Fellowship Residents
   (f) Reference Resources

Select “Biomedical/Clinical Research Investigator” which should be the first option.

3) Answer "I have NOT previously completed a CITI Basic Course"

Once you have finished the basic course, you can always go back into CITI and in the reference section review modules from any of the other options. There is a wealth of information there, so it is a valuable resource.


Evaluation will be based on the followings:
1) Term paper (35%)
2) Class participation (25%)
3) Journal Club presentation (30%)
4) Completion of CITI/HIPAA training (10%)