Human Subjects Protection Training Program FAQs

1. **Who must complete CITI Human Subjects Protection training?**
   All human subjects researchers, including staff, students, postdocs and others, must complete CITI Human Subjects Protection (HSP) training as a prerequisite for IRB approval.

2. **What if I have previously completed CITI HSP training at Columbia?**
   Once you have completed the full Columbia-required CITI HSP training, you will be required to complete an abbreviated continuing education every 3 years. You will receive reminders when the three year period is approaching.

3. **What happens if I don't complete the training?**
   As of **June 1, 2012**, the IRB may not approve an initial human subjects research protocol, or a modification or renewal of an existing protocol unless all researchers listed on the Data Sheet have completed CITI training within the past three years.

4. **What is CITI?**
   The Collaborative Institutional Training Initiative (CITI) is a Web-based education program designed to promote the responsible conduct of research. It is used by more than 1,500 institutions around the world to provide training to researchers and IRB members. As a

result, many of our collaborators and new faculty arriving to Columbia are likely to have already completed many of the required modules.

5. **Why did Columbia adopt CITI training?**
Columbia chose CITI training because the content is extensively reviewed, critiqued and updated, participant satisfaction is high, and the program was recommended by a faculty work group. In addition, the CITI training offers a modular structure that can be tailored to individual researcher needs, including customized modules for researchers in the social sciences and humanities (the "Social/Behavioral Research" track). Finally, CITI is easily accessible on the World Wide Web, and interfaces with Rascal.

6. **How do I access CITI?**
In order to ensure documentation of your training in Rascal, you must access CITI through the Human Subjects Protection course in Rascal:
https://www.rascal.columbia.edu/tc/TC0087.

7. **What are the training requirements?**
Each researcher is required to complete 5 core modules. In addition, the module on "Research with Minors" must be completed by anyone conducting such research and the module on "FDA-Regulated Research" must be completed by anyone conducting clinical research (research involving an investigational drug, device or biologic).

8. **Is there a requirement to take continuing education?**
Yes, once you have completed the full CITI HSP training, you will be required to complete an abbreviated continuing education every 3 years. You will receive reminders when the three year period is approaching.

9. **How do I know which modules I am required to take?**
When you first register for CITI, you will be asked a series of questions about your research activities to determine your Learner Group and any required additional modules. The basic Learner Groups are Biomedical (principally for researchers at CUMC) and Social/Behavioral (principally for researchers at the non-biomedical campuses). The additional groups are "Research with Minors" and "FDA-Regulated Research."

10. **What is the "Biomedical Research Group"?**
The Biomedical Research group includes most health sciences research involving human subjects, such as clinical research, epidemiological research, and most other research involving tissues, fluids, radiographic scans, biomedical information, or treatment and/or diagnosis of individuals.

11. **What is the "Social/Behavioral Research Group"?**
The Social/Behavioral Research (SBR) Group includes human subjects research involving behaviors, cognitive function, or social interactions, such as research conducted in the humanities, social sciences, the School of Social Work, Department of Psychology, the Business School, and some research on the CUMC campus.

12. **What if I need to add research with Minors or FDA-regulated research modules after completing CITI training?**
If your research changes to include (or no longer include) research with Minors or FDA-regulated research, you must change your Learner Group in CITI. *Do not simply take the relevant module as an Elective as the completion will not be captured in Rascal.* Log into

CITI, click "Add a Course" and answer the Curriculum Selection questions about your current or future research. You will be placed into the corresponding Learner Groups. If additional modules are required, your Status will be listed as Incomplete. Click Re-enter and complete the modules indicated.

13. **I am conducting a clinical trial, but it also includes a behavioral survey. Which Learner Group should I choose?**
You should choose the Biomedical Research Group for your core modules and then, as one of your additional modules, you should complete the elective module on "Social and Behavioral Research for Biomedical Researchers."

14. **I am conducting biomedical research, but some of the SBR modules relate to my research. If I take the SBR modules, will they count toward fulfilling my training requirement?**
Yes. If you have electives available, you should choose whichever modules are most applicable to the work you do.

15. **I conduct both Biomedical and Social/Behavioral research. Which Learner Group should I choose?**
You should choose the Biomedical Research Group for your core modules and then, as one of your additional modules, you should complete the elective module on "Social and Behavioral Research for Biomedical Researchers." However, if you are conducting biomedical research involving clinical trials with children, you will be required to take the "FDA-Regulated Research" and "Research with Minors" modules.

16. **What is the CITI "Integrity Assurance Statement"?**
The Integrity Assurance Statement is a CITI requirement that all learners must read and complete, indicating that they are taking the course for themselves. Learners can not access any modules until the Integrity Assurance Statement has been completed.

17. **What if I completed some CITI training previously as a Columbia affiliate?**
For those individuals who have already completed some CITI training, such as the Research with Minors course, your completed coursework will count toward Columbia's requirements although additional modules may be required. If you are already registered in CITI with Columbia University, after logging in, click on "Add a Course" to answer the new questions. If you have not already done so, click on "Update my profile information for Columbia University" and accurately enter your Columbia email and Uni to ensure you receive proper credit.

18. **What if I completed CITI training previously with another institution?**
For those individuals who have already completed CITI training (at another institution, e.g., NYSPI), your completed coursework will count toward Columbia's requirements although additional Columbia-specified modules may be required. If you are already registered in CITI with another institution, you should NOT create a new registration. Rather, after logging in, click on "Affiliate with another institution," choose Columbia University from the dropdown menu, and follow the registration process. Be sure to accurately enter your Columbia email and Uni to ensure you receive proper credit.

19. **How do I make sure I am credited for completing the course at another institution?**
When you add your Columbia affiliation to your CITI profile, all courses previously completed are automatically displayed as "Completed" on your Columbia "Gradebook" and you will

need to take only those Columbia-required modules that have not been previously completed. Be sure to accurately enter your Columbia email and Uni to ensure you receive proper credit. See question 16 for additional details.

20. Will my training be documented in Rascal?
Yes, completion data from CITI are uploaded to Rascal once each day. You can also download a CITI certificate as proof of completion. Be sure you have accurately entered your Columbia email and Uni to ensure you receive proper credit.

21. How can I check my training status?
You can check the status of your training by clicking View Certified Test History in the Rascal Training Center. Note: CITI data are not immediately visible in Rascal; completion data are transferred to Rascal once each day.

22. What happened to the Rascal Human Subjects Protection courses for CUMC and Morningside?
As of March 4, 2009, the Rascal courses were removed and replaced with the CITI course.

23. Whom should I contact if I have questions?
If you have any questions about the requirements, please feel free to contact the IRB at 212.305.5883 or irboffice@columbia.edu, or the Office of Research Compliance and Training at research-compliance@columbia.edu. For questions or problems with Rascal, contact the Rascal helpdesk at rascal@columbia.edu or (212) 851-0213. For questions or problems with CITI, such as logging into your CITI account, contact the CITI helpdesk at 305.243.7970.

24. Are there any other human subjects research training opportunities at Columbia?

Yes, and we encourage you to take advantage of these opportunities. CITI offers modules on many topics in addition to those required. These "Optional Modules" are available once you have completed all requirements. Also, a number of University offices offer education and training opportunities related to human subjects research, including the Human Research Protection Office/IRB (https://research.columbia.edu/content/human-research-protection-office-and-irbs), the Office of Research Compliance and Training (http://www.researchcompliance.columbia.edu/), the Clinical Trials Office (https://research.columbia.edu/content/clinical-trials-office and the Irving Institute for Clinical and Translational Research (http://irvinginstitute.columbia.edu/). Additional information about these and other offices can be found on the Columbia Research home page (https://research.columbia.edu).

If you would like specialized human subjects research training for your department or research team please contact the IRB office at 212.305.5883.