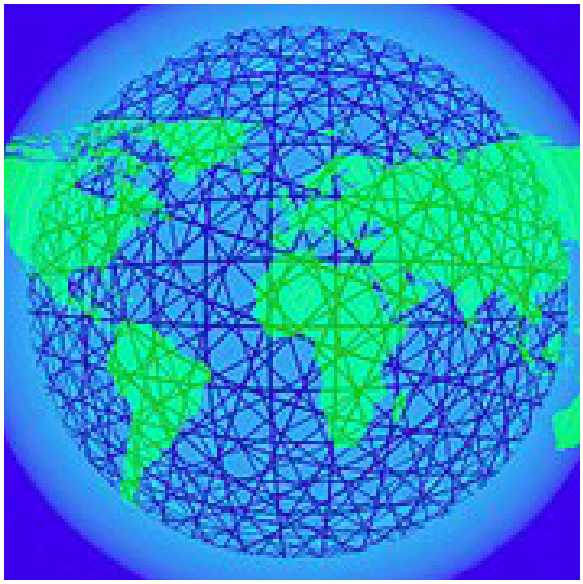
1
FALL 2014

THE CITY UNIVERSITY OF NEW YORK
College of Staten Island

Research Compliance



Training Updates

Faculty, Graduate and Undergraduate Students

CITI Responsible Conduct of Research (RCR) training is only valid for five years. You must redo the training after that. Graduate and Undergraduate Students Graduate and undergraduate students who are involved in research, regardless of funding, must complete CUNY-required modules of the Collaborative Institutional Training Initiative's (CITI) on-line training in RCR within six weeks of initiating their research activities. Instructions for completing this training are available at http://www.cuny.edu/research/compliance/training-education/citi-training.html

Everyone

Here is a link to a useful online training on plagiarism. Plagiarism in Research: Common Pitfalls and Unforeseen Consequences

For all of the following CITI Trainings, you will find details about how to get to the training, and a chart identifying who is responsible for participating in what trainings here. The Collaborative Institutional Training Initiative (CITI) website is: www.citiprogram.org Upon registering, **be sure to affiliate with CUNY** in order to complete the appropriate courses.

Training in the Protection of Human Subjects

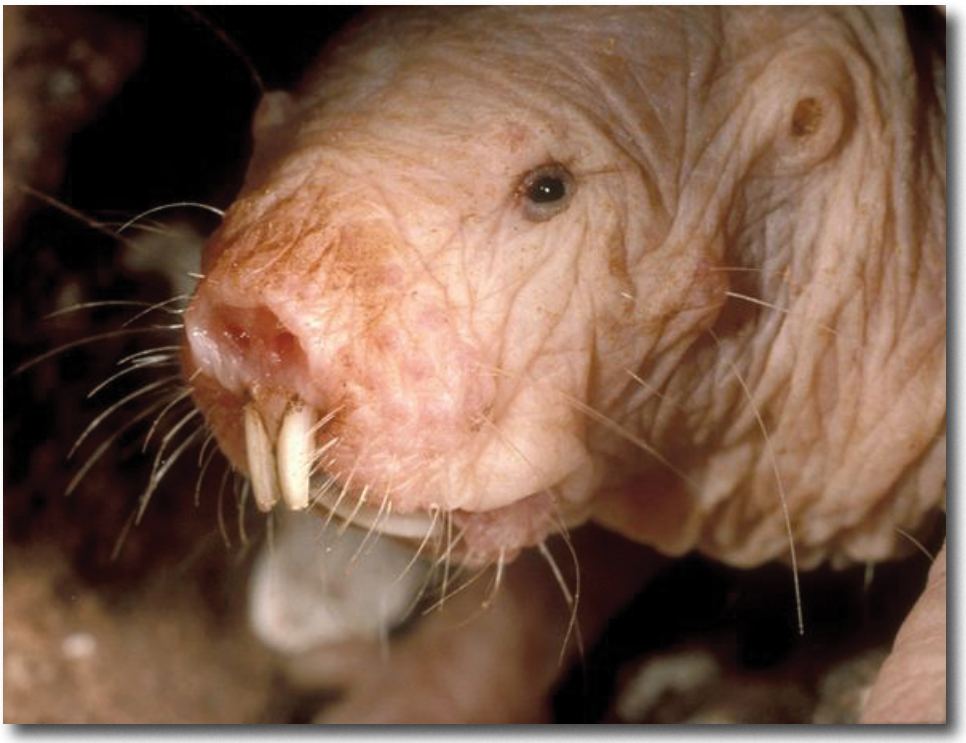
Anyone involved in human subject research must complete the basic course in the protection of human subjects (SBR or Biomedical) prior to obtaining approval of their project. **This training is valid for three years** at which time a refresher course must be completed to remain in compliance.

Training in the Care and Use of Animals

Anyone involved in animal care, use or treatment must complete the CITI training in Laboratory Animal Welfare for Investigators, Staff and Students prior to Institutional Animal Care and Use Committee (IACUC) approval of their protocol.

Training in Conflict of Interest

Anyone involved in research related to any Public Health Service (PHS) funded* grant or contract, all College Conflicts Officers (CCOs) and Conflicts Committee members are required to complete the CITI training in Conflict of Interest (COI). In addition, a CCO or the Conflicts Committee may require individuals to complete this course on a case-by-case basis. Individual training requirements may be based on the nature of an existing conflict; non-compliance with CUNY's Conflict of Interest Policy; or non-compliance with a Conflict of Interest management plan. **COI training is valid for four years**. CUNY researchers are required to re-take the CITI COI training course every four years.



New Rules!

The Standard Operating Procedure for Occupational Health and Safety Program for Human and Animal research has been updated, passed by the IACUC and sent to the Office of Laboratory Animal Welfare (OLAW). Here is the link: http://csivc.csi.cuny.edu/irb/files/iacuc/Occupational%20Health%20and%20Safety%20Standard%20Operating%20Procedure.pdf Remember that only people with a FLAS username and password can access the IACUC information

Cautionary Tale

Instances of noncompliance – including **research conducted after a protocol approval has expired**, is reportable to OLAW. You jeopardize your permission to conduct research, the College's permission to conduct research, the College's ability to secure research grants from any federal agency, and in extreme cases, the College's access to federal financial aid for all students, by failing to renew your protocols on time or otherwise conducting research outside of approved protocols. It might feel like a minor scheduling snafu to a PI, but it has potentially dire consequences for the College. Unfortunately, we have a pattern of noncompliance in this area that OLAW has begun to question. **This is serious**. The Provost visited a specially convened meeting of IACUC this semester to recommend more stringent enforcement and to emphasize the gravity of this situation. The Provost is the one who must write to any federal entity informing them of the College's noncompliance whenever a PI is noncompliant.

Dr. Axel Wolf, director of the Division of Compliance Oversight, Office of Laboratory Animal Welfare, NIH provided the following cautions to the College of Staten Island:

1. If a project is funded by NIH and the investigator is noncompliant, NIH can require the investigator to pay back all the money they awarded him/her for the research.
2. When an investigator seeks publication, he/she certifies that he/she has been compliant (federally, institutionally, etc.). If he/she has in fact been noncompliant (regardless of funding) this can be considered a form of research misconduct (falsification and or fabrication). The publication can redact the article and the data can be deemed useless.

Dr. Wolff is sufficiently concerned about the College's noncompliance that he offered to speak with the IACUC and the Institutional Officer (Provost Naider) via teleconference to express the magnitude of noncompliance. Daisy Lausell is working with the Provost's office to arrange this meeting. **Please watch for a request for your availability to participate in this teleconference**.

News

As Daisy Hernández Lausell noted in her message to you in November, CUNY is moving to a new software program for submitting Human Research Protection Program/Institutional Review Board (HRPP/IRB) applications. As a reminder of the change – or in case you missed it – here is a copy of Daisy's message.

Dear Researchers:

We will be transitioning to a new HRPP/IRB submission software program, Ideate, in early February 2015. There are several plans and tentative deadlines that you should be aware of to ensure a smooth transition:

- **November 26, 2014—Submission Deadline for Full Board applications**.
- **December 17, 2014—Submission Deadline for Exempt/Expedited applications**.
- **January 12, 2015—Processing Deadline for Baruch HRPP Office**.
- **January 19 – 30, 2015—Processing Freeze (no submissions will be processed)**.

Submit all anticipated amendments and continuing reviews **well in advance** of the submission deadlines. **No exempt or expedited submissions will be accepted after December 17th. The CSI HRPP Office will have until January 12th to process existing IRBNet submissions. There will be a processing freeze beginning January 19th through 30th as HRPP staff will be transferring protocols into Ideate.**

Data Transfer Information: CUNY will be transferring protocol and submission level data into Ideate for all **active non-exempt** human subject research protocols. This means that CUNY will **not** transfer closed projects/non-active projects and active exempt protocols/submission data into Ideate. **Although CUNY will have backup data, please be sure to have a copy of all protocol related materials available to you in your research records in order to avoid any inadvertent mistakes or data loss**.

CUNY will provide CSI with training on using the new system in three forms: Webinars (prior to rollout), One-on-one Sessions (after rollout) and "Help Documents by Topic" will be available within IDEATE. We will send out information about training as it becomes available.

For more details regarding the IDEATE implementation please see the attached "IDEATE What to Expect" document.

For all updates and announcements regarding the IDEATE implementation, please refer to the CUNY Human Research Protection Program website at:
http://www.cuny.edu/research/compliance/human-subjects-research-1.html

Please send inquiries regarding the IDEATE roll out to hrpp@cuny.edu.
The CSI HRPP Office will send updates regarding the final IDEATE implementation and training dates when announced by the CUNY Office of Research Compliance.

Best Regards,
Daisy Hernández Lausell, MPA, CIP
Human and Animal Research Protection Program Manager

Did you Know?

If you are planning to use a hazardous substance or chemical in your research — you need to get a signature from the Chemical Hygiene Office, James Saccardo. See contact list at the end of this Newsletter.

Essential Links

College of Staten Island Office for the Protection of Research Subjects—This page contains many useful links.

Research Compliance at the City University of New York—This page provides an overview of CUNY rules, with information and additional resources.

Responsible Conduct of Research at CUNY—Includes: CUNY's RCR Training policy, Research Misconduct policy, List of campus Research Integrity Officers, Regulatory requirements

Dedicated to Dean Alex

AREA	NAME	CONTACT INFORMATION	POSITION
Executive Responsibility	**William J. Fritz**	President@csi.cuny.edu I 718.982.2400 (1A-404)	President
Institutional Officer (IO) for Institutional Biosafety Committee (IBC)	**Fred Naider**	Provost@csi.cuny.edu 718.982.2440 (1A-305)	Provost
IO IBC Administrator	**Alejandra Alonso**	alejandra.alonso@csi.cuny.edu I 718.982.3905 or 4153 (6S-316A; 6S-229A)	Faculty Member
Institutional Official (IO) for IACUC	**Fred Naider**		
IACUC Administrator	**Daisy Hernandez Lausell**	Daisy.H.Lausell@csi.cuny.edu I 718.982.3867 (5S-102)	Administrator
EHS/OHS Officer[1]	**Kathleen Collins**	kathleen.collins@csi.cuny.edu I 718.982.3213 (1M-203)	Director, EHS
Consultation: OHS issues in Field Studies	**Kathleen Collins**		
Laboratory Safety	**James Saccardo**	james.saccardo@csi.cuny.edu I 718,982.3906 (6S-001E)	Chemical Hygiene Officer
Chemical Hygiene Specialist	**James Saccardo**		
Hazardous Materials Specialist	**James Saccardo**		
Hazardous Materials Program Coordinator	**James Saccardo**		
Radiation Safety Officer	**William Wallace**	william.wallace@csi.cuny.edu I 718.982.3876 (6S-304)	Professor, Biology
Biological Safety	**Alejandra Alonso**	alejandra.alonso@csi.cuny.edu I 718.982.4153 (6S-229A)	
LASER Safety	**managed by PIs**		
Public Safety	**Robert A. Wilson**	robert.wilson@csi.cuny.edu I 718.982.2113 (2A-108)	Director
Research Integrity Officer[2]	**Lisa Ebert**	lisa.ebert@csi.cuny.edu I 718.982.2254 (1A-302)	Director, Sponsored Programs and Research
Vivarium[3]	**Joanne Niekrash-Camhi**	joanne.neikrash@csi.cuny.edu I 718.982.3907 (6S-003)	Director
Consulting Veterinarians[4]	**Richard Carp** **Mark Valitutto**	richard.carp@opwdd.ny.gov I 718.494.5157 mvalitutto@statenislandzoo.org I 917.543.6323	Consulting Veterinarians6

Notes

[1]The Occupational Health and Safety Program (OHSP) is responsible for the following: **1.** Identifying existing/potential hazards: biologic agents (infectious agents, toxins); chemical agents (carcinogens, mutagens); radiation (radionuclides, x-rays, lasers); physical hazards (needles, syringes); other hazards (animal bites; exposure to allergens; chemical cleaning agents; wet floors; cage washers; lifting; zoonoses; etc.) **2.** Assessing the risks based on: the facilities; types of research activities; hazards **3.** Managing the risks through: design and operation (engineering controls) of facilities; safety equipment; SOPS for administrative controls; personnel protective equipment **4.** Training the staff on: safety procedures; SOPs; hazards.

[2]Oversees RCR (CITI) participates in and provides training to CSI. Receives complaints related to research misconduct (defined as fabrication, falsification, plagiarism); coordinates investigation process. Record retention for RCR and misconduct.

[3]Health evaluations and immunizations of staff: pre-employment and periodic; appropriate immunization schedules and documentation for employees are managed by the Vivarium Director. For non-employees, P.I.s manage health evaluations and immunizations.

[4]The Consulting Veterinarian assesses risks based on animal species.

COMMITTEE CHAIRS	NAME	CONTACT INFORMATION	NOTES
Chemical Hygiene Committee[5, 6, 7, 8]	**Prof. Alan Lyons**	alan.lyons@csi.cuny.edu |718.982.3951 (6S-225)	Meets bimonthly
IACUC	**Prof. Andrzej Wieraszko**	andrzej.wieraszko@csi.cuny.edu | 718.982.3941 (6S-324A)	
HRPP (IRB) Administrator	**Daisy Hernandez Lausell**	Daisy.H.Lausell@csi.cuny.edu | 718.982.3867 (5S-102)	CUNY wide committees
Biosafety	**Alejandra Alonso**	alejandra.alonso@csi.cuny.edu | 718.982.4153 (6S-229A)	

CONFLICTS OFFICER[9]	NAME	CONTACT INFORMATION	POSITION
	Alfred Levine	alfred.levine@csi.cuny.edu | 718.982.2430 (1A-313)	Dean

EXPORT CONTROL[10]	NAME	CONTACT INFORMATION	NOTES
Chemical	**James Saccardo**	james.saccardo@csi.cuny.edu | 718.982.3906 (6S-001)	
All other Export Control items	**Kathleen Galvez**	andrzej.wieraszko@csi.cuny.edu | 718.982.3941 (6S-324A)	Special Counsel and Labor Designee

RESEARCH COMPLIANCE COORDINATOR	NAME	CONTACT INFORMATION	POSITION
	Christine Flynn Saulnier	Christine.FlynnSaulnier@csi.cuny.edu 718.982.2020 (2A, 201G)	Special Assistant to the Provost Professor and Chair of Social Work

Notes

[5]Committee Members: "Review academic and research protocols to ensure that proper controls are available to protect faculty members, staff and students" (CSI Chemical Hygiene Plan, p. 8).

[6]Chemical Hygiene Officer: "Review specific research protocols and operating procedures, which are developed and enforced by principal investigators and laboratory personnel for the safe use, disposal, spill cleanup, and decontamination of hazardous chemicals" (CSI Chemical Hygiene Plan, p. 7).

[7]"Principal investigators, faculty, and other laboratory supervisors have responsibility for chemical hygiene in the research or teaching laboratories in which they work" (CSI Chemical Hygiene Plan, p. 9).

[8]The Laboratory Supervisor, or Principal Investigator is responsible for developing, with the assistance of the Chemical Hygiene Officer, a set of Standard Operating Procedures" (CSI Chemical Hygiene Plan, p. 44).

[9]Receives complaints of possible conflict of interest, assembles committee to review and investigate.

[10]Gillian Small, 5.11.12: "These rules have a direct impact on what hardware, laboratory equipment, materials, software, technology and technical data that we, as a responsible institution, can export out of the country by any means and, in certain cases, allow access to by individuals working in and visiting our research laboratories. These regulations also potentially affect what institutional research partners we work with during the course of our U.S.-based and international collaborations; how we disseminate research results and to whom; and travel abroad for teaching and research purposes. Export controls affect all scientific disciplines (regardless of whether the activity concerns sponsored or non-sponsored research) as well as business and service transactions with restricted countries and restricted end users."

The City University of New York

University Director for Research Compliance

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TO: CUNY Human Subject Research Community

FROM: Farida Lada, University Director for Research Compliance

DATE: November 3, 2014

RE: IMPORTANT ALERT: Upcoming change in HRPP/IRB software

Dear CUNY Researcher:

As part of our research compliance efforts, we perform ongoing informal and formal assessments of CUNY's Human Research Protection Program (HRPP), and use these assessments to implement improvements to the program. One key tool in alleviating unnecessary process constraints is the web-based compliance management system and database. As you know, we implemented IRBNet almost 3 years ago. Unfortunately, during this time period, we received unsatisfactory feedback regarding the use of IRBNet from users at all levels, including researchers, IRB members, and administrators. As a result of user feedback, we searched for a user-friendly compliance management system that would minimize procedural burdens for all parties, and thus reduce the turnaround time for HRPP/IRB reviews.

You may have heard of this impending change from your Chief Academic Officer, who was notified last year. We identified Ideate by Enterprise Web as the solution of choice. We included a subset of all parties involved in the IRB process (researchers, IRB members, and HRPP staff) from across CUNY in product demonstrations, and all parties agreed that Ideate would provide the best solution for CUNY's HRPP needs. We spent greater part of a year configuring and customizing the Ideate software to meet CUNY's specific needs, and we are now completing final testing and piloting sessions involving all stakeholders. We expect to roll out the new system in early February.

We understand that switching systems requires a lot of effort and wish to assure you that we have strategically planned to minimize any efforts on the part of the researchers. Here is what you, as a researcher, can expect:

1. **IRBNet Submission and Processing Deadlines**
   In order to ensure a smooth transition from IRBNet to Ideate, we will implement a final deadline for all submissions into IRBNet, and a final deadline for processing all submissions in IRBNet. It is expected that the submission deadline for convened IRB submissions will be November 26, 2014; and the submission deadline for exempt and expedited submissions in IRBNet will be December 17, 2014. The processing deadline for all submissions in IRBNet will be January 12, 2015. These are tentative dates, and, once we get closer to the time, we will confirm this information via additional announcements and through our web site.

   Please submit all anticipated amendments and continuing reviews well in advance of the submission deadline so that we can complete processing all submissions in advance of our internal processing deadline.

2. **Submission and Processing Freeze**
In order to ensure that the final data that was input into IRBNet is accurately transferred into Ideate, we will implement a two-week submission and processing freeze, during which time the CUNY HRPP will not be accepting any new submissions nor processing any existing submissions. This freeze is expected to occur between January 19, 2015 and January 30, 2015. Again, we will confirm this information closer to the time via additional announcements and through our web site.

Although we will be available to address valid urgent needs of our researchers during this two-week period, we ask that you please allow the HRPP staff with sufficient uninterrupted time to complete transferring your protocols into Ideate during the freeze.

3. **Data Transfer for Ongoing Protocols**
We are transferring protocol and submission level data into Ideate for all ***active non-exempt*** human subject research protocols. Due to the nature of the data stored in IRBNet, our data transfer efforts involve both electronic and manual data transfer. Therefore, data transfer will take place in 3 steps as follows:

   a. We have been implementing periodic electronic data transfers for high-level protocol data. The final electronic data transfer will take place at the beginning of the freeze. This high level data allows us to create placeholders in Ideate for your existing non-exempt protocols. The high level data includes:
      - Protocol title
      - PI name
      - IRBNet project ID
      - Submission level data for each project, to include:
        - Each submission type
        - Reviewing IRB
        - Review type (expedited versus convened)
        - Actions taken by the IRB
        - Effective date of action taken
        - Project status
        - Project expiration date

   b. During the freeze period, we will perform manual data transfer to attach the following files to your protocol in Ideate:
      - Most current Application Part II
      - Most current consent document(s)
      - Most current grant application, if any

      Although we will have backup data, please be sure to have a copy of all protocol related materials available to you in your research records in order to avoid any inadvertent mistakes or data loss.

   c. Prior to and during the two-week freeze, we will be collecting information from all researchers on any anticipated amendments for submission upon roll out. If you have no amendments at this time, you do not need to take any action during this process. If, however, you do anticipate amendments to your protocol, we will work with you to prioritize manual entry of your protocol data into the Ideate smart forms. Protocol without anticipated amendments will be

prioritized based on protocol expiration dates. This final step will bring your active protocol up to date in Ideate.

We ask that, at the time of your first submission in Ideate for an ongoing protocol, you verify that the data that was transferred is accurate and make any modifications or corrections that are necessary.

4. **Researcher Training**
   We will provide you with training on using the new system in three forms:

   a. **Webinars**
      We will schedule several webinars on multiple dates and times ***prior to rollout***. The webinars will provide in-depth training on using Ideate from a researcher's perspective. Please stay tuned for dates and times.

   b. **One-on-one Sessions**
      After rollout, we will implement in-person training on a one-on-one or small group basis at each of the colleges, starting with the most research-intensive colleges. This will be most helpful to you when you are ready to create your first submission in Ideate. Please stay tuned for instructions on scheduling your one-on-one or small group session.

   c. **Help Documents by Topic**
      Help documents by topic will be available within Ideate. These documents open in a new window so that you can use them side-by-side as you create and complete your submission. Please note that the most current version of these documents will always be available within Ideate. Therefore, in order to prevent the use of outdated documents, we ask that you do not download and save these on your desktops. Help documents will also be available on our web site in a password protected form.

For all updates and announcements regarding the Ideate implementation, please refer to the CUNY Human Research Protection Program web site at
http://www.cuny.edu/research/compliance/human-subjects-1.html

If you have any questions, please contact us at hrpp@cuny.edu.