
Dear Graduate Center Researchers:

We will be transitioning to a new HRPP/IRB submission software program, Ideate in early February 2015. Please see attached memo from Farida Lada, University Director for Research Compliance. 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 The Graduate Center 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 Graduate Center 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 The Graduate Center 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 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 Graduate Center HRPP Office will send updates regarding the final implementation dates when announced by the CUNY Office of Research Compliance.

There is a good possibility that many of you will be receiving duplicates of this email.

Best regards,

Kay Powell
Human Research Protection Program (HRPP) Coordinator
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-research-1.html](http://www.cuny.edu/research/compliance/human-subjects-research-1.html).

If you have any questions, please contact us at hrpp@cuny.edu.
CUNY has an ongoing agreement with the Federal Office for Human Research Protection (OHRP) of the Department of Health & Human Services concerning all research involving human participants. This agreement requires prior approval of all research proposals and, if applicable, an annual continuing review by an official CUNY HRPP (Human Research Protection Program).

When is it “Human Subjects Research?”

Definition of Research:

- Research – a **systematic investigation** designed to develop or contribute to generalizable knowledge. A “**systematic investigation**” is an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question.

Definition of Human Subject

- Human Subject – a living individual about whom an investigator conducting research obtains
  - data through intervention or interaction with the individual, or
  - Identifiable private information

Identifiable Private Information

- Private information – information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- Identifiable information – information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

When is it Human Subjects Research?

- Depends on
  - How the activity is carried out. Is it a systematic investigation?
  - The purpose of the activity. Is it intended to contribute to generalizable knowledge?
  - Whether the subjects are actually human subjects according to the definition.
    - Living individuals
    - Data obtained is about them
    - Data is obtained through intervention or interaction or private identifiable information is obtained

FOR MORE INFORMATION ON SUBMITTING AN IRB APPLICATION PLEASE GO TO:
http://www.cuny.edu/research/compliance/human-subjects-research-1.html

For further information contact Kay Powell, HRPP Coordinator at The Graduate Center:
kpowell@gc.cuny.edu.
Dissertation Proposal Clearance: Human Participants Form

All students who have advanced to Level III and/or when they have received IRB approval for their dissertation research must submit a Dissertation Proposal Clearance: Human Participants Form to:
  Kay Powell, HRPP (Human Research Protection Program) Coordinator
  Room 8309
  212 817-7525, kpowell@gc.cuny.edu

- Every student in every program must submit this form – regardless if their research involves human participants.
- The form needs to include the following;
  1) A short project abstract (one to two pages) including methodology.
  2) Advisor’s signature.
  3) If applicable, a copy of the IRB approval letter.
- The form becomes part of the student’s file in the Registrar’s Office and the “Human Subjects Hold” is removed from their record.
- A student will not be able to deposit their dissertation unless this form has been submitted and accepted.
- All research that involves human participants (including informal interviews or pre-existing data) needs to be reviewed and approved by the IRB before research can begin.
- IRB approval cannot be given retroactively.
- Doctoral students and their advisers must work together to ensure that these requirements are met.

PLEASE NOTE: Not submitting this form DOES NOT prevent a student from any other student activities, e.g. Registration.
Requirement for All Dissertations and Clinical Research Projects
Human Participants Clearance Form

CUNY has an ongoing agreement with the federal Office for Human Research Protection (OHRP) of the Department of Health & Human Services concerning all research involving human participants (including interviews, oral history, and database research). That agreement requires prior approval of all research proposals and, if applicable, an annual continuing review by an official CUNY HRPP (Human Research Protection Program) Office.

To assure compliance with this agreement, The Graduate Center has a requirement that all Ph.D., D.M.A. and D.S.W students must submit a Dissertation Proposal Clearance: Human Participants Form or Clinical Research Project Clearance Form. The Registrar's Office at The Graduate Center sends the forms to all Ph.D., D.M.A. and D.S.W. students when they advance to Level 3 and the form is distributed to all Clinical Doctoral (AUD, DPT, & DNS degrees) students in class. Students should submit an IRB application to the HRPP Office at the CUNY College with which their faculty advisor has primary affiliation and before research begins.

If human participants are involved in your research: Before you begin your research, submit a human subjects application to the HRPP Coordinator at the campus where your advisor has their primary affiliation. Applications and guidance information are available at http://www.cuny.edu/research/compliance.html.

After your research has been approved by the HRPP Office at your campus, complete the Clearance Form and attach a copy of the approval letter. Submit the form to the Office for Research and Sponsored Programs (address below).

If human participants are not involved in your research: Complete the form and attach your project abstract and methodology and submit to: Kay Powell, HRPP Coordinator, The Graduate Center, Room 8309, 365 Fifth Avenue, New York, NY 10016.

If you are uncertain about the classification of your dissertation research, or have any questions, please contact the HRPP Coordinator at your advisor's primary campus.

2/2012 (revised)
The City University of New York  
365 Fifth Avenue  
New York, NY 10016

DISSEPTION PROPOSEAL CLEARANCE: HUMAN PARTICIPANTS

Must be submitted by all students before dissertation deposit

All dissertation proposals that involve research with human participants (including interviews, oral history, and database research) must be reviewed and approved by a CUNY HRPP Committee. The review should take place, and final approval be obtained, during the proposal stage of the dissertation; research involving human participants may not begin until approval has been granted. Approval must be obtained before the research has begun; approval will not be granted for research that has already begun. If the dissertation proposal is changed, the proposal must be reviewed and approved again by the CUNY HRPP Committee.

Any questions should be directed to the HRPP Coordinator at The Graduate Center Kay Powell, HRPP Coordinator, at 212-817-7525, kpowell@gc.cuny.edu.

(Student’s Name) __________________________ (Dissertation Advisor’s Name) __________________________  
(Student’s Program) __________________________  
I.D. No. __________________________

Student’s Home Phone & email __________________________  
Project Title: __________________________

***REQUIRED: Project Abstract (including methodology); attach and submit this form.***

Please check one:

_____ YES, this dissertation involves the use of human participants or data from human participants.  
Attached is a copy of the IRB approval letter from a CUNY campus.

_____ NO, this dissertation does not involve the use of human participants or data from human participants.

Student’s Signature __________________________ Date __________________________

Dissertation Advisor’s Signature __________________________ Date __________________________

Send form and abstract to: Kay Powell, HRPP Coordinator, Room 8309

Approved: __________________________ Kay Powell  
Signature, HRPP Coordinator, The Graduate Center Date __________________________

2/2012