

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>.

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