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Research Protection Office RPO Quarterly

Lifespan

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Welcome to the New RPO Newsletter!

It is with great pleasure that the Research Protection Office (RPO) delivers to the Lifespan research community the first issue of **RPO Quarterly.** This quarterly newsletter will provide information and updates on the IRB submission and review process, details regarding relevant Federal, state and institutional regulations as well as tips to help make your submission experience a little easier.

The newsletter will be sent out as an email attachment but will also be archived on the ORA website and on IRBNet. To access it on the website, go to the Research Administration site on the Lifespan Intranet, click on the RPO tab on the left side of the screen then click on "Quarterly Newsletter" in the box on the right. In IRBNet, the newsletters will be located in the Forms and Templates section.

We hope you find this newsletter informative and look forward to your feedback.

Inside this issue:

RPO Office Changes

Earlier this year there were several changes within the RPO Office:

- After ten years of dedicated service to the IRBs and protection of human subjects, Patricia Houser retired from Lifespan as Director of the Research Protection Office.
- Janice Muratori, NP, was promoted to Director, Research Protection Office. She had been the RPO Manager since 2012. Previously she worked in cardiology research for 15 years.
- We welcomed S. Candace (Candy) Frater, MD as Manager. Before joining RPO, Candy was the Project Director for Drs. Michelle Lally and Philip Chan of the Immunology Center and Dr. Martin Miner of Men's Health Center.
- Each of the 3 IRBs (RIH1, RIH2 and TMH) will continue to have a Research Review Coordinator. Committee assistants for the three IRBs are Liz Rebocho and Sara Spangenberger. Contact information for all RPO staff is located on page 3.

Submission Tip #1

- Whenever you submit a Research Application Part 1 (RA1), please make sure that all CITI dates are current and have not expired. Lifespan CITI training is good for 3 years.

- The RPO staff reviews CITI dates each time a RA Part 1 is submitted for **all** submission types: new project, revision, continuing review.

- A list of Lifespan CITI certification dates can be found on IRBNet.

Submission Tip #2

- As new submission templates are loaded into IRBNet, we will send out an announcement using the RPO email so make sure you read all RPO communications before deleting them!

- When you call or email to ask a question regarding one of your submissions, please make sure to reference your project using either the IRBNet number or the committee number (RPO assigns this to the project on initial submission).

Updated Forms and Templates

If you will be submitting a Continuing Review package after 9/1/2015, be sure to use the **NEW CRR FORM** located in the Forms & Template library in IRBNet. We are in the process of updating many of the submission forms, including the check-lists, so please check the Forms & Template Library when you are submitting a package.

In October 2014, the IRBs approved administrative changes to the Informed Consent Template. When you submit either a new project or a revision or continuing review for an existing project, please make sure you are utilizing the most current consent template (footer "RPO-Adult IC and Authorization –v.8-2013[3]).

All submission forms can be found in the Forms and Templates section of IRBNet which is located under the "Other Tools" heading on the left-hand side of the screen.

IRBNet Training for Researchers and Support Staff

Training is the second and fourth Tuesday of every month from 10:00am to 12:00pm, Coro West, Suite 1.300, Conference Room 1.312.

IRBNet training is not only about how to use IRBNet, but also for:

- How/When do I summit to the IRB?
- General IRB Information—what is an IRB? What does the IRB do? What are the regulations that govern research and why?
- When/why do I need to submit to the IRB?
- HIPAA and the Preparatory to Research.
- When do I need a Prep?
- When do I need a Waiver of Consent?

Please contact Adrienne McParlin at 401-444-3527 or amcparlin@lifespan.org to schedule training.

Q: Where can I find the current IRB rosters?

A: If you need an anonymous roster for your study, they are now located in the Forms and Templates section of IRBNet .

The RPO welcomes questions you may have regarding package submissions, HIPAA, Waiver of Consent vs Waiver of Consent Form, etc.

Submit your questions to Cyndi Chrostek (cchrostek@lifespan.org)

Submission Hold-Ups

Before you hit the "Submit this Package" tab, make sure that these items have been addressed– it will make the review process go smoother and faster!

⇒ The PI must sign all package types except a response package. No one can sign for him/her.

⇒ The Department Chair needs to sign all new project packages and revisions that include a change in PI but does not need to sign continuing review submissions.

⇒ Please make sure that a funding source is indicated in the project IRBNet profile. It can be Federally funded, a sponsor or a Lifespan department but it has to be there for all projects even chart reviews.

⇒ PIs must submit a signed HIPAA Security Certificate annually.

⇒ Please make sure that project information is consistent between all submitted documents– the information in the consent needs to match what the protocol says and what is listed in all application forms.

Compliance Corner

Have you recently added new staff, students, or volunteers? Remember to obtain approval from the IRB before new personnel begin working on your project. DHHS regulations 45CFR46.103(b)(4), as well as GCP Guidelines 4.5.2 and 8.2.7 require that researchers obtain IRB review and approval in writing before changes are made to approved protocols, this includes personnel lists. The **Lifespan IRB Policy and Procedure Manual**, Section 12.4 states that the investigator must provide the IRB with a list all of the persons in direct contact with the subject and verify that Human Subject Protection training has been successfully completed. **The IRB must be informed when there are personnel changes to ensure that added staff have been appropriately trained.**

Please contact Jacqui Poore, Research Compliance Program Manager, if you have any questions about your responsibilities as a researcher, Good Clinical Practice (GCP), or the requirements for obtaining and documenting informed consent. JPoore@lifespan.org, 401-444-5843.

IRBNet Update

IRBNet just announced a powerful new enhancement to your Submission Manager toolset, "Project Status View". This enhancement allows users to view and sort submissions according to the current Project Expiration Date and Project Status. On the top of the Submission Manager table, to the left to the "Collapse by Project" link, you will find the new "Project Status View" link. Clicking this link will reveal the most recent Project Expiration Date and Project status.

Stay Connected with RPO

There are three Institutional Review Boards (IRBs) for Human Research Protection at Lifespan: RIH 1, RIH 2 & TMH. If you have any questions pertaining to your studies, contact either the Coordinator of the Board that reviewed your study or one of the IRB Assistants.

Director: Janice Muratori; jmuratori@lifespan.org
Manager: S. Candace (Candy) Frater; sfrater@lifespan.org

RIH IRB 1
Committee Coordinator: Dawn Roux; droux@lifespan.org
RIH IRB 2
Committee Coordinator: Cyndi Chrostek; cchrostek@lifespan.org
TMH IRB
Committee Coordinator: Adrienne McParlin; amcparlin@lifespan.org

IRB Assistants: Liz Rebocho; irebocho@lifespan.org
Sara Spangenberger; sspangenberger@lifespan.org

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