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Research Protection Office RPO Quarterly

Lifespan

Delivering health with care™

HAPPY NEW YEAR!

As we begin the new year, the Research Protection Office (RPO) would like to give you an idea of the number of projects that were processed and reviewed at Lifespan in 2015:

- New projects (both expedited and Full Board): **576**
- Continuing Review Reports (both expedited and Full Board): **993**
- Revisions (both expedited and Full Board): **1868**
- Other types of submissions (AEs, terminations, deviations, response packages, etc): **1943**
- As of December 31, 2015, there were a total of **1314** active research protocols at Lifespan!

There have been some changes to my project—do I need to submit a revision?

When there has been a change to your IRB approved project, you do need to let the IRB know by submitting a revision report. If you are looking to add someone to your study personnel, that needs to be submitted AND approved before they can start working on the project. Also, any updates to your consent documents, protocol or funding source need to be submitted as soon as possible.

However, not all revisions need to be reported right away– some can wait until you submit your annual Continuing Review Report. If you are removing personnel, you can wait until your Annual Continuing Review submission to let us know that.

Other things do not require IRB notification such as required administrative changes like an update to personnel CITI training date or an update to a new form template.

If you are unsure if you need to submit a revision package for a change, please call one of the Research Coordinators or Assistants (see page 3 for contact information for all RPO staff).

What does De-Identified Mean?

When you submit a project and indicate that you are collecting or receiving de-identified data, you are saying that you are not collecting any of the 18 HIPAA identifiers that qualify as PHI which are listed to the right.
Notice that ANY date, including date of service or treatment is considered identifiable PHI.
IP (web) addresses are also considered identifiable so if you are using an online survey site, you will need to state that you are not collecting IP addresses.

1. Name	10. Phone number
2. Fax Number	11. Medical record Number (MRN)
3. Health care beneficiary #	12. biometric id-voice prints/finger prints
4. address (except State)	13. device identifier
5. email address	14. web URLS
6. member or account #	15. IP address
7. ANY Dates, such as DOB or date of treatment/surgery, etc	16. vehicle ID #
8. SSN #	17. full face photo
9. certificate/license #	18. any other unique ID

Compliance Corner

Do You Maintain a Staff Signature Log in the Regulatory Binder for your Study?

Have all staff included on the IRB approved personnel list (in Research application part 1) signed the log?

Good Clinical Practice (GCP) guidelines 4.1.5 and 8.3.24 refer to the need to maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial related duties and the need for a Staff Signature Log for each study. This is an ongoing list of staff approved to work on the study with their signatures. A Staff Signature Log can easily provide an updated reference of research staff, past and present which can be especially helpful for studies that are long in duration, have large staff number, and/or have had staff turnover during the study. Capturing the original signature and initials of all staff members prior to start and as the study progresses, may help authenticate or verify data entry if questioned, based on time frame and handwriting/signature.

Please contact Jacqui Poore, Research Compliance Program Manager for a sample Staff Signature log, or 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.

Q: Do I need to submit a CV and COI form for all study personnel?

A: No– we only need the CV for the study PI and you only need to submit the COI form if the PI has a conflict of interest with the study. The COI form is 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.

Project Terminations

If you are not enrolling subjects and research activities are limited to analysis of de-identified data, then you can terminate your project by submitting a termination report.

All Lifespan research projects need to comply with the state of RI regulations requiring investigators to maintain records for a minimum of 5 years after a study closes. If your project enrolled patients, then HIPAA regulations require that those research records be kept for a minimum of 6 years. If the project involves an investigational drug or device, all records must be kept for a minimum of 2 years after FDA marketing approval is granted. Individual sponsors may have additional requirements for records retention so please check with them before destroying any records.

You can store your deidentified research records and the consent forms with a Lifespan approved storage vendor (check with your Department administrator to get a list). However, the link between the consent form and the de-identified research record should be kept separate (we recommend keeping it on your computer in a locked, password protected file).

When the required length of time has elapsed, you can destroy the stored paper records as well as the electronic link.

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 a training session.

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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