The Importance of Organized Record Keeping in Research

The practice of keeping organized and legible documentation of study files is essential for data integrity and will help to prevent issues of unintentional non-compliance. Additionally, data files that are precise and clear allows for other investigators or student researchers to replicate findings, and is necessary for a clear understanding of the data. Because a research file is an account of a subject’s activities in research and provides a link to participation, records that are poorly maintained could lead to data that are unusable or difficult to interpret.

There are many reasons to organize your research records carefully. After preliminary analyses, you may have to refer to case report forms after finding data that are missing or out of range, or to look for errors with data entry. It is also easier to train new study staff when processing and filing your study documents in an organized way, and also makes for follow up of participants who have multiple visits easier. Maintaining organized study files and documentation is especially important for longitudinal studies, that have multiple subject visits.

Management of study records is particularly important with larger studies that have several people on the research team. Entries on study measures should be uniform and consistent showing the dates of procedures. Research records should be complete, legible, and accurate. If mistakes are made, make a single strike through and initial. Do not scribble, white out, or black out mistakes. Label each measure with headers that include the date, study phase, initial of researcher, and participant ID number.

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Data should be collected in such a way that others, such as sponsors, auditors, and study personnel, can easily understand. Inclusion and exclusion criteria and tracking of adverse events and protocol deviations should be documented in real time if possible. Keeping your research records organized will prevent non-compliance and ensure integrity of data.

Good record keeping allows for all members of the study team to know what is going on, and is easier for data entry, with less time spent on re-checking for accuracy, or having to code the data as missing due to unreadable documentation.

In addition to subject files, IRB approved documents should be kept in one place that are accessible to both the investigator and study staff. Good Clinical Practice (GCP) and studies with oversight by the FDA, require these documents to be located in a study “Regulatory Binder”. The binder should include the approved protocol, consent form, recruitment material, and study measures. Having a study binder will help to keep the research organized.

Also, make sure that your data are stored and maintained as was written in the study protocol.

It is best to periodically evaluate your study data. Review the first few subject files to make sure that forms and procedures are administered correctly and accurately, and that signatures and dates are recorded. And most importantly, have regular meetings with your research staff/graduate students. Regular communication with your research team will ensure compliance and organization of the research.

### Mandated Reporters

On October 1, 2014, the State of Connecticut expanded the existing law on mandated reporters to include state employees who work in higher education. All employees at UConn, with the exception of student employees, are now considered mandated reporters. If you have knowledge of or suspect that a child under the age of 18 is being abused or neglected, you must report this to the Department of Children and Families (DCF).

Because many researchers here at UConn include families and children as research participants in their studies, we have added reporting language to the informed consent form templates that must be included if children are participants in research.


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**IRB Meeting Dates**

- Thursday, December 11, 2014
- Thursday, January 8, 2015
- Thursday, January 29, 2015
- Thursday, February 19, 2015
- Thursday March 12, 2015
- Thursday April 2, 2015
- Thursday, April 23, 2015
- Thursday, May 14, 2015
Jackson (JAX) Labs

In early 2013, the Jackson Laboratory for Genomic Medicine (JAX) broke ground on a 17-acre parcel of land located at UConn Health in Farmington, CT. The 183,500 foot lab will create over six hundred jobs in Connecticut. Since JAX had opened its doors its employees have been working in collaboration with researchers from UConn. The partnership between the independent, non-profit facility and UConn is expected to be beneficial to both entities, by collaborating on new cures and treatments for genomic diseases and taking on new approaches to early detection, treatment and prevention of disease.

Stem Cell Awards

The Connecticut Stem Cell Awards have been announced: Of the $10 million in awards, $3 million have been issued to UConn. In addition, the Jackson Labs received over $1 million.

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SCRO Meeting Dates

Wednesday, December 17, 2014
Wednesday, January 28, 2015
Wednesday, February 25, 2015
Wednesday, March 25, 2015
Wednesday, April 22, 2015
Wednesday, May 27, 2015
Electronic Protocol Forms

Starting in November 2014, the IACUC division of Research Compliance Services (RCS) will begin its efforts to migrate over to an electronic protocol development and submission system. This process is expected to take at least 1 year as we develop the forms, test the software and develop new business processes to accommodate a fully electronic protocol management system.

The highlights of the new electronic system include:

- Smart form capabilities—information can be prepopulated as appropriate.
- Real time workflow views—see where your protocol is in the review process.
- Completely browser based—develop and manage all your IACUC protocols online and in an electronic format.
- Branching logic—only see the questions that pertain to the work you are doing.

We are certain that the implementation of the new electronic protocol system will save you time and effort in developing and managing your animal use protocols. We welcome feedback from our stakeholders and encourage you to contact us with your suggestions. Stay tuned, as we will be sending out information periodically to keep you abreast of our progress over the next year.

Meet Dr. Holly Fitch, our new IACUC Chairperson and Dr. Randy Walikonis, Vice Chair

Please join us in welcoming Dr. Holly Fitch, Psychology, as our new IACUC Chairperson. She is a member of the Department of Psychology’s Behavioral Neuroscience Program. Holly has served on the committee since January 2008, and has also served as vice chair. She is one of our most experienced members and an avid advocate for faculty on the committee. Her research interests include hormones, brain development and cognition and animal models of brain damage and developmental disabilities. Her research focuses on the behavioral consequences of injury or disruption to the developing brain.

Please also welcome Dr. Randy Walikonis, Physiology and Neurobiology, as Vice Chair. Randy has been an IACUC member since January 2011, has served on several investigative subcommittees for the IACUC and often takes a leadership role on the committee. His research is directed at studying the postsynaptic signal transduction systems of excitatory synapses. His laboratory uses biochemical and molecular biological techniques to identify proteins associated with N-Methyl-D-aspartic acid (NMDA) glutamate receptors, and has been testing the effects of mutations in synaptic proteins that cause intellectual disability and autism on the structure and function of synapses.
Institutional Animal Care and Use Committee (IACUC)

IACUC Classroom Trainings-New Location to be Announced

Due to construction in the Whetten building during the spring semester, monthly IACUC classroom trainings will be held in Homer Babbidge Library in the Class of 1947 Conference Room located on the Plaza level near the Bookworms Café. Check our webpage for dates and times: http://research.uconn.edu/iacuc/iacuc-training/.

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IACUC Meeting Dates
Wednesday, December 3, 2014
Wednesday, December 17, 2014
Wednesday, January 28, 2015
Wednesday, February 25, 2015
Wednesday, March 25, 2015
Wednesday, April 22, 2015
Wednesday, May 27, 2015
Wednesday, June 24, 2015
National Biosafety Stewardship Month

September was National Biosafety Stewardship Month.

“Stewardship: “the careful and responsible management of something entrusted to one’s care”

On August 27, 2014 the National Institutes of Health declared September to be National Biosafety Stewardship Month. During September, laboratories at the NIH and other Health and Human Services agencies evaluated their biosafety policies, practices and training. The laboratories also conducted biological agent inventories. Institutions who receive NIH funding were encouraged to join them in these efforts. Follow this link to read the notice - http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-127.html.

Stewardship Month was partially prompted by the discovery of forgotten samples at the NIH campus. UConn PIs were asked to take time in September to review their inventories and make any necessary updates. Those who work with human materials were also reminded of the requirement to attend annual Bloodborne Pathogens training. The Biosafety team (David Cavallaro, Laina Hancock, and Tekechia Hester) conducted an inventory verification audit of laboratories registered to use infectious biological agents. Laboratories with deficient inventories were given until January 2015 to create new or revised inventories.