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Institutional Review Board IRB

Use of New UConn Visual Identity/Brand on Study Documents

As you are aware, the University has adopted a new visual identity/brand (including use of the wordmark and logos). The transition to the new visual identity/brand should be completed by June 30, 2014. The IRB recently updated the consent form, information sheet and parental permission/notification templates to reflect the new logo. Use of the old logo on consent forms has already presented issues for some investigators. For example, the IRB is aware that the Design & Document Production Center will no longer provide copy services for documents, such as consent forms, that have not adopted the University’s new visual identity. So it is important to transition to the new identity/brand.

Investigators should submit revised consent forms, recruitment material, etc., to the IRB office before June 30, 2014. This applies to printed consent forms, recruitment material, etc. Use of the visual identity/brands also extends to how the word “UConn” is represented. Note: When writing or typing UConn, please do so as “UConn” as opposed to “UCONN.” The all-caps UCONN is reserved for the logo treatment.

Use of the Husky Dog logo on documents related to human subject research is not permitted. This logo is reserved primarily for use on athletic uniforms and retail merchandise.

IMPORTANT: For studies conducted online involving the use of an information sheet with the old logo, the IRB will allow investigators to change the old logo to the new one without the need to submit an amendment to the IRB as long as the visual identity/brand is the ONLY change made to the online information sheet. Also, website set-ups as a means to recruit participants must also comply with the new visual identity/brand standards. The logo may be changed on the website without the need to submit an amendment to the IRB.

Please visit brand.uconn.edu for standards for print and web, color and logo usage; as well as downloadable wordmarks, a printable copy of the Brand Standards Manual, and other resources. As the need arises, please email brand@uconn.edu with any questions, or to ensure that your items are compliant.

Investigators are urged to contact the IRB office with questions about logo changes that require submission of an amendment and those that do not.
New No-Cost Sample Size Calculation Tool for Investigators

SampleSizeShop.org “provides educational materials and software tools to assist researcher in the study design process.” This website and its related programs have been made possible by support from the National Institute of Health (NIH). The website provides free access to the GLIMMPSE software for calculating sample size and power, tutorials related to sample size and power, and links to related sites and software. Use of SampleSizeShop.com and the GLIMMPSE software is free. As noted on the website:

“Researchers do not often have access to the statistical tools needed to create a successful study. Our goal at SampleSizeShop.org is to make accurate power and sample size outputs available to all scientists and researchers. The GLIMMPSE software provides free, user friendly power and sample size analyses to assist researchers in creating the most successful study possible. GLIMMPSE is available both online and as a free download.

In addition to the GLIMMPSE software and website, SampleSizeShop.org provides tutorials for calculating sample size and power in both written and video form, and has open forum for questions related to power and sample size analyses. While we encourage the free use of our own GLIMMPSE software, our primary goal is the adoption of the most accurate methods for power and sample size analyses.”

A link to SampleSizeShop.org will be made available from the Related Websites section of the IRB website located here - http://www.irb.uconn.edu/websites.html. Links to other UConn, State of Connecticut, Greater Hartford Area Hospital and Medical Center and Federal Government human subjects related links are also provided. In addition there are links to the CITI and HIH human participants training sites, as well as links to bioethics websites in the US and around the world.

Record Retention Policy

As noted in the IRB’s policies and procedures, investigators must maintain research records for three years beyond the completion/termination of the study, per federal regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)). This is the minimum standard. Investigators may retain research records for longer than three years. The retention of research records and procedures to maintain confidentiality of the records must be described in the protocol application and in the consent document. Research records that have been stripped of identifiable information (and the key to the code linking the code to identifiable information has been destroyed), may be kept indefinitely.

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IRB Meeting Dates
Thursday, April 24, 2014
Thursday, May 15, 2014
Thursday, June 5, 2014
Thursday, June 26, 2014
Thursday, July 17, 2014
Thursday, August 7, 2014
Thursday, September 4, 2014
Thursday, September 25, 2014
Thursday, October 16, 2014
Thursday, November 13, 2014
Thursday, December 11, 2014
New Research Study Photo/Video Release Form Template

The IRB created a new research study photo/video release form template for use by investigators - http://www.irb.uconn.edu/forms.html#templates. Please note that investigators must provide a rationale for why the use of photographs and videos of participants is necessary for the conduct of research, analysis of data, and/or publication/presentation.

2014 Edition of International Compilation of Human Research Standards


The Compilation features listings of over 1,000 laws, regulations, and guidelines on human subject protections in 107 countries, as well as standards issued by a number of international and regional organizations. The standards address such issues as informed consent, research ethics committee review, reporting requirements, vulnerable populations, and more.


The listings are organized into seven categories:

1. General Research
2. Drugs and Devices
3. Research Injury
4. Privacy/Data Protection
5. Human Biological Materials
6. Genetic
7. Embryos, Stem Cells, and Cloning

Many of the listings include a hyperlink, allowing the user to link directly to the law, regulation, or guideline of interest. The Compilation is available in both PDF and MS Word versions.

Prepared by the Office for Human Research Protections of the U.S. Department of Health and Human Services, the Compilation is designed for use by IRBs, researchers, sponsors, and others involved in human subjects research around the world. The Compilation was first published in 2005 and is updated annually.

Seeking Assistance to Test InfoEd System Enhancements

InfoEd will undergo a version update that will enhance the protocol submission process in addition to other improved capabilities. The IRB will transition to the use of online protocol application forms with the goal of having the submission process take place entirely on-line by the end of the year. The new version is currently undergoing development. The IRB is seeking faculty researchers to assist with testing the new submission process. If you would be willing to assist with the testing, please contact Doug Bradway by email at doug.bradway@uconn.edu or by phone at 6-0986.
Research Compliance Services has a New Post Approval Monitoring Program for Research with Human Participants

Research Compliance Services has welcomed Joan Levine, MPH as their new Post Approval Monitor. Joan joins us from the Health Center where she worked as a Regulatory Specialist for CICATS and Study Coordinator in the Department of Psychiatry. She assisted investigators with IRB related issues, oversaw study procedures with ethno-culturally and developmentally diverse community populations, and behavioral interventions for over 10 years. Joan has managed complex research data collection and storage systems for several externally funded epidemiologic and interventional studies.

The Monitoring Program is a resource for both Investigators and students. The Assistant Vice President for Research Compliance will oversee the program to ensure that monitoring reports will be sent to the PI’s and the Institutional Review Board (IRB), that recommendations included in the report are made, and that any issues with compliance are remediated with training and support. Joan Levine, the post approval monitor, is not an IRB member. The goal of the program is not to look for errors or deviations from the protocol, but to support investigators in fulfilling the goals of their protocol and to help ensure the protection of human subjects. We encourage Investigators and students to use this program as a resource beginning with the development of study protocols through the completion of the study.

Monitoring Process

For-cause audits will be a priority for the Monitoring Program. However, special emphasis may be placed on studies that include vulnerable populations or have activities that may place participants at greater risk than what may be anticipated in ordinary circumstances. Monitoring will be done with an emphasis on quality improvement and support for researchers. A pre-monitoring process can be completed with investigators and students before enrollment begins. This can include helping researchers prepare staff for record keeping procedures, the informed consent process, eligibility screening, form development, data storage, and study management.

Categories of Audits

Routine: Studies will primarily be randomly selected by the IRB Monitor. However, selection may include monitoring only certain elements of study activities.

- **Informed consent**: This audit is intended to support researchers in conducting the informed consent process. It may include observation (when possible) of the consent process and/or a thorough review of the process including training of people obtaining consent, and review of signatures and storing.

- **For-cause**: Under 45 CFR 46.113 requirements, this review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the IRB or the IRB Monitor. This would be an on-site review that may include a review of all or any related study activities.

  Investigator Initiated: A PI may request an on-site review to help keep records and procedures in compliance with federal regulations and institutional policies or to prepare for an external audit by a sponsor or federal agency.
Audit Notice

Except in cases where the safety of participants is a concern, or where the IRB specifically requests an unannounced audit, written notification of an audit will be sent from Research Compliance Services. Depending on the nature of the research study, an IRB member who has experience in the study topic may also be present at the audit. The Investigator will contact the Post Approval Monitor to arrange a visit.

Elements of Audit Review

Before Audit: Investigators will receive a letter informing them that their study has been chosen for an audit. The investigator will then contact the Monitor, and a time will be scheduled for the audit.

Before the audit the Monitor will review the Study Protocol and all documentation related to the study in the IRB file.

Investigators can prepare for the audit by reviewing the checklist of questions below. (Please note that not all items on the checklist apply to all research studies).

Audit Preparation Questions for PI and Research Study Team

- Does the researcher have available the most recently approved protocol, consent form, and study documents?
- How many participants are currently enrolled? How many have been approved by the IRB?
- Are all key personnel listed on Appendix A? Are personnel conducting procedures according to their role in the study?
- Have any participants withdrawn/dropped from study? If so, why?
- Have any adverse events occurred? Were any reported to the IRB?
- Are participants consented with the most recently IRB approved stamped version? Have all the consent forms been signed and dated by the participant and the person obtaining consent?
- Have all study measures and procedures been approved by the IRB before implementation?
- Are all study records stored as indicated in the protocol?
- Are all advertisements and methods of recruitment being used IRB-approved?
- Are study documents maintained as outlined in the protocol?
- Are participant ID numbers generated per protocol?
- Have all enrolled participants met eligibility criteria? Is there documentation of eligibility?
- Have there been any protocol deviations? Have they been reported to the IRB?
- Have there been any unanticipated problems with protocol implementation?
- Has participant compensation been documented?
- Have there been any participant complaints?
- Are raw data files organized, complete, and legible?
During the Audit: At the time of the audit, the Monitor will meet with the PI to briefly discuss the study. The PI will provide the Monitor with study files. The PI must make available the use of a quiet space for the Monitor to review the study files. The PI or designee who is familiar with the study will be available during the audit in case the Monitor has questions. As needed, during the audit, the Monitor will provide recommendations and educational support on record retention and documentation, and other compliance related issues. Documents pertaining to research will be held strictly confidential.

After the Audit: After the audit is complete the Monitor will meet with the PI and provide a brief summary of findings.

Report of Findings

A Summary Report will be drafted by the IRB Monitor and sent to the PI for his/her review and responses. The report will provide a detailed summary of the audit identifying areas of improvement and recommendations for improvement. The PI and the IRB Monitor will sign the report. A copy of the signed report will be provided to the Assistant Vice President for Research Compliance of Research Compliance, the PI, and the IRB Chair. When indicated, the PI will be invited to respond to each indication of non-compliance listed in the summary with a plan of corrective action for each item. This plan will be submitted to the IRB within 2 weeks of the date of the summary.

It is anticipated that in most cases serious violations involving risk of injury to participants will have already been reported to the IRB. However, if an audit demonstrates that a serious violation involving risk of injury to participants has not been reported, it will be reported immediately to the IRB Chair, Assistant Vice President for Research Compliance, and to the Vice President for Research (or his/her designee).

If you have questions regarding the auditing process or would like to schedule a time to meet with Joan for an individual or group education session please contact:

Joan Levine, MPH  
Post Approval Monitor  
Phone (860) 486-7145  
e-mail: joan.levine@uconn.edu

For a full description of the Monitoring Program, please visit: http://irb.uconn.edu/monitoring_program.html
UConn Stem Cell Lines Are Now Global

An agreement was recently signed between KeraFast, which is a global supplier of biological research tools and the University of Connecticut. This agreement will help ease the ability for institutions to obtain stem cell lines. KeraFast will aid in speeding up the licensing process so that institutions will receive their materials quickly and more efficiently. The University of Connecticut’s two lines will be distributed worldwide to test and compare findings in standardized stem cell models for personalized medicine and other applications. These cells were developed at the University of Connecticut in 2009. These cells were generated from skin cells from patients who developed Angelman Syndrome and Prader-Willi Syndrome, two rare neurogenic disorders. UConn hopes that by making the lines more available it will broaden research base and eventually expanding it’s use to common disorders such as Autism and Schizophrenia.

Information:

April Semi-Annual Inspection Cycle

In an effort to standardize our inspection and program review process we have formalized the creation of two inspection cycles per year. These inspections will always fall in the months of April and October. Expect the IACUC office to contact you to schedule an inspection of your lab or other decentralized animal procedure area. Feel free to contact our office if you have questions about the inspection process, or how to prepare!

Training

IACUC classroom training times have been changed to reflect the new class schedule at UConn. Classroom trainings are held in Whetten Rm 200; sessions typically fall on the first Wednesday of each month from 12:15-1:30. Visit our website for more training information, including an updated class schedule: http://iacuc.uconn.edu/training.html.

IACUC Protocols-Spotlight on the “Project Overview”

Have you ever wondered what the IACUC expects you to include in the project overview section of the protocol form? This section requests a broad overview of the work that you are proposing and justification for the project by describing the benefits it may impart. It should be written in layman’s language not grant language. Where scientific terms are unavoidable, they should be defined as simply as possible.

Some researchers find it helpful to imagine how they would describe their work to a reporter writing a story on their project. Others find it helpful to imagine describing it to their mother or their teenager. However, you choose to approach this task, think about the context: Why the work may be an important contribution to animal or human health. Give a bird’s eye view, broad strokes, keep it simple, and save the details for the Procedures section of the form.

If you are having trouble, give us a call at the IACUC Office (860-486-4110), we may be able to assist you!

The intersection of EH&S and the IACUC

Have you ever felt like you are mired in an alphabet soup of acronyms? We, in the IACUC Office certainly do! EH&S? IACUC? OSHA? OLAW? APHIS? EPA? ANSI? It’s all COMPLIANCE! Isn’t it?

Yes and No.

There are important distinctions from the background regulatory framework and enforcement agencies to the specific day to day operations and forms that ultimately impact you as a researcher. In future editions of GUIDELINES, we will highlight where EH&S and IACUC differ and where they intersect with a focus on the specific programs and processes at UConn. Stay tuned!
Welcome

Research Compliance Services would like welcome Tekechia Hester (Kechia) our new IBC Program Specialist. Kechia comes to us from Plum Island Animal Disease Center (PIADC). There she worked as a research scientist with the Department of Homeland Security, Science and Technology (DHS) branch. While at PIADC she partook in foot and mouth disease virus (FMDV) bovine and swine clinical trials and biotherapeutic studies. Her background includes developing molecular based assays as well as serving as a liaison between the scientific staff and the biosafety office. She has participated in numerous select agent safety audits with third-party auditors including the United States Department of Agriculture (USDA) and DHS regulatory compliance office. Other notable contributions include collaborating with DHS IT, USDA’s Animal and Plant Health Inspection Service and Agricultural Research Service with the creation, design and implementation of a traceable select agent database system. Kechia has played a significant role in maintaining DHS’s compliance to federal regulations.

Here at UConn she will be tasked with managing the IBC program. We would like to again welcome Kechia to UConn. If you have any questions regarding the IBC please feel free to contact her at 6-1838 or tekechia.hested@uconn.edu

Top 10 IBC Registration Questions

Q1: How do I register my research project with the IBC?

All forms are available on-line on the IBC webpage http://ibc.uconn.edu/forms

Q2. How can you receive assistance regarding technical questions or the submission process of my registration form?

Contact Research Compliance Services at IBC@uconn.edu or call 860-486-1838.

Q3. What type of research must be registered with the IBC?
All research conducted by UConn employees or students involving biohazardous material or agents listed below, must be approved by UConn IBC prior to initiation:

Pathogens and potential pathogens of humans, animals, or plants;
Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines);
Recombinant and Synthetic Nucleic Acid Molecules including creation or use of transgenic plants and animals.

**UConn does not allow the possession, use, or transfer of Select Agents or Toxins that would require registration with USDA or the CDC**

**Q4. I do not receive funding from the NIH am I required to register my project with the IBC?**

Yes. **ALL** research utilizing biohazardous material or agents are subject to IBC oversight and require IBC approval. The source of the funding does not alter this requirement.

**Q5: How long is my approval for?**

Each registration shall be active for a maximum period of three (3) years. The term period is noted in the approval letter. At the end of the term the registration expires. A courtesy e-mail will be sent to the PI in advance of the expiration date.

**Q6. My research has changed; do I need to modify my IBC registration?**

Yes. You must inform the IBC of any changes to you IBC registration. An amendment must be submitted for IBC review and approval prior to being implemented. An exception may be made when the changes are necessary to eliminate apparent immediate hazards to human health or the environment.

**Q7. Why is the project design of my research important?**

The project design allows the IBC to properly classify and assess all biohazard risks associated with your proposed research project. This section of the registration does not need to be too lengthy or detailed, but should include all manipulations with biohazardous material, including Infectious Biological Agents/Toxins and Recombinant or Synthetic Nucleic Acid Molecules.

**Q8. What if I’m unsure of which NIH Guidelines sections apply to my research?**

If you are unsure which sections of the *NIH Guidelines* apply to your research, you may leave these sections blank. The IBC will review your submission and ensure that the correct section of the *NIH Guidelines* (if one applies to your research) is selected.

**Q9. Where can I find the risk group of agents I’m working with?**


**Q10. Where can I find additional information regarding UConn’s IBC program and/or concerning recombinant or synthetic nucleic acids?**

UConn Institutional Biosafety Committee website:  [http://ibc.uconn.edu](http://ibc.uconn.edu)
Office of Biotechnology Activities News

The Office of Biotechnology Activities has released a new revision of *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* in November 2013. Amendments include two minor actions with the additions to Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazards*. Please see the insertions below.

**Appendix B-II-A. Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia**

– *Pseudomonas aeruginosa*

**Appendix B-III-D. Risk Group 3 (RG3) – Viruses and Prions**

Coronaviruses

– Middle East respiratory syndrome coronavirus (MERS-CoV)