

Partial Regulatory Overview for Research at the UCHC (11/2006)

Issues (What you want to do in research)	Biohazards & Use of non-exempt rDNA host/vector/ DNA of interest systems	Use of vertebrate animals in research, or in testing or training of students	Use of humans , identifiable human products or identifiable information in research.	Procurement of all hESC lines for <i>in vitro</i> and animal studies and Clinical trials	Procurement and Use of Radioactive Materials, Xrays and Lasers	Procurement and use of Hazardous Chemicals
What you have to do before you do what you want to do. <u>Note:</u> Compliance to some of these things is prerequisite to funding, especially continuations.	For funding, a PI must follow the NIH rDNA Guidelines as well as the rules to the right. For Sect. III-D experiments get registration approval. See http://ors.uchc.edu/bio/ibc/ibc.html . For work with non rDNA human or infectious materials; OSHA Bloodborne Pathogen Standard or CT DPH registration respectively. Trainings required.	In order to use animals in experiments at the UCHC, you need to have an approved ACC protocol and have training.	In order to use humans or identifiable human products or information in your experiments you need to have an approved IRB protocol and have training.	In order to use hESC & receive state hESC funding, some or all of the approvals to the left as well as ESCRO approval are needed. For human use development, FDA's GLP/GMP may be needed. http://www.escro.uconn.edu	In order to use radioactive materials and radiation producing instruments you need to be licensed with the Office of Radiation Safety and have training. http://ors.uchc.edu	Adhere to Chemical Hygiene Plan Policies http://www.ors.uchc.edu/ehs/CHP-index.html and participate in Laboratory Safety Training
Whom to contact: UCHC Oversight Committee (UCHC Name) & Contact	UCHC Institutional Biosafety Committee (IBC); IBC Coordinator/Biological Safety Officer: Ron Wallace; rwallace@adp.uchc.edu ; x3781;	UCHC Animal Care Committee (ACC); ACC Coordinator: Alison Pohl; pohl@uchc.edu ; x4129	UCHC Institutional Review Board (IRB); IRB Coordinators – see web: http://resadm.uchc.edu/hspo/index.html	UConn & UCHC ESCRO Committee; contact Dr. Hiskes: anne.hiskes@uconn.edu (860) 486 2215	UCHC Radiation Safety Committee (RSC); Asst. Rad. Safety Officer: James Fomenko; fomenko@adp.uchc.edu ; x3817	Office of Research Safety (ORS); Chem. Hygiene Officer: Steve Jacobs; Jacobs@adp.uchc.edu ; x2723
Consequences of non-compliance.	<i>Institutional:</i> Freeze PI's funding; <i>Federal:</i> Sanctions against the PI and their funding OR the Institution and its funding. OSHA fines. <i>State:</i> ConnOSHA fines. Shutdown by the CT Department of Public Health (CT DPH).	<i>Institutional:</i> Protocol suspension; permanent withdrawal of animal use privileges. <i>Federal:</i> Loss of funding; Loss of Institution PHS Assurance; Loss of AAALAC accreditation; Suspension/ withdrawal of USDA Facility Registration	<i>Institutional:</i> Protocol suspension; permanent withdrawal of human research privileges. <i>Federal:</i> Loss of funding; Loss of Institution PHS Assurance; Loss of AAHRPP accreditation; Suspension	Legal sanctions against researchers who research with non-approved hESC lines using federal funding.	Sanctions up to and including suspension of privileges; Fines against the Institution.	Institutional Sanctions; Fines against the Institution.
Federally Mandated Local Oversight by Committee (Federal Name) or Institutional Office	Institutional Biosafety Committee (IBC)	Institutional Animal Care and Use Committee (IACUC)	Institutional Review Board (IRB)	Embryonic Stem Cell Research Oversight (ESCRO) committee [but not fed. Mandated]	UCHC Radiation Safety Committee & the Office of Research Safety	Office of Research Safety
Authority	NIH rDNA Guidelines (nihG); Biosafety in Microbiol. and Biomed. Labs (BMBL) OSH Act and UCHC Policy	Animal Welfare Act, Public Health Service Policy on Humane Care and Use of Laboratory Animals and UCHC Policy	Department of Health and Human Services Regulation – Protection of Human Subjects 45CFR 46	Involvement of all of the mechanisms to the left and right, State Statute and Institutional Policy.	Nuclear Regulatory Agency (NRC); Food and Drug Admin. (FDA); CT Dept. of Envir. Protection (CT DEP)	OSHA HazComm & Lab Std. 29CFR 1910.1200 & ~.1450; EPA RCRA 40CFR... ; CT State Statutes
Federal Oversight Agency(ies)	NIH Office of Biotechnology Activities (NIH OBA);	Office of Laboratory Animal Welfare (OLAW); USDA Animal and Plant Health Inspection Service (APHIS)	DHHS Office for Human Subject Protections, Division of Compliance Oversight (DCO), FDA	Same as all those to the left.	NRC; FDA	Environmental Protection Agency (EPA)
State Oversight Agencies	CT DPH; ConnOSHA	CT DPH – for use of dogs	NA	NA (yet)	CT DEP	ConnOSHA CT DEP