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Responsible Conduct of Research and Research Compliance

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Responsible Conduct of Research (RCR)

Responsible Conduct in Research (RCR) | UT Tyler Office of Research, Scholarship, and Sponsored Programs

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RCR Training

- Conducting research with integrity requires more than the scientific or technical expertise essential to carry out a research study. Acting with integrity in research entails the ability to identify and respond appropriately to the ethical questions that inevitably arise throughout the research process.

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RCR

"All of these compliance rules and regulations are such a bother. I never thought we actually had to read our policies and procedures."

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RCR Training

- **All UT Tyler faculty, staff, and students involved in research activities must take Responsible Conduct of Research training offered by the university. This training is provided by the university and is available through Collaborative Institutional Training Initiative (CITI Program). Once completed, the certification is valid for three years.**
- **CITI: Online RCR training is provided by the Collaborative Institutional Training Initiative (CITI).**

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RCR CITI Training Instructions

Step 1– Create an account or Sign into CITI Training.
Step 2 – Click on “View Courses”
Step 3 – Click on “Add a Course”
Step 4 – Go to Question #3
Step 5 – Select an RCR option, and click on “Submit”
Step 6 – At this point you will see the Assurance Statement; click on “I agree” and then on “Submit”
Step 7– Start the first module; you can choose either “Audiovisual”(spoken narrative) or “Classic” (text only) option for each module
Step 8 – Once you’ve completed the relevant RCR module, please select the link for the “Quiz” and complete the questions for credit. Participants must obtain a score of 80% or higher on each quiz. When a passing score is achieved, the quiz will be marked “COMPLETE”. You will then have access to the next module.
Step 9 – Complete all 7 modules
Step 10 - You will receive an e-mail with a permanent link that may be used to access or share your Completion Report and Completion Certificate. It is not necessary to log in to the CITI Program site to view these links. We suggest you retain this email for your records.

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RCR Training

Authorship Issues

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Authorship/Publication

All authors should have been directly involved in all three of the following:
- **planning and contribution to some component (conception, design, conduct, analysis, or interpretation) of the work which led to the paper or interpreting at least a portion of the results,**
- **writing a draft of the article or revising it,**
- **final approval of the version to be published. All authors should review and approve the manuscript before it is submitted for publication, at least as it pertains to their roles in the project.**

Adopted from Yale University Guidelines

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Authorship/Publication Continued

The first author **is usually the person who has performed the central experiments of the project. Often, prepares the first draft of the manuscript.**

The corresponding author: **responsible for ensuring that all other authors meet the requirements for authorship; ensuring the integrity of the work itself; overall responsibility to all facets of work.**

Co-Author(s): **Performed some of the experiments or contributed to other aspects of scholarly activities; each co-author is responsible for considering his or her role in the project and whether that role merits attribution of authorship; co-authors should review and approve the manuscript, at least as it pertains to their roles in the project.**

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Authorship/Publication Continued

The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following 4 criteria:

- **Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND**
- **Drafting the work or revising it critically for important intellectual content; AND**
- **Final approval of the version to be published; AND**
- **Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.**

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Authorship/Publication Continued

Individuals should not be added as co-authors based on the individual's stature as an attempt to increase the likelihood of publication or credibility of the work. Further, routine technical services, to refer patients for a study, to provide a valuable reagent, to assist with data collection and assembly, or to review a completed manuscript for suggestions do not warrant the authorship. Senior faculty members/department chairs/lab director etc. should be named as co-authors on work independently generated by their junior colleagues only if they have made substantial intellectual contributions to the experimental design, interpretation of findings and manuscript preparation.

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Authorship/Publication Continued

Determinations of authorship roles are often complex, delicate and potentially controversial.
To avoid confusion and conflict, discussion of attribution should be initiated early in the development of any collaborative publication (if possible before the study starts).
If the roles are changed during the investigation, re-evaluate the attribution with honest and open dialogue with other investigators involved in the project.

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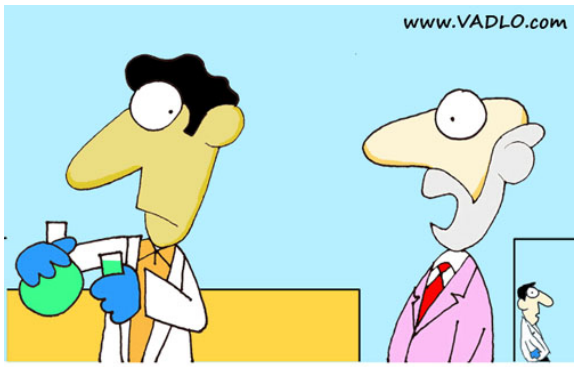
Authorship/Publication Continued



"No, it's my wife's turn to be the first author on **your** paper."

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IACUC – Institutional Animal Care and Use Committee

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IACUC Responsibilities

- **Primary Concern is animal welfare**
- **Responsible for overseeing and evaluating all aspects of animal care and use and is charged with reviewing proposals that involve animals to ensure that the criteria established in the Public Health Service (PHS) Policy, and the Animal Welfare Regulations are implemented.**

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IACUC Functions

- **Review the animal program (encompasses anything that could have a negative impact on the health or wellbeing of animals).**
- **Inspect animal facilities.**
- **Review animal care and use concerns.**
- **Review and approve, require modifications in (to secure approval), or withhold approval of proposed animal activities.**
- **Conduct continuing review of previously approved, ongoing activities.**
- **Institutions receiving Public Health Service support for animal activities must base their animal care and use programs on the 8th edition of the Guide for the Care and Use of Laboratory Animals.**

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Animal Welfare Assurance

- Institutions receiving federal funding for projects involving animal use must be registered with the Office of the Laboratory Animal Welfare (OLAW) and have an approved Animal Welfare Assurance (Assurance).
- As described on the OLAW website the Assurance contains:
- a commitment that the institution will comply with the PHS Policy, with the Guide for the Care and Use of Laboratory Animals, and with the Animal Welfare Act and Regulations;
- a description of the institution's program for animal care and use; and
- the designation of the Institutional Official responsible for compliance.

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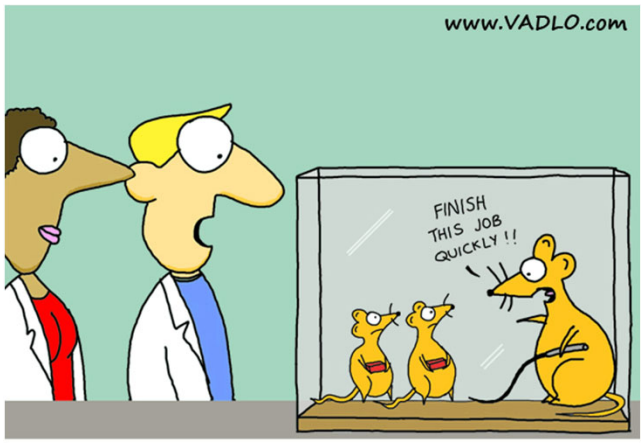
Using Animals in Research



"We call him mouse model of PI."

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IBC – Institutional Biosafety Committee

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IBC Responsibilities

- Reviewing recombinant or synthetic nucleic acid molecule research and educational activities conducted at or sponsored by the institution for compliance with the NIH Guidelines and approving those research projects that are found to conform with the NIH Guidelines.

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IBC Responsibilities Continued

Transgenic Animals:

1. **Made by a vendor – local IBC approval is required**
2. **Breeding of transgenic strains at the UTT – IBC protocol maybe needed**

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Hazardous Chemicals

- **The IBC also oversees the use of hazardous materials**
- **When ordering a hazardous chemical that is not currently listed on PI's lab chemical inventory (new use chemical) or other biohazardous material (such as tetracycline), an application for approval to use carcinogenic, highly toxic, or acutely hazardous chemicals must be submitted to the committee for approval.**
- **Each PI is responsible for training laboratory personnel in the health risks associated with the material, required personal protective equipment for working with the material, safe handling of the material, and proper storage and disposal of the material.**

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Hazardous Materials

1. Formal HC policy approved by the IBC.
2. Help with SOPs is available.

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IORRC – Infectious Organism Research Review Committee

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IORRC Responsibilities

- Reviews protocols for research projects involving biosafety level 2 (BSL2) and biosafety level 3 (BSL3) infectious organisms and infectious materials.
- Advises researchers on safe procedures for handling infectious agents.
- Oversees rules, regulations, and procedures governing the use of research BSL3 facilities at the UTT HSC Campus.
- Updates Principal Investigators on new federal, state, and local laws, rules, and regulations regarding infectious agents.

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MTAs

- A Material Transfer Agreement (MTA) is required in most cases when:
- Samples, animals, or other materials are sent from another state or country.
- Samples, animals, or other materials will be sent to another state or country.
- Please note that the MTAs from many companies do not allow transfer of material to other investigators within the same institution or transfer to another institution even if the investigator changes institutions.

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Controlled Items

- Applies to chemical precursors and certain laboratory apparatus that could be used to manufacture illicit drugs (based on the Memorandum of Understanding [MOU] between the Department of Public Safety [DPS] and THECB [Texas Higher Education Coordinating Board]).
- For questions on controlled items, contact the Associate VP for Research Compliance, Anna Kurdowska, Ph.D.

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Erlenmeyer Flasks

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Filtering Flask

Florence Flasks / Round Bottom Flasks

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Filtering Funnels

Buchner Funnel

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Precursor Chemicals

Methylamine	Red phosphorus
Ethylamine	Hypophosphorus acid
D-lysergic acid	Phenylpropanolamine
Ergotamine tartrate	Norpseudoephedrine
Diethyl malonate	Pseudoephedrine
Malonic acid	Anthranilic acid
Ethyl malonate	Ephedrine
Barbituric acid	Phenylacetic acid
Piperidine	Pyrrolidine

Added: Phenethyl bromide, Propionyl chloride, and Sodium borohydride

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NIH Grants - PHS Policy

Just in Time or JIT:

Institution must make sure that all proposed animal and / or human subjects' experiments are covered by a valid protocol or protocols.

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Shipping

Shipping Infectious Substances, Biological Substances, and Related Hazards Training

- **Applies to dry ice as well which is considered a hazardous substance.**
- **Provided as on-line training as needed.**
- **At least one employee from every lab needs to complete this training.**
- **Certificate is valid for 2 years.**

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Shipping Continued

The Toxic Substances Control Act (TSCA) places requirements on those importing chemicals into, or exporting chemicals out of, the customs territory of the United States.

- **Imports of chemical substances, mixtures or articles that contain a chemical substance or mixture must comply TSCA (section 13) in order to enter the US.**
- **Under TSCA section 12(b), any person who exports or intends to export a chemical substance or mixture that is subject to certain TSCA regulations is required to notify the Agency.**

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Shipping Continued

Additional regulations (USDA and / or CDC) may apply to the following:

- **Receiving samples, animals, infectious organisms or other materials from another state or country.**
- **Shipping samples, animals, infectious organisms or other materials to another state or country.**

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Research Security Officer and Policy Framework

1. **Cybersecurity**
2. **Foreign influence**
3. **Export Controls**

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Export Controls

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Overview of Export Controls

- In addition to activities involving military items or weapons, it is critical to note that many normal, everyday University activities are subject to Export Controls, including:
  - Traveling overseas on University business (e.g., conferences, conducting field work, international symposia),
  - Research collaborations with foreign nationals (here or abroad),
  - Visits or tours of research facilities by foreign nationals,
  - Sponsoring research (e.g., via a subcontract) to an embargoed or sanctioned country, and
  - Providing professional services (e.g., consulting) internationally or to problematic end-users.

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Summary of Export Controls

- **Export Controls apply to all international university activities, not just to shipping equipment overseas and not just to research.**
- **If your activity includes interaction with international entities or individuals, an Export Control assessment will need to be done to determine if an export license is needed.**

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Intellectual Property Advisory Committee (IPAC)

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IPAC Functions

- An investigator notifies IPAC Chair that they want to present a new invention.
- Chair organizes a meeting.
- IPAC reviews the disclosure and makes a recommendation whether to proceed with patent application.
- The Chair communicates with Dr. Calhoun and patent attorney.
- Contact: akurdowska@uttyler.edu or anna.kurdowska@uthct.edu

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Intellectual Property

- Patents – protect inventions = a discovery or finding

- Invention must be:
- Novel – new – not known before; not a product of nature.
- Useful – has utility, specific, and credible.
- Non-obvious – was not obvious to a person having ordinary skill in the area of the invention.

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Intellectual Property

- "Intellectual property (a) developed within the course and scope of employment of the individual, (b) resulting from activities performed on U. T. System time or with support of state funds, or (c) resulting from using facilities or resources owned by the U. T. System or any U. T. System institution (other than incidental use) is owned by the Board of Regents."

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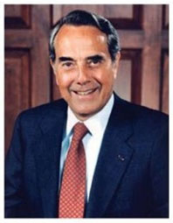
Intellectual Property


Birch Bayh


Bob Dole

- **Bayh-Dole Act:** Recipients of grants, cooperative agreements, or contracts have the right to retain title to inventions supported by federal funds. However, they must comply with regulations (37 CFR 401 et seq.) so the technology can be timely transferred to the public sector.
- For example, they must use Interagency Edison (iEdison) to report inventions (disclosures), post provisional, nonprovisional, Patent Cooperation Treaty (PCT) patent applications, and awarded patents.

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