# RESPONSIBLE CONDUCT IN RESEARCH [RCR] "Training Implementation Plan"

For additional information please contact the Office of Research Compliance at: research.compliance@aamu.edu

James O. Bukenya, Ph.D



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# Compliance with:



CFR Part 200: Implemented Dec. 26, 2014



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### The Super Circular

CFR Part 200: Implemented Dec. 26, 2014







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# 1. Uniform Guidance





United States Department of Agriculture

National Institute of Food and Agriculture

NSR

✓ NIFA, NSF, SBA, DOD, NIH, ... requires all program directors, faculty, graduate students, undergraduate students, postdoctoral researchers and staff who are paid from NIFA, NSF, SBA, DOD, NIH, ... grants to receive mandatory training in **Responsible Conduct of Research (RCR)**.

✓ The RCR training provided to each individual must be documented and is <u>subject to agency review</u>.



















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# Compliance



### AAMU Training Requirement

✓ To comply with NIFA, NSF, NIH and other Federal and State regulations, AAMU requires all PIs, faculty, graduate students, undergraduate students, postdoctoral researchers and staff who are paid (salary and/or stipend) directly from NIFA, NSF, NIH or any other Federal and State sponsored project to complete the Mandatory RCR Training.



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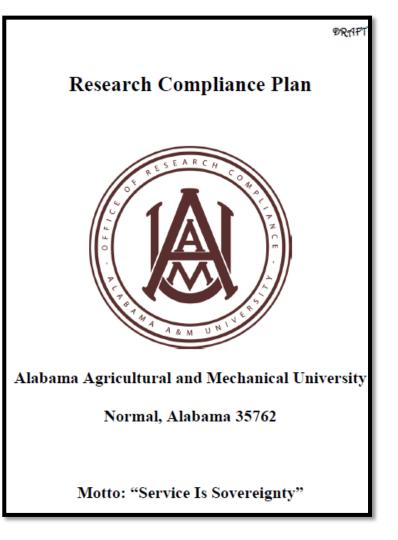
# Does your research or university service involve:

- Human Subjects?
- Animals?
- Recombinant DNA?
- $\circ$  Chemicals or other Hazardous Materials?
- Radioactive Materials?
- Shipment of Hazardous Materials?
- Biological Safety Cabinets?
- X-rays or Lasers?
- International Transport of Materials, Supervision of Foreign Nationals, or Sharing Scientific Information Abroad?
- Inventions, Patents, Materials Transfer, or Other Intellectual Property Issues?
- Outside Activities that May Pose Conflicts of Interest?
- Closing or Moving a Laboratory?



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# 2. Internal Controls





I will need your help here ....



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# The Office of Research Compliance will Offer RCR Training through CITI



Collaborative Institutional Training Initiative at the University of Miami

The **Training** will be on-line and free to AAMU research community. It will covers the following topics:

- ✓ Research Misconduct
- Data Acquisition and Management
- ✓ Responsible Authorship
- ✓ Peer Review
- ✓ Laboratory Animal Welfare
- ✓ Human Subjects Protections
- ✓ Mentoring
- ✓ Conflicts of Interest
- ✓ Collaborative Research

- ✓ Good Clinical Practices
- ✓ Information Privacy and Security
- ✓ Animal Care and Use
- ✓ Biosafety and Biosecurity
- ✓ Disaster Planning for the Research Enterprise
- ✓ Export Control
- ✓ Good Laboratory Practices



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# The Office of Research Compliance will Offer RCR Training

### To access and complete this <u>mandatory</u> training:

- 1. Go to https://www.citiprogram.org/default.asp.
- 2. Click "Register"
- 3. Under "Select Your Organization Affiliation" or "Participating Institutions" type in or select "Alabama A&M University". Leave the other fields blank
- 4. Click "Continue to Step 2".
- 5. Complete the personal information section
- 6. Click "Continue to Step 3".
- 7. Use your Banner ID as your user name, create a password and fill in the remaining fields, then press submit.
- 8. Complete your profile
- 9. In Step 7 of the registration process, there are questions to determine your course enrollment.
  - <u>Question 6</u> pertains to the RCR course. Click the button next to the topic that pertains to your unit and click "Submit" at the bottom of the page.
  - Review of the required materials and completion of the quizzes will take about 30-35 minutes per topic.
  - Multiple sessions may be used to complete your course. The program will
     "remember" your progress and a certificate will be generated upon completion. A
     minimum aggregate score of 80% is required to pass the course.
  - Upon completion, you will be able to print a course completion certificate. Please print and retain for your records. Also, an e-mail will be sent to the Office of Research Compliance when you have completed the RCR course.



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### The Office of Research Compliance will Offer RCR Training

 Collaborative Institutional Training Initiative at the University of Miami
 Search Knowledge Base
 Collaborative Institutional Training Initiative At the University of Miami

 Main Menu
 My Profiles
 My CEUs
 My Reports
 Support
 Admin

Main Menu > Add Course/Update Learner Groups

### Select Curriculum - Alabama A&M University

\* indicates a required field.

View instructions page

### Question 1

### Human Subjects Research

Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

#### Choose one answer

- O College of Agricultural, Life and Natural Sciences
- O College of Business and Public Affairs
- O College of Education, Humanities, and Behavioral Sciences
- O IRB Members
- Not at this time.



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### The Office of Research Compliance will Offer RCR Training

# Required: Everyone must take

### Responsible Conduct of Research

Please make your selection below to receive the courses in the Responsible Conduct of Research.

#### Choose one answer

**Question 6** 

- O College of Agricultural, Life & Natural Sciences
- College of Business and Public Affairs
- O College of Engineering, Technology & Physical Sciences
- $\bigcirc$  College of Education, Humanities, and Behavioral Sciences
- Students
- Research Administration
- O Not at this time.

#### \* Question 7

Would you like to take the Conflicts of Interest course?

#### Choose one answer

Yes
No



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# Research Involving Human Subjects



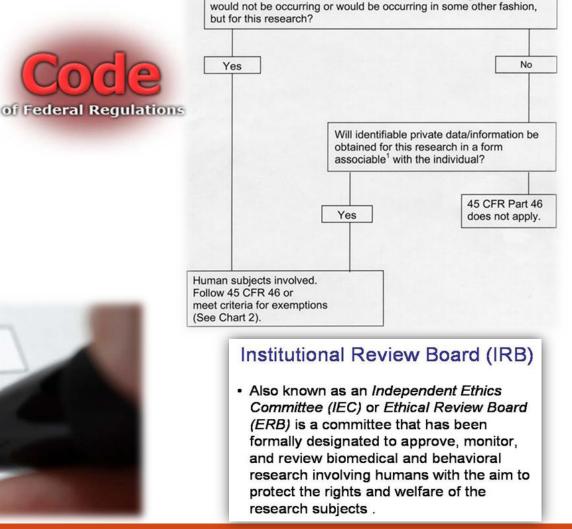


# Does your research or university service involve Human Subject?

- >A human subject is defined by federal regulations as "a living individual about whom an investigator conducting research obtains:
  - data through intervention or interaction with the individual, or
  - 2) identifiable private information."







Is there an intervention or an interaction with a living person that



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WE DON'T SMOKE. WE DON'T DRIVE. WE DON'T WEAR MAKE-UP OR PERFUME. WE DON'T USE PAINT. WE DON'T DRINK ALCOHOL. WE DON'T DROP BOMBS. WE DON'T TAKE DRUGS. JUST BECAUSE YOU DO, WHY SHOULD WE SUFFER?



# Research Involving Animals



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# Research or university service involving Animals

Laboratory animals or animals: Any vertebrate animal (e.g., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

Animal use: The proper care, use, and humane treatment of laboratory animals produced for or used in research, testing, or teaching.

Animal biosecurity includes all measures to control known or unknown infections in laboratory animals.

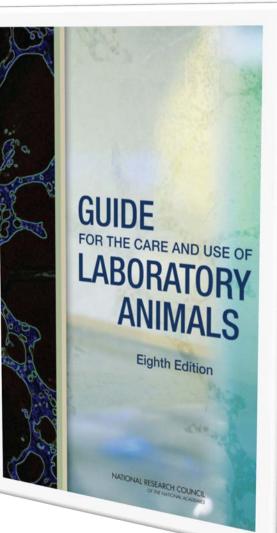


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# If your research or university service involve Animals

### Then you need to:

- ✓ Complete <u>Animal Care and Use Training</u>
- ✓<u>Obtain approval</u> from the IACUC before beginning any project using live vertebrate animals
- ✓ Appoint a Laboratory Animal Coordinator and have your coordinator complete required species-specific <u>hands-on training</u>
- ✓ Submit <u>medical history registration form</u> for all animal handlers and caretakers
- Order research animals, arrange facilities, or identify and talk with a veterinarian about veterinary or technical services

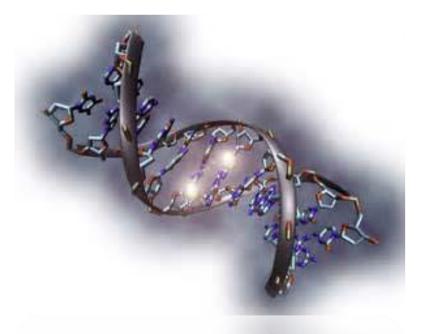






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# Research Involving Recombinant DNA



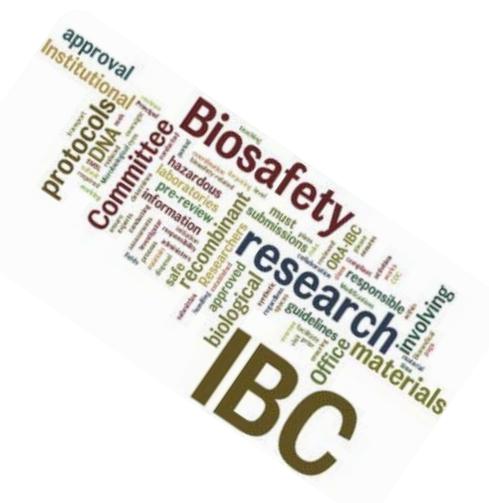
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### If your research involve Recombinant DNA/Human Gene

Research Involving the Following Materials Must be Reviewed and Approved by the IBC:

- Recombinant DNA
- Infectious Agents
- Human-Derived Materials
- HHS/USDA Select Agents or Toxins

All labs conducting research with the materials indicated above must be inspected annually





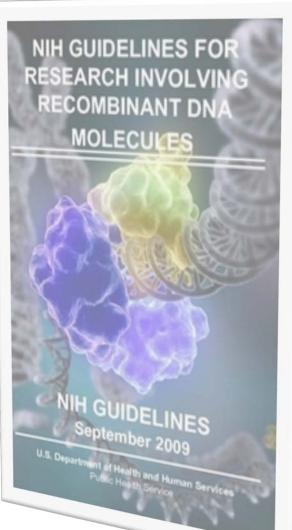
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# If your research involve Recombinant DNA/Human Gene

Then you need to:

✓Review "Responsibilities of Researchers using recombinant DNA/human gene transfer experiments" to determine whether your experiment is exempt or requires approval

- ✓ Complete the <u>Recombinant DNA and Human Gene</u> <u>Transfer Training</u> required for all investigators and staff who are using Recombinant DNA/Human Gene Transfer Experiments
- ✓ Register your experiment with <u>the Institutional</u> <u>Biosafety Committee (IBC)</u> and obtain approval before starting your research







# If you work with Chemicals or other Hazardous Materials

Then you need to:

- ✓ Review the Office of Environment, Health and Safety (EHS) <u>Laboratory Safety Manual</u>
- Develop a <u>Laboratory Safety Plan</u> (LSP) addressing hazards and precautions in your specific laboratory
- ✓ Complete the <u>Safe Use of Hazardous Materials Training</u> required for all investigators and staff who work with chemicals or other hazardous materials
- ✓Ensure training of laboratory personnel in LSP procedures and appropriate use of <u>Material Safety Data Sheets</u>



Friday 8:00 a.m. to 5:00 p.m. call x7273

Holidays, and in case Env. Health and Safety sonnel cannot be reached, please call 911

Hours: Call 343-9645







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# Research Generating Hazardous Waste in the Laboratory

- ✓ Know the options and requirements for disposal of biological, chemical, and radiological wastes
- ✓ Submit online requests for waste pickups









ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

Hazard Identity: \_\_\_

Permit Holder's Name:

### In Case of an Emergency

Monday - Friday 8:00 a.m. to 5:00 p.m. call x7273 After Hours: Call 343-9645

On Holidays, and in case Env. Health and Safety Personnel cannot be reached, please call 911



## If you use Biological Safety Cabinets

- ✓Get your cabinets reviewed and approved by the Office of Health and Safety:
  - At time of purchase,
  - installation,
  - whenever they are moved,
  - prior to use, and
  - periodically thereafter
- ✓<u>Report any concerns</u> regarding the use of biological safety cabinets to the office of EHS or the Research Compliance Officer [email: researchcompliance@aamu.edu].







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# Do you Work with X-Ray Machines or Operate Lasers?

- ✓Get approval from Radiation Safety Office before acquiring equipment
- $\checkmark$  Develop written safety plan and safe operating procedures
- Acquire the necessary training:
  - At a minimum, the training must include basic instruction on the following topics:
    - the biological effects of laser radiation,
    - the physical properties of lasers, including specular and diffuse reflection,
    - access control,
    - use of protective eyewear,
    - control of related non-beam hazards, including electrical safety, fire safety, and chemical safety related to handling and storage, and
    - emergency response procedures.









# Does your Research or University Services involve:

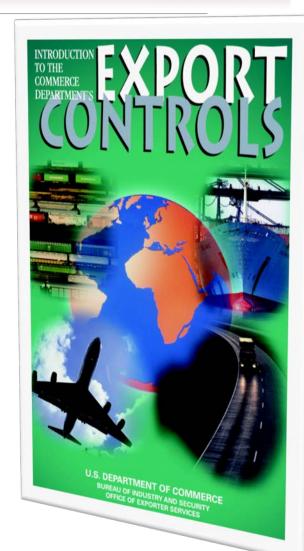
- ✓International Shipping, Mailing, or Transport of research materials, equipment, or scientific samples?
- ✓ Supervise Foreign Nationals engaged in research?
- ✓ Travel Abroad to Present Results, Consult with others, or otherwise Share Scientific Information with international colleagues?

Then:

Review the university Policy on Export Control

Consult the Office of Research Compliance for guidance specific on international travel, sponsored research, and shipping







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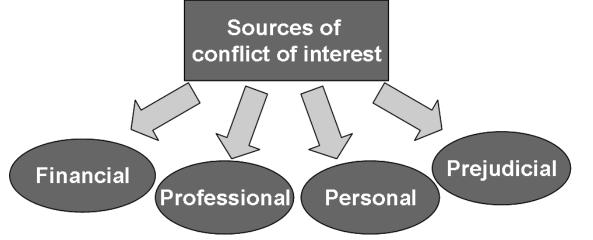
# Do you Have Conflict of Interest:

✓ Such as Financial Relationships, Time Commitments, or other interests that may compete with your University responsibilities?

Then:

Review the University's "Policy on Conflicts of Interest and Commitment" online

Complete the project-specific evaluation form for possible conflict of interest for each sponsored research application and IRB protocol





You have a conflict of interest if, in the environment of offering an opinion, reaching a judgment, or making a decision, you have

- (nonmoral) personal interests or
- inappropriate business or professional interests

that conflict with the appropriate interests to be taken into account,

regardless of whether or not the presence of those competing interests affects your judgment.





# Are you Closing or Moving a Laboratory?

 Remove all materials, including chemicals and biologicals
 Clean and decontaminate laboratory and storage areas
 Contact the Office of Environment, Health and Safety (EHS) at least 60 days prior to vacating

 ✓ Contact Institutional Animal Care and Use committee (IACUC) to terminate any animal use protocol or amend protocol to name new principal investigator



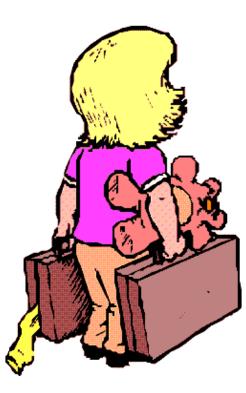








# Are you going to be on Sabbatical or absent for more than 30 days?



- ✓ Appoint someone familiar with procedures to provide laboratory oversight in your absence
- Empower a co-investigator to make necessary decisions on animal use protocols

Contact IACUC if you have questions....





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