The University of Arizona’s Responsible Conduct of Research Program

Scott Pryor
Training Program Manager
Office for Research & Discovery
PROGRAM GOALS

- Provide quality, discussion-based instruction in responsible conduct of research and scholarship
- Provide a flexible means for eligible individuals supported by NIH, NSF, and NIFA to fulfill their federal training requirements.

All are welcome to participate!
WHAT IS RESPONSIBLE CONDUCT OF RESEARCH?

- Practicing good citizenship within the academic community
- A combination of best practices, guidelines, and ethical standards
- Professional development
- A means of helping to maintain public trust in the scientific enterprise
# FEDS REQUIRE IT, BUT DO WE REALLY NEED IT?

<table>
<thead>
<tr>
<th>Article</th>
<th>Year of retraction</th>
<th>Cites before retraction</th>
<th>Cites after retraction</th>
<th>Total cites from journals indexed by Web of Science</th>
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<tbody>
<tr>
<td><strong>1. Visfatin: A protein secreted by visceral fat that mimics the effects of insulin.</strong> SCIENCE, JAN 21 2005</td>
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<td>Tanaka M, Kishimoto K, Matsuki Y, Murakami M,</td>
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<td>Ichisaka T, Murakami H, Watanabe E, Takagi T,</td>
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<td>Akiyoshi M, Ohtsubo T, Kihara S, Yamashita S,</td>
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The Purdue scientist’s claim of independent replication of tabletop fusion was false, a school panel says.

According to the report by the Purdue committee -- composed of scientists from inside and outside the university -- [Dr.] Taleyarkhan asked master's candidate Adam Butt to review [postdoc] Xu's data. Butt's name was then added to the paper, even though he had not participated in the research.

That, said the panel, was clearly scientific misconduct because it was designed to give the appearance of a collaboration that had not occurred.
RCR: THE BASIC RULES OF THE ROAD
OKAY, SO WHAT IS RCR?

No definitive guidebook

Rules vary from discipline to discipline and from profession to profession

So how do you know what “responsible conduct” actually looks like in your area?
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No definitive guidebook. Rules vary from discipline to discipline and from profession to profession. So how do you know what “responsible conduct” actually looks like in your area?
THREE OVERARCHING GOALS OF RCR

1. Help students, researchers and administrators navigate regulatory requirements relating to research. For example:
   - Conflict of Interest
   - Human Subjects and the Institutional Review Board (IRB)
   - Institutional Animal Care and Use Committee (IACUC)
   - Handling research misconduct
   - Radiological, chemical, and biological safety
   - Tribal research protocols
THREE OVERARCHING GOALS OF RCR

2. Develop, hone, and practice applying sound reasoning skills to common ethical issues in research.
THREE OVERARCHING GOALS OF RCR

3. Help students and early career researchers develop key professional skills and ultimately advance successful careers!

- Authorship, Co-Authorship & Publication
- Collaborative Research
- Peer Review
- Mentoring
- Data Management, Acquisition, and Ownership
FEDERAL FUNDING AGENCIES WITH RCR REQUIREMENTS

National Institutes of Health (NIH)
National Science Foundation (NSF)
National Institute of Food and Agriculture (NIFA)
TO MEET THE FEDERAL REQUIREMENTS...

UA offers four RCR Certificates:

- NIH RCR Certificate
- NSF RCR Certificate
- NIFA RCR Certificate
- Undergraduate RCR Certificate
IF YOU ARE FUNDED BY NIH

NIH requires RCR training for all trainees, fellows, participants, and scholars supported by the following kinds of awards:
- training grants
- career development awards
- dissertation research grants

Other NIH-funded programs may have RCR requirements.

Check funding opportunity announcement or award docs to verify
NIH RCR CERTIFICATE

- Requires a minimum of nine (9) hours of training
- Training must begin within 30 days of being paid on an NIH grant
- You have a full year to complete the required 9 hours
- The certificate is good for three (3) years, at which point you have another full year to renew the certificate
IF YOU ARE FUNDED BY NSF

- NSF requires RCR training for all postdocs, graduate, and undergraduate students supported by NSF to conduct research.

- Conference, symposium, workshop, and travel grants are exempt.
NSF RCR CERTIFICATE

- Requires a minimum of six (6) hours of training
- Training must begin within 30 days of being paid on an NIH grant
- You have a full year to complete the required 6 hours
- The certificate is good for three (3) years, at which point you have another full year to renew the certificate
NEW REQUIREMENTS FROM NIFA

Anyone working on a NIFA-funded research project is required to complete RCR training:
- Faculty
- Staff
- Postdocs
- Students
The NIFA RCR Certificate is required for all CALS employees and students who are not subject to NIH or NSF RCR requirements.
Currently: Any CITI RCR Module

Will eventually consist of three 30-minute online video modules:

- Research Integrity and Reporting Misconduct
- Authorship and Co-Authorship
- Data Management, Integrity, and Ownership
Individuals subject to multiple agencies’ RCR requirements must complete only the most extensive corresponding certificate.
To learn more about the federal guidelines, register for RCR certificates, and enroll in training, visit:

http://rgw.arizona.edu/rcr
RESPONSIBLE CONDUCT OF RESEARCH PROGRAM

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Animal Research
Administrative & regulatory considerations

B. Helen Jost, PhD
IACUC Co-Chair
Director, IACUC Program
Institutional Animal Care and Use Program

University Animal Care
- Director of UAC
- Attending Veterinarian
- UAC veterinarians
- UAC husbandry staff

IACUC
- Chair and Co-Chair
- Attending Veterinarian
- IACUC members
- IACUC Program Office

The IACUC oversees regulated animals
IACUC

• The IACUC Program is part of RDI’s Research Compliance Services
• Assists RDI with regulatory issues related to animal research
• Reviews and approves the research animal activities
  – Approved protocols
• Ensures animal activities are congruent with PHS and NSF grants

University Animal Care

• Purchases animals
• Cares for animals
  – Food/water/housing
• Provides veterinary care and services
• Recharge costs to PI accounts
  – Cost of the animals/transport
  – Per diem – cost of daily care
  – Special services – vet services & supplies
Not all animals are the same

• Unlike Vulcans, government regulations are not logical

• Also, forget what you learned in biology

• From a research or grant standpoint, animals are either:
  – Regulated – subject to regulatory and fiscal restrictions
  – Unregulated – not subject to restrictions
A regulated animal is...

- Alive
- Has a backbone - vertebrate
- Used by a commercial vendor to produce custom antibodies
- Close to “hatching”
  - Even if some regulations have exclusions [e.g., USDA], we consider any animal that meets these standards as a regulated animal
Onboarding new PIs

• The PI should establish relationships with units prior starting at UA
  – Sponsored Project Services (SPS)
  – University Animal Care (UAC)
  – Institutional Animal Care and Use Committee (IACUC)

• A number of activities can/should be started prior to the move

• Work with the PI to anticipate needs
  – Develop a list of specific questions...
    • Does your grant list animal activities?
    • Have you contacted the IACUC Office/got IACUC approval?
    • Will you be transferring animals
  – An “I need it tomorrow” usually had a two week deadline
• Establish a relationship with the IACUC
  – Contact the IACUC Office at orcr-iacuc@email.arizona.edu
  – Most emails are turned around the same day
• Remember that not all IACUCs are the same
  – The IACUC Office works diligently with our faculty colleagues to facilitate research
    • The UA IACUC Office is in the top 25\textsuperscript{th} percentile for protocol turn around time [\textasciitilde30 days from first submission to approval]
• We use an online protocol submission system [eSirius] that is customized for UA
  – PI/staff will need a UA NetID before they can log in
  – One on one training is available
IACUC requirements

- **eSirius**
  - Obtain a **UA Net/ID and password**
  - Be on campus or have access to the VPN client [UITS]
  - Contact the IACUC Office to establish **eSirius credentials**

- **IACUC training and occupational health**
  - The PI can **submit a protocol before starting IACUC training or enrolling with occupational health**; however a protocol will not be approved unless all requirements are complete
  - Protocol staff will not be added until requirements are complete

- **Access to UAC**
  - Requires being listed on an approved protocol
  - Is **not an IACUC function**; contact UAC directly
The IACUC uses the CITI platform for online training [http://orcr.arizona.edu/iacuc/Personnel%20Amendments#CITI%20courses]
- Training can be started/completed before the move
- Training records can be transferred from another institution
- The training requirements depend on the species and activities

Hands on training depends on the species/activity
- GRST [http://orcr.arizona.edu/iacuc/Personnel%20Amendments#GRST]
- UAC also provide specific training

Contact the IACUC Office if there are specific training questions [orcr-iacuc@email.arizona.edu]
Regulations require that individuals working with animals participate in an occupational health program

- Animal Hazards Program [http://orcr.arizona.edu/iacuc/animalhazards]
- The program is provided through campus health
- Participation cannot be declined

Individuals must participate by submission of a Risk Assessment Questionnaire [RAQ]

The RAQ is reviewed by a provider

- Medical surveillance is recommended based on health history and planned activities
- Medical Surveillance may be declined

Due to privacy, the IACUC Office does not participate in this process

- Contact the AHP if there are specific questions [francesd@email.arizona.edu; jamesmetras@email.arizona.edu]
IACUC grant considerations

• Clarify the **exact** request with the PI

• NIH or NSF grant requirements
  – Requirements are non-negotiable
  – Deadlines usually have some “wiggle room”

• Non UA-institutional requirements
  – Other institutions may impose “IACUC requirements” to release grant funds
    • Reasonable requirements will be accommodated
    • Overly burdensome requirements will be “negotiated”

• When in doubt, **contact the IACUC Office**
IACUC grant considerations

• Regulations require that PHS [NIH; NCI] and NSF grants must be reviewed for congruency
  – A complete copy of the grant must be submitted with the protocol
  – Includes SF 424 and PHS 398 sections

• The IACUC must determine that the grant and the IACUC protocol are congruent in scope, species and general methods
  – The IACUC protocol determines the approved activities
    • The grant is not the same thing as an IACUC-approved protocol

• The IACUC and SPS must determine whether the type of grant and performance site has additional requirements, e.g.,
  – Animal work subcontracted to another institution
  – SBIR/STTRs where animal work is conducted at UA
  – A non-UU prime grantee subcontracts animal work to UA
Go with the flow... chart

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**So, you get a JIT score or a grant from NIH or NSF**
Well done! Pat yourself on the back and breathe a sign of relief

Do I need to get approval from the IACUC for my work?

- **Does your research involve animals?**
  - **NO**
    - Stop here: Good luck in your future endeavors!
  - **YES**
    - **Are you sure you are using "animals"?**
      - **NO**
        - **Is it alive and has a backbone?**
          - **NO**
            - **Is it at ≥ 80% of hatching age?**
              - **NO**
                - **Is it used for custom antibodies?**
                  - **NO**
                    - **Is all of the live animal work occurring at UA?**
                      - **YES**
                        - Stop here: An IACUC protocol or amendment is needed
                      - **NO**
                        - Stop here: An IACUC MOU* is needed
        - **YES**
          - Is any of the live animal work occurring at UA?
            - **YES**
              - Stop here: An IACUC MOU* is needed
            - **NO**
              - **Stop here... you won the jackpot!**
                - An IACUC protocol/amendment and an IACUC MOU* is needed

- **STOP HERE**

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**You need to add a grant to your IACUC protocol**

- **NIH or NSF recognized your genius and awarded you a grant!**
  - Or you were awarded an NIH subcontract for animal activities on someone else's grant

- **Do you have an IACUC protocol?**
  - **NO**
    - Stop here: Submit an IACUC protocol in eSirius. You will need the complete grant submission [SF424 and PHS398].
  - **YES**
    - Are the grant activities within the scope of your current protocol?
      - **NO**
        - Provide the submission/review letter to NIH, until IACUC approval
      - **YES**
        - Are all the experiments described on the grant proposal already described on your protocol?
          - **YES**
            - Stop here: Submit an IACUC amendment in eSirius to add the new funding. You will need the complete grant submission [SF424 and PHS398].
          - **NO**
            - Stop here: Amend the protocol to add the funding and the new animal activities. You will need the complete grant submission [SF424 and PHS398].

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*An MOU is a Memorandum of Understanding between the two IACUCs that specifically outlines who is responsible for animal welfare, as required by PHS Policy.*
Helen Jost, Director, IACUC Program Office
520-626-5304  jost@email.arizona.edu
orcr-iacuc@email.arizona.edu

What my friends think I do
What my mom thinks I do
What my boss thinks I do

What PIs think I do
What I think I do
What I really do
So, you got a JIT score or a grant from NIH or NSF
Well done! Pat yourself on the back and breathe a sigh of relief
Do I need to get approval from the IACUC for my work?

Does your research involve animals?

YES

Are you sure you are using “animals”?

YES

Is all of the live animal work occurring at UA?

YES

Stop here... you won the jackpot!
An IACUC protocol /amendment and an IACUC MOU* is needed

Stop here
An IACUC protocol or amendment is needed

NO

NO

Is any of the live animal work occurring at UA?

YES

Is any animal work subcontracted to an external institution [not UA]?

Stop here
An IACUC MOU* is needed

NO

NO

Start here
Good luck in your future endeavors!

Is it alive and has a backbone?
Is it ≥ 3 dpf for zebrafish?
Is it at ≥ 80% of hatching age?
Is it used for custom antibodies?

NO

Stop here
Good luck in your future endeavors!

An IACUC MOU* is needed

For MOUs*, contact the IACUC Office
You will need:
The complete grant submission [SF424 and PHS398];
The approved IACUC protocol from the other institution

Stop here
An IACUC MOU* is needed

Go to add a grant to my IACUC protocol

Stop here
An IACUC protocol or amendment is needed

Go to add a grant to my IACUC protocol

*An MOU is a Memorandum of Understanding between the two IACUCs that specifically outlines who is responsible for animal welfare, as required by PHS Policy.
You need to add a grant to your IACUC protocol
NIH or NSF recognized your genius and awarded you a grant!
Or you were awarded an NIH subcontract for animal activities on someone else’s grant.

Do you have an IACUC protocol?  →  NO

STOP HERE
Submit an IACUC protocol in eSirius.
You will need the complete grant submission [SF424 and PHS398].

Are the grant activities within the scope of your current protocol?  →  NO

STOP HERE
Provide the submission/review letter to NIH, until IACUC approval.

Are all the experiments described on the grant proposal already described on your protocol?  →  YES

STOP HERE
Submit an IACUC amendment in eSirius to add the new funding.
You will need the complete grant submission [SF424 and PHS398].

STOP HERE
Amend the protocol to add the funding and the new animal activities.
You will need the complete grant submission [SF424 and PHS398].

Provide the submission/review letter to NIH, until IACUC approval.
Institutional Review Board Overview

Mariette Marsh, MPA, CIP
What is the purpose of an IRB?

To protect the rights and welfare of subjects participating in research activities on or behalf of an organization that is engaged in human research.
### The Elements of the Belmont Report

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<th>Respect for Persons</th>
<th>Beneficence</th>
<th>Justice</th>
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<td>Protecting autonomy, having courtesy and respect for individuals as persons, including those who are not autonomous (e.g., infants, the mentally retarded, senile persons)</td>
<td>Maximizing good outcomes for science, humanity, and the individual research participants while avoiding or minimizing unnecessary risk, harm, or wrong</td>
<td>Ensuring reasonable, non-exploitative and carefully considered benefits among persons and groups</td>
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<tr>
<td>• Each person has individual rights</td>
<td>• Provide benefit, protect from harm, limit risk</td>
<td>• Equitable selection of subjects</td>
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<tr>
<td>• Obtain informed consent, protect privacy, maintain confidentiality</td>
<td>• Risk-benefit assessment, standard procedures used</td>
<td>• Includes all groups that may benefit but does not single out one group</td>
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How does an IRB protect subjects?

- Risks are minimized
- Benefits are maximized
- Subject selection is equitable
- Informed consent is appropriately sought and documented
- Privacy and confidentiality are maintained, as applicable

45 CFR 46.111
DEFINITIONS
**Research**

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

*The University of Arizona interprets *generalizable* to mean that results can be applied to the population at large.*

**Human Subject**

*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.
# FDA regulations

**Clinical Investigation**

- Any experiment that involves a test article administered to one or more humans (except marketed drugs in the course of medical practice)

**Test Article**

- Any drug (including biological product for human use), device, food/color additive, electrical product, or any other article subject to regulation

- Research, clinical research, clinical study, study, and clinical investigation are deemed synonymous
What does research include?

- Recruitment
- Consenting process
- Study intervention(s)/procedures
- Identifiable data analysis
What are the types of review?

Projects are classified into three categories:

- Exempt → Low Risk
- Expedited → Minimal Risk
- Full Committee → Greater than Minimal Risk
Responsibilities
Shared Responsibilities

- Risks are minimized
- Benefits are maximized
- Informed consent obtained and documented
- Subject selection is equitable
- Privacy and confidentiality
Investigator Responsibilities

- Conduct study **ethically** and according to **approved IRB protocol**
- Submit **ALL** changes to the protocol prior to implementation
- Submit an annual report (if required) **BEFORE** project expires
- Submit **ongoing issues**, such as unanticipated problems or noncompliance
- Maintain all IRB **paperwork** according to protocol and university regulations
THINGS TO CONSIDER
Common Pitfalls

• Failure to submit renewal paperwork for re-approval
• Materials submitted too late for review
• Current templates not used
• Insufficient detail provided about the study
• Not all attachments submitted
• Signatures not obtained
• Additional approvals not obtained
THINGS TO THINK ABOUT...

• Communication
• Regulatory implications
• Timing
• COMMUNICATION
CONTACT INFORMATION

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