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?

Article	Year of retraction	Cites before retraction	Cites after retraction	Total cites from journals indexed by Web of Science
1. Visfatin: A protein secreted by visceral fat that mimics the effects of insulin. SCIENCE, JAN 21 2005				
Fukuhara A, Matsuda M, Nishizawa M, Segawa K, Tanaka M, Kishimoto K, Matsuki Y, Murakami M, Ichisaka T, Murakami H, Watanabe E, Takagi T, Akiyoshi M, Ohtsubo T, Kihara S, Yamashita S, Makishima M, Funahashi T, Yamanaka S, Hiramatsu R, Matsuzawa Y, Shimomura I.	2007	247	776	1023
2. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. LANCET, FEB 28 1998				
Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA.	2010	675	308	983

http://retractionwatch.com/the-retraction-watch-leaderboard/top-10-most-highly-cited-retracted-papers/

FEDS REQUIRE IT, BUT DO WE REALLY NEED IT?

From *The Los Angeles Times*, July 19, 2008

PHYSICIST IS FOUND GUILTY OF MISCONDUCT

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


540
40
OUEST
Montréal
134-0
1 km
73
40
NORD
EST
Chicoutimi
Ste-Anne-de-Beaupré
175
NORD
Boul. Laurier
Québec
CENTRE-VILLE
134-E
1 km
Boul. Champlain
Av. des Hôtels
132
Parc de la Chute-Montmorency 25
Station tour. Stoneham 39
Mont-Ste-Anne 55
SAINTE-FOY


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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

MEETING THE NIFA RCR REQUIREMENT

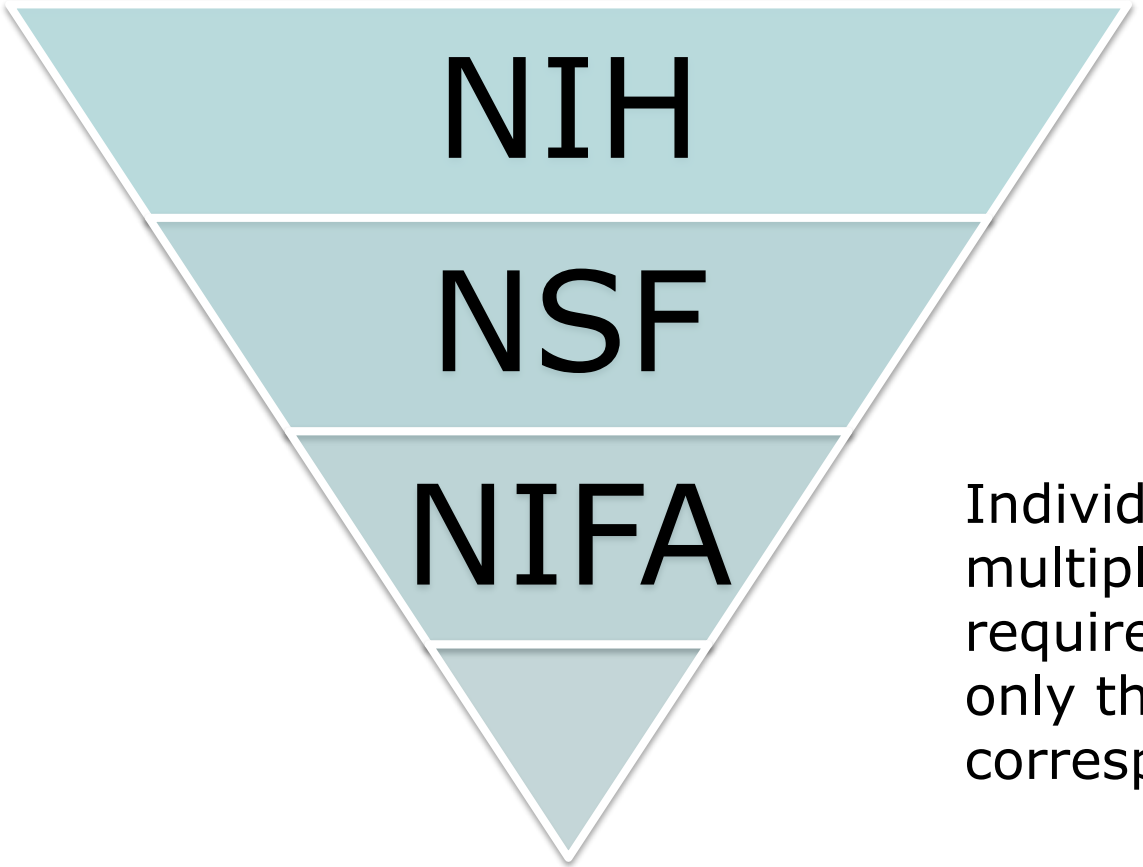
The NIFA RCR Certificate is required for all CALS employees and students who are not subject to NIH or NSF RCR requirements.

NIFA RCR TRAINING

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.

RCR ON THE RESEARCH GATEWAY

To learn more about the federal guidelines, register for RCR certificates, and enroll in training, visit:

http://rgw.arizona.edu/rcr

CONTACT INFO

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http://rgw.arizona.edu/rcr

Animal Research

Administrative & regulatory considerations

B. Helen Jost, PhD
IACUC Co-Chair
Director, IACUC Program

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Research, Discovery & Innovation

The IACUC oversees regulated animals

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

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

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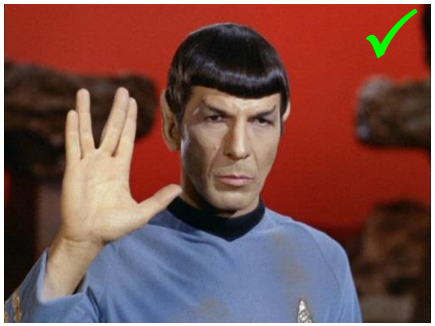
- Unlike Vulcans, government regulations are not logical



- 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

The IACUC Office

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- 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 25th percentile for protocol turn around time [~30 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

IACUC training

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- 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]

Occupational health [RAQ]

- 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 de 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

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- 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

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- 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-UA prime grantee subcontracts animal work to UA

Go with the flow… chart

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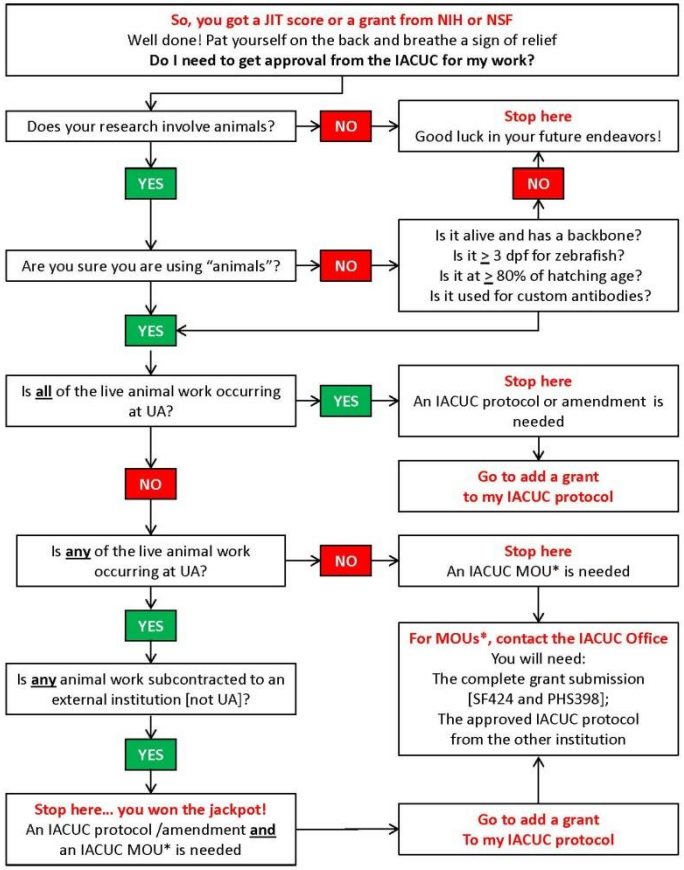
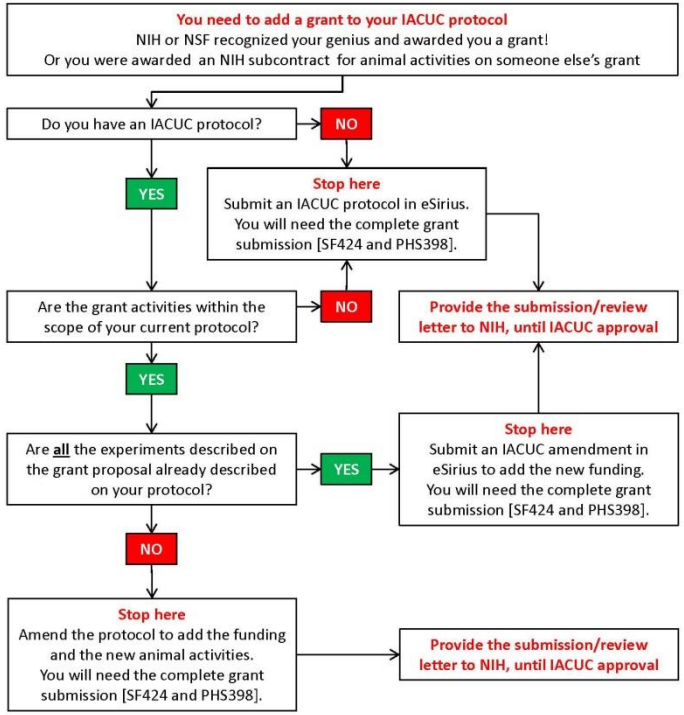


*An MOU is a Memorandum of Understanding between the two IACUCs that specifically outlines who is responsible for animal welfare, as required by PHS Policy.



Helen Jost, Director, IACUC Program Office

520-626-5304 jost@email.arizona.edu

orcr-iacuc@email.arizona.edu

What my friends think I do

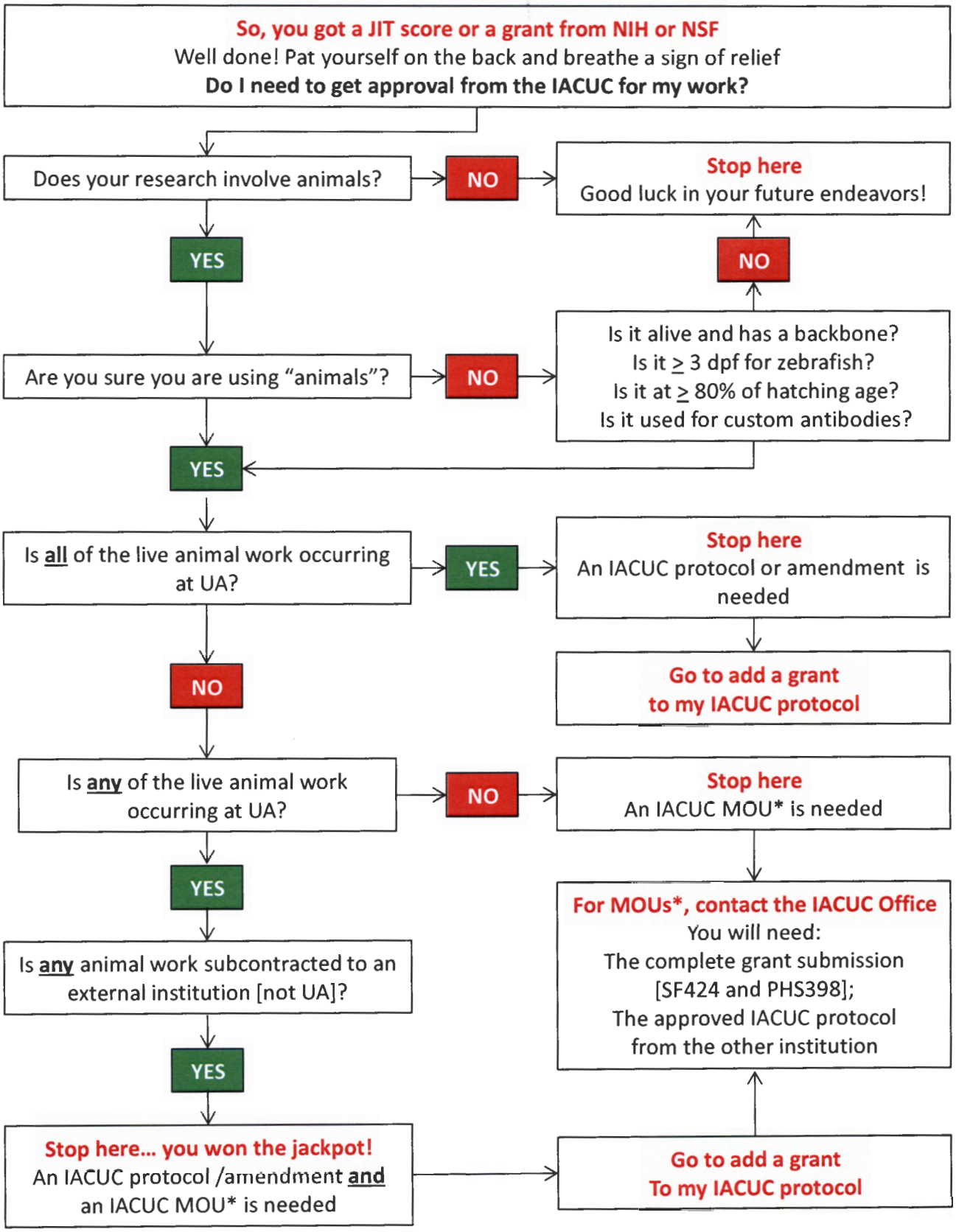
What my mom thinks I do

What my boss thinks I do

What PIs think I do

What I think I do

What I really do



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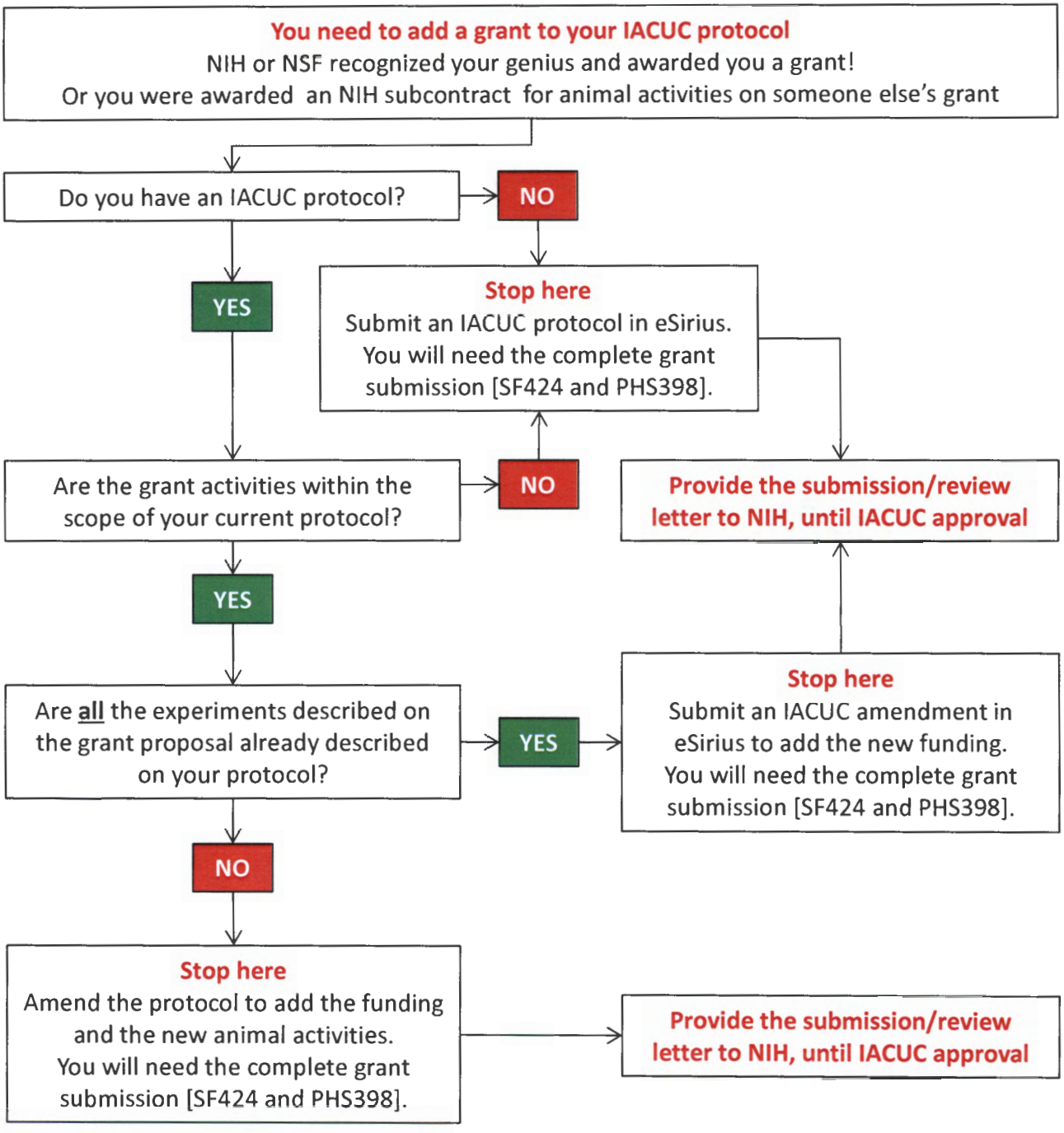
You need to add a grant to your IACUC protocol
NIH or NSF recognized your genius and awarded you a grant!
Or you were awarded an NIH subcontract for animal activities on someone else's grant
Do you have an IACUC protocol?
NO
YES
Stop here
Submit an IACUC protocol in eSirius.
You will need the complete grant submission [SF424 and PHS398].
Are the grant activities within the scope of your current protocol?
NO
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].
Provide the submission/review letter to NIH, until IACUC approval


Research
Office for Research & Discovery
Institutional Review Board
Overview
Mariette Marsh, MPA, CIP
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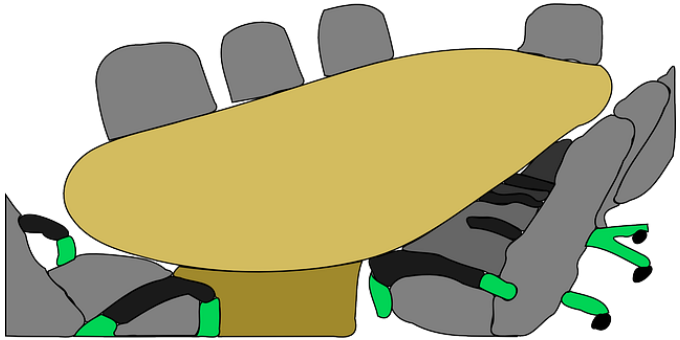
What is the purpose of an IRB?

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

Respect for Persons

Protecting autonomy, having courtesy and respect for individuals as persons, including those who are not autonomous (e.g., infants, the mentally retarded, senile persons)

- Each person has individual rights
- Obtain informed consent, protect privacy, maintain confidentiality

Beneficence

Maximizing good outcomes for science, humanity, and the individual research participants while avoiding or minimizing unnecessary risk, harm, or wrong

- Provide benefit, protect from harm, limit risk
- Risk-benefit assessment, standard procedures used

Justice

Ensuring reasonable, non-exploitative and carefully considered benefits among persons and groups

- Equitable selection of subjects
- Includes all groups that may benefit but does not single out one group

How does an IRB protect subjects?

45 CFR 46.111

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


DEFINITIONS

Common Rule

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

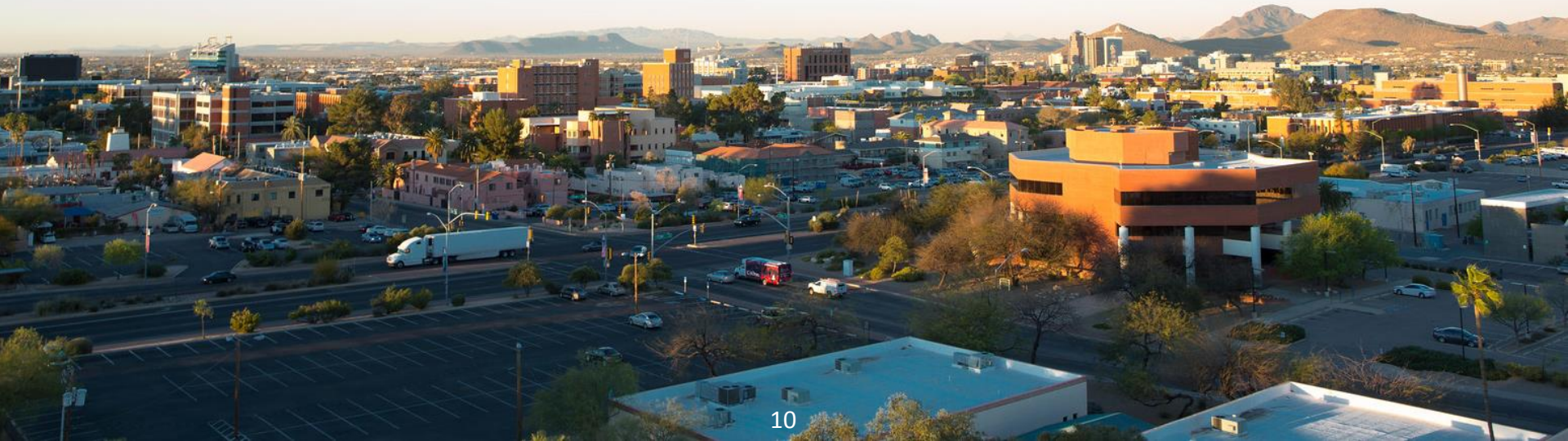
- Study intervention(s)/procedures
- Identifiable data analysis

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

IRB and Investigator

- 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**

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