

Animal Research at DARPA

2013

What is an Animal?

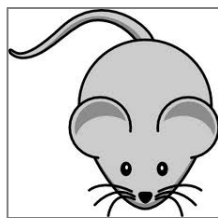
According to the DoD, an animal **IS**

✓ A living or dead **vertebrate**

✓ A larval fish or amphibian

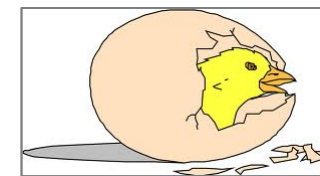
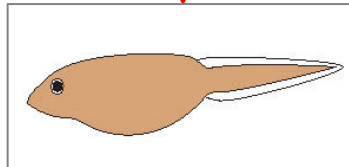
✓ An egg-laying vertebrate is only an animal **after hatching**

Dead = killed for the direct purpose of conducting RDT&E or training



Animal

Animal



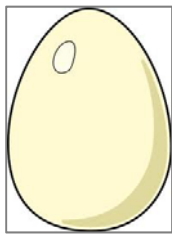
Animal

What is not an Animal?

An animal is **NOT**

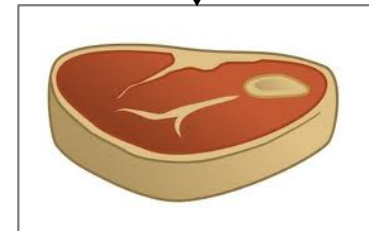
- × An un-hatched egg
- × An invertebrate
- × Dead animals or parts of dead animals purchased at grocery stores or slaughterhouses

Not an animal



Not an animal

Not an animal



What Animal Use is Regulated by the DoD?

Regulated

All research, development, testing, and evaluation or training using animals that is conducted or supported by the DoD within and outside of the US

Not Regulated

There are uses for animals that do not fall under these DoD regulations, however, DARPA almost never funds them

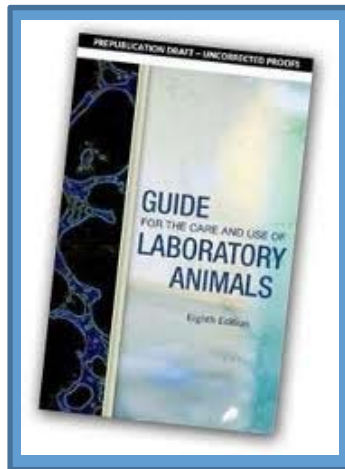
Ex. Military working dogs



Rule of thumb: If part of a protocol involves touching an animal, it probably falls under these regulations!

ALL Animal Research in the US Must Follow

**Animal Welfare Act/Animal
Welfare Regulations**



**Guide for the Care and Use of
Laboratory Animals**

These regulations are available on the web

DARPA Animal Research Must ALSO Follow

DoD Instruction 3216.01 “Use of Lab Animals in DoD
Programs”

Applies to all animal research conducted or supported by the DoD

Available on the web

Do You *Need* Animals?

DoDI 3216.01 requires that **methods other than animal use** and alternatives to animal use be considered and used whenever possible

First question for DARPA research: Are animals necessary to get relevant results?



Pay attention to the following steps, noncompliant efforts are not enjoyable!



Then don't use them, and you don't have to follow these regulations

Contract Policies

DoD vet approval (secondary approval) is needed **before** any money can be awarded for animal related expenses

Animal Related

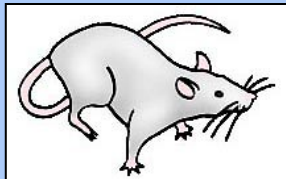


Food



Housing

Purchase of animals



Non - Animal Related



Question: What is DoD vet review and approval?

Answer: All protocols have to be reviewed by the DoD to make sure regulations are being followed. Details coming up.

Other questions about your contract? Contact your agent!

Protocol and Amendment Review and Approval

Review of the Protocol

All DARPA animal use protocols must go through **two** reviews

1st review

Local Level (IACUC Review)



2nd review

DoD Level (Secondary Review)



The IACUC Review

All animal use protocols in the United States **must** be approved by an IACUC



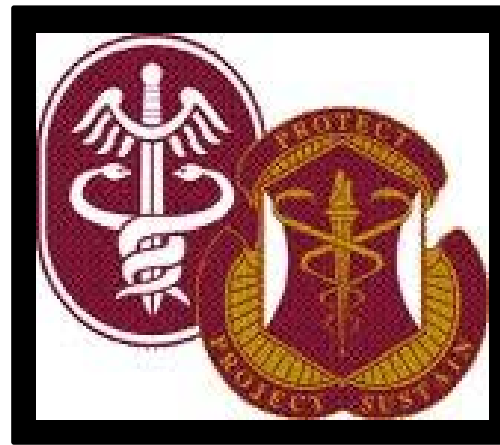
Generally, PIs are aware of IACUC requirements

It's the secondary review that might be new!

The Secondary Review

All **DoD** funded efforts **must** go through DoD vet review
Similar to IACUC review, performed by a DoD vet at DoD regulatory office

Research at Navy facility
= Navy vet review



Research at Air Force facility
= AF vet review



All other research is reviewed
by an Army vet at USAMRMC
Animal Care and Use Review
Office (**ACURO**)

PI Submits Documents to DoD Review Office (Usually ACURO)

Required Submission Documents:



- ✓ IACUC approved protocol
- ✓ Evidence of IACUC approval
- ✓ ACURO (or Navy/Air Force) appendix

Available on the web

Initial Secondary Review Process

ACURO reviews submission documents, asks PI for clarifications, then forwards to DoD vet for final review



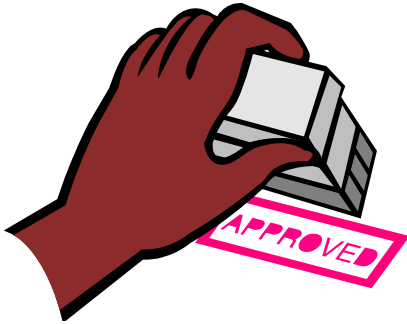
Secondary review can take up to **2** or **3** months



Need approval quickly?

Responsive PI = faster review = quick release of money = **Prompt Start To Research**

Initial Protocol Approval



After ACURO approval...

the agent removes prohibition on funds for animal work...

and approval is good for the length of the award or length of IACUC approval



EXCEPT AMENDMENTS!

Amendments

ANY change to the protocol requires an
amendment

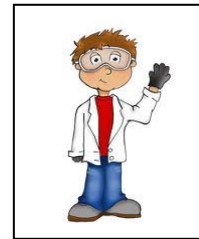
Examples of Changes



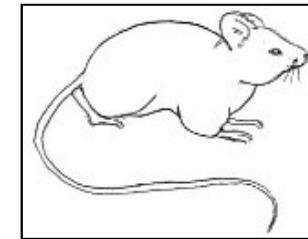
room



test procedure



personnel



animal numbers

**NO work can be done on an amendment
until reviewed by the IACUC and **ACURO****

Review of the Amendment

All animal use amendments must go through **two** reviews

1st review

Local Level (IACUC Review)



2nd review

DoD Level (Secondary Review)



There is **NO EXCEPTION** to this policy

Amendments

At IACUC review,
amendments are
labeled as
major or **minor**

These decisions are
not always the
same

At ACURO review,
amendments are
labeled as
major or **minor**



Amendments

After amendments are approved by IACUC and sent to ACURO:

MINOR AMENDMENTS

Require administrative review

1-3 days



MAJOR AMENDMENTS

Require veterinary review

Approx. 1-2 weeks



After amendments are reviewed and approved by ACURO,
the changes described can be implemented

Amendments

If amendments are worked on before DoD review, the research is **NONCOMPLIANT**

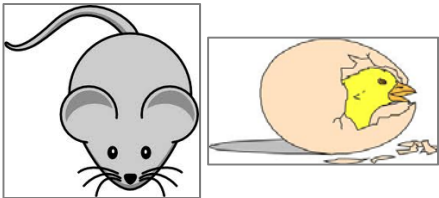
Noncompliance may be cause to cancel the contract!



BUT, you can prevent this!

- Keep in touch with all subcontractor PIs and your DARPA PM
- Let the DARPA animal use POC know when amendments are expected. She can help you remember to submit for the correct approvals.

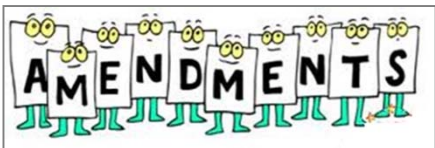
Take Home Messages



1. If a protocol involves touching an animal, it must follow DoD animal use regulations



2. All animal use protocols require TWO approvals



3. All amendments must be reviewed by DoD, usually ACURO

Questions?

DARPA's **Animal Use POC** is here to help with all aspects of animal research at DARPA including:

Approval process



Acting as liaison between PIs, PMs, agents, and ACURO

Locating and understanding regulations



Any other animal use questions or issues

AU POC Contact Information:

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