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
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
What Animal Use is Regulated by the DoD?

<table>
<thead>
<tr>
<th>Regulated</th>
<th>Not Regulated</th>
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<tbody>
<tr>
<td>All research, development, testing, and evaluation or training using animals that is conducted or supported by the DoD within and outside of the US</td>
<td>There are uses for animals that do not fall under these DoD regulations, however, DARPA almost never funds them</td>
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**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.

1\textsuperscript{st} review
Local Level (IACUC Review)

2\textsuperscript{nd} 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

1\(^{st}\) review
Local Level (IACUC Review)

2\(^{nd}\) review
DoD Level (Secondary Review)

There is **NO EXCEPTION** to this policy
Amendments

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

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

These decisions are **not** always the same.
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
DARPA’s Animal Use POC is here to help with all aspects of animal research at DARPA including:

- Approval process
- Locating and understanding regulations
- Acting as liaison between PIs, PMs, agents, and ACURO
- Any other animal use questions or issues

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