

# **Animal/Human Subjects Research at DARPA**

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INTERCEPT Proposers Day

April 28, 2016



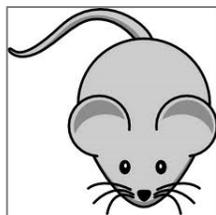


# What is an Animal?

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

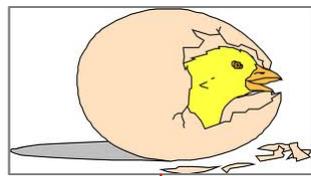
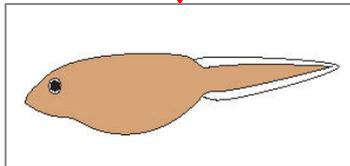
- ✓ A living or dead **vertebrate**
- ✓ A **larval fish or amphibian**
- ✓ An **egg-laying vertebrate** is only an animal **after hatching**

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



Animal

Animal



Animal

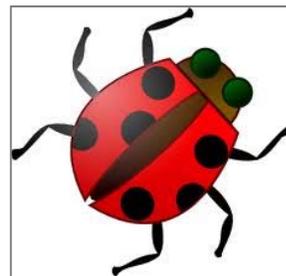
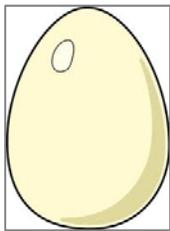


# What is not an Animal?

## An animal is **NOT**

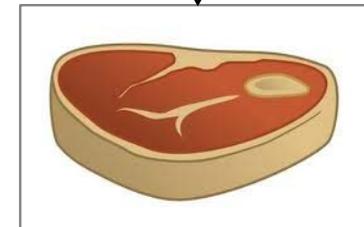
- × An un-hatched egg
- × An invertebrate
- × Dead animals or parts of dead animals purchased at grocery stores or slaughterhouses

Not an animal



Not an animal

Not an animal





# Regulations

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## ALL Animal Research in the US Must Follow

1. Animal Welfare Act/Animal Welfare Regulations
2. Guide for the Care and Use of Laboratory Animals

## DARPA animal research must also follow

3. DoD Instruction 3216.01 “Use of Lab Animals in DoD Programs”  
Applies to all animal research conducted or supported by the DoD

**These regulations are available on the web**



# Contract Policies

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

## Animal Related

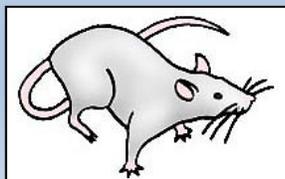


*Food*



*Housing*

*Purchase of animals*



## Non - Animal Related





# Review of the Protocol

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

**1<sup>st</sup> review**

Local Level (IACUC Review)



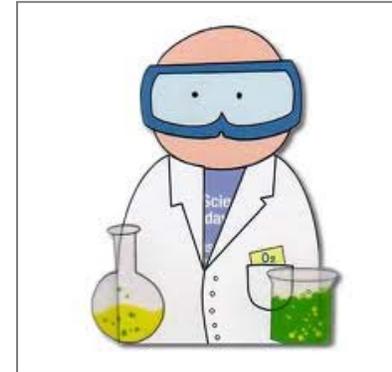
**2<sup>nd</sup> review**

DoD Level (Secondary Review)



# The Reviews

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



All **DoD** funded animal use must also be approved by a DoD vet

DARPA funded animal use protocols are reviewed by a DoD vet at MRMC Animal Care and Use Review Office (ACURO)





# ACURO Approval

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## Required Submission Docs

- ✓ IACUC approved protocol
- ✓ Evidence of IACUC approval
- ✓ ACURO appendix
  - Available on Web

## Approval Process

- ✓ ACURO reviews docs
- ✓ Askes PI for clarification
- ✓ Sends to DoD vet for approval

Approval can take 2-3 months

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



# Review of Amendments

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All amendments to protocols (including minor) must also go through two reviews prior to implementation

**1<sup>st</sup> review**

Local Level (IACUC Review)



**2<sup>nd</sup> review**

DoD Level (Secondary Review)

There is **NO EXCEPTION** to this policy



# Take Home Messages

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1. If a protocol involves animal research, it must follow DoD animal use regulations
2. All animal use protocols require TWO approvals
3. All amendments must be reviewed by ACURO



## Definition of Human Subjects Research in the DoD

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The term “human subjects research” (HSR) can be applied to research efforts that meet EITHER of the following criteria outlined in the Common Rule:

- 1) Any research involving an INTERVENTION or an INTERACTION with a living person that would not be occurring but for this research
  - Intervention: physical procedures by which data is gathered (for example, blood sampling) or manipulation of the subject or the subject's environment performed for research purposes.
  - Interaction: communication or interpersonal contact between investigator and subject.
- 2) Any research in which the principal investigator (PI) conducting research obtains IDENTIFIABLE PRIVATE INFORMATION.
  - Identifiable private information: information about a behavior that:
    - (i) occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and
    - (ii) information which has been provided for specific purposes by an individual and the individual can reasonably expect will not be made public. Identifiable information includes but is not limited to names, addresses, medical record numbers, social security numbers and video recordings.

**Any DARPA-funded research which involves humans as defined on this page MUST be considered HSR.**



## HSR approval Process

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- Principal Investigator submits protocol to local IRB for review and approval
- HSR package is then submitted for HQ level approval
  - Includes local IRB approval letter
  - Federal Wide Assurance (of institution performing research)
  - Informed Consent Document
    - \*\*\*Make sure informed consent document includes statement that the research is being funded by DOD\*\*\*
  - Recruiting Materials
  - Biosketches/CVs
  - Training Certifications
- DOD HQ reviews entire package
  - May go back to PI with comments/recommendations/changes
- Once DOD gives approval, HSR research can begin

Note – HQ approval can take anywhere from 3-6 months. Do not delay in starting this process!



# Review of the Protocol

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All DARPA human subjects research protocols must go through **two** reviews

**1<sup>st</sup> review**

Local Level (local IRB)



**2<sup>nd</sup> review**

DoD Level (Headquarters Review)



## Helpful Hints/FAQs

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- **If possible, submit an IRB approval letter with proposal.** Especially, in cases where humans are involved you don't know that the work is really HSR. Having an IRB already look at it will help you and DARPA in moving forward faster.
- **If you do not have an internal IRB, you have one of three options**
  - Hire a commercial IRB
  - Work with the Contracting Agent to determine if they have an internal IRB that could assist
  - If work involves collaboration with other performers, considering using their IRB
- **If you have a contract involving subcontractors who are conducting HSR; they will also need to obtain human use approval.** Any performer including subcontractors must receive HSR approval through the local IRB and the DoD headquarters before start of their research.
- **If you make changes to the statement of work, they also need to be approved.** If the changes are to the HSR portion of the work, the revisions will have to go through the local IRB for review, as well as DoD headquarters level review for approval and concurrence.



## Points of Contact

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## Common issues

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- Both Animal Use and Human Use require two approvals (local and DOD HQ) before work can begin
- HQ process can take 3-6 months
- Any time a change is made, an amendment is required
  - Amendments must be approved by both local and DOD HQ
  
- **REMINDER – NO ASR OR HSR CAN BEGIN UNTIL ALL APPROVALS ARE OBTAINED!!!**