

## **Animals and Human Subjects: Policy and Process**

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## **This presentation will:**

- Describe protocol approval processes for use of humans and use of animals in research
- Highlight similarities in the processes and the areas of risk
- Discuss OSP's role in ensuring compliance
  - At the proposal stage
  - At award stage
- Describe key changes in award set up and their impact

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## Protocols: A key step in ethical, humane scientific inquiry

### Animals in research

#### Objective

- Broadly, ensures the safe and humane use of animals

### Human subjects

#### Objectives

- Respect for persons
  - Voluntary, non-coercive participation
  - Informed consent
- Beneficence
  - Maximize benefits and minimize harm
- Justice
  - In selection of subjects

**CAC and COUHES: compliance standard-bearer, maintain policy and procedures, track and report as required**

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## Why compliance is so important

- Standards are closely monitored by oversight agencies
- Non-compliance can:
  - Result in disqualification of data for use, publication
  - Damage MIT's reputation for holding to high ethical standards
  - PI can be suspended from doing human subject or animal research at MIT and/or have sanctions imposed, tainting her or his reputation

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## Why compliance is so important, cont'd.

- In serious cases, can result in findings and fines
  - Has long-term effect on MIT's reputation
  - Office for Human Research Protection (OHRP) can suspend all human subject research at MIT
  - Office of Laboratory Animal Welfare (OLAW) can suspend or terminate PHS funding for animal research at MIT
  - USDA can levy fines, suspend, or permanently revoke ability to conduct animal research at MIT

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## Animals

### Degree of oversight is considerable

- CAC: Committee on Animal Care =  
MIT's IACUC (Institutional Animal Care and Use Committee)
  - Mandated by Animal Welfare Act (AWA) and Public Health Service (PHS) at institutions that receive federal funds for vertebrate animal use in research or teaching
  - At MIT, same standards apply regardless of funding source or site of animal use
  - CAC Role: Ensure compliance with federal, state, local, and institutional regulations and policies for animal care and use
  - Thru protocol review, personnel training, periodic inspections of animal care and use areas, and general program oversight
- Inspections by USDA and Cambridge Commissioner (annually), AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care, triennially), Mass Dept. of Public Health (sporadically)
- Annual and Incidental reports of institutional animal use filed with USDA and OLAW (Office of Laboratory Animal Welfare)

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## Humans

### Oversight defined by Federal regulation

- The US Federal mandate
  - “...applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.” [Title 45 Code of Federal Regulations, part 46](#)
- FDA and State regulations also apply
- At MIT, standards apply regardless of funding source
- Federalwide Assurance mandated
  - “Each institution ... shall provide written assurance satisfactory to the [US] department or agency head that it will comply with the requirements set forth in this policy.”
- Training and retraining required

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## Animals

### Determining whether regulation applies

- On **vertebrate animals**, including
  - Eggs/embryos
  - Carcass/tissues
  - Lab animals, wild animals, pets, etc...
- Funded from **sponsored or discretionary accounts**
- At **MIT, Whitehead or Broad Institutes**
  - On-campus, or
  - Outdoors
- At **collaborator's campus**
- At **contract facility**

Protocol required

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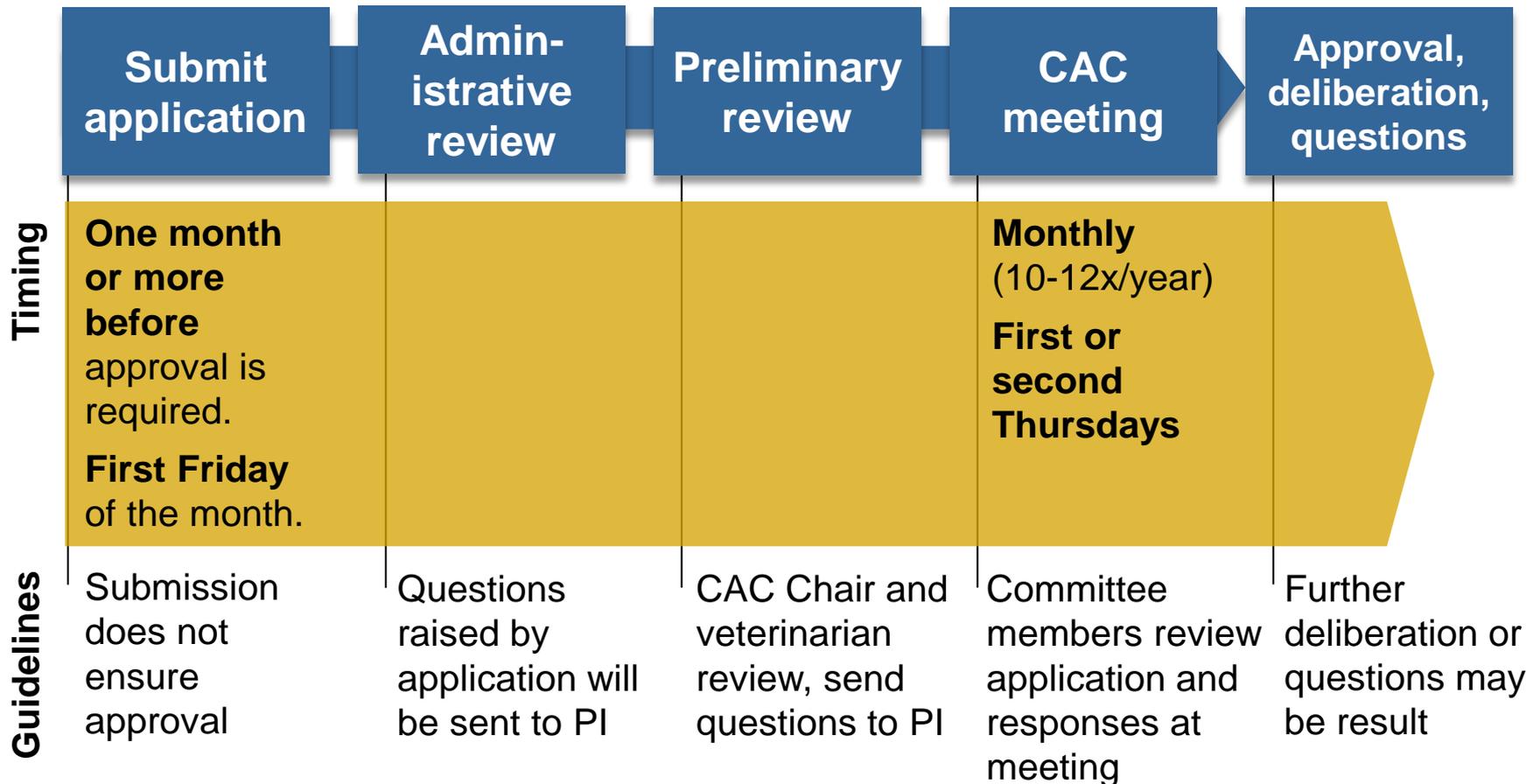
## Humans

### Determining whether regulation applies

- COUHES is responsible for reviewing research performed **under the auspices of MIT** or any part of MIT
  - Involving any form of MIT support, such as funding, personnel, facilities, academic credit or access to experimental subjects
- It's **research** when it is...
  - Systematic investigation to develop, contribute to generalizable knowledge, and includes:
    - Research development, testing, and evaluation
    - Formal interviews, questionnaires, and related activities that may be quantified as part of study data
- It involves **human subjects** when...
  - A living individual about whom an investigator conducting research obtains:
    - Data through intervention or interaction with the individual or
    - Identifiable private information

# Animals

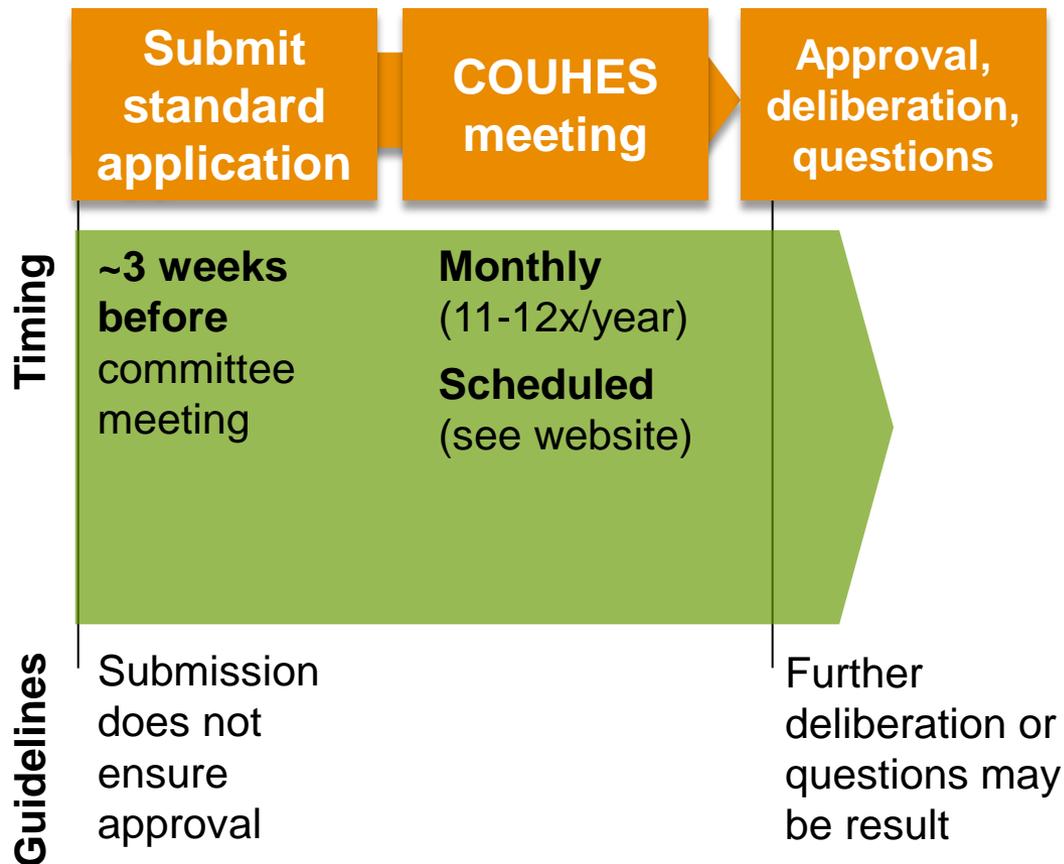
## Request and approval process



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# Humans

## Request and approval process



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## Adding a New Source of Funding to Existing Protocol

- An existing approved protocol doesn't mean you can automatically use it with new projects
  - PI must initiate an amendment to the existing protocol through CAC or COUHES
- For CAC, submit form **Request to Add Funding to Protocol**
- For COUHES, submit form **Application for Changes to an Approved Protocol**

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## Role of DLC at Proposal Stage

- Mark the proposal if using human subjects or animals based on information from PI

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## Role of OSP at Proposal Stage

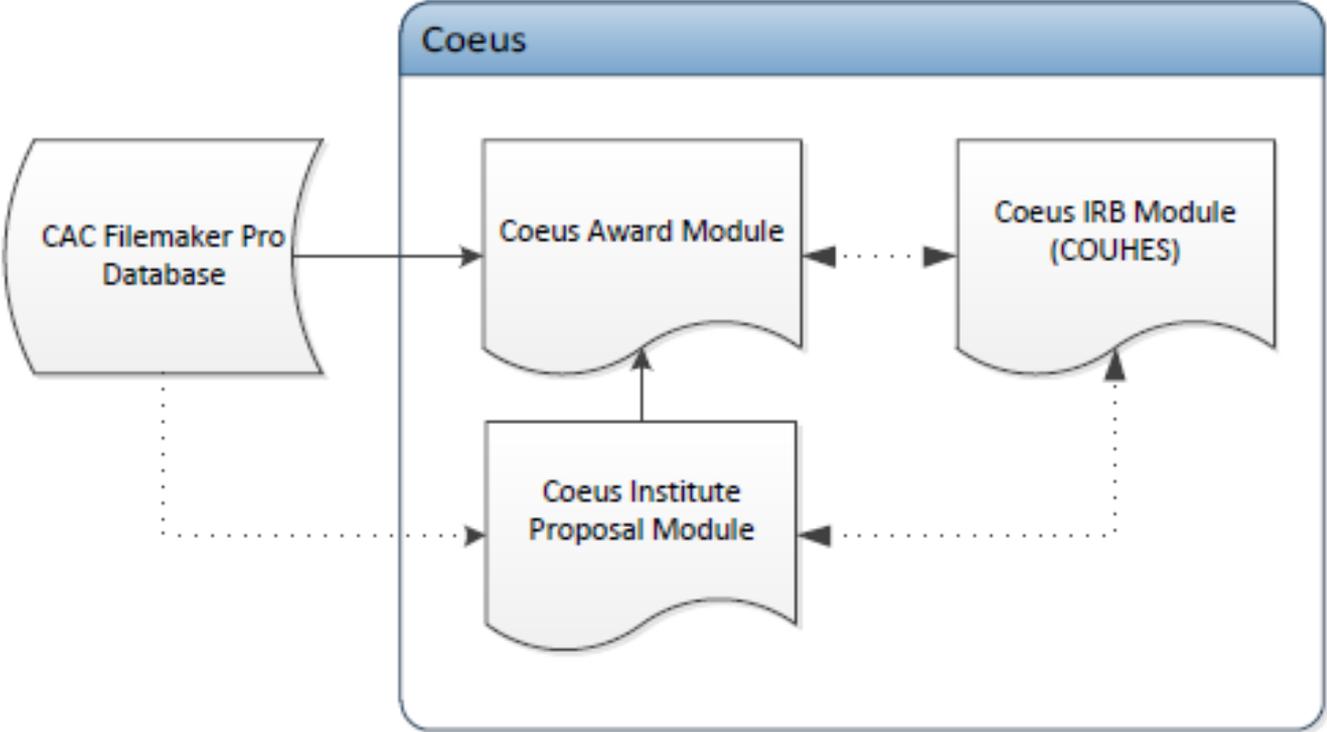
- OSP review looks for these items or others that may indicate human or animal subjects required:
  - Terms like “murine”, “MRI”, “surveys”, “mice”, “custom antibodies” in SOW
  - Items like “human subjects payments;” “animal purchase” in budget
- OSP will ask DLC to confirm with PI if the proposal should be marked as human or animal subjects work
  - May refer them to CAC or COUHES office
- If protocol is required, OSP or DLC can mark the protocol pending or can provide an existing protocol number.
  - Okay to submit with a pending approval at proposal stage.

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## Role of OSP at Award Stage

- Remain in hold status until protocols are approved or a note in Coeus if deferred.
- Accounts can be made active once approved protocols that have the new source of funding linked. Can be existing protocol or new protocol

# Systems Data Flow for CAC and COUHES



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## Coeus Process for IRB Protocol Approvals

- CAs inform Coeus Data Team of human subjects approved protocol information and instruct them to activate the award as appropriate
- No change to this communication process is currently planned
- Activation of linkage between Coeus Award, Institute Proposal & IRB modules will pass protocol information
  - As protocols are entered in IRB they will be “linked” to the associated award and institute proposal records
  - Will validate funding information and ensure accuracy
  - Will streamline and simplify the communication process.
  - Under review for implementation effort and timeline.

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# Coeus Updates to CAC Process – Protocol Approvals

## Current Process

- Contract Administrators inform Coeus Data Team of approved protocol information.

## New Process

- A nightly feed will update individual Coeus Award records with new and renewal protocol numbers and approval dates.

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## **Coeus Updates to CAC Process – Pre-Award**

### **Current Process**

- When protocol is required prior to the award and the account number has not been established, DLC provides this information to the Contract Administrator at time of award.

### **New Process**

- DLC administrator will provide CAC office with Institute Proposal (IP) number where the award account number has not yet been established.

**Coeus will match IP number with award account number when award is set up.**

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# Coeus Update to Special Review Entry in Award Hierarchy

## Current Process

- Inconsistency in how Special Reviews are entered within the award hierarchy (structure)
- Special Reviews are manually deleted in Coeus when systemically copied from parent to child

## New Process

- Protocols entered at the parent and only on child accounts where human subjects or animal usage applies
- Automatic copy functionality in Coeus will be removed

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## Coeus Updates to Protocol Status

### Current Process

- No term to specify where Human Subjects or Animal Usage protocols are needed.
- Inconsistent handling of situation in which research with animals and human subjects is to begin in subsequent year of project

### New Process

- New term added: “No Human Subject/Animal Usage work can begin prior to the effective date of the protocol.”
- Status of “*Delayed Requirement*” added to identify situations when research with animals or human subjects is to begin in a subsequent year of a project.

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## Where to turn to learn more

- COUHES policies, procedures and forms:  
[web.mit.edu/committees/couhes](http://web.mit.edu/committees/couhes)
- CAC policies, procedures, and forms:  
[web.mit.edu/comp-med/restrict/cac](http://web.mit.edu/comp-med/restrict/cac)

**If in doubt, call to ask**