



SRA INTERNATIONAL
ANNUAL MEETING
SEATTLE 2023
OCTOBER 14-18

We're Better Together: IACUC 101 for Research Administrators

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Getting to Know You

How many audience members are from:

- Research Administration (e.g., Sponsored programs or Departmental administrators)?
- Compliance Office?
- Other?

Getting to Know You

How many audience members are experienced animal users or have worked with animal protocols?

(as researchers, IACUC members, IACUC office support staff)

Getting to Know You

What are your interactions with the IACUC/IACUC support office?

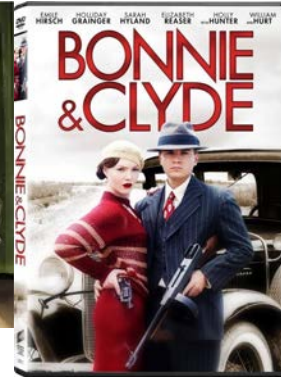
Are there pain points in those interactions?

If so, what or where are they?

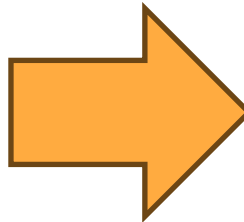
congruence
partner delay
amendment **slow** animal
research
hold up black box identify issues/problems
approval letter **collaborations**
unclear **grant** alphabet soup
subaward MOU regulations

I've
been
waiting
for some
time.

The Perfect Partnership....



- Common understanding
(We need to stop the Joker!)
- Knowing your role
(You kick and I'll punch....)
- Communication
(Which way to Gotham City?)
- Clear Streamlined Processes
(To the Batmobile, Robin!)



Seamless Collaboration!

IACUC 101: The Regulations





Pepper Goes Missing

1965; Story featured in [Sports Illustrated](#)

THE LOST PETS THAT STRAY TO THE LABS

Science's need for experimental animals is very real but is often filled by unscrupulous and cruel professional dognappers **by COLES PHINIZY**

Brief History of Animal Welfare Regulations

1966: Animal Welfare Act Passed into Law

Establishes licensing for dog and cat dealers, and authorizes the Secretary of Agriculture to regulate transport, sale, and handling of animals pre-research
Covers dogs, cats, NHPs, guinea pigs, hamsters, rabbits



Image Credit: <https://www.nal.usda.gov>

Brief History of Animal Welfare Regulations

1966: Animal Welfare Act Passed into Law

**1985: Health Research
Extension Act;
U.S. Government Principals
for the Utilization and Care of
Vertebrate Animals Used in
Research, Teaching & Testing
Animal Welfare Act Amended**
*Big year! Establishes requirement
for an IACUC. Covers all vertebrate
animals.*

Brief History of Animal Welfare Regulations

1966: Animal Welfare Act Passed into Law



2002: AWA Revises Definition of “Animal”

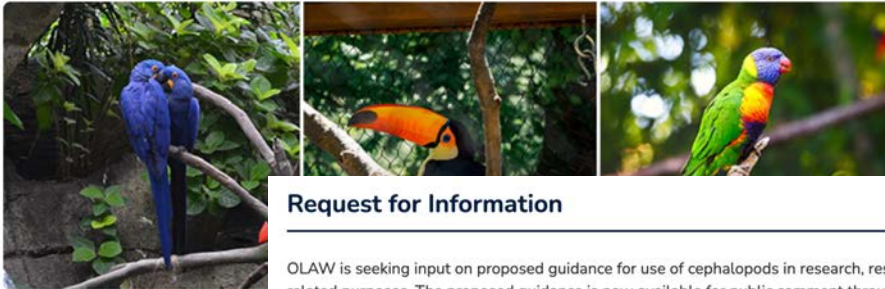
Excludes birds, rats of the genus Rattus, and mice of the genus Mus bred for use in research.

The Regulations Are Evolving

AWA Standards for Birds

Last Modified: Mar 31, 2023

Print



[Introduction](#) | [Do I need](#)

Request for Information

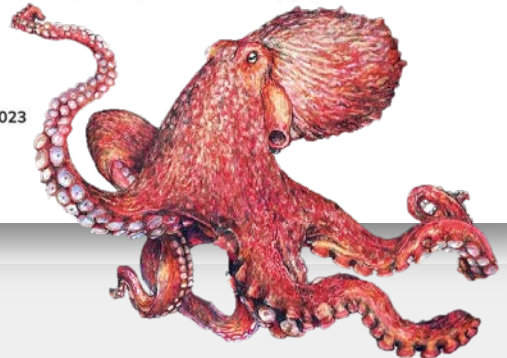
OLAW is seeking input on proposed guidance for use of cephalopods in research, research training, experimentation, or biological testing or for related purposes. The proposed guidance is now available for public comment through a Request for Information (RFI).

The proposed text can be found here: [NOT-OD-23-176](#)

Comment should be submitted online: [Submit Here](#)

Comments will be accepted from September 8, 2023 - December 22, 2023

The final text will be published once comments have been considered.



- New AWA standards for birds (*Feb 2023*)
- OLAW RFI cephalopods (*Sept 2023*)

Summary of Key Regulations

OLAW/PHS Policy	USDA/Animal Welfare Act	AAALAC
<ul style="list-style-type: none"> • Applies to all vertebrate animals. • Applies to work supported by PHS funds (e.g., NIH, CDC, FDA). • Enforced by OLAW • Uses <i>The Guide</i> as basis for evaluation • Assurance document, renewed every 5 years • Annual report 	<ul style="list-style-type: none"> • Applies to all warm-blooded animals, except mice/rats/birds bred for research and ag animals, regardless of funding source. • Enforced by USDA • Documented literature searches for alternatives • Registration • Unannounced annual inspections • Annual report 	<ul style="list-style-type: none"> • Applies to all vertebrate animals and cephalopods owned by the institution/program. • Voluntary • Not part of government • Uses <i>The Guide</i> as basis for evaluation. • Comprehensive Program Description and site visit every 3 years

NSF

NASA

MOUs with OLAW

Institutional Animal Care and Use Committee

- Oversees the use of animals in research, teaching, and testing
- Primary responsibilities include:
 - Semiannual review of program and animal facilities
 - Reviews protocols describing animal activities
 - Review and investigate animal welfare concerns
 - Make recommendations to IO
 - Authorized to suspend animal activities

For which of these species does the IACUC have oversight?



Illustration by Denise Nestor

IACUC Review of Animal Activities

- Animal activities are described in an IACUC protocol
 - New protocols, triennial reviews, amendments
- Includes traditional laboratory based work, as well as field work in remote locations, classes that involve animals, and collaborative projects
- Must be written for a lay audience

WHAT DOES THE COMMITTEE LOOK AT?

- Rationale for study and model used
- Sequential description of the procedures involved
- Procedure details, including appropriate analgesia and anesthesia, and monitoring plans
- Justification of species and animal numbers
- Method of euthanasia
- Literature search, 3Rs
- Nonstandard housing and husbandry requirements
- Use of hazardous materials and safe working environment

IACUC Review of Animal Activities

In addition to IACUC review, protocol items are typically reviewed by several other stakeholders:

- Veterinarians
- IACUC administrators
 - Personnel training
- Animal care staff (e.g., NHP behavioral management)
- Environmental health and safety team
- Other compliance offices (e.g., embryonic stem cell oversight)

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IACUC Review of Animal Activities

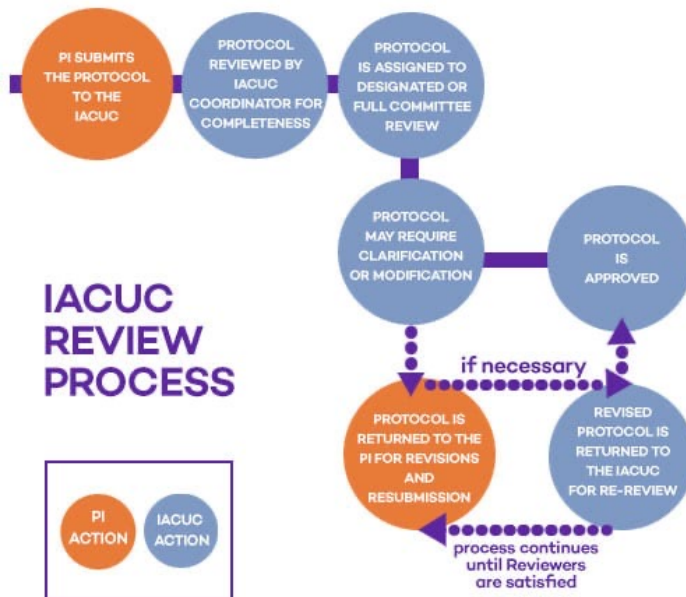
Two mechanisms for protocol review*:

- Full committee review
- Designated member review

Possible outcomes of review:

- Approval
- Require modifications (to secure approval)
- Withhold approval

**Some amendments may be approved via VVC or administrative approval*



Where & how do these regulations intersect with the grant life cycle?

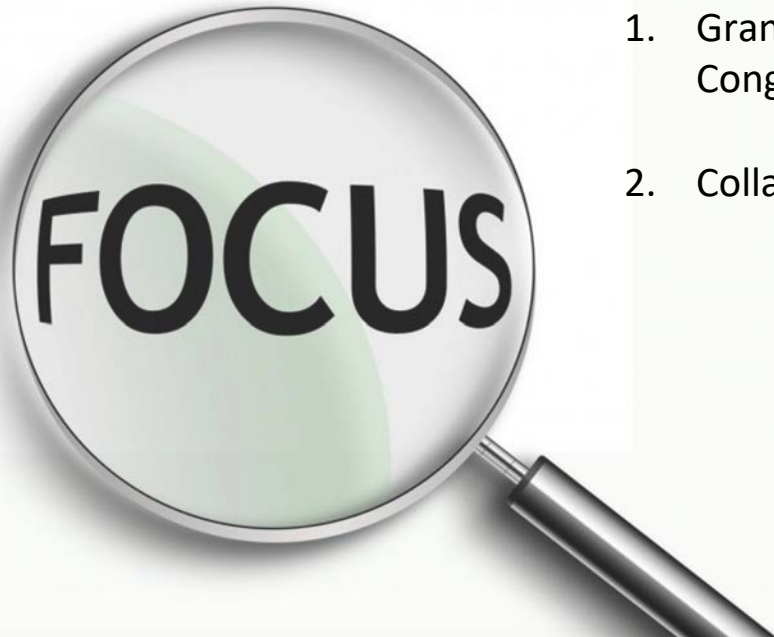


Where & how do these regulations intersect with the grant life cycle?



Fun
here

Let's Focus on Two Primary Points of Intersection:



1. Grant/Contract to Protocol Congruence Review
2. Collaborations

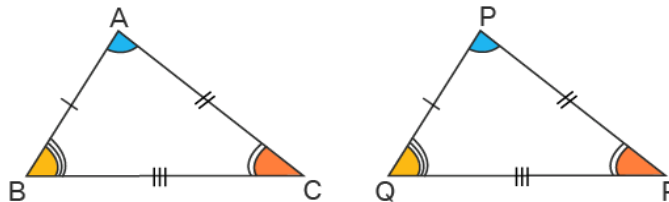
1. Grant to Protocol Congruence Review



What is Congruence Review?

Congruence: The quality of being similar to or in agreement with something

- Verification that animal activities described in the grant application are approved on an IACUC protocol(s).
- An institutional responsibility (may or may not be delegated to the IACUC)



Grant to Protocol Congruence Review



... PHS Policy & NIH Grants Policy Statement

"Applications or proposals (competing and noncompeting) covered by this Policy from institutions that have an approved Assurance on file with OLAW shall include **verification of approval (including the date of the most recent approval) by the IACUC of those components related to the care and use of animals**. For competing applications or proposals only, such verification may be filed at any time prior to award unless specifically required earlier by the funding component. If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the Institutional Official." [PHS Policy, IV.D.2]

"PHS awarding units may not make an award for an activity involving animals unless the prospective awardee institution...has provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals...**No award shall be made until...the institution or institutions have provided verification of approval by the IACUC** of those components of the application or proposal related to the care and use of animals." [PHS Policy, V.B]

"NIH will delay an award for research involving live vertebrate animals until the recipient organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the recipient has **provided verification of IACUC approval** of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted within three years of the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate." [NIH Grants Policy Statement 4.1.1.2]

Grant to Protocol Congruence Review: Process

- Side-by-side review of the grant proposal with the protocol(s) is a common strategy.
- What content is compared?
 - Species
 - Procedures
 - Proposed animal numbers
 - = Vertebrate Animal Section, Research Strategies sections of grant proposal
- If work is not covered, researcher must submit an amendment to the protocol.
- Once all work is approved, a congruence or grant approval letter is issued.



**HOW LONG
DOES IT TAKE
TO GET A GRANT
APPROVED?**



Grant to Protocol Congruence Review: Timing

What contributes to the delay of a congruence review?

*Unexpected funding from sponsor (e.g., last-minute funding, released at end of FY; discretionary fund availability)

*PI waited to provide grant to IACUC office since they didn't think funding was likely. Best for PI to reach out when notified of a fundable score to allow time for review.

Grant is reviewed and now protocol needs an amendment to

- Describe two new experiments
- Include a behavioral test in another already-approved experiment
- Change the dose for one of the drug being tested
- Increase the animal numbers
- Include a new collaborator's lab at the University of Paris

*What can be done at this point?

The IACUC office can offer to send the sponsor a Pending Letter to indicate the amendment is underway.

Protocol Approval vs Congruence Letter



UNIVERSITY of WASHINGTON

APPROVAL OF AMENDMENT SUBMISSION

April 1, 2022

Dear Mr. Wayne,

This letter is written notification of Institutional Animal Care and Use Committee (IACUC) approval for animal use. **It serves as verification of approval of this submission and does not indicate congruence with any grants or contracts.**

Type of Review:	Designated Member Review
Short Title of Protocol:	1234-56: Crime Fighting and Chiroptera
Investigator:	Bruce Wayne
HoverBoard ID:	PROTO123450000

Prior to starting work, please review with your staff the specific health and safety requirements and best practice recommendations provided in the Occupational Health Recommendations (OHR) and, if applicable, the Biological Use Authorization (BUA) letter. These are accessible in the protocol workspace in Hoverboard.

Please note the approval and expiration dates below. Please refer to the assigned protocol number for all animal orders in Animal Operations (AOps) and correspondence with the OAW and IACUC.

Amendment Approval Date: 4/1/2022

Protocol Triennial Expiration Date: 10/5/2023

If you have any questions, please contact OAW at oafrss@uw.edu.

Sincerely,
Office of Animal Welfare



OFFICE of ANIMAL WELFARE

Research Support Services



UNIVERSITY OF WASHINGTON

Office of Animal Welfare

DATE: April 5, 2022

TO: National Institutes of Health

SUBJECT: *Notice of Institutional Animal Care and Use Committee Approval*

The following application has been reviewed and the associated IACUC protocol is approved. The grant/contract and the associated IACUC protocol are concordant in terms of animal use.

Principal Investigator: Bruce Wayne

eGCI: A123456

Sponsor Number: 1R0112345-01

Project Title: Crime Fighting Reflexes in Chiroptera

Protocol Number: 1234-56

Approval Dates: 12/4/2020 – 12/3/2023; amendment approved 4/1/2022

The project as proposed meets the standards of the Guide for the Care and Use of Laboratory Animals and applicable University policies and procedures. The University of Washington has an approved Animal Welfare Assurance (A3464-01) on file with the NIH Office of Laboratory Animal Welfare (OLAW), and the University is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International.

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Box 357160 Seattle, Washington 98195-7160 | <http://oaw.washington.edu>

Regulatory requirements that affect the protocol and grant review process

Partner departments: **Sponsored projects, Funding Agencies**

The Office of Sponsored Programs at each institution is responsible for collecting and dispersing the funding that is provided by research grants.

This office needs to communicate with the IACUC Office to determine whether funded grants are approved by the IACUC so they can release funding to the research lab.

How is this done at your institution? How does your institution perform congruence review? Is there occasionally any disconnect or confusion about protocol approval vs grant approval?

2. Collaborations

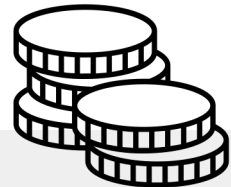


“We have an agreement in principle. The question is, do we all have the same principles?”

Collaborations = Subcontracts



- Funds used to support all or some of the animal work at Institution B, or the purchase of services (e.g., custom antibodies)
- Federal funds supporting animal work can only be conducted by entities that are PHS-assured
- Third party subcontracting?



How Do We Manage These Collaborations?

“Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the **participating institutions should have a formal written understanding** (e.g., a contract, memorandum of understanding, or agreement) that **addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight** (AAALAC 2003). In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.” [Guide, p.15]

Common Agreements to Support Collaborations

MOU (Memorandum of Understanding):

In the case that research is occurring at Institution B with funding from Institution A (e.g., a sub-contract), MOUs are signed by both institutions with the agreement typically indicating that a PI at Institution B will perform the specific project noted and all animal work will be according to the regulations. In addition, Institution A will be informed if there are any deviations.

Interinstitutional Agreement:

These agreements are standing arrangements between institutions that have frequent collaborations so that specific MOUs for each project don't have to be signed.

Interinstitutional Assurance:

Institution A is receiving federal funds for animal work and does not have their own animal program or PHS Assurance. Animal work for this project will be performed at Institution B, which has an Assured animal program.

Communication



How does time and space affect your interactions with partner departments?

- **In the post-Covid world, does a hybrid work schedule change your review time and efficiency?** If so, in what way? Can you be as effective communicating with colleagues in a Zoom meeting? Does it matter if it's a large group vs a 1:1 discussion?
- **How does the physical location and interaction affect relationships between offices/groups?** Does proximity help alleviate some of the obstacles?
- **Can Slack or similar tools be used to connect and communicate with offices that aren't physically nearby?** Or do you tend to call or e-mail colleagues? Are there perhaps too many ways to contact each other? Is it becoming more difficult to locate communication threads?

Communication Improvement Brainstorm

The other component of this is a good training program and making sure our OSP understands the process. In addition to training, providing process documents and job aids for the team is critical.

Having OAW staff come to our All Staff meetings once a year to get a finger on the pulse and just check in is also incredibly helpful.

One of the most critical things for us is to have an excellent line of communication with our partner central offices.

Direct line of contact

Streamlining Processes



Addressing administrative burden

Over the past 30 years, there have been more than 50 new regulations that directly affect federally funded research management. (That doesn't even include changes to existing regulations!)

Studies were done to determine the administrative burden faced by researchers and administrators.

Results showed areas of greatest burden were:

- *compliance (humans, animals, etc),
- *monitoring subcontracts
- *more and more training requirements

In addition, Administrative burden comes from not only implementing new regulations, but also figuring out how to interpret them, since the wording and expectations can be confusing or vague sometimes.



What about speeding up the review and approval process?

Are we overstepping regulatory expectations? Do we do more than we need to? How many institutions are reviewing all proposals and/or non-competing renewals (progress reports)? Are you using the same standards for all sponsored research or only for PHS-funded projects?

Electronic database: can make the review process more efficient, especially if the review is done by DMR and communication between the reviewer and PI is within a web-based system.

MOU template and Universal Protocol template: these are being developed to be shared among all institutions to reduce review time.

Standard procedures: Does your IACUC offer Standard Procedures for researchers to use in their protocols? This speeds the review process since these procedures have been pre-approved by the IACUC.

Workflow Improvement Brainstorm

In an ideal world it would be so excellent if our electronic systems truly could speak to each other - It would be incredible if we could receive auto alerts and confirmations once your review was complete so we could move forward with releasing funding.

It seems overreaching and unnecessary to apply the same standards for PHS-funded work to small funding agencies that aren't concerned about upholding those same regulations, but in the end, it's probably a more streamlined process because we don't have to differentiate between sponsors and have a two-tiered system of review and approval.

It's great that these universal templates and procedure standards are being developed and shared with institutions across the country because after everyone starts using them, they will be very familiar regardless of where you work. We will all be using common language and working with common forms and that should streamline the workflow in a big way!

Federal Demonstration Partnership (FDP)

FEDERAL DEMONSTRATION PARTNERSHIP

MEMBER LOGIN JOIN LISTSERVS

Organization Committees & Subcommittees Demonstrations & Resources Meetings & Listening Sessions Get Involved Elections 2023

NATIONAL ACADEMIES Science Engineering Medicine

Mission: To **streamline the administration of federally sponsored research** and foster collaboration to enhance the national research enterprise while maintaining high standards of stewardship and accountability. The FDP achieves measurable results in its demonstrations and projects for the benefit of all in the research enterprise.

WHO WE ARE

The Federal Demonstration Partnership (FDP) is an association of federal agencies, research policy organizations and academic research institutions with the goal of streamlining the administration of federally sponsored research and fostering collaboration to enhance the national research enterprise while maintaining high

Several FDP Initiatives:

1. MOU Sample and Guidance

[Home](#) / [Committees & Subcommittees](#) / [Research Compliance Committee](#) / [Animal Subjects Subcommittee](#)

ANIMAL SUBJECTS SUBCOMMITTEE

Purpose

Reviews existing and new administrative requirements imposed by federal regulations and program officers related to animal use and care. The emphasis should be on harmonization of requirements across federal agencies, reduction of redundancies and identifying good practices.

Current Activities & Initiatives

- [Compliance Unit Standard Protocol \(CUSP\)](#)
- [Universal Protocol Sample \(UPS\)](#)

Committee Resources & Tools

Webinar hosted by OLAW: [MOUs for Collaborating Institutions: New Template \(Sample\)](#)

[FDP IACUC MOU Sample](#) (May 2022)

[FDP IACUC MOU User Guide](#) (May 2022)

- **Background of the FDP IACUC MOU Sample:**
- Webinar – [Agreements between collaborating institutions using vertebrate animal](#)
- [Slides to 10/9/2019 webinar](#)

FDP MEMORANDUM OF UNDERSTANDING FOR ANIMAL CARE AND USE OVERSIGHT BETWEEN COLLABORATING PUBLIC HEALTH SERVICE (PHS)-ASSURED INSTITUTIONS

The purpose of this Memorandum of Understanding (MOU) is to establish expectations and responsibilities of collaborating institutions for the humane care and use of vertebrate animals for research, teaching, and/or testing. In accordance with the *Guide for the Care and Use of Laboratory Animals* (p. 15)^{1,2}, and/or USDA Inspection Guide³ and/or as stipulated by the applicable federal funding agency, institutions should have a formal written understanding (e.g., a Memorandum of Understanding) that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight. This MOU may be used for both funded and unfunded collaborations.

APPLICABILITY: This MOU applies only to the protocol(s) specifically listed below.

NAME OF INSTITUTION A (Initiating institution and/or recipient of prime award if grant funded):

USDA Registration Number:

OLAW Assurance Number:

<https://thefdp.org/committees-subcommittees/research-compliance-committee/animal-subjects-subcommittee/>

Several FDP Initiatives:

2. CUSP Sharing Site

[Home](#) / [Demonstrations & Resources](#) / CUSP

COMPLIANCE UNIT STANDARD PROCEDURES



What is CUSP?

CUSP or "Compliance Unit Standard Procedures" is a multi-institutional initiative in collaboration with the FDP community. CUSP can share standard procedures used in animal care protocols. CUSP hopes to relieve administrative burden for researchers and regulators while improving animal care through the promulgation of procedures that are consistent across researchers, and national regulatory bodies.

GOAL: To create an online repository where institutions can share standard procedures used in animal care across the research community.

Learn More!
CUSP Session on
10/17 at 10:15am

A screenshot of the CUSP SHARING SITE website. The header features the site's logo and title. Below, a text box explains the site's purpose: "The Compliance Unit Standard Procedure (CUSP) Sharing Site is an online repository where participating institutions can share standard procedures used in animal care protocols, supporting the development of high-quality protocols, while reducing burden for researchers, IACUCs and IACUC support staff." It also notes that "CUSP is a burden-reducing initiative of the 21st Century Cures Act." To the right is a diagram showing the site's structure with icons for "Privacy", "Security", "Designated Institutional Representatives", and "Community Members". A red box titled "How will it work?" lists three bullet points: "Community members will be able to browse and read procedures of interest to them and their home institution.", "Participating institutions will have a Designated Institutional Representative who will add and manage procedures and user accounts on behalf of their institution.", and "Multiple security features support a safe browsing experience." Below this, a section titled "Our partners + sponsors" shows logos for the FDP (Animal Demonstrations Partnership) and the NIH (National Institutes of Health, Office of Laboratory Animal Welfare). The bottom section, "HOW CAN CUSP HELP YOU?", lists four numbered points: "01 Easily build a library of standard procedure for use at your institution.", "02 Identify new approaches and refinements to procedures.", "03 Benchmark with animal programs of similar size and scope.", and "04 Provides consistency within and across institutions." To the right of these points are four circular icons: a building for "Open to all institutions", interlocking puzzle pieces for "Broad compatibility", a calendar for "Available 2022/2023", and a QR code for "Learn More!". The email address "cusp@thefdp.org" is at the bottom left.

<https://thefdp.org/demonstrations-resources/cusp/>

Several FDP Initiatives:

3. Universal Protocol Sample

[Home](#) / [Committees & Subcommittees](#) / [Research Compliance Committee](#) / [Animal Subjects Subcommittee](#)

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- [FDP IACUC MOU Sample](#) (May 2022)
- [FDP IACUC MOU User Guide](#) (May 2022)
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<https://thefdp.org/committees-subcommittees/research-compliance-committee/animal-subjects-subcommittee/>

Multiple evolving processes for improvement of research administrative processes

- robust ethical and regulatory oversight for animal welfare is important but comes with extra work (New rules! More training! Fill out forms!)
- recognition of the burden is the first step and now there are efforts underway to reduce it
- more widespread acceptance and integration of electronic protocol systems
- newly developed templates and standard procedures should be adopted at the majority of institutions nationwide
- communication with colleagues using forums (e.g. AALAS)



Thank You!

Questions?