


Duke University Animal Care & Use Program 

## The NEW Duke IACUC Protocol Template

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Director, Office of Animal Welfare Assurance  
Member, Duke IACUC

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### Agencies Requiring IACUC Oversight of Animal Activities

USDA – Animal Welfare Act 

OLAW / NIH – PHS Policy  

AAALAC – Our accrediting agency 

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### IACUC Goals for Protocol Review

- ✓ Apply regulations / guidelines / policies consistently
- ✓ Full consideration of animal care and use concerns
- ✓ Appropriate expertise used to evaluate protocols
- ✓ Evaluate protocols objectively
- ✓ Perform protocol reviews efficiently and smoothly



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**General Problems with Protocol Review**

- ✓ Funding agency requirements
- ✓ Research focus varies across campus / Matching review expertise to research proposal
- ✓ USDA / PHS / AAALAC obligations
- ✓ Collaborative efforts at other locations
- ✓ Deadlines (JIT / Publication submission / etc.)
- ✓ Lacks Sufficient Administrative Information
- ✓ Too Much Scientific Jargon
- ✓ Reference on Other Documents (not included)

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**General Problems with Protocol Review**

- ✓ Pain/Distress Reporting Not Accurate
- ✓ Poor Justifications for Species / Strain or Number of Animals
- ✓ Poor Justification for Exemptions to NIH Policy
- ✓ Lit. Search / Alternatives & Refinement Strategies Not Clear
- ✓ Sedation / Anesthesia / Analgesia Plans Not Clear
- ✓ Procedure Detail Not Sufficient
- ✓ Collaborative Activity Not Clear
- ✓ Humane Endpoints / Euthanasia Methodology Not Clear
- ✓ Safety / Employee Health Requirements Not Performed

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**Duke IACUC Efforts Thus Far**

- ✓ Define the problem
- ✓ Consider Solutions, and Choose a Preferred Option
- ✓ Establish an IACUC Sub-Committee to Develop Solution
- ✓ Incorporate Community Opinion
- ✓ Beta-Test The Solution
- ✓ Field The Solution with a Grace Period

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**The Solution**

**PART I: CORE INFORMATION** (Always Required)

**PART II: PROTOCOL SPECIFIC INFORMATION** (Only if Necc.)

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**PART I: CORE INFORMATION** (Always Required)

- SECTION A: ADMINISTRATIVE INFORMATION
- SECTION B: ANIMAL USE JUSTIFICATION
- SECTION C: HOUSING & PROCEDURES LOCATIONS
- SECTION D: SPECIAL CONCERNS FOR ANIMAL USE
- SECTION E: EUTHANASIA & DISPOSITION
- SECTION F: PRINCIPAL INVESTIGATOR AGREEMENT
- SECTION G: PERSONNEL QUALIFICATIONS FORM (PQF)

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**PART II: SPECIFIC PROTOCOL INFORMATION**

- SECTION H: HAZARDOUS AGENT USE
- SECTION I: TRANSPORTATION
- SECTION J: NON-SURGICAL PAIN MANAGEMENT & CHEMICAL RESTRAINT
- SECTION K: SURVIVAL SURGICAL PROCEDURES
- SECTION L: NON-SURVIVAL SURGICAL PROCEDURES
- SECTION M: NON-SURGICAL PROCEDURES
- SECTION N: FIELD CAPTURE / FIELD STUDIES
- SECTION O: ANIMAL USE IN HUMAN PATIENT CARE AREAS
- SECTION P: GENETICALLY ENGINEERED ANIMAL USE
- SECTION Q: BREEDING COLONY
- SECTION R: ANTIBODY PRODUCTION
- SECTION S: SPECIAL INSTRUCTIONS / EMERG. ANIMAL CARE
- SECTION T: PI MANAGED ANIMAL HOLDING FACILITY

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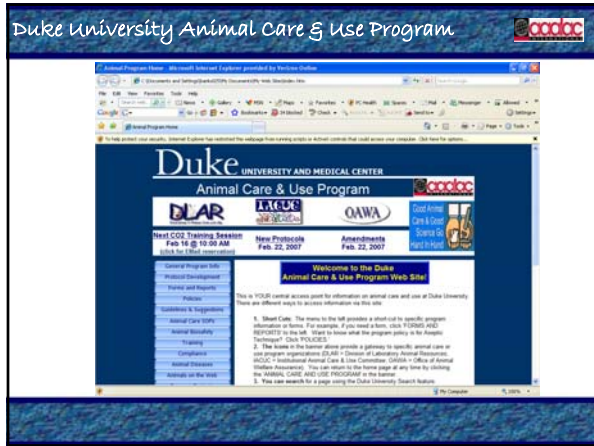
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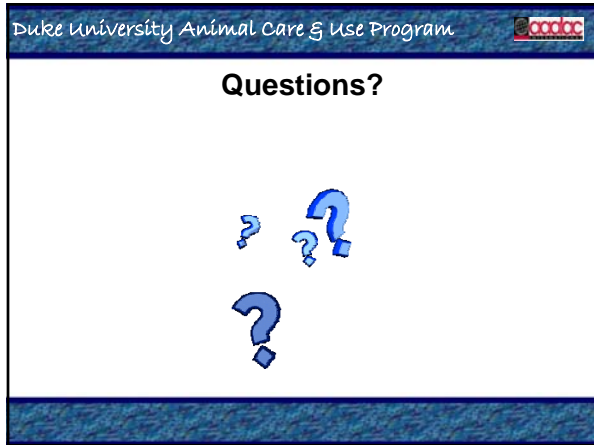
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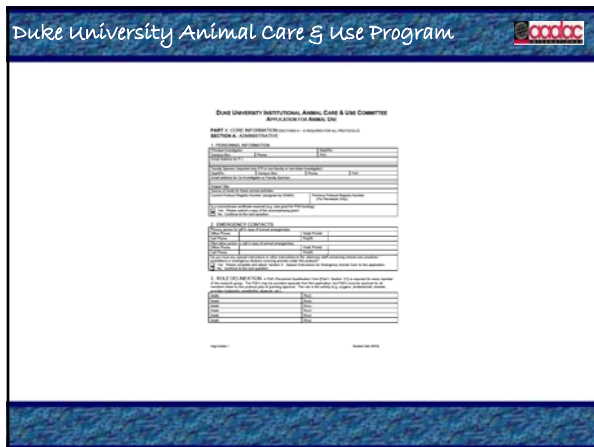
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INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

1. ANIMAL IDENTIFICATION AND/OR STUDY NUMBER

1	Species	
2	Strain	
3	Sex	
4	Age	
5	Weight	
6	Height	
7	Color	
8	Other	

2. ANIMAL IDENTIFICATION AND/OR STUDY NUMBER

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3	Sex	
4	Age	
5	Weight	
6	Height	
7	Color	
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SECTION 1: IDENTIFICATION OF SUBJECTS

1. TITLE OF STUDY: \_\_\_\_\_

2. PI: \_\_\_\_\_

3. INSTITUTION: \_\_\_\_\_

4. FUNDING: \_\_\_\_\_

5. DATE OF PROTOCOL SUBMISSION: \_\_\_\_\_

6. DATE OF PROTOCOL APPROVAL: \_\_\_\_\_

7. DATE OF PROTOCOL RENEWAL: \_\_\_\_\_

8. DATE OF PROTOCOL EXPIRATION: \_\_\_\_\_

9. DATE OF PROTOCOL CLOSURE: \_\_\_\_\_

10. DATE OF PROTOCOL REVISION: \_\_\_\_\_

11. DATE OF PROTOCOL AMENDMENT: \_\_\_\_\_

12. DATE OF PROTOCOL SUSPENSION: \_\_\_\_\_

13. DATE OF PROTOCOL RESCINDMENT: \_\_\_\_\_

14. DATE OF PROTOCOL REINSTATEMENT: \_\_\_\_\_

15. DATE OF PROTOCOL REEVALUATION: \_\_\_\_\_

16. DATE OF PROTOCOL REAPPROVAL: \_\_\_\_\_

17. DATE OF PROTOCOL REAPPROVAL: \_\_\_\_\_

18. DATE OF PROTOCOL REAPPROVAL: \_\_\_\_\_

19. DATE OF PROTOCOL REAPPROVAL: \_\_\_\_\_

20. DATE OF PROTOCOL REAPPROVAL: \_\_\_\_\_

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SECTION 2: DESCRIPTION OF EXPERIMENTAL PROCEDURES

1. PURPOSE OF STUDY: \_\_\_\_\_

2. OBJECTIVES: \_\_\_\_\_

3. METHODS: \_\_\_\_\_

4. PROCEDURES: \_\_\_\_\_

5. EQUIPMENT: \_\_\_\_\_

6. MATERIALS: \_\_\_\_\_

7. SUBJECTS: \_\_\_\_\_

8. SAMPLE SIZE: \_\_\_\_\_

9. ASSIGNMENT: \_\_\_\_\_

10. INTERVENTIONS: \_\_\_\_\_

11. MEASUREMENTS: \_\_\_\_\_

12. ANALYSIS: \_\_\_\_\_

13. RESULTS: \_\_\_\_\_

14. DISCUSSION: \_\_\_\_\_

15. CONCLUSIONS: \_\_\_\_\_

16. REFERENCES: \_\_\_\_\_

17. APPENDICES: \_\_\_\_\_

18. TABLES: \_\_\_\_\_

19. FIGURES: \_\_\_\_\_

20. OTHER: \_\_\_\_\_

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SECTION 3: IDENTIFICATION OF SUBJECTS

1. TITLE OF STUDY: \_\_\_\_\_

2. PI: \_\_\_\_\_

3. INSTITUTION: \_\_\_\_\_

4. FUNDING: \_\_\_\_\_

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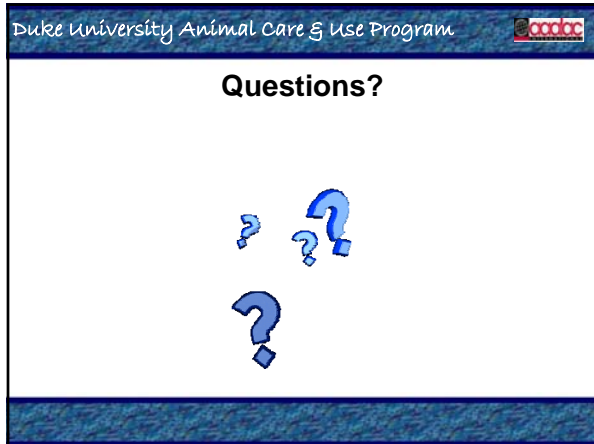
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