




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


Duke University Animal Care & Use Program 

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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Form 100-1 (01/05)

II. ANIMAL IDENTIFICATION AND/OR LABELING

1. Species	
2. Sex	
3. Age	
4. Weight	
5. Height	
6. Color	
7. Other identifying characteristics	
8. Date of identification	
9. Identification method	
10. Identification number	
11. Date of last check	
12. Name of investigator	
13. Name of animal	
14. Name of facility	
15. Name of principal investigator	
16. Name of sponsor	
17. Name of institution	
18. Name of country	
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Duke University Animal Care & Use Program 

SECTION 1: IDENTIFICATION OF SUBJECTS

1. TITLE OF STUDY: _____

2. PI: _____

3. INSTITUTION: _____

4. FUNDING: _____

5. DATE OF PROTOCOL SUBMISSION: _____

6. DATE OF APPROVAL: _____

7. DATE OF EXPIRATION: _____

8. DATE OF REVISION: _____

9. DATE OF REVIEW: _____

10. DATE OF RE-EVALUATION: _____

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20. DATE OF RE-EVALUATION: _____

Duke University Animal Care & Use Program 

SECTION 2: PURPOSE AND JUSTIFICATION

1. STATEMENT OF PURPOSE: _____

2. STATEMENT OF JUSTIFICATION: _____

3. STATEMENT OF SIGNIFICANCE: _____

4. STATEMENT OF BENEFIT: _____

5. STATEMENT OF RISK: _____

6. STATEMENT OF ALTERNATIVES: _____

7. STATEMENT OF ETHICAL CONSIDERATIONS: _____

8. STATEMENT OF COMPLIANCE: _____

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SECTION 3: IDENTIFICATION OF SUBJECTS

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Duke University Animal Care & Use Program 

SECTION 1: PURPOSE AND SCOPE OF THE PROTOCOL

SECTION 2: PROJECT INFORMATION

SECTION 3: INVESTIGATOR INFORMATION

SECTION 4: PROJECT DESCRIPTION

SECTION 5: RATIONALE AND SIGNIFICANCE


SECTION 6: METHODS AND PROCEDURES

SECTION 7: MONITORING AND REPORTING

SECTION 8: ETHICAL CONSIDERATIONS

SECTION 9: APPROVALS

SECTION 10: ADDITIONAL INFORMATION

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