

Form CP-W: Worksheet for Designing Clinical Field Trials under Channel Catfish Pituitary (CP) INAD 11-468

INSTRUCTIONS

1. Investigator must fill out Form CP-W for each trial conducted under this INAD **before** actual use of channel catfish pituitary. The Investigator is responsible that Form CP-W is completed accurately.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the Bozeman NIO for assignment of the Study Number.
4. The Bozeman NIO will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form CP-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

		Fish species to be treated			
Average fish size (in)			Average fish weight (gm)		
Number of treated males			Number of treated females		
Number of control males			Number of control females		
Anticipated date of treatment			Estimated total amount of drug for proposed treatments (g)		
Intended CP dosage (mg/kg body weight)	Females		Males	Method of administration	Injection
Number of injections	Females		Males	Injection interval (hours)	
Drug manufacturer	Hybrid Catfish Company		Drug lot number		

Worksheet for Designing Clinical Field Trials - Version 1

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare dosage, or treated fish compared to untreated fish. Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

Fish treated with channel catfish pituitary (CP) must be maintained in culture facilities or captivity for at least 3 days following final CP treatment before they can be harvested for human consumption or released/stocked. Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

Investigator should initial here to indicate that all personnel handling channel catfish pituitary have read the Material Safety Data Sheet for common carp pituitary (CCP) and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

Form CP-1: Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form CP-1 **immediately** upon receipt of channel catfish pituitary (CP).
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CP-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted in triplicate:

Name of Drug	Channel Catfish Pituitary (CP)	INAD Number	11-468
Proposed Use of Drug	To induce gamete maturation in catfish species		
Date of CVM Authorization Letter	12/06/2006		
Source of Drug	Hybrid Catfish Company		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Study Worksheet Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)	Yes	Non-pivotal Study (yes/no)	-----
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously ¹			
Study Protocol Number	11-468		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum total dose	25 mg/Kg body weight		
Methods of Administration	Injection		
Withdrawal Period	3 days		

¹ To be filled out by the NIO

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

Date Reviewed: _____ Sponsor: _____

Form CP-2: Drug Inventory Form

For Use in Channel Catfish Pituitary (CP) Clinical Field Trials Conducted under CP INAD 11-468

INSTRUCTIONS

- Investigator should initiate a new form CP-2 **immediately** upon receipt of each shipment of channel catfish pituitary.
- Form CP-2 should be updated whenever drug is used, transferred, or discarded.
- Investigator should save all copies of this form until the end of the calendar year, at which time they should maintain all originals on file and send one copy of the completed form(s) to their Study Monitor. Within 10 days of receipt, the Study Monitor will ensure accuracy and send a copy to the Bozeman NIO for inclusion in the permanent file.
- Note:** Both Investigator and Study Monitor should sign and date Form CP-2.

Qty of CP from previous page (g) _____ Facility _____ Reporting individual _____

Date	Amount of new CP received (g)	Lot number of CP received	Study Number	Amount of CP used in treatment (g)	Amount of CP transferred (g)	Amount of CP discarded (g)	Amount of CP remaining on hand (g)	Inventory by (Initials)
			xxxxxx	xx	xx	xx		
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						
	xxxx	xxxx						

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

Form CP-3: Results Report Form

For Use in Channel Catfish Pituitary (CP) Clinical Field Trials Conducted under CP INAD 11-468

INSTRUCTIONS

1. Investigator must fill out Form CP-3 no later than 10 days after completion of the study period. Study Number must be recorded on all pages of Form CP-3. Attach lab reports and other information.
2. If channel catfish pituitary was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CP-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Drug lot number		Total amount drug used (g)	
Fish species treated		Water temperature (°F)	
Drug dosage - males (mg/kg body wt)		Drug dosage - females (mg/kg body wt)	
Average fish weight (gm)		Average fish length (in)	
Number of treated males		Number of treated females	
Number of control males		Number of control females	
Treatment date(s)		Treatment Method	Injection
Injection Type (i.e., IM or IP)		Injection interval (hours)	
Number of injections/male		Number of injections/females	
If more than one injection used, please describe dosage regimen (e.g., 1 st injection = 2 mg/kg bw; 2 nd injection = 8 mg/kg bw)			
Spawning/evaluation date(s)		Spawning/evaluation interval (time from treatment until spawning)	

CP Results Record

INSTRUCTIONS

1. "Green" females are those fish that have not ovulated or released their eggs, "green" males are those fish that are not actively spermiating.
2. Motility Score based on a scale of 0 - 4 (see Study Protocol Section XII).
3. Use additional copies of this form for additional treatment days.

Be sure the facility name is written here: _____

		CP TREATED FISH - Females						CONTROL FISH - Females					
Date Treated	Date Evaluated	# of Fish	Number Ripe	Number Green	% Ripe	% Eye-Up	% Hatch	Number of Fish	Number Ripe	Number Green	% Ripe	% Eye-up	% Hatch

		CP TREATED FISH - Males						CONTROL FISH - Males					
Date Treated	Date Evaluated	# of Fish	Number Ripe	Number Green	% Ripe	Milt/ fish (mL)	Motility Score	# of Fish	Number Ripe	Number Green	% Ripe	Milt/ fish (mL)	Motility Score

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol? Attach pathology reports; Both Pre-and Post-Treatment.

Toxicity observations: Report any apparent drug toxicity or adverse effect including a description of unusual fish behavior/events.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Fish treated with CP must be maintained in culture facilities or captivity for at least 3 days following final CP treatment before they can be harvested for human consumption or released/stocked. Investigator should initial here to indicate compliance with disposition requirements of CP treated fish.

Actual number of days between final CP treatment and harvest or release _____
(Note: If fish maintained in culture facilities indefinitely and ultimately destroyed, please write *no release*).

_____ **NEGATIVE REPORT** Catfish pituitary (CP) was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Form CP-4N: Necropsy Report Form**For Use in Channel Catfish Pituitary (CP) Clinical Field Trials
Conducted under CP INAD 11-468****INSTRUCTIONS**

- Investigator must fill out Form CP-4N for all fish that die or are euthanized during the study period.
Use a new copy of Form CP-4N for each individual fish.
- Append and submit all Form CP-4Ns with appropriate Form CP-3s.

Date _____ Fish Species/ID _____ Fish Length (cm) _____

Evaluator(s): _____

Body surface: normal excess mucus irregular color other _____**Dermal lesion:** none hemorrhagic other _____ closed open**Location:** dorsal caudal ventral lateral cranial base of fin - Pectoral (right), Pectoral (left), Adipose, Dorsal, Anal, or Caudal**Gills:** normal pale hemorrhagic other _____**Liver:** normal pale mottled other _____**Spleen:** normal pale enlarged other _____**Kidney:** normal pale swollen other _____**Notes and comments of gross pathologies on other organs and tissues.**eyes exophthalmia _____

stomach _____

body cavity _____

gastrointestinal tract _____

gall bladder _____

gas bladder _____

adipose tissue _____

musculature _____

injection site _____

other _____

Investigator: _____ Date: _____